

Disclaimer

The following report(s) provides findings from an FDA-initiated query using Sentinel. While Sentinel queries may be undertaken to assess potential medical product safety risks, they may also be initiated for various other reasons. Some examples include determining a rate or count of an identified health outcome of interest, examining medical product use, exploring the feasibility of future, more detailed analyses within Sentinel, and seeking to better understand Sentinel capabilities.

Data obtained through Sentinel are intended to complement other types of evidence such as preclinical studies, clinical trials, postmarket studies, and adverse event reports, all of which are used by FDA to inform regulatory decisions regarding medical product safety. The information contained in this report is provided as part of FDA's commitment to place knowledge acquired from Sentinel in the public domain as soon as possible. Any public health actions taken by FDA regarding products involved in Sentinel queries will continue to be communicated through existing channels.

FDA wants to emphasize that the fact that FDA has initiated a query involving a medical product and is reporting findings related to that query does not mean that FDA is suggesting health care practitioners should change their prescribing practices for the medical product or that patients taking the medical product should stop using it. Patients who have questions about the use of an identified medical product should contact their health care practitioners.

The following report contains a description of the request, request specifications, and results from the modular program run(s).

If you are using a web page screen reader and are unable to access this document, please contact the Sentinel Operations Center for assistance at info@sentinelssystem.org.

Overview for Request: cder_mpl2r_wp015

Request ID: cder_mpl2r_wp015_nsdv_v03

Request Description: In this report we replicated the Hernandez-Diaz, et al.¹ study assessing risk of oral clefts with topiramate use during the first trimester of pregnancy in the Sentinel Distributed Database (SDD). This is report 1 of 2. Report 2 includes the same analysis but requires that mothers and infants have 90 days of medical and drug coverage after delivery.

Sentinel Routine Querying Module: Cohort Identification and Descriptive Analysis (CIDA) module, version 8.1.1, with the Propensity Score Analysis module and ad hoc programming

Data Source: We distributed this request to 6 Sentinel Data Partners on June 19, 2020. These 6 Data Partners are a subset of the SDD and only include those that populate the Mother-Infant Linkage Table. Not all data partners contributed to all cohorts in the study. The study period included data from January 1, 2000 to September 30, 2015. Please see Appendix A for a list of dates of available data for each Data Partner.

Study Design: We identified women between the ages of 12 and 54 years of age with evidence of a live birth linked to an infant record, who did not have evidence of known teratogen use in the first trimester, who did not have evidence in the mother's or infant's record of a chromosomal abnormality diagnosis from pregnancy start until 273 days after pregnancy start, and who had prevalent use of topiramate, lamotrigine, or were unexposed in the first trimester of pregnancy (and 90 days prior to pregnancy start for the unexposed cohort). We evaluated the occurrence of oral clefts and compared the exposed (topiramate) and referent (lamotrigine or unexposed) groups matched on propensity score. This is a Type 4 analysis using the Propensity Score Analysis module in the Query Request Package (QRP) documentation.

Exposure and Comparators: We defined the exposure of interest (topiramate) and comparator (lamotrigine) using outpatient dispensing data and National Drug Codes (NDCs). Each qualifying dispensing of the exposures of interest in the first trimester (index) was identified. Please see Appendix B for a list of generic and brand names of medical products used to define exposures in this request.

Outcomes of Interest: We defined oral clefts using International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) and Current Procedural Terminology, Fourth Edition (CPT-4) diagnosis and procedure codes. Oral cleft outcomes were defined by presence of 2 diagnosis codes on different dates or 1 diagnosis code and 1 procedure/surgery code. Qualifying codes had to be within 90 days of each other and the first of the 2 codes had to appear in the mother's or the infant's record between delivery and 90 days after delivery. Please see Appendix C for a list of codes used to define outcomes in this request.

Pregnancy Episode Creation: We identified pregnancies ending in a live birth using the Sentinel Common Data Model (SCDM) Mother-Infant Linkage (MIL) Table. The MIL Table identifies live birth deliveries and matches mother patient IDs to infant patient IDs when possible. Live birth deliveries, as identified in the description above, are eligible for the MIL table when they have the following additional characteristics: the encounter occurred at least one year later than the start of Data Partner data availability, there is no evidence of delivery for 180 days prior, and the women had 391 days of continuous medical coverage, with gaps of up to 45 days allowed, through the delivery date and 90 days after delivery. We excluded pregnancies with evidence of known teratogen use in the first trimester and pregnancies with evidence of chromosomal abnormalities from 301 days before to 30 days after delivery. We defined known teratogens using NDC codes, and chromosomal abnormalities using ICD-9-CM diagnosis codes. Please see Appendix D for a list of generic and brand names of medical products and Appendix E for diagnosis and procedure codes used to defined exclusions.

Overview for Request: cder_mpl2r_wp015

Infant records with the following characteristics are eligible for MIL table: date of birth identified at least one year later than the start of Data Partner data availability, and at least one day of enrollment with medical coverage during first year of life.

We estimated pregnancy episode duration using a claims-based algorithm.² This algorithm used International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) diagnosis codes indicative of weeks of gestation, and ICD-9-CM and ICD-10-CM diagnosis codes for pre-term and post-term deliveries, to calculate the length of the pregnancy episode. Codes had to occur within 7 days of a delivery date in the inpatient setting. In the absence of pre-/post-term codes, pregnancy duration was set to 273 days. Pre-term birth was defined as having a pregnancy duration of less than 259 days. Post-term birth was defined as having a pregnancy duration of greater than 287 days. Pregnancies were excluded from the cohort if there was evidence of a prior delivery in the 301 days before the delivery date of interest. Please see Appendix F for a list of ICD-9-CM and ICD-10-CM codes used in the gestational age algorithm.

Follow-up Time: We looked for outcomes from the delivery date through 90 days after delivery.

Baseline Characteristics: We assessed the following characteristics at the delivery date: age, ethnicity, race, and year. We assessed the following characteristics in the 90 days prior to pregnancy through the first trimester: topiramate indications (epilepsy or seizures, migraine or headache, bipolar disorder, neuropathic pain, nonneuropathic pain), obesity, smoking, depression, anxiety, psychosis, other psychiatric disorders, sleep disorders, fibromyalgia, diabetes mellitus, hypertension, other pain conditions, attention deficit/hyperactivity disorder, alcohol or drug abuse and dependence, chronic fatigue syndrome, kidney disease; and use of the following in the first trimester: valproate, carbamazepine, phenytoin, benzodiazepines, triptans, antipsychotics, antidepressants, antihypertensives, anxiolytics, stimulants, barbiturates, insulin, noninsulin antidiabetics, opioids, hypnotics, buprenorphine, methadone, naloxone, naltrexone, nonsteroidal anti-inflammatory drugs, and suspected teratogens. The Combined Comorbidity Index³ was also calculated for each patient. We defined baseline characteristics using ICD-9-CM diagnosis codes, CPT-4 procedure codes, and NDCs. Please see Appendix G for a list of diagnosis and procedure codes and Appendix H for a list of generic and brand names of medical products used to define baseline characteristics in this request.

Sensitivity Analyses: We performed the following sensitivity analyses, all compared to unexposed patients as the referent group:

- Non-epilepsy indication: we excluded patients if they had evidence of epilepsy or seizures in the 90 days prior to pregnancy start through the first trimester
- Topiramate monotherapy: we excluded patients if they had dispensings of other anticonvulsants during the first trimester
- Require 2 fills of topiramate: patients were classified as exposed to topiramate if they had at least 2 dispensings of topiramate in the first trimester
- Redefine exposure based on timing of days supply: patients were classified as exposed to topiramate if they had a dispensing during first trimester or a dispensing prior to first trimester with a days supply that overlapped with the start of pregnancy

Propensity Score Estimation: We created propensity scores for each analysis by including maternal age, baseline characteristics, concomitant medications, the Combined Comorbidity Index, and healthcare utilization variables that were expected to have sufficient prevalence in the topiramate and referent cohorts. The Propensity Score Analysis module was used to calculate the propensity scores and identify matched cohorts based on propensity scores within each Data Partner. Please see Appendix J to see documentation of the baseline characteristics included in the propensity score for each analysis.

Matching: The matching ratio for the propensity score was 1:1. Pregnancy episodes in the exposed and referent cohorts were nearest neighbor matched without replacement. The matching caliper was 0.05.

Overview for Request: cder_mpl2r_wp015

Percentile analysis: The percentile analysis was completed using 10 strata. Odd ratios were calculated within each strata and combined into a summary estimate using Mantel-Haenszel pooling.

Analysis: For each comparison, we used logistic regression models to estimate odds ratios and corresponding 95% confidence intervals for the unmatched and matched analyses. Subgroups of effect estimation included: epilepsy indication and migraine/headache or bipolar indication.

Please see Appendix I.1-I.3 for specifications of parameters used in this request.

Limitations: Algorithms to define exposures, outcomes, inclusion and exclusion criteria, and characteristics are imperfect and may be misclassified. Race data may be incompletely reported by Data Partner. Therefore, data should be interpreted with this limitation in mind.

Notes: Please contact the Sentinel Operations Center (info@sentinelssystem.org) for questions and to provide comments/suggestions for future enhancements to this document. For more information on Sentinel's routine querying modules, please refer to the documentation (<https://dev.sentinelssystem.org/projects/SENTINEL/repos/sentinel-routine-querying-tool-documentation/browse>).

¹Hernández-Díaz, S., et al. Topiramate use early in pregnancy and the risk of oral clefts: A pregnancy cohort study. *Neurology*. 2018; 90(4):e342-e351.

²Andrade, S. E., et al. Medication Exposure in Pregnancy Risk Evaluation Program. *Matern Child Health J*. 2011; 16(7):1349-1354

³Gagne JJ, Glynn RJ, Avorn J, Levin R, Schneeweiss S. A combined comorbidity score predicted mortality in elderly patients better than existing scores. *J Clin Epidemiol*. 2011;64(7):749-759)

Table of Contents

<u>Glossary</u>	List of Terms Found in this Report and their Definitions
<u>Table 1a</u>	Baseline Characteristics of the Topiramate Pregnancy Cohort and the Unexposed Pregnancy Cohort, Main Analysis, in the Sentinel Distributed Database (SDD) From January 1, 2000 to September 30, 2015 (Unmatched, Aggregated)
<u>Table 1b</u>	Baseline Characteristics of the Topiramate Pregnancy Cohort and the Unexposed Pregnancy Cohort, Excluding Epilepsy Cases, in the Sentinel Distributed Database (SDD) From January 1, 2000 to September 30, 2015 (Unmatched, Aggregated)
<u>Table 1c</u>	Baseline Characteristics of the Topiramate Pregnancy Cohort and the Unexposed Pregnancy Cohort, Topiramate Monotherapy, in the Sentinel Distributed Database (SDD) From January 1, 2000 to September 30, 2015 (Unmatched, Aggregated)
<u>Table 1d</u>	Baseline Characteristics of the Topiramate Pregnancy Cohort and the Lamotrigine Pregnancy Cohort, Lamotrigine Comparator, in the Sentinel Distributed Database (SDD) From January 1, 2000 to September 30, 2015 (Unmatched, Aggregated)
<u>Table 1e</u>	Baseline Characteristics of the Topiramate Pregnancy Cohort and the Unexposed Pregnancy Cohort, Two Fills of Topiramate Required, in the Sentinel Distributed Database (SDD) From January 1, 2000 to September 30, 2015 (Unmatched, Aggregated)
<u>Table 1f</u>	Baseline Characteristics of the Topiramate Pregnancy Cohort and the Unexposed Pregnancy Cohort, Exposure Defined by Overlapping Days Supply, in the Sentinel Distributed Database (SDD) From January 1, 2000 to September 30, 2015 (Unmatched, Aggregated)
<u>Table 2a</u>	Baseline Characteristics of the Topiramate Infant Cohort and the Unexposed Infant Cohort, Main Analysis, in the Sentinel Distributed Database (SDD) From January 1, 2000 to September 30, 2015 (Unmatched, Aggregated)
<u>Table 2b</u>	Baseline Characteristics of the Topiramate Infant Cohort and the Unexposed Infant Cohort, Excluding Epilepsy Cases, in the Sentinel Distributed Database (SDD) From January 1, 2000 to September 30, 2015 (Unmatched, Aggregated)
<u>Table 2c</u>	Baseline Characteristics of the Topiramate Infant Cohort and the Unexposed Infant Cohort, Topiramate Monotherapy, in the Sentinel Distributed Database (SDD) From January 1, 2000 to September 30, 2015 (Unmatched, Aggregated)
<u>Table 2d</u>	Baseline Characteristics of the Topiramate Infant Cohort and the Lamotrigine Infant Cohort, Lamotrigine Comparator, in the Sentinel Distributed Database (SDD) From January 1, 2000 to September 30, 2015 (Unmatched, Aggregated)
<u>Table 2e</u>	Baseline Characteristics of the Topiramate Infant Cohort and the Unexposed Infant Cohort, Two Fills of Topiramate Required, in the Sentinel Distributed Database (SDD) From January 1, 2000 to September 30, 2015 (Unmatched, Aggregated)
<u>Table 2f</u>	Baseline Characteristics of the Topiramate Infant Cohort and the Unexposed Infant Cohort, Exposure Defined by Overlapping Days Supply, in the Sentinel Distributed Database (SDD) From January 1, 2000 to September 30, 2015 (Unmatched, Aggregated)
<u>Table 3a</u>	Baseline Characteristics of the Topiramate Pregnancy Cohort and the Unexposed Pregnancy Cohort, Main Analysis, in the Sentinel Distributed Database (SDD) From January 1, 2000 to September 30, 2015 (Matched, Aggregated), Ratio: 1:1, Caliper: 0.05
<u>Table 3b</u>	Baseline Characteristics of the Topiramate Pregnancy Cohort and the Unexposed Pregnancy Cohort, Excluding Epilepsy Cases, in the Sentinel Distributed Database (SDD) From January 1, 2000 to September 30, 2015 (Matched, Aggregated), Ratio: 1:1, Caliper: 0.05

Table of Contents

<u>Table 3c</u>	Baseline Characteristics of the Topiramate Pregnancy Cohort and the Unexposed Pregnancy Cohort, Topiramate Monotherapy, in the Sentinel Distributed Database (SDD) From January 1, 2000 to September 30, 2015 (Matched, Aggregated), Ratio: 1:1, Caliper: 0.05
<u>Table 3d</u>	Baseline Characteristics of the Topiramate Pregnancy Cohort and the Lamotrigine Pregnancy Cohort, Lamotrigine Comparator, in the Sentinel Distributed Database (SDD) From January 1, 2000 to September 30, 2015 (Matched, Aggregated), Ratio: 1:1, Caliper: 0.05
<u>Table 3e</u>	Baseline Characteristics of the Topiramate Pregnancy Cohort and the Unexposed Pregnancy Cohort, Two Fills of Topiramate Required, in the Sentinel Distributed Database (SDD) From January 1, 2000 to September 30, 2015 (Matched, Aggregated), Ratio: 1:1, Caliper: 0.05
<u>Table 3f</u>	Baseline Characteristics of the Topiramate Pregnancy Cohort and the Unexposed Pregnancy Cohort, Exposure Defined by Overlapping Days Supply, in the Sentinel Distributed Database (SDD) From January 1, 2000 to September 30, 2015 (Matched, Aggregated), Ratio: 1:1, Caliper: 0.05
<u>Table 4a</u>	Effect Estimates for Risk of Oral Clefts comparing the Topiramate Cohort to the Unexposed Cohort by Analysis Type, Main Analysis, in the Sentinel Distributed Database (SDD) From January 1, 2000 to September 30, 2015
<u>Table 4b</u>	Effect Estimates for Risk of Oral Clefts comparing the Topiramate Cohort to the Unexposed Cohort by Analysis Type, Excluding Epilepsy Cases, in the Sentinel Distributed Database (SDD) From January 1, 2000 to September 30, 2015
<u>Table 4c</u>	Effect Estimates for Risk of Oral Clefts comparing the Topiramate Cohort to the Unexposed Cohort by Analysis Type, Topiramate Monotherapy, in the Sentinel Distributed Database (SDD) From January 1, 2000 to September 30, 2015
<u>Table 4d</u>	Effect Estimates for Risk of Oral Clefts comparing the Topiramate Cohort to the Lamotrigine Cohort by Analysis Type, Lamotrigine Comparator, in the Sentinel Distributed Database (SDD) From January 1, 2000 to September 30, 2015
<u>Table 4e</u>	Effect Estimates for Risk of Oral Clefts comparing the Topiramate Cohort to the Unexposed Cohort by Analysis Type, Two Fills of Topiramate Required, in the Sentinel Distributed Database (SDD) From January 1, 2000 to September 30, 2015
<u>Table 4f</u>	Effect Estimates for Risk of Oral Clefts comparing the Topiramate Cohort to the Unexposed Cohort by Analysis Type, Exposure Defined by Overlapping Days Supply, in the Sentinel Distributed Database (SDD) From January 1, 2000 to September 30, 2015
<u>Table 5a</u>	Effect Estimates for Risk of Oral Clefts comparing the Topiramate Cohort to the Unexposed Cohort in the Sentinel Distributed Database (SDD) by Analysis Type and Subgroups by Epilepsy or Seizures, Main Analysis, From January 1, 2000 to September 30, 2015
<u>Table 5b</u>	Effect Estimates for Risk of Oral Clefts comparing the Topiramate Cohort to the Unexposed Cohort in the Sentinel Distributed Database (SDD) by Analysis Type and Subgroups by Migraine or Bipolar Disorder, Main Analysis, From January 1, 2000 to September 30, 2015
<u>Table 5c</u>	Effect Estimates for Risk of Oral Clefts comparing the Topiramate Cohort to the Unexposed Cohort in the Sentinel Distributed Database (SDD) by Analysis Type and Subgroups by Epilepsy or Seizures, Exposure Defined by Overlapping Days Supply, From January 1, 2000 to September 30, 2015
<u>Table 5d</u>	Effect Estimates for Risk of Oral Clefts comparing the Topiramate Cohort to the Unexposed Cohort in the Sentinel Distributed Database (SDD) by Analysis Type and Subgroups by Migraine or Bipolar Disorder, Exposure Defined by Overlapping Days Supply, From January 1, 2000 to September 30, 2015
<u>Figure 1a</u>	Distribution of Propensity Scores Before Matching, Main Analysis, From January 1, 2000 to September 30, 2015

Table of Contents

<u>Figure 1b</u>	Distribution of Propensity Scores Before Matching, Excluding Epilepsy Cases, From January 1, 2000 to September 30, 2015
<u>Figure 1c</u>	Distribution of Propensity Scores Before Matching, Topiramate Monotherapy, From January 1, 2000 to September 30, 2015
<u>Figure 1d</u>	Distribution of Propensity Scores Before Matching, Lamotrigine Comparator, From January 1, 2000 to September 30, 2015
<u>Figure 1e</u>	Distribution of Propensity Scores Before Matching, Two Fills of Topiramate Required, From January 1, 2000 to September 30, 2015
<u>Figure 1f</u>	Distribution of Propensity Scores Before Matching, Exposure Defined by Overlapping Days Supply, From January 1, 2000 to September 30, 2015
<u>Figure 2a</u>	Distribution of Propensity Scores After Matching, Main Analysis, From January 1, 2000 to September 30, 2015
<u>Figure 2b</u>	Distribution of Propensity Scores After Matching, Excluding Epilepsy Cases, From January 1, 2000 to September 30, 2015
<u>Figure 2c</u>	Distribution of Propensity Scores After Matching, Topiramate Monotherapy, From January 1, 2000 to September 30, 2015
<u>Figure 2d</u>	Distribution of Propensity Scores After Matching, Lamotrigine Comparator, From January 1, 2000 to September 30, 2015
<u>Figure 2e</u>	Distribution of Propensity Scores After Matching, Two Fills of Topiramate Required, From January 1, 2000 to September 30, 2015
<u>Figure 2f</u>	Distribution of Propensity Scores After Matching, Exposure Defined by Overlapping Days Supply, From January 1, 2000 to September 30, 2015
<u>Figure 3a</u>	Forest Plot of Odds Ratios and 95% Confidence Intervals Comparing the Risk of Oral Clefts in the Topiramate Pregnancy Cohort to the Referent Pregnancy Cohort in the Sentinel Distributed Database (SDD) from January 1, 2000 to September 30, 2015
<u>Appendix A</u>	Dates of Available Data for Each Data Partner (DP) as of Request Distribution Date (June 19, 2020)
<u>Appendix B</u>	Generic and Brand Names of Medical Products Used to Define Exposures in this Request
<u>Appendix C</u>	List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) and Current Procedural Terminology, 4th Edition (CPT-4) Diagnosis and Procedure Codes Used to Define Outcomes in this Request
<u>Appendix D</u>	Generic and Brand Names of Medical Products Used to Define Exclusions in this Request
<u>Appendix E</u>	List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) Diagnosis Codes Used to Define Exclusions in this Request
<u>Appendix F</u>	List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) Diagnosis Codes Used to Define Gestational Age in this Request
<u>Appendix G</u>	List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) Healthcare Common Procedure Coding System (HCPCS), Current Procedural Terminology, Second Edition (CPT-2), and Current Procedural Terminology, Fourth Edition (CPT-4), Diagnosis and Procedure Codes Used to Define Baseline Characteristics in this Request
<u>Appendix H</u>	Generic and Brand Names of Medical Products Used to Define Baseline Characteristics in this Request
<u>Appendix I.1</u>	Specifications for Parameters Used to Define This Request; Analysis 1 and Analysis 2
<u>Appendix I.2</u>	Specifications for Parameters Used to Define This Request; Analysis 3 and Analysis 4

Table of Contents	
<u>Appendix I.3</u>	Specifications for Parameters Used to Define This Request; Analysis 5 and Analysis 6
<u>Appendix J</u>	Baseline Covariate Groups Evaluated in this Request

**Glossary of Terms for Analyses Using
Cohort Identification and Descriptive Analysis (CIDA) Tool***

Amount Supplied - number of units (pills, tablets, vials) dispensed. Net amount per NDC per dispensing.

Blackout Period - number of days at the beginning of a treatment episode that events are to be ignored. If an event occurs during the blackout period, the episode is excluded.

Care Setting - type of medical encounter or facility where the exposure, event, or condition code was recorded. Possible care settings include: Inpatient Hospital Stay (IP), Non-Acute Institutional Stay (IS), Emergency Department (ED), Ambulatory Visit (AV), and Other Ambulatory Visit (OA). For laboratory results, possible care settings include: Emergency Department (E), Home (H), Inpatient (I), Outpatient (O), or Unknown or Missing (U). The Care Setting, along with the Principal Diagnosis Indicator (PDX), forms the Care Setting/PDX parameter.

Ambulatory Visit (AV) - includes visits at outpatient clinics, same-day surgeries, urgent care visits, and other same-day ambulatory hospital encounters, but excludes emergency department encounters.

Emergency Department (ED) - includes ED encounters that become inpatient stays (in which case inpatient stays would be a separate encounter). Excludes urgent care visits.

Inpatient Hospital Stay (IP) - includes all inpatient stays, same-day hospital discharges, hospital transfers, and acute hospital care where the discharge is after the admission date.

Non-Acute Institutional Stay (IS) - includes hospice, skilled nursing facility (SNF), rehab center, nursing home, residential, overnight non-hospital dialysis and other non-hospital stays.

Other Ambulatory Visit (OA) - includes other non overnight AV encounters such as hospice visits, home health visits, skilled nursing facility visits, other non-hospital visits, as well as telemedicine, telephone and email consultations.

Charlson/Elixhauser Combined Comorbidity Score - calculated based on comorbidities observed during a requester-defined window around the exposure episode start date (e.g., in the 183 days prior to index).

Cohort Definition (drug/exposure) - indicates how the cohort will be defined: 01: Cohort includes only the first valid treatment episode during the query period; 02: Cohort includes all valid treatment episodes during the query period; 03: Cohort includes all valid treatment episodes during the query period until an event occurs.

Days Supplied - number of days supplied for all dispensings in qualifying treatment episodes.

Eligible Members - number of members eligible for an incident treatment episode (defined by the drug/exposure and event washout periods) with drug and medical coverage during the query period.

Enrollment Gap - number of days allowed between two consecutive enrollment periods without breaking a "continuously enrolled" sequence.

Episodes - treatment episodes; length of episode is determined by days supplied in one dispensing or consecutive dispensings bridged by the episode gap.

Episode Gap - number of days allowed between two (or more) consecutive exposures (dispensings/procedures) to be considered the same treatment episode.

Event Deduplication - specifies how events are counted by the Modular Program (MP) algorithm: 0: Counts all occurrences of a health outcome of interest (HOI) during an exposure episode; 1: de-duplicates occurrences of the same HOI code and code type on the same day; 2: de-duplicates occurrences of the same HOI group on the same day (e.g., de-duplicates at the group level).

Exposure Episode Length - number of days after exposure initiation that is considered "exposed time."

Exposure Extension Period - number of days post treatment period in which the outcomes/events are counted for a treatment episode. Extensions are added after any episode gaps have been bridged.

Lookback Period - number of days wherein a member is required to have evidence of pre-existing condition (diagnosis/procedure/drug dispensing).

Maximum Episode Duration - truncates exposure episodes after a requester-specified number of exposed days. Applied after any gaps are bridged and extension days added to the length of the exposure episode.

Member-Years - sum of all days of enrollment with medical and drug coverage in the query period preceded by an exposure washout period all divided by 365.25.

Minimum Days Supplied - specifies a minimum number of days in length of the days supplied for the episode to be considered.

Minimum Episode Duration - specifies a minimum number of days in length of the episode for it to be considered. Applied after any gaps are bridged and extension days added to the length of the exposure episode.

Monitoring Period - used to define time periods of interest for both sequential analysis and simple cohort characterization requests.

Principal Diagnosis (PDX) - diagnosis or condition established to be chiefly responsible for admission of the patient to the hospital. 'P' = principal diagnosis, 'S' = secondary diagnosis, 'X' = unspecified diagnosis, '.' = blank. Along with the Care Setting values, forms the Caresetting/PDX parameter.

Query Period - period in which the modular program looks for exposures and outcomes of interest.

Treatment Episode Truncation Indicator - indicates whether the exposure episode will be truncated at the occurrence of a requester-specified code.

Washout Period (drug/exposure) - number of days a user is required to have no evidence of prior exposure (drug dispensing/procedure) and continuous drug and medical coverage prior to an incident treatment episode.

Washout Period (event/outcome) - number of days a user is required to have no evidence of a prior event (procedure/diagnosis) and continuous drug and medical coverage prior to an incident treatment episode.

Years at Risk - number of days supplied plus any episode gaps and exposure extension periods all divided by 365.25.

*all terms may not be used in this report

Table 1a. Baseline Characteristics of the Topiramate Pregnancy Cohort and the Unexposed Pregnancy Cohort, Main Analysis, in the Sentinel Distributed Database (SDD) From January 1, 2000 to September 30, 2015 (Unmatched, Aggregated)

	Cohorts				Covariate Balance	
	Topiramate Pregnant Cohort		Unexposed Pregnant Cohort		Between Topiramate and Unexposed Pregnant Cohorts	
	Number	Percent	Number	Percent	Absolute Difference	Standardized Difference
Number of pregnant patients	2,364	100.0%	1,235,734	100.0%	-	-
Demographic Characteristics	Mean	Standard Deviation	Mean	Standard Deviation		
Mean maternal age at index date	29.9	5.1	29.8	4.8	0.138	0.028
Maternal age categories (years)	Number	Percent	Number	Percent		
12-20	171	7.2%	95,909	7.8%	-0.528	-0.020
21-30	1,156	48.9%	611,543	49.5%	-0.588	-0.012
31-40	991	41.9%	507,611	41.1%	0.843	0.017
41-54	46	1.9%	20,671	1.7%	0.273	0.020
Year of index date						
2001	5	0.2%	21,028	1.7%	-1.490	-0.154
2002	9	0.4%	20,499	1.7%	-1.278	-0.127
2003	15	0.6%	16,739	1.4%	-0.720	-0.073
2004	47	2.0%	14,970	1.2%	0.777	0.062
2005	63	2.7%	14,780	1.2%	1.469	0.107
2006	38	1.6%	15,192	1.2%	0.378	0.032
2007	115	4.9%	68,899	5.6%	-0.711	-0.032
2008	156	6.6%	76,521	6.2%	0.407	0.017
2009	304	12.9%	183,440	14.8%	-1.985	-0.057
2010	350	14.8%	168,407	13.6%	1.177	0.034
2011	329	13.9%	146,545	11.9%	2.058	0.061
2012	260	11.0%	133,249	10.8%	0.215	0.007
2013	252	10.7%	133,993	10.8%	-0.183	-0.006
2014	276	11.7%	146,565	11.9%	-0.185	-0.006
2015	145	6.1%	74,907	6.1%	0.072	0.003
Race						
Race (American Indian or Alaska Native)	4	0.2%	902	0.1%	0.096	0.028
Race (Asian)	5	0.2%	12,862	1.0%	-0.829	-0.105
Race (Black or African American)	49	2.1%	45,645	3.7%	-1.621	-0.097
Race (Native Hawaiian or Other Pacific Islander)	-	0.0%	558	0.0%	-0.045	-
Race (Unknown)	1,931	81.7%	1,031,545	83.5%	-1.793	-0.047
Race (White)	375	15.9%	144,222	11.7%	4.192	0.122
Hispanic	24	1.0%	16,029	1.3%	-0.282	-0.026
Pregnancy Characteristics						
Preterm ¹	179	7.6%	69,502	5.6%	1.948	0.079
Postterm ²	227	9.6%	166,793	13.5%	-3.895	-0.122
Unknown term (assigned 273 days duration, term)	1,958	82.8%	999,439	80.9%	1.948	0.051

Table 1a. Baseline Characteristics of the Topiramate Pregnancy Cohort and the Unexposed Pregnancy Cohort, Main Analysis, in the Sentinel Distributed Database (SDD) From January 1, 2000 to September 30, 2015 (Unmatched, Aggregated)

	Cohorts				Covariate Balance	
	Topiramate Pregnant Cohort		Unexposed Pregnant Cohort		Between Topiramate and Unexposed Pregnant Cohorts	
	Mean	Standard Deviation	Mean	Standard Deviation	Absolute Difference	Standardized Difference
Mean gestational age ³ at delivery	39.9	1.3	40.0	1.2	-0.156	-0.125
Exposure Characteristics						
Gestational age ³ of first exposure (weeks)	3.4	2.3	0.0	0.2	3.391	2.040
Mean number of dispensings in first trimester	1.4	0.8	0.0	0.0	1.410	-
Mean number of dispensings in second trimester	0.4	1.0	0.0	0.0	0.408	0.587
Mean number of dispensings in third trimester	0.4	1.0	0.0	0.0	0.381	0.544
	Number	Percent	Number	Percent		
Exposed during first trimester		100.0%	-	0.0%	100.000	-
Exposed during second trimester	442	18.7%	58	0.0%	18.692	0.678
Exposed during third trimester	388	16.4%	46	0.0%	16.409	0.626
Baseline⁴ Health Characteristics						
	Mean	Standard Deviation	Mean	Standard Deviation		
Combined comorbidity score ⁵	0.2	0.6	0.0	0.3	0.168	0.381
	Number	Percent	Number	Percent		
Epilepsy or seizures	328	13.9%	1,998	0.2%	13.713	0.557
Migraine or headache	1,309	55.4%	64,220	5.2%	50.175	1.303
Bipolar disorder	166	7.0%	4,139	0.3%	6.687	0.361
Neuropathic pain	213	9.0%	27,373	2.2%	6.795	0.298
Nonneuropathic pain	796	33.7%	173,667	14.1%	19.618	0.473
Obesity	167	7.1%	28,394	2.3%	4.767	0.227
Smoking	185	7.8%	31,252	2.5%	5.297	0.241
Depression	467	19.8%	47,615	3.9%	15.901	0.509
Anxiety	300	12.7%	40,361	3.3%	9.424	0.353
Psychotic conditions	13	0.5%	575	0.0%	0.503	0.092
Other psychiatric conditions	236	10.0%	29,384	2.4%	7.605	0.320
Sleep disorders	136	5.8%	11,382	0.9%	4.832	0.272
Fibromyalgia	164	6.9%	21,486	1.7%	5.199	0.257
Diabetes	69	2.9%	13,345	1.1%	1.839	0.132
Hypertension	148	6.3%	23,771	1.9%	4.337	0.220
Other pain conditions	74	3.1%	5,507	0.4%	2.685	0.204
ADHD	67	2.8%	8,449	0.7%	2.150	0.164
Drug or alcohol abuse	79	3.3%	6,721	0.5%	2.798	0.204
Chronic fatigue syndrome	16	0.7%	2,482	0.2%	0.476	0.072
Kidney disease	11	0.5%	3,315	0.3%	0.197	0.033
Migraine or bipolar disorder	1,422	60.2%	67,722	5.5%	54.672	1.432

Table 1a. Baseline Characteristics of the Topiramate Pregnancy Cohort and the Unexposed Pregnancy Cohort, Main Analysis, in the Sentinel Distributed Database (SDD) From January 1, 2000 to September 30, 2015 (Unmatched, Aggregated)

Baseline ⁴ Medical Product Use	Cohorts				Covariate Balance	
	Topiramate Pregnant Cohort		Unexposed Pregnant Cohort		Between Topiramate and Unexposed Pregnant Cohorts	
	Number	Percent	Number	Percent	Absolute Difference	Standardized Difference
Valproate	28	1.2%	-	0.0%	1.184	-
Carbamazepine	18	0.8%	-	0.0%	0.761	-
Phenytoin	19	0.8%	-	0.0%	0.804	-
Benzodiazepines	258	10.9%	18,812	1.5%	9.391	0.396
Triptans	461	19.5%	6,878	0.6%	18.944	0.665
Antipsychotics	174	7.4%	6,209	0.5%	6.858	0.359
Antidepressants	967	40.9%	71,296	5.8%	35.136	0.913
Antihypertensives	271	11.5%	22,879	1.9%	9.612	0.393
Anxiolytics	415	17.6%	24,519	2.0%	15.571	0.543
Stimulants	111	4.7%	11,058	0.9%	3.801	0.232
Barbiturates	8	0.3%	3	0.0%	0.338	0.082
Insulin	25	1.1%	6,166	0.5%	0.559	0.064
Noninsulin antidiabetics	94	4.0%	21,264	1.7%	2.256	0.136
Opioids	680	28.8%	62,462	5.1%	23.710	0.667
Hypnotics	158	6.7%	10,239	0.8%	5.855	0.312
Buprenorphine	8	0.3%	524	0.0%	0.296	0.068
Methadone	7	0.3%	111	0.0%	0.287	0.074
Naloxone	-	0.0%	-	0.0%	0.000	-
Naltrexone	-	0.0%	85	0.0%	-0.007	-
Suspected teratogens	176	7.4%	81,555	6.6%	0.845	0.033
NSAIDs	259	11.0%	30,854	2.5%	8.459	0.343
Other anticonvulsants	325	13.7%	-	0.0%	13.748	-
Baseline ⁴ Health Service Utilization Intensity	Mean	Standard Deviation	Mean	Standard Deviation		
Mean number of ambulatory encounters	4.0	4.4	1.9	2.9	2.118	0.566
Mean number of inpatient hospital encounters	0.0	0.2	0.0	0.1	0.023	0.136
Mean number of unique generics dispensed	5.0	3.5	1.3	1.9	3.671	1.292

¹Preterm birth defined as a pregnancy duration less than 259 days

²Postterm birth defined as a pregnancy duration greater than 287 days

³Gestational age estimated using a claims-based algorithm, previously validated in the Medication Exposure in Pregnancy Risk Evaluation Program (MEPREP), to identify pregnancies ending in a live birth. ICD-10-CM diagnosis codes indicative of weeks of gestation, and ICD-9-CM and ICD-10-CM diagnosis codes for pre-term and post-term deliveries, were used to calculate the length of the pregnancy episode. Codes had to occur within 7 days of a delivery date in the inpatient setting. In absence of pre/post-term code, pregnancy duration was set to 273 days

⁴Related to user defined index date (pregnancy start, exposure date, or delivery date)

⁵The Charlson/Elixhauser Combined Comorbidity Score is calculated based on comorbidities observed during a requester-defined window around the exposure episode start date. (Gagne JJ, Glynn RJ, Avorn J, Levin R, Schneeweiss S. A combined comorbidity score predicted mortality in elderly patients better than existing scores. J Clin Epidemiol. 2011;64(7):749-759)

⁶Covariates in blue show a standardized difference greater than 0.1

Table 1b. Baseline Characteristics of the Topiramate Pregnancy Cohort and the Unexposed Pregnancy Cohort, Excluding Epilepsy Cases, in the Sentinel Distributed Database (SDD) From January 1, 2000 to September 30, 2015 (Unmatched, Aggregated)

	Cohorts				Covariate Balance	
	Topiramate Pregnant Cohort		Unexposed Pregnant Cohort		Between Topiramate and Unexposed Pregnant Cohorts	
	Number	Percent	Number	Percent	Absolute Difference	Standardized Difference
Number of pregnant patients	1,988	100.0%	1,182,064	100.0%	-	-
Demographic Characteristics	Mean	Standard Deviation	Mean	Standard Deviation		
Mean maternal age at index date	30.3	5.1	29.7	4.9	0.541	0.109
Maternal age categories (years)	Number	Percent	Number	Percent		
12-20	124	6.2%	94,730	8.0%	-1.777	-0.069
21-30	953	47.9%	589,602	49.9%	-1.941	-0.039
31-40	868	43.7%	478,206	40.5%	3.207	0.065
41-54	43	2.2%	19,526	1.7%	0.511	0.037
Year of index date						
2001	2	0.1%	16,059	1.4%	-1.258	-0.148
2002	8	0.4%	15,833	1.3%	-0.937	-0.101
2003	11	0.6%	12,623	1.1%	-0.515	-0.057
2004	32	1.6%	11,089	0.9%	0.672	0.060
2005	53	2.7%	11,110	0.9%	1.726	0.130
2006	25	1.3%	11,365	1.0%	0.296	0.028
2007	94	4.7%	65,177	5.5%	-0.785	-0.036
2008	125	6.3%	73,090	6.2%	0.104	0.004
2009	257	12.9%	179,741	15.2%	-2.278	-0.066
2010	307	15.4%	165,050	14.0%	1.480	0.042
2011	274	13.8%	143,251	12.1%	1.664	0.050
2012	221	11.1%	130,080	11.0%	0.112	0.004
2013	217	10.9%	130,809	11.1%	-0.151	-0.005
2014	235	11.8%	143,444	12.1%	-0.314	-0.010
2015	127	6.4%	73,343	6.2%	0.184	0.008
Race categories						
Race (American Indian or Alaska Native)	3	0.2%	877	0.1%	0.077	0.023
Race (Asian)	4	0.2%	11,896	1.0%	-0.805	-0.104
Race (Black or African American)	35	1.8%	44,686	3.8%	-2.020	-0.123
Race (Native Hawaiian or Other Pacific Islander)	-	0.0%	548	0.0%	-0.046	-
Race (Unknown)	1,660	83.5%	991,300	83.9%	-0.361	-0.010
Race (White)	286	14.4%	132,757	11.2%	3.155	0.095
Hispanic	18	0.9%	15,431	1.3%	-0.400	-0.038
Pregnancy Characteristics						
Preterm ¹	152	7.6%	66,628	5.6%	2.009	0.081
Postterm ²	185	9.3%	157,290	13.3%	-4.001	-0.127
Unknown term (assigned 273 days duration, term)	1,651	83.0%	958,146	81.1%	1.991	0.052

Table 1b. Baseline Characteristics of the Topiramate Pregnancy Cohort and the Unexposed Pregnancy Cohort, Excluding Epilepsy Cases, in the Sentinel Distributed Database (SDD) From January 1, 2000 to September 30, 2015 (Unmatched, Aggregated)

	Cohorts				Covariate Balance	
	Topiramate Pregnant Cohort		Unexposed Pregnant Cohort		Between Topiramate and Unexposed Pregnant Cohorts	
	Mean	Standard Deviation	Mean	Standard Deviation	Absolute Difference	Standardized Difference
Mean gestational age ³ at delivery	39.9	1.3	40.0	1.2	-0.160	-0.128
Exposure Characteristics						
Gestational age ³ of first exposure (weeks)	3.3	2.3	0.0	0.2	3.304	2.058
Mean number of dispensings in first trimester	1.3	0.6	0.0	0.0	1.315	-
Mean number of dispensings in second trimester	0.2	0.7	0.0	0.0	0.239	0.475
Mean number of dispensings in third trimester	0.2	0.7	0.0	0.0	0.190	0.411
	Number	Percent	Number	Percent		
Exposed during first trimester	1,988	100.0%	-	0.0%	100.000	-
Exposed during second trimester	249	12.5%	57	0.0%	12.520	0.535
Exposed during third trimester	191	9.6%	45	0.0%	9.604	0.461
Baseline⁴ Health Characteristics						
	Mean	Standard Deviation	Mean	Standard Deviation		
Combined comorbidity score ⁵	0.2	0.6	0.0	0.3	0.164	0.372
	Number	Percent	Number	Percent		
Epilepsy or seizures	-	0.0%	-	0.0%	0.000	-
Migraine or headache	1,143	57.5%	61,492	5.2%	52.293	1.365
Bipolar disorder	142	7.1%	3,955	0.3%	6.808	0.365
Neuropathic pain	190	9.6%	26,300	2.2%	7.332	0.315
Nonneuropathic pain	680	34.2%	166,355	14.1%	20.132	0.484
Obesity	152	7.6%	27,376	2.3%	5.330	0.247
Smoking	141	7.1%	30,483	2.6%	4.514	0.212
Depression	400	20.1%	44,583	3.8%	16.349	0.521
Anxiety	248	12.5%	38,079	3.2%	9.253	0.349
Psychotic conditions	6	0.3%	522	0.0%	0.258	0.062
Other psychiatric conditions	184	9.3%	26,900	2.3%	6.980	0.303
Sleep disorders	121	6.1%	10,878	0.9%	5.166	0.284
Fibromyalgia	139	7.0%	20,683	1.7%	5.242	0.259
Diabetes	61	3.1%	12,858	1.1%	1.981	0.139
Hypertension	133	6.7%	22,832	1.9%	4.759	0.236
Other pain conditions	61	3.1%	5,377	0.5%	2.614	0.200
ADHD	61	3.1%	8,135	0.7%	2.380	0.176
Drug or alcohol abuse	66	3.3%	6,420	0.5%	2.777	0.203
Chronic fatigue syndrome	15	0.8%	2,376	0.2%	0.554	0.080
Kidney disease	8	0.4%	3,170	0.3%	0.134	0.023
Migraine or bipolar disorder	1,248	62.8%	64,853	5.5%	57.290	1.516

Table 1b. Baseline Characteristics of the Topiramate Pregnancy Cohort and the Unexposed Pregnancy Cohort, Excluding Epilepsy Cases, in the Sentinel Distributed Database (SDD) From January 1, 2000 to September 30, 2015 (Unmatched, Aggregated)

Baseline ⁴ Medical Product Use	Cohorts				Covariate Balance	
	Topiramate Pregnant Cohort		Unexposed Pregnant Cohort		Between Topiramate and Unexposed Pregnant Cohorts	
	Number	Percent	Number	Percent	Absolute Difference	Standardized Difference
Valproate	15	0.8%	-	0.0%	0.755	-
Carbamazepine	3	0.2%	-	0.0%	0.151	-
Phenytoin	3	0.2%	-	0.0%	0.151	-
Benzodiazepines	220	11.1%	17,947	1.5%	9.548	0.401
Triptans	422	21.2%	6,633	0.6%	20.666	0.703
Antipsychotics	153	7.7%	5,857	0.5%	7.201	0.369
Antidepressants	858	43.2%	67,695	5.7%	37.432	0.968
Antihypertensives	234	11.8%	22,070	1.9%	9.904	0.401
Anxiolytics	349	17.6%	23,486	2.0%	15.568	0.543
Stimulants	108	5.4%	10,684	0.9%	4.529	0.261
Barbiturates	2	0.1%	3	0.0%	0.100	0.045
Insulin	19	1.0%	5,880	0.5%	0.458	0.054
Noninsulin antidiabetics	87	4.4%	20,656	1.7%	2.629	0.153
Opioids	603	30.3%	60,578	5.1%	25.207	0.699
Hypnotics	138	6.9%	9,952	0.8%	6.100	0.319
Buprenorphine	7	0.4%	500	0.0%	0.310	0.070
Methadone	7	0.4%	105	0.0%	0.343	0.081
Naloxone	-	0.0%	-	0.0%	0.000	-
Naltrexone	-	0.0%	78	0.0%	-0.007	-
Suspected teratogens	152	7.6%	78,679	6.7%	0.990	0.038
NSAIDs	222	11.2%	29,900	2.5%	8.638	0.347
Other anticonvulsants	207	10.4%	-	0.0%	10.412	-
Baseline ⁴ Health Service Utilization Intensity	Mean	Standard Deviation	Mean	Standard Deviation		
Mean number of ambulatory encounters	4.0	4.4	1.9	2.9	2.134	0.568
Mean number of inpatient hospital encounters	0.0	0.2	0.0	0.1	0.014	0.090
Mean number of unique generics dispensed	5.0	3.5	1.3	1.9	3.709	1.309

¹Preterm birth defined as a pregnancy duration less than 259 days

²Postterm birth defined as a pregnancy duration greater than 287 days

³Gestational age estimated using a claims-based algorithm, previously validated in the Medication Exposure in Pregnancy Risk Evaluation Program (MEPREP), to identify pregnancies ending in a live birth. ICD-10-CM diagnosis codes indicative of weeks of gestation, and ICD-9-CM and ICD-10-CM diagnosis codes for pre-term and post-term deliveries, were used to calculate the length of the pregnancy episode. Codes had to occur within 7 days of a delivery date in the inpatient setting. In absence of pre/post-term code, pregnancy duration was set to 273 days

⁴Related to user defined index date (pregnancy start, exposure date, or delivery date)

⁵The Charlson/Elixhauser Combined Comorbidity Score is calculated based on comorbidities observed during a requester-defined window around the exposure episode start date. (Gagne JJ, Glynn RJ, Avorn J, Levin R, Schneeweiss S. A combined comorbidity score predicted mortality in elderly patients better than existing scores. J Clin Epidemiol. 2011;64(7):749-759)

⁶Covariates in blue show a standardized difference greater than 0.1

Table 1c. Baseline Characteristics of the Topiramate Pregnancy Cohort and the Unexposed Pregnancy Cohort, Topiramate Monotherapy, in the Sentinel Distributed Database (SDD) From January 1, 2000 to September 30, 2015 (Unmatched, Aggregated)

	Cohorts				Covariate Balance	
	Topiramate Pregnant Cohort		Unexposed Pregnant Cohort		Between Topiramate and Unexposed Pregnant Cohorts	
	Number	Percent	Number	Percent	Absolute Difference	Standardized Difference
Number of pregnant patients	1,728	100.0%	1,144,212	100.0%	-	-
Demographic Characteristics	Mean	Standard Deviation	Mean	Standard Deviation		
Mean maternal age at index date	29.9	5.1	29.7	4.9	0.220	0.044
Maternal age categories (years)	Number	Percent	Number	Percent		
12-20	127	7.3%	94,283	8.2%	-0.890	-0.033
21-30	849	49.1%	569,562	49.8%	-0.646	-0.013
31-40	717	41.5%	461,529	40.3%	1.157	0.024
41-54	35	2.0%	18,838	1.6%	0.379	0.028
Year of index date						
2001	3	0.2%	16,109	1.4%	-1.234	-0.140
2002	4	0.2%	15,899	1.4%	-1.158	-0.129
2003	9	0.5%	12,667	1.1%	-0.586	-0.065
2004	21	1.2%	11,129	1.0%	0.243	0.023
2005	43	2.5%	11,143	1.0%	1.515	0.116
2006	20	1.2%	11,403	1.0%	0.161	0.016
2007	81	4.7%	65,263	5.7%	-1.016	-0.046
2008	109	6.3%	69,172	6.0%	0.262	0.011
2009	229	13.3%	172,207	15.1%	-1.798	-0.052
2010	283	16.4%	158,995	13.9%	2.482	0.069
2011	246	14.2%	138,229	12.1%	2.155	0.064
2012	189	10.9%	125,414	11.0%	-0.023	-0.001
2013	187	10.8%	126,100	11.0%	-0.199	-0.006
2014	201	11.6%	139,159	12.2%	-0.530	-0.016
2015	103	6.0%	71,323	6.2%	-0.273	-0.011
Race categories						
Race (American Indian or Alaska Native)	2	0.1%	879	0.1%	0.039	0.013
Race (Asian)	4	0.2%	11,907	1.0%	-0.809	-0.102
Race (Black or African American)	32	1.9%	44,784	3.9%	-2.062	-0.123
Race (Native Hawaiian or Other Pacific Islander)	-	0.0%	545	0.0%	-0.048	-
Race (Unknown)	1,441	83.4%	952,983	83.3%	0.104	0.003
Race (White)	249	14.4%	133,114	11.6%	2.776	0.083
Hispanic	17	1.0%	15,444	1.3%	-0.366	-0.034
Pregnancy Characteristics						
Preterm ¹	126	7.3%	64,674	5.7%	1.639	0.067
Postterm ²	159	9.2%	152,581	13.3%	-4.134	-0.131
Unknown term (assigned 273 days duration, term)	1,443	83.5%	926,957	81.0%	2.494	0.065

Table 1c. Baseline Characteristics of the Topiramate Pregnancy Cohort and the Unexposed Pregnancy Cohort, Topiramate Monotherapy, in the Sentinel Distributed Database (SDD) From January 1, 2000 to September 30, 2015 (Unmatched, Aggregated)

	Cohorts				Covariate Balance	
	Topiramate Pregnant Cohort		Unexposed Pregnant Cohort		Between Topiramate and Unexposed Pregnant Cohorts	
	Mean	Standard Deviation	Mean	Standard Deviation	Absolute Difference	Standardized Difference
Mean gestational age ³ at delivery	39.9	1.3	40.0	1.2	-0.146	-0.118
Exposure Characteristics						
Gestational age ³ of first exposure (weeks)	3.3	2.3	0.0	0.2	3.326	2.050
Mean number of dispensings in first trimester	1.4	0.7	0.0	0.0	1.360	-
Mean number of dispensings in second trimester	0.3	0.9	0.0	0.0	0.344	0.540
Mean number of dispensings in third trimester	0.3	0.8	0.0	0.0	0.292	0.492
	Number	Percent	Number	Percent		
Exposed during first trimester	1,728	100.0%	-	0.0%	100.000	-
Exposed during second trimester	278	16.1%	56	0.0%	16.083	0.619
Exposed during third trimester	233	13.5%	45	0.0%	13.480	0.558
	Mean	Standard Deviation	Mean	Standard Deviation		
Baseline⁴ Health Characteristics						
Combined comorbidity score ⁵	0.2	0.5	0.0	0.3	0.110	0.267
	Number	Percent	Number	Percent		
Epilepsy or seizures	149	8.6%	1,915	0.2%	8.455	0.422
Migraine or headache	987	57.1%	60,358	5.3%	51.843	1.350
Bipolar disorder	73	4.2%	3,962	0.3%	3.878	0.262
Neuropathic pain	136	7.9%	25,667	2.2%	5.627	0.259
Nonneuropathic pain	543	31.4%	162,457	14.2%	17.225	0.419
Obesity	121	7.0%	26,265	2.3%	4.707	0.225
Smoking	105	6.1%	30,124	2.6%	3.444	0.169
Depression	271	15.7%	43,675	3.8%	11.866	0.408
Anxiety	180	10.4%	37,177	3.2%	7.168	0.287
Psychotic conditions	8	0.5%	539	0.0%	0.416	0.083
Other psychiatric conditions	124	7.2%	26,467	2.3%	4.863	0.230
Sleep disorders	88	5.1%	10,597	0.9%	4.166	0.246
Fibromyalgia	95	5.5%	20,207	1.8%	3.732	0.200
Diabetes	50	2.9%	12,524	1.1%	1.799	0.129
Hypertension	105	6.1%	22,140	1.9%	4.141	0.212
Other pain conditions	41	2.4%	5,270	0.5%	1.912	0.162
ADHD	50	2.9%	7,880	0.7%	2.205	0.167
Drug or alcohol abuse	36	2.1%	6,414	0.6%	1.523	0.134
Chronic fatigue syndrome	12	0.7%	2,303	0.2%	0.493	0.074
Kidney disease	6	0.3%	3,089	0.3%	0.077	0.014
Migraine or bipolar disorder	1,039	60.1%	63,699	5.6%	54.560	1.427

Table 1c. Baseline Characteristics of the Topiramate Pregnancy Cohort and the Unexposed Pregnancy Cohort, Topiramate Monotherapy, in the Sentinel Distributed Database (SDD) From January 1, 2000 to September 30, 2015 (Unmatched, Aggregated)

	Cohorts				Covariate Balance	
	Topiramate Pregnant Cohort		Unexposed Pregnant Cohort		Between Topiramate and Unexposed Pregnant Cohorts	
	Number	Percent	Number	Percent	Absolute Difference	Standardized Difference
Baseline⁴ Medical Product Use						
Valproate	-	0.0%	-	0.0%	0.000	-
Carbamazepine	-	0.0%	-	0.0%	0.000	-
Phenytoin	-	0.0%	-	0.0%	0.000	-
Benzodiazepines	164	9.5%	17,401	1.5%	7.970	0.355
Triptans	345	20.0%	6,440	0.6%	19.402	0.675
Antipsychotics	93	5.4%	5,810	0.5%	4.874	0.291
Antidepressants	645	37.3%	65,638	5.7%	31.590	0.832
Antihypertensives	185	10.7%	21,339	1.9%	8.841	0.370
Anxiolytics	197	11.4%	22,849	2.0%	9.404	0.383
Stimulants	72	4.2%	10,252	0.9%	3.271	0.209
Barbiturates	-	0.0%	3	0.0%	-0.000	-
Insulin	19	1.1%	5,711	0.5%	0.600	0.067
Noninsulin antidiabetics	72	4.2%	19,944	1.7%	2.424	0.143
Opioids	450	26.0%	59,334	5.2%	20.856	0.600
Hypnotics	87	5.0%	9,651	0.8%	4.191	0.250
Buprenorphine	4	0.2%	495	0.0%	0.188	0.051
Methadone	5	0.3%	106	0.0%	0.280	0.073
Naloxone	-	0.0%	-	0.0%	0.000	-
Naltrexone	-	0.0%	74	0.0%	-0.006	-
Suspected teratogens	130	7.5%	76,612	6.7%	0.828	0.032
NSAIDs	171	9.9%	29,324	2.6%	7.333	0.307
Other anticonvulsants	-	0.0%	-	0.0%	0.000	-
Baseline⁴ Health Service Utilization Intensity	Mean	Standard Deviation	Mean	Standard Deviation		
Mean number of ambulatory encounters	3.6	4.0	1.9	3.0	1.712	0.487
Mean number of inpatient hospital encounters	0.0	0.1	0.0	0.1	0.008	0.056
Mean number of unique generics dispensed	4.5	3.2	1.3	1.9	3.155	1.205

¹Preterm birth defined as a pregnancy duration less than 259 days

²Postterm birth defined as a pregnancy duration greater than 287 days

³Gestational age estimated using a claims-based algorithm, previously validated in the Medication Exposure in Pregnancy Risk Evaluation Program (MEPREP), to identify pregnancies ending in a live birth. ICD-10-CM diagnosis codes indicative of weeks of gestation, and ICD-9-CM and ICD-10-CM diagnosis codes for pre-term and post-term deliveries, were used to calculate the length of the pregnancy episode. Codes had to occur within 7 days of a delivery date in the inpatient setting. In absence of pre/post-term code, pregnancy duration was set to 273 days

⁴Related to user defined index date (pregnancy start, exposure date, or delivery date)

⁵The Charlson/Elixhauser Combined Comorbidity Score is calculated based on comorbidities observed during a requester-defined window around the exposure episode start date. (Gagne JJ, Glynn RJ, Avorn J, Levin R, Schneeweiss S. A combined comorbidity score predicted mortality in elderly patients better than existing scores. J Clin Epidemiol. 2011;64(7):749-759)

⁶Covariates in blue show a standardized difference greater than 0.1

Table 1d. Baseline Characteristics of the Topiramate Pregnancy Cohort and the Lamotrigine Pregnancy Cohort, Lamotrigine Comparator, in the Sentinel Distributed Database (SDD) From January 1, 2000 to September 30, 2015 (Unmatched, Aggregated)

	Cohorts				Covariate Balance	
	Topiramate Pregnant Cohort		Lamotrigine Pregnant Cohort		Between Topiramate and Lamotrigine Pregnant Cohorts	
	Number	Percent	Number	Percent	Absolute Difference	Standardized Difference
Number of pregnant patients	2,321	100.0%	3,299	100.0%	-	-
Demographic Characteristics	Mean	Standard Deviation	Mean	Standard Deviation		
Mean maternal age at index date	29.7	5.1	29.1	5.2	0.637	0.124
Maternal age categories (years)	Number	Percent	Number	Percent		
12-20	186	8.0%	380	11.5%	-3.505	-0.118
21-30	1,147	49.4%	1,621	49.1%	0.282	0.006
31-40	947	40.8%	1,242	37.6%	3.154	0.065
41-54	41	1.8%	56	1.7%	0.069	0.005
Year of index date						
2001	3	0.1%	1	0.0%	0.099	0.035
2002	9	0.4%	2	0.1%	0.327	0.069
2003	15	0.6%	5	0.2%	0.495	0.079
2004	53	2.3%	33	1.0%	1.283	0.101
2005	76	3.3%	51	1.5%	1.729	0.113
2006	30	1.3%	65	2.0%	-0.678	-0.054
2007	112	4.8%	167	5.1%	-0.237	-0.011
2008	134	5.8%	192	5.8%	-0.047	-0.002
2009	275	11.8%	486	14.7%	-2.883	-0.085
2010	328	14.1%	461	14.0%	0.158	0.005
2011	305	13.1%	420	12.7%	0.410	0.012
2012	263	11.3%	349	10.6%	0.752	0.024
2013	265	11.4%	442	13.4%	-1.981	-0.060
2014	295	12.7%	415	12.6%	0.130	0.004
2015	158	6.8%	210	6.4%	0.442	0.018
Race categories						
Race (American Indian or Alaska Native)	4	0.2%	2	0.1%	0.112	0.033
Race (Asian)	5	0.2%	13	0.4%	-0.179	-0.032
Race (Black or African American)	64	2.8%	76	2.3%	0.454	0.029
Race (Native Hawaiian or Other Pacific Islander)	-	0.0%	1	0.0%	-0.030	-
Race (Unknown)	1,835	79.1%	2,427	73.6%	5.493	0.129
Race (White)	413	17.8%	780	23.6%	-5.849	-0.145
Hispanic	23	1.0%	30	0.9%	0.082	0.008
Pregnancy Characteristics						
Preterm ¹	169	7.3%	265	8.0%	-0.751	-0.028
Postterm ²	208	9.0%	328	9.9%	-0.981	-0.034
Unknown term (assigned 273 days duration, term)	1,944	83.8%	2,706	82.0%	1.732	0.046

Table 1d. Baseline Characteristics of the Topiramate Pregnancy Cohort and the Lamotrigine Pregnancy Cohort, Lamotrigine Comparator, in the Sentinel Distributed Database (SDD) From January 1, 2000 to September 30, 2015 (Unmatched, Aggregated)

	Cohorts				Covariate Balance	
	Topiramate Pregnant Cohort		Lamotrigine Pregnant Cohort		Between Topiramate and Lamotrigine Pregnant Cohorts	
	Mean	Standard Deviation	Mean	Standard Deviation	Absolute Difference	Standardized Difference
Mean gestational age ³ at delivery	39.9	1.2	39.9	1.4	0.019	0.015
Exposure Characteristics						
Gestational age ³ of first exposure (weeks)	3.4	2.4	3.8	2.7	-0.354	-0.138
Mean number of dispensings in first trimester	1.4	0.8	1.9	1.1	-0.541	-0.587
Mean number of dispensings in second trimester	0.4	0.9	1.4	1.6	-1.001	-0.774
Mean number of dispensings in third trimester	0.3	0.9	1.4	1.6	-1.052	-0.803
	Number	Percent	Number	Percent		
Exposed during first trimester	2,321	100.0%	3,299	100.0%	0.000	-
Exposed during second trimester	414	17.8%	1,761	53.4%	-35.543	-0.799
Exposed during third trimester	338	14.6%	1,691	51.3%	-36.695	-0.848
	Mean	Standard Deviation	Mean	Standard Deviation		
Baseline⁴ Health Characteristics						
Combined comorbidity score ⁵	0.2	0.6	0.5	0.6	-0.300	-0.495
	Number	Percent	Number	Percent		
Epilepsy or seizures	286	12.3%	1,004	30.4%	-18.111	-0.453
Migraine or headache	1,352	58.3%	480	14.5%	43.701	1.019
Bipolar disorder	138	5.9%	1,199	36.3%	-30.399	-0.802
Neuropathic pain	222	9.6%	173	5.2%	4.321	0.166
Nonneuropathic pain	817	35.2%	901	27.3%	7.889	0.171
Obesity	179	7.7%	136	4.1%	3.590	0.153
Smoking	205	8.8%	415	12.6%	-3.747	-0.121
Depression	455	19.6%	1,042	31.6%	-11.982	-0.277
Anxiety	300	12.9%	613	18.6%	-5.656	-0.156
Psychotic conditions	17	0.7%	33	1.0%	-0.268	-0.029
Other psychiatric conditions	218	9.4%	491	14.9%	-5.491	-0.169
Sleep disorders	136	5.9%	146	4.4%	1.434	0.065
Fibromyalgia	169	7.3%	127	3.8%	3.432	0.150
Diabetes	73	3.1%	68	2.1%	1.084	0.068
Hypertension	162	7.0%	148	4.5%	2.494	0.107
Other pain conditions	87	3.7%	84	2.5%	1.202	0.069
ADHD	62	2.7%	184	5.6%	-2.906	-0.147
Drug or alcohol abuse	83	3.6%	207	6.3%	-2.699	-0.125
Chronic fatigue syndrome	17	0.7%	10	0.3%	0.429	0.060
Kidney disease	9	0.4%	21	0.6%	-0.249	-0.035
Migraine or bipolar disorder	1,439	62.0%	1,513	45.9%	16.137	0.328

Table 1d. Baseline Characteristics of the Topiramate Pregnancy Cohort and the Lamotrigine Pregnancy Cohort, Lamotrigine Comparator, in the Sentinel Distributed Database (SDD) From January 1, 2000 to September 30, 2015 (Unmatched, Aggregated)

Baseline ⁴ Medical Product Use	Cohorts				Covariate Balance	
	Topiramate Pregnant Cohort		Lamotrigine Pregnant Cohort		Between Topiramate and Lamotrigine Pregnant Cohorts	
	Number	Percent	Number	Percent	Absolute Difference	Standardized Difference
Valproate	31	1.3%	50	1.5%	-0.180	-0.015
Carbamazepine	14	0.6%	55	1.7%	-1.064	-0.101
Phenytoin	20	0.9%	38	1.2%	-0.290	-0.029
Benzodiazepines	248	10.7%	417	12.6%	-1.955	-0.061
Triptans	479	20.6%	86	2.6%	18.031	0.586
Antipsychotics	156	6.7%	577	17.5%	-10.769	-0.335
Antidepressants	942	40.6%	1,433	43.4%	-2.851	-0.058
Antihypertensives	265	11.4%	191	5.8%	5.628	0.202
Anxiolytics	390	16.8%	760	23.0%	-6.234	-0.157
Stimulants	99	4.3%	317	9.6%	-5.344	-0.211
Barbiturates	7	0.3%	10	0.3%	-0.002	-0.000
Insulin	25	1.1%	30	0.9%	0.168	0.017
Noninsulin antidiabetics	93	4.0%	81	2.5%	1.552	0.088
Opioids	708	30.5%	568	17.2%	13.287	0.316
Hypnotics	155	6.7%	317	9.6%	-2.931	-0.107
Buprenorphine	8	0.3%	5	0.2%	0.193	0.039
Methadone	7	0.3%	7	0.2%	0.089	0.018
Naloxone	-	0.0%	-	0.0%	0.000	-
Naltrexone	1	0.0%	6	0.2%	-0.139	-0.041
Suspected teratogens	191	8.2%	271	8.2%	0.015	0.001
NSAIDs	283	12.2%	255	7.7%	4.463	0.149
Other anticonvulsants	315	13.6%	640	19.4%	-5.828	-0.158
Baseline ⁴ Health Service Utilization Intensity	Mean	Standard Deviation	Mean	Standard Deviation		
Mean number of ambulatory encounters	4.0	4.5	4.3	4.5	-0.290	-0.065
Mean number of inpatient hospital encounters	0.0	0.2	0.0	0.3	-0.009	-0.037
Mean number of unique generics dispensed	5.0	3.5	4.6	3.2	0.440	0.131

¹Preterm birth defined as a pregnancy duration less than 259 days

²Postterm birth defined as a pregnancy duration greater than 287 days

³Gestational age estimated using a claims-based algorithm, previously validated in the Medication Exposure in Pregnancy Risk Evaluation Program (MEPREP), to identify pregnancies ending in a live birth. ICD-10-CM diagnosis codes indicative of weeks of gestation, and ICD-9-CM and ICD-10-CM diagnosis codes for pre-term and post-term deliveries, were used to calculate the length of the pregnancy episode. Codes had to occur within 7 days of a delivery date in the inpatient setting. In absence of pre/post-term code, pregnancy duration was set to 273 days

⁴Related to user defined index date (pregnancy start, exposure date, or delivery date)

⁵The Charlson/Elixhauser Combined Comorbidity Score is calculated based on comorbidities observed during a requester-defined window around the exposure episode start date. (Gagne JJ, Glynn RJ, Avorn J, Levin R, Schneeweiss S. A combined comorbidity score predicted mortality in elderly patients better than existing scores. J Clin Epidemiol. 2011;64(7):749-759)

⁶Covariates in blue show a standardized difference greater than 0.1

Table 1e. Baseline Characteristics of the Topiramate Pregnancy Cohort and the Unexposed Pregnancy Cohort, Two Fills of Topiramate Required, in the Sentinel Distributed Database (SDD) From January 1, 2000 to September 30, 2015 (Unmatched, Aggregated)

	Cohorts				Covariate Balance	
	Topiramate Pregnant Cohort		Unexposed Pregnant Cohort		Between Topiramate and Unexposed Pregnant Cohorts	
	Number	Percent	Number	Percent	Absolute Difference	Standardized Difference
Number of pregnant patients	955	100.0%	1,144,271	100.0%	-	-
Demographic Characteristics	Mean	Standard Deviation	Mean	Standard Deviation		
Mean maternal age at index date	30.4	5.1	29.7	4.9	0.670	0.135
Maternal age categories (years)	Number	Percent	Number	Percent		
12-20	64	6.7%	94,291	8.2%	-1.539	-0.059
21-30	436	45.7%	569,590	49.8%	-4.123	-0.083
31-40	438	45.9%	461,551	40.3%	5.528	0.112
41-54	17	1.8%	18,839	1.6%	0.134	0.010
Year of index date						
2001	2	0.2%	16,109	1.4%	-1.198	-0.134
2002	2	0.2%	15,899	1.4%	-1.180	-0.133
2003	2	0.2%	12,667	1.1%	-0.898	-0.111
2004	11	1.2%	11,130	1.0%	0.179	0.017
2005	30	3.1%	11,143	1.0%	2.168	0.153
2006	17	1.8%	11,406	1.0%	0.783	0.067
2007	50	5.2%	65,263	5.7%	-0.468	-0.021
2008	56	5.9%	69,179	6.0%	-0.182	-0.008
2009	128	13.4%	172,212	15.0%	-1.647	-0.047
2010	159	16.6%	158,998	13.9%	2.754	0.077
2011	138	14.5%	138,238	12.1%	2.369	0.070
2012	101	10.6%	125,424	11.0%	-0.385	-0.012
2013	94	9.8%	126,105	11.0%	-1.178	-0.039
2014	110	11.5%	139,168	12.2%	-0.644	-0.020
2015	55	5.8%	71,330	6.2%	-0.475	-0.020
Race categories						
Race (American Indian or Alaska Native)	2	0.2%	879	0.1%	0.133	0.035
Race (Asian)	1	0.1%	11,907	1.0%	-0.936	-0.124
Race (Black or African American)	18	1.9%	44,784	3.9%	-2.029	-0.121
Race (Native Hawaiian or Other Pacific Islander)	-	0.0%	545	0.0%	-0.048	-
Race (Unknown)	786	82.3%	953,031	83.3%	-0.984	-0.026
Race (White)	148	15.5%	133,125	11.6%	3.863	0.113
Hispanic	9	0.9%	15,445	1.3%	-0.407	-0.038
Pregnancy Characteristics						
Preterm ¹	71	7.4%	64,677	5.7%	1.782	0.072
Postterm ²	92	9.6%	152,583	13.3%	-3.701	-0.116
Unknown term (assigned 273 days duration, term)	792	82.9%	927,011	81.0%	1.919	0.050

Table 1e. Baseline Characteristics of the Topiramate Pregnancy Cohort and the Unexposed Pregnancy Cohort, Two Fills of Topiramate Required, in the Sentinel Distributed Database (SDD) From January 1, 2000 to September 30, 2015 (Unmatched, Aggregated)

	Cohorts				Covariate Balance	
	Topiramate Pregnant Cohort		Unexposed Pregnant Cohort		Between Topiramate and Unexposed Pregnant Cohorts	
	Mean	Standard Deviation	Mean	Standard Deviation	Absolute Difference	Standardized Difference
Mean gestational age ³ at delivery	39.9	1.3	40.0	1.2	-0.145	-0.116
Exposure Characteristics						
Gestational age ³ of first exposure (weeks)	3.1	1.9	0.0	0.2	3.056	2.238
Mean number of dispensings in first trimester	1.7	0.9	0.0	0.0	1.720	-
Mean number of dispensings in second trimester	0.6	1.2	0.0	0.0	0.598	0.714
Mean number of dispensings in third trimester	0.6	1.2	0.0	0.0	0.560	0.645
	Number	Percent	Number	Percent		
Exposed during first trimester	955	100.0%	-	0.0%	100.000	-
Exposed during second trimester	242	25.3%	56	0.0%	25.335	0.824
Exposed during third trimester	207	21.7%	47	0.0%	21.671	0.744
	Mean	Standard Deviation	Mean	Standard Deviation		
Baseline⁴ Health Characteristics						
Combined comorbidity score ⁵	0.2	0.6	0.0	0.3	0.175	0.380
	Number	Percent	Number	Percent		
Epilepsy or seizures	174	18.2%	1,915	0.2%	18.053	0.658
Migraine or headache	513	53.7%	60,366	5.3%	48.442	1.254
Bipolar disorder	73	7.6%	3,966	0.3%	7.297	0.379
Neuropathic pain	81	8.5%	25,670	2.2%	6.238	0.280
Nonneuropathic pain	322	33.7%	162,476	14.2%	19.518	0.470
Obesity	55	5.8%	26,270	2.3%	3.463	0.177
Smoking	72	7.5%	30,130	2.6%	4.906	0.225
Depression	185	19.4%	43,681	3.8%	15.554	0.501
Anxiety	115	12.0%	37,178	3.2%	8.793	0.336
Psychotic conditions	4	0.4%	540	0.0%	0.372	0.077
Other psychiatric conditions	109	11.4%	26,467	2.3%	9.101	0.366
Sleep disorders	47	4.9%	10,599	0.9%	3.995	0.239
Fibromyalgia	67	7.0%	20,213	1.8%	5.249	0.258
Diabetes	25	2.6%	12,525	1.1%	1.523	0.113
Hypertension	56	5.9%	22,141	1.9%	3.929	0.204
Other pain conditions	36	3.8%	5,271	0.5%	3.309	0.232
ADHD	22	2.3%	7,881	0.7%	1.615	0.133
Drug or alcohol abuse	28	2.9%	6,416	0.6%	2.371	0.182
Chronic fatigue syndrome	8	0.8%	2,303	0.2%	0.636	0.089
Kidney disease	4	0.4%	3,089	0.3%	0.149	0.025
Migraine or bipolar disorder	566	59.3%	63,709	5.6%	53.699	1.401

Table 1e. Baseline Characteristics of the Topiramate Pregnancy Cohort and the Unexposed Pregnancy Cohort, Two Fills of Topiramate Required, in the Sentinel Distributed Database (SDD) From January 1, 2000 to September 30, 2015 (Unmatched, Aggregated)

Baseline ⁴ Medical Product Use	Cohorts				Covariate Balance	
	Topiramate Pregnant Cohort		Unexposed Pregnant Cohort		Between Topiramate and Unexposed Pregnant Cohorts	
	Number	Percent	Number	Percent	Absolute Difference	Standardized Difference
Valproate	11	1.2%	-	0.0%	1.152	-
Carbamazepine	10	1.0%	-	0.0%	1.047	-
Phenytoin	5	0.5%	-	0.0%	0.524	-
Benzodiazepines	108	11.3%	17,406	1.5%	9.788	0.408
Triptans	191	20.0%	6,442	0.6%	19.437	0.675
Antipsychotics	75	7.9%	5,814	0.5%	7.345	0.373
Antidepressants	406	42.5%	65,639	5.7%	36.777	0.952
Antihypertensives	109	11.4%	21,342	1.9%	9.548	0.391
Anxiolytics	178	18.6%	22,854	2.0%	16.641	0.569
Stimulants	48	5.0%	10,253	0.9%	4.130	0.245
Barbiturates	5	0.5%	3	0.0%	0.523	0.103
Insulin	8	0.8%	5,711	0.5%	0.339	0.042
Noninsulin antidiabetics	43	4.5%	19,945	1.7%	2.760	0.159
Opioids	295	30.9%	59,340	5.2%	25.704	0.709
Hypnotics	77	8.1%	9,653	0.8%	7.219	0.355
Buprenorphine	6	0.6%	496	0.0%	0.585	0.101
Methadone	4	0.4%	106	0.0%	0.410	0.089
Naloxone	-	0.0%	-	0.0%	0.000	-
Naltrexone	-	0.0%	74	0.0%	-0.006	-
Suspected teratogens	72	7.5%	76,615	6.7%	0.844	0.033
NSAIDs	94	9.8%	29,326	2.6%	7.280	0.305
Other anticonvulsants	145	15.2%	-	0.0%	15.183	-
Baseline ⁴ Health Service Utilization Intensity	Mean	Standard Deviation	Mean	Standard Deviation		
Mean number of ambulatory encounters	4.1	4.3	1.9	3.0	2.216	0.596
Mean number of inpatient hospital encounters	0.0	0.2	0.0	0.1	0.021	0.129
Mean number of unique generics dispensed	5.4	3.5	1.3	1.9	4.045	1.451

¹Preterm birth defined as a pregnancy duration less than 259 days

²Postterm birth defined as a pregnancy duration greater than 287 days

³Gestational age estimated using a claims-based algorithm, previously validated in the Medication Exposure in Pregnancy Risk Evaluation Program (MEPREP), to identify pregnancies ending in a live birth. ICD-10-CM diagnosis codes indicative of weeks of gestation, and ICD-9-CM and ICD-10-CM diagnosis codes for pre-term and post-term deliveries, were used to calculate the length of the pregnancy episode. Codes had to occur within 7 days of a delivery date in the inpatient setting. In absence of pre/post-term code, pregnancy duration was set to 273 days

⁴Related to user defined index date (pregnancy start, exposure date, or delivery date)

⁵The Charlson/Elixhauser Combined Comorbidity Score is calculated based on comorbidities observed during a requester-defined window around the exposure episode start date. (Gagne JJ, Glynn RJ, Avorn J, Levin R, Schneeweiss S. A combined comorbidity score predicted mortality in elderly patients better than existing scores. J Clin Epidemiol. 2011;64(7):749-759)

⁶Covariates in blue show a standardized difference greater than 0.1

Table 1f. Baseline Characteristics of the Topiramate Pregnancy Cohort and the Unexposed Pregnancy Cohort, Exposure Defined by Overlapping Days Supply, in the Sentinel Distributed Database (SDD) From January 1, 2000 to September 30, 2015 (Unmatched, Aggregated)

	Cohorts				Covariate Balance	
	Topiramate Pregnant Cohort		Unexposed Pregnant Cohort		Between Topiramate and Unexposed Pregnant Cohorts	
	Number	Percent	Number	Percent	Absolute Difference	Standardized Difference
Number of pregnant patients	3,499	100.0%	1,234,695	100.0%	-	-
Demographic Characteristics	Mean	Standard Deviation	Mean	Standard Deviation		
Mean maternal age at index date	29.9	5.1	29.8	4.8	0.084	0.017
Maternal age categories (years)	Number	Percent	Number	Percent		
12-20	256	7.3%	95,711	7.8%	-0.435	-0.016
21-30	1,736	49.6%	611,089	49.5%	0.121	0.002
31-40	1,444	41.3%	507,237	41.1%	0.187	0.004
41-54	63	1.8%	20,658	1.7%	0.127	0.010
Year of index date						
2001	5	0.1%	21,023	1.7%	-1.560	-0.164
2002	12	0.3%	20,490	1.7%	-1.317	-0.133
2003	21	0.6%	16,734	1.4%	-0.755	-0.077
2004	58	1.7%	14,952	1.2%	0.447	0.038
2005	89	2.5%	14,757	1.2%	1.348	0.100
2006	63	1.8%	15,171	1.2%	0.572	0.047
2007	175	5.0%	68,848	5.6%	-0.575	-0.026
2008	222	6.3%	76,485	6.2%	0.150	0.006
2009	468	13.4%	183,366	14.9%	-1.476	-0.042
2010	500	14.3%	168,292	13.6%	0.660	0.019
2011	483	13.8%	146,412	11.9%	1.946	0.058
2012	377	10.8%	133,088	10.8%	-0.005	-0.000
2013	378	10.8%	133,834	10.8%	-0.036	-0.001
2014	423	12.1%	146,411	11.9%	0.231	0.007
2015	225	6.4%	74,832	6.1%	0.370	0.015
Race categories						
Race (American Indian or Alaska Native)	4	0.1%	902	0.1%	0.041	0.013
Race (Asian)	5	0.1%	12,862	1.0%	-0.899	-0.117
Race (Black or African American)	75	2.1%	45,621	3.7%	-1.551	-0.092
Race (Native Hawaiian or Other Pacific Islander)	-	0.0%	557	0.0%	-0.045	-
Race (Unknown)	2,864	81.9%	1,030,780	83.5%	-1.633	-0.043
Race (White)	551	15.7%	143,973	11.7%	4.087	0.119
Hispanic	35	1.0%	16,018	1.3%	-0.297	-0.028
Pregnancy Characteristics						
Preterm ¹	279	8.0%	69,426	5.6%	2.351	0.093
Postterm ²	342	9.8%	166,665	13.5%	-3.724	-0.116
Unknown term (assigned 273 days duration, term)	2,878	82.3%	998,604	80.9%	1.373	0.035

Table 1f. Baseline Characteristics of the Topiramate Pregnancy Cohort and the Unexposed Pregnancy Cohort, Exposure Defined by Overlapping Days Supply, in the Sentinel Distributed Database (SDD) From January 1, 2000 to September 30, 2015 (Unmatched, Aggregated)

	Cohorts				Covariate Balance	
	Topiramate Pregnant Cohort		Unexposed Pregnant Cohort		Between Topiramate and Unexposed Pregnant Cohorts	
	Mean	Standard Deviation	Mean	Standard Deviation	Absolute Difference	Standardized Difference
Mean gestational age ³ at delivery	39.9	1.3	40.0	1.2	-0.166	-0.132
Exposure Characteristics						
Gestational age ³ of first exposure (weeks)	-9.3	24.6	0.0	0.2	-9.348	-0.537
Mean number of dispensings in first trimester	1.7	0.9	0.0	0.0	1.708	-
Mean number of dispensings in second trimester	0.5	1.1	0.0	0.0	0.477	0.641
Mean number of dispensings in third trimester	0.4	1.0	0.0	0.0	0.377	0.524
	Number	Percent	Number	Percent		
Exposed during first trimester		100.0%	-	0.0%	100.000	-
Exposed during second trimester	766	21.9%	57	0.0%	21.887	0.748
Exposed during third trimester	519	14.8%	65	0.0%	14.828	0.590
	Mean	Standard Deviation	Mean	Standard Deviation		
Baseline⁴ Health Characteristics						
Combined comorbidity score ⁵	0.2	0.6	0.0	0.3	0.168	0.384
	Number	Percent	Number	Percent		
Epilepsy or seizures	395	11.3%	1,971	0.2%	11.129	0.493
Migraine or headache	1,983	56.7%	64,000	5.2%	51.490	1.341
Bipolar disorder	242	6.9%	4,015	0.3%	6.591	0.358
Neuropathic pain	300	8.6%	27,302	2.2%	6.363	0.285
Nonneuropathic pain	1,139	32.6%	173,343	14.0%	18.513	0.449
Obesity	256	7.3%	28,347	2.3%	5.021	0.236
Smoking	258	7.4%	31,126	2.5%	4.853	0.225
Depression	664	19.0%	47,419	3.8%	15.136	0.490
Anxiety	440	12.6%	40,218	3.3%	9.318	0.350
Psychotic conditions	15	0.4%	570	0.0%	0.383	0.079
Other psychiatric conditions	319	9.1%	29,273	2.4%	6.746	0.293
Sleep disorders	188	5.4%	11,342	0.9%	4.454	0.257
Fibromyalgia	224	6.4%	21,440	1.7%	4.665	0.238
Diabetes	101	2.9%	13,322	1.1%	1.808	0.130
Hypertension	197	5.6%	23,735	1.9%	3.708	0.195
Other pain conditions	99	2.8%	5,485	0.4%	2.385	0.189
ADHD	90	2.6%	8,411	0.7%	1.891	0.150
Drug or alcohol abuse	108	3.1%	6,675	0.5%	2.546	0.192
Chronic fatigue syndrome	20	0.6%	2,477	0.2%	0.371	0.060
Kidney disease	15	0.4%	3,313	0.3%	0.160	0.027
Migraine or bipolar disorder	2,144	61.3%	67,399	5.5%	55.816	1.469

Table 1f. Baseline Characteristics of the Topiramate Pregnancy Cohort and the Unexposed Pregnancy Cohort, Exposure Defined by Overlapping Days Supply, in the Sentinel Distributed Database (SDD) From January 1, 2000 to September 30, 2015 (Unmatched, Aggregated)

	Cohorts				Covariate Balance	
	Topiramate Pregnant Cohort		Unexposed Pregnant Cohort		Between Topiramate and Unexposed Pregnant Cohorts	
	Number	Percent	Number	Percent	Absolute Difference	Standardized Difference
Baseline⁴ Medical Product Use						
Valproate	42	1.2%	-	0.0%	1.200	-
Carbamazepine	27	0.8%	-	0.0%	0.772	-
Phenytoin	21	0.6%	-	0.0%	0.600	-
Benzodiazepines	340	9.7%	18,746	1.5%	8.199	0.362
Triptans	666	19.0%	6,815	0.6%	18.482	0.654
Antipsychotics	233	6.7%	6,140	0.5%	6.162	0.336
Antidepressants	1,366	39.0%	71,069	5.8%	33.284	0.871
Antihypertensives	367	10.5%	22,827	1.8%	8.640	0.365
Anxiolytics	554	15.8%	24,426	2.0%	13.855	0.501
Stimulants	169	4.8%	11,004	0.9%	3.939	0.238
Barbiturates	9	0.3%	3	0.0%	0.257	0.072
Insulin	40	1.1%	6,153	0.5%	0.645	0.072
Noninsulin antidiabetics	149	4.3%	21,241	1.7%	2.538	0.149
Opioids	937	26.8%	62,270	5.0%	21.736	0.622
Hypnotics	225	6.4%	10,189	0.8%	5.605	0.303
Buprenorphine	12	0.3%	516	0.0%	0.301	0.069
Methadone	7	0.2%	109	0.0%	0.191	0.059
Naloxone	-	0.0%	-	0.0%	0.000	-
Naltrexone	-	0.0%	85	0.0%	-0.007	-
Suspected teratogens	264	7.5%	81,456	6.6%	0.948	0.037
NSAIDs	349	10.0%	30,773	2.5%	7.482	0.313
Other anticonvulsants	432	12.3%	-	0.0%	12.346	-
Baseline⁴ Health Service Utilization Intensity	Mean	Standard Deviation	Mean	Standard Deviation		
Mean number of ambulatory encounters	4.1	4.3	1.9	2.9	2.145	0.580
Mean number of inpatient hospital encounters	0.0	0.2	0.0	0.1	0.019	0.117
Mean number of unique generics dispensed	5.1	3.5	1.3	1.9	3.735	1.332

¹Preterm birth defined as a pregnancy duration less than 259 days

²Postterm birth defined as a pregnancy duration greater than 287 days

³Gestational age estimated using a claims-based algorithm, previously validated in the Medication Exposure in Pregnancy Risk Evaluation Program (MEPREP), to identify pregnancies ending in a live birth. ICD-10-CM diagnosis codes indicative of weeks of gestation, and ICD-9-CM and ICD-10-CM diagnosis codes for pre-term and post-term deliveries, were used to calculate the length of the pregnancy episode. Codes had to occur within 7 days of a delivery date in the inpatient setting. In absence of pre/post-term code, pregnancy duration was set to 273 days

⁴Related to user defined index date (pregnancy start, exposure date, or delivery date)

⁵The Charlson/Elixhauser Combined Comorbidity Score is calculated based on comorbidities observed during a requester-defined window around the exposure episode start date. (Gagne JJ, Glynn RJ, Avorn J, Levin R, Schneeweiss S. A combined comorbidity score predicted mortality in elderly patients better than existing scores. J Clin Epidemiol. 2011;64(7):749-759)

⁶Covariates in blue show a standardized difference greater than 0.1

Table 2a. Baseline Characteristics of the Topiramate Infant Cohort and the Unexposed Infant Cohort, Main Analysis, in the Sentinel Distributed Database (SDD) From January 1, 2000 to September 30, 2015 (Unmatched, Aggregated)

Characteristics	Topiramate Pregnant Cohort		Unexposed Pregnant Cohort	
	Mean	Standard Deviation	Mean	Standard Deviation
Mean enrollment time after birth (days)	1,187.8	1102.8	1,219.4	1149.0
Mean difference in days between date of birth and date of enrollment	2.0	48.1	3.6	38.6

Table 2b. Baseline Characteristics of the Topiramate Infant Cohort and the Unexposed Infant Cohort, Excluding Epilepsy Cases, in the Sentinel Distributed Database (SDD) From January 1, 2000 to September 30, 2015 (Unmatched, Aggregated)

Characteristics	Topiramate Pregnant Cohort		Unexposed Pregnant Cohort	
	Mean	Standard Deviation	Mean	Standard Deviation
Mean enrollment time after birth (days)	1,154.1	1085.9	1,206.1	1128.7
Mean difference in days between date of birth and date of enrollment	1.9	51.8	3.6	39.2

Table 2c. Baseline Characteristics of the Topiramate Infant Cohort and the Unexposed Infant Cohort, Topiramate Monotherapy, in the Sentinel Distributed Database (SDD) From January 1, 2000 to September 30, 2015 (Unmatched, Aggregated)

Characteristics	Topiramate Pregnant Cohort		Unexposed Pregnant Cohort	
	Mean	Standard Deviation	Mean	Standard Deviation
Mean enrollment time after birth (days)	1,171.5	1088.2	1,226.8	1139.0
Mean difference in days between date of birth and date of enrollment	1.8	53.2	3.7	39.8

Table 2d. Baseline Characteristics of the Topiramate Infant Cohort and the Lamotrigine Infant Cohort, Lamotrigine Comparator, in the Sentinel Distributed Database (SDD) From January 1, 2000 to September 30, 2015 (Unmatched, Aggregated)

Characteristics	Topiramate Pregnant Cohort		Lamotrigine Pregnant Cohort	
	Mean	Standard Deviation	Mean	Standard Deviation
Mean enrollment time after birth (days)	1,245.6	1114.9	1,312.2	1040.6
Mean difference in days between date of birth and date of enrollment	2.3	48.9	2.9	33.1

Table 2e. Baseline Characteristics of the Topiramate Infant Cohort and the Unexposed Infant Cohort, Two Fills of Topiramate Required, in the Sentinel Distributed Database (SDD) From January 1, 2000 to September 30, 2015 (Unmatched, Aggregated)

Characteristics	Topiramate Pregnant Cohort		Unexposed Pregnant Cohort	
	Mean	Standard Deviation	Mean	Standard Deviation
Mean enrollment time after birth (days)	1,230.3	1108.2	1,226.8	1139.0
Mean difference in days between date of birth and date of enrollment	1.8	25.0	3.7	39.8

Table 2f. Baseline Characteristics of the Topiramate Infant Cohort and the Unexposed Infant Cohort, Exposure Defined by Overlapping Days Supply, in the Sentinel Distributed Database (SDD) From January 1, 2000 to September 30, 2015 (Unmatched, Aggregated)

Characteristics	Topiramate Pregnant Cohort		Unexposed Pregnant Cohort	
	Mean	Standard Deviation	Mean	Standard Deviation
Mean enrollment time after birth (days)	1,172.5	1105.4	1,219.2	1149.0
Mean difference in days between date of birth and date of enrollment	2.6	42.2	3.6	38.6

Table 3a. Baseline Characteristics of the Topiramate Pregnancy Cohort and the Unexposed Pregnancy Cohort, Main Analysis, in the Sentinel Distributed Database (SDD) From January 1, 2000 to September 30, 2015 (Matched, Aggregated), Ratio: 1:1, Caliper: 0.05

	Cohorts				Covariate Balance	
	Topiramate Pregnant Cohort		Unexposed Pregnant Cohort		Between Topiramate and Unexposed Pregnant Cohorts	
	Number	Percent	Number	Percent	Absolute Difference	Standardized Difference
Number of pregnant patients	2,330	98.6%	2,330	0.2%	-	-
Demographic Characteristics	Mean	Standard Deviation	Mean	Standard Deviation		
Mean maternal age at index date	29.9	5.1	30.0	5.2	-0.101	-0.020
Maternal age categories (years)	Number	Percent	Number	Percent		
12-20	167	7.2%	173	7.4%	-0.258	-0.010
21-30	1,143	49.1%	1,128	48.4%	0.644	0.013
31-40	974	41.8%	975	41.8%	-0.043	-0.001
41-54	46	2.0%	54	2.3%	-0.343	-0.024
Year of index date						
2001	5	0.2%	23	1.0%	-0.773	-0.100
2002	9	0.4%	62	2.7%	-2.275	-0.187
2003	15	0.6%	45	1.9%	-1.288	-0.114
2004	46	2.0%	29	1.2%	0.730	0.058
2005	62	2.7%	35	1.5%	1.159	0.081
2006	38	1.6%	39	1.7%	-0.043	-0.003
2007	115	4.9%	116	5.0%	-0.043	-0.002
2008	152	6.5%	157	6.7%	-0.215	-0.009
2009	300	12.9%	338	14.5%	-1.631	-0.047
2010	346	14.8%	302	13.0%	1.888	0.055
2011	323	13.9%	265	11.4%	2.489	0.075
2012	254	10.9%	249	10.7%	0.215	0.007
2013	252	10.8%	254	10.9%	-0.086	-0.003
2014	272	11.7%	284	12.2%	-0.515	-0.016
2015	141	6.1%	132	5.7%	0.386	0.016
Race categories						
Race (American Indian or Alaska Native)	4	0.2%	3	0.1%	0.043	0.011
Race (Asian)	5	0.2%	18	0.8%	-0.558	-0.080
Race (Black or African American)	49	2.1%	59	2.5%	-0.429	-0.029
Race (Native Hawaiian or Other Pacific Islander)	-	0.0%	1	0.0%	-0.043	-
Race (Unknown)	1,905	81.8%	1,873	80.4%	1.373	0.035
Race (White)	367	15.8%	376	16.1%	-0.386	-0.011
Hispanic	24	1.0%	27	1.2%	-0.129	-0.012
Pregnancy Characteristics						
Preterm ¹	178	7.6%	181	7.8%	-0.129	-0.005
Postterm ²	226	9.7%	226	9.7%	0.000	0.000
Unknown term (assigned 273 days duration, term)	1,926	82.7%	1,923	82.5%	0.129	0.003

Table 3a. Baseline Characteristics of the Topiramate Pregnancy Cohort and the Unexposed Pregnancy Cohort, Main Analysis, in the Sentinel Distributed Database (SDD) From January 1, 2000 to September 30, 2015 (Matched, Aggregated), Ratio: 1:1, Caliper: 0.05

	Cohorts				Covariate Balance	
	Topiramate Pregnant Cohort		Unexposed Pregnant Cohort		Between Topiramate and Unexposed Pregnant Cohorts	
	Mean	Standard Deviation	Mean	Standard Deviation	Absolute Difference	Standardized Difference
Mean gestational age ³ at delivery	39.9	1.3	39.9	1.3	0.010	0.008
Exposure Characteristics						
Gestational age ³ of first exposure (weeks)	3.4	2.3	0.0	0.4	3.388	2.012
Mean number of dispensings in first trimester	1.4	0.8	0.0	0.0	1.402	-
Mean number of dispensings in second trimester	0.4	1.0	0.0	0.0	0.405	0.583
Mean number of dispensings in third trimester	0.4	1.0	0.0	0.0	0.382	-
	Number	Percent	Number	Percent		
Exposed during first trimester		100.0%	-	0.0%	100.000	-
Exposed during second trimester	432	18.5%	1	0.0%	18.498	0.672
Exposed during third trimester	382	16.4%	-	0.0%	16.395	-
Baseline⁴ Health Characteristics						
	Mean	Standard Deviation	Mean	Standard Deviation		
Combined comorbidity score ⁵	0.2	0.6	0.2	0.6	0.008	0.014
	Number	Percent	Number	Percent		
Epilepsy or seizures	309	13.3%	238	10.2%	3.047	0.095
Migraine or headache	1,277	54.8%	1,442	61.9%	-7.082	-0.144
Bipolar disorder	158	6.8%	119	5.1%	1.674	0.071
Neuropathic pain	206	8.8%	214	9.2%	-0.343	-0.012
Nonneuropathic pain	777	33.3%	820	35.2%	-1.845	-0.039
Obesity	164	7.0%	181	7.8%	-0.730	-0.028
Smoking	177	7.6%	185	7.9%	-0.343	-0.013
Depression	449	19.3%	470	20.2%	-0.901	-0.023
Anxiety	292	12.5%	313	13.4%	-0.901	-0.027
Psychotic conditions	13	0.6%	14	0.6%	-0.043	-0.006
Other psychiatric conditions	226	9.7%	223	9.6%	0.129	0.004
Sleep disorders	131	5.6%	129	5.5%	0.086	0.004
Fibromyalgia	163	7.0%	180	7.7%	-0.730	-0.028
Diabetes	68	2.9%	87	3.7%	-0.815	-0.045
Hypertension	145	6.2%	173	7.4%	-1.202	-0.048
Other pain conditions	69	3.0%	62	2.7%	0.300	0.018
ADHD	64	2.7%	74	3.2%	-0.429	-0.025
Drug or alcohol abuse	73	3.1%	57	2.4%	0.687	0.042
Chronic fatigue syndrome	16	0.7%	14	0.6%	0.086	0.011
Kidney disease	11	0.5%	19	0.8%	-0.343	-0.043
Migraine or bipolar disorder	1,388	59.6%	1,533	65.8%	-6.223	-0.129

Table 3a. Baseline Characteristics of the Topiramate Pregnancy Cohort and the Unexposed Pregnancy Cohort, Main Analysis, in the Sentinel Distributed Database (SDD) From January 1, 2000 to September 30, 2015 (Matched, Aggregated), Ratio: 1:1, Caliper: 0.05

	Cohorts				Covariate Balance	
	Topiramate Pregnant Cohort		Unexposed Pregnant Cohort		Between Topiramate and Unexposed Pregnant Cohorts	
	Number	Percent	Number	Percent	Difference	Difference
Baseline⁴ Medical Product Use						
Valproate	25	1.1%	-	0.0%	1.073	-
Carbamazepine	17	0.7%	-	0.0%	0.730	-
Phenytoin	17	0.7%	-	0.0%	0.730	-
Benzodiazepines	250	10.7%	226	9.7%	1.030	0.034
Triptans	444	19.1%	427	18.3%	0.730	0.019
Antipsychotics	165	7.1%	155	6.7%	0.429	0.017
Antidepressants	940	40.3%	1,001	43.0%	-2.618	-0.053
Antihypertensives	261	11.2%	281	12.1%	-0.858	-0.027
Anxiolytics	400	17.2%	373	16.0%	1.159	0.031
Stimulants	108	4.6%	121	5.2%	-0.558	-0.026
Barbiturates	7	0.3%	-	0.0%	0.300	-
Insulin	25	1.1%	32	1.4%	-0.300	-0.027
Noninsulin antidiabetics	93	4.0%	100	4.3%	-0.300	-0.015
Opioids	656	28.2%	685	29.4%	-1.245	-0.027
Hypnotics	151	6.5%	142	6.1%	0.386	0.016
Buprenorphine	7	0.3%	3	0.1%	0.172	0.037
Methadone	7	0.3%	1	0.0%	0.258	0.062
Naloxone	-	0.0%	-	0.0%	0.000	-
Naltrexone	-	0.0%	-	0.0%	0.000	-
Suspected teratogens	171	7.3%	178	7.6%	-0.300	-0.011
NSAIDs	249	10.7%	257	11.0%	-0.343	-0.011
Other anticonvulsants	313	13.4%	-	0.0%	13.433	-
Baseline⁴ Health Service Utilization Intensity		Standard		Standard		
	Mean	Deviation	Mean	Deviation		
Mean number of ambulatory encounters	4.0	4.3	4.2	4.1	-0.209	-0.050
Mean number of inpatient hospital encounters	0.0	0.2	0.0	0.2	0.006	0.032
Mean number of unique generics dispensed	4.9	3.4	5.1	3.9	-0.155	-0.042

¹Preterm birth defined as a pregnancy duration less than 259 days

²Postterm birth defined as a pregnancy duration greater than 287 days

³Gestational age estimated using a claims-

⁴Related to user defined index date (pregnancy start, exposure date, or delivery date)

⁵The Charlson/Elixhauser Combined Comorbidity Score is calculated based on comorbidities observed during a requester-defined window around the exposure episode start date. (Gagne JJ, Glynn RJ, Avorn J, Levin R, Schneeweiss S. A combined comorbidity score predicted mortality in elderly patients better than existing scores. J Clin Epidemiol. 2011;64(7):749-759)

⁶Covariates in blue show a standardized difference greater than 0.1

Table 3b. Baseline Characteristics of the Topiramate Pregnancy Cohort and the Unexposed Pregnancy Cohort, Excluding Epilepsy Cases, in the Sentinel Distributed Database (SDD) From January 1, 2000 to September 30, 2015 (Matched, Aggregated), Ratio: 1:1, Caliper: 0.05

	Cohorts				Covariate Balance	
	Topiramate Pregnant Cohort		Unexposed Pregnant Cohort		Between Topiramate and Unexposed Pregnant Cohorts	
	Number	Percent	Number	Percent	Absolute Difference	Standardized Difference
Number of pregnant patients	1,975	99.3%	1,975	0.2%	-	-
Demographic Characteristics	Mean	Standard Deviation	Mean	Standard Deviation		
Mean maternal age at index date	30.2	5.1	30.2	5.1	0.077	0.015
Maternal age categories (years)	Number	Percent	Number	Percent		
12-20	124	6.3%	140	7.1%	-0.810	-0.032
21-30	950	48.1%	951	48.2%	-0.051	-0.001
31-40	858	43.4%	842	42.6%	0.810	0.016
41-54	43	2.2%	42	2.1%	0.051	0.003
Year of index date						
2001	2	0.1%	18	0.9%	-0.810	-0.114
2002	8	0.4%	34	1.7%	-1.316	-0.129
2003	11	0.6%	38	1.9%	-1.367	-0.124
2004	32	1.6%	19	1.0%	0.658	0.058
2005	52	2.6%	27	1.4%	1.266	0.091
2006	25	1.3%	17	0.9%	0.405	0.040
2007	94	4.8%	112	5.7%	-0.911	-0.041
2008	125	6.3%	129	6.5%	-0.203	-0.008
2009	256	13.0%	270	13.7%	-0.709	-0.021
2010	303	15.3%	300	15.2%	0.152	0.004
2011	273	13.8%	220	11.1%	2.684	0.081
2012	219	11.1%	211	10.7%	0.405	0.013
2013	217	11.0%	224	11.3%	-0.354	-0.011
2014	232	11.7%	243	12.3%	-0.557	-0.017
2015	126	6.4%	113	5.7%	0.658	0.028
Race categories						
Race (American Indian or Alaska Native)	3	0.2%	4	0.2%	-0.051	-0.012
Race (Asian)	4	0.2%	3	0.2%	0.051	0.012
Race (Black or African American)	35	1.8%	48	2.4%	-0.658	-0.046
Race (Native Hawaiian or Other Pacific Islander)	-	0.0%	-	0.0%	0.000	-
Race (Unknown)	1,649	83.5%	1,644	83.2%	0.253	0.007
Race (White)	284	14.4%	276	14.0%	0.405	0.012
Hispanic	18	0.9%	13	0.7%	0.253	0.029
Pregnancy Characteristics						
Preterm ¹	152	7.7%	162	8.2%	-0.506	-0.019
Postterm ²	185	9.4%	203	10.3%	-0.911	-0.031
Unknown term (assigned 273 days duration, term)	1,638	82.9%	1,610	81.5%	1.418	0.037

Table 3b. Baseline Characteristics of the Topiramate Pregnancy Cohort and the Unexposed Pregnancy Cohort, Excluding Epilepsy Cases, in the Sentinel Distributed Database (SDD) From January 1, 2000 to September 30, 2015 (Matched, Aggregated), Ratio: 1:1, Caliper: 0.05

	Cohorts				Covariate Balance	
	Topiramate Pregnant Cohort		Unexposed Pregnant Cohort		Between Topiramate and Unexposed Pregnant Cohorts	
	Mean	Standard Deviation	Mean	Standard Deviation	Absolute Difference	Standardized Difference
Mean gestational age ³ at delivery	39.9	1.3	39.9	1.3	0.000	0.000
Exposure Characteristics						
Gestational age ³ of first exposure (weeks)	3.3	2.3	0.1	1.4	3.232	1.713
Mean number of dispensings in first trimester	1.3	0.6	0.0	0.0	1.314	-
Mean number of dispensings in second trimester	0.2	0.7	0.0	0.1	0.238	0.467
Mean number of dispensings in third trimester	0.2	0.7	0.0	0.1	0.186	0.398
	Number	Percent	Number	Percent		
Exposed during first trimester	1,975	100.0%	-	0.0%	100.000	-
Exposed during second trimester	249	12.6%	3	0.2%	12.456	0.527
Exposed during third trimester	190	9.6%	4	0.2%	9.418	0.447
Baseline⁴ Health Characteristics						
	Mean	Standard Deviation	Mean	Standard Deviation		
Combined comorbidity score ⁵	0.2	0.6	0.2	0.6	-0.003	-0.005
	Number	Percent	Number	Percent		
Epilepsy or seizures	-	0.0%	-	0.0%	0.000	-
Migraine or headache	1,130	57.2%	1,224	62.0%	-4.759	-0.097
Bipolar disorder	140	7.1%	123	6.2%	0.861	0.035
Neuropathic pain	186	9.4%	177	9.0%	0.456	0.016
Nonneuropathic pain	672	34.0%	687	34.8%	-0.759	-0.016
Obesity	152	7.7%	159	8.1%	-0.354	-0.013
Smoking	138	7.0%	152	7.7%	-0.709	-0.027
Depression	393	19.9%	403	20.4%	-0.506	-0.013
Anxiety	245	12.4%	245	12.4%	0.000	0.000
Psychotic conditions	6	0.3%	10	0.5%	-0.203	-0.032
Other psychiatric conditions	180	9.1%	189	9.6%	-0.456	-0.016
Sleep disorders	119	6.0%	118	6.0%	0.051	0.002
Fibromyalgia	138	7.0%	131	6.6%	0.354	0.014
Diabetes	61	3.1%	59	3.0%	0.101	0.006
Hypertension	133	6.7%	132	6.7%	0.051	0.002
Other pain conditions	59	3.0%	46	2.3%	0.658	0.041
ADHD	60	3.0%	60	3.0%	0.000	0.000
Drug or alcohol abuse	65	3.3%	51	2.6%	0.709	0.042
Chronic fatigue syndrome	15	0.8%	13	0.7%	0.101	0.012
Kidney disease	8	0.4%	17	0.9%	-0.456	-0.057
Migraine or bipolar disorder	1,235	62.5%	1,325	67.1%	-4.557	-0.096

Table 3b. Baseline Characteristics of the Topiramate Pregnancy Cohort and the Unexposed Pregnancy Cohort, Excluding Epilepsy Cases, in the Sentinel Distributed Database (SDD) From January 1, 2000 to September 30, 2015 (Matched, Aggregated), Ratio: 1:1, Caliper: 0.05

	Cohorts				Covariate Balance	
	Topiramate Pregnant Cohort		Unexposed Pregnant Cohort		Between Topiramate and Unexposed Pregnant Cohorts	
	Number	Percent	Number	Percent	Difference	Difference
Baseline⁴ Medical Product Use						
Valproate	14	0.7%	-	0.0%	0.709	-
Carbamazepine	3	0.2%	-	0.0%	0.152	-
Phenytoin	3	0.2%	-	0.0%	0.152	-
Benzodiazepines	214	10.8%	197	10.0%	0.861	0.028
Triptans	411	20.8%	370	18.7%	2.076	0.052
Antipsychotics	150	7.6%	127	6.4%	1.165	0.046
Antidepressants	845	42.8%	872	44.2%	-1.367	-0.028
Antihypertensives	229	11.6%	205	10.4%	1.215	0.039
Anxiolytics	339	17.2%	301	15.2%	1.924	0.052
Stimulants	105	5.3%	89	4.5%	0.810	0.037
Barbiturates	2	0.1%	-	0.0%	0.101	-
Insulin	19	1.0%	24	1.2%	-0.253	-0.024
Noninsulin antidiabetics	87	4.4%	87	4.4%	0.000	0.000
Opioids	591	29.9%	579	29.3%	0.608	0.013
Hypnotics	136	6.9%	131	6.6%	0.253	0.010
Buprenorphine	7	0.4%	1	0.1%	0.304	0.068
Methadone	7	0.4%	2	0.1%	0.253	0.053
Naloxone	-	0.0%	-	0.0%	0.000	-
Naltrexone	-	0.0%	-	0.0%	0.000	-
Suspected teratogens	149	7.5%	157	7.9%	-0.405	-0.015
NSAIDs	217	11.0%	203	10.3%	0.709	0.023
Other anticonvulsants	201	10.2%	-	0.0%	10.177	-
Baseline⁴ Health Service Utilization Intensity		Standard		Standard		
	Mean	Deviation	Mean	Deviation		
Mean number of ambulatory encounters	4.0	4.4	4.1	4.4	-0.141	-0.032
Mean number of inpatient hospital encounters	0.0	0.2	0.0	0.2	-0.003	-0.013
Mean number of unique generics dispensed	5.0	3.4	4.9	3.8	0.085	0.023

¹Preterm birth defined as a pregnancy duration less than 259 days

²Postterm birth defined as a pregnancy duration greater than 287 days

³Gestational age estimated using a claims-

⁴Related to user defined index date (pregnancy start, exposure date, or delivery date)

⁵The Charlson/Elixhauser Combined Comorbidity Score is calculated based on comorbidities observed during a requester-defined window around the exposure episode start date. (Gagne JJ, Glynn RJ, Avorn J, Levin R, Schneeweiss S. A combined comorbidity score predicted mortality in elderly patients better than existing scores. J Clin Epidemiol. 2011;64(7):749-759)

⁶Covariates in blue show a standardized difference greater than 0.1

Table 3c. Baseline Characteristics of the Topiramate Pregnancy Cohort and the Unexposed Pregnancy Cohort, Topiramate Monotherapy, in the Sentinel Distributed Database (SDD) From January 1, 2000 to September 30, 2015 (Matched, Aggregated), Ratio: 1:1, Caliper: 0.05

	Cohorts				Covariate Balance	
	Topiramate Pregnant Cohort		Unexposed Pregnant Cohort		Between Topiramate and Unexposed Pregnant Cohorts	
	Number	Percent	Number	Percent	Absolute Difference	Standardized Difference
Number of pregnant patients	1,725	99.8%	1,725	0.2%	-	-
Demographic Characteristics	Mean	Standard Deviation	Mean	Standard Deviation		
Mean maternal age at index date	29.9	5.1	30.0	5.1	-0.107	-0.021
Maternal age categories (years)	Number	Percent	Number	Percent		
12-20	126	7.3%	128	7.4%	-0.116	-0.004
21-30	849	49.2%	844	48.9%	0.290	0.006
31-40	715	41.4%	716	41.5%	-0.058	-0.001
41-54	35	2.0%	37	2.1%	-0.116	-0.008
Year of index date						
2001	3	0.2%	15	0.9%	-0.696	-0.097
2002	4	0.2%	25	1.4%	-1.217	-0.134
2003	9	0.5%	27	1.6%	-1.043	-0.103
2004	21	1.2%	18	1.0%	0.174	0.016
2005	43	2.5%	24	1.4%	1.101	0.080
2006	20	1.2%	14	0.8%	0.348	0.035
2007	81	4.7%	97	5.6%	-0.928	-0.042
2008	108	6.3%	108	6.3%	0.000	0.000
2009	228	13.2%	252	14.6%	-1.391	-0.040
2010	282	16.3%	224	13.0%	3.362	0.095
2011	246	14.3%	201	11.7%	2.609	0.078
2012	189	11.0%	213	12.3%	-1.391	-0.043
2013	187	10.8%	187	10.8%	0.000	0.000
2014	201	11.7%	213	12.3%	-0.696	-0.021
2015	103	6.0%	107	6.2%	-0.232	-0.010
Race categories						
Race (American Indian or Alaska Native)	2	0.1%	2	0.1%	0.000	0.000
Race (Asian)	4	0.2%	7	0.4%	-0.174	-0.031
Race (Black or African American)	32	1.9%	43	2.5%	-0.638	-0.044
Race (Native Hawaiian or Other Pacific Islander)	-	0.0%	-	0.0%	0.000	-
Race (Unknown)	1,439	83.4%	1,439	83.4%	0.000	0.000
Race (White)	248	14.4%	234	13.6%	0.812	0.023
Hispanic	17	1.0%	17	1.0%	0.000	0.000
Pregnancy Characteristics						
Preterm ¹	126	7.3%	118	6.8%	0.464	0.018
Postterm ²	159	9.2%	160	9.3%	-0.058	-0.002
Unknown term (assigned 273 days duration, term)	1,440	83.5%	1,447	83.9%	-0.406	-0.011

Table 3c. Baseline Characteristics of the Topiramate Pregnancy Cohort and the Unexposed Pregnancy Cohort, Topiramate Monotherapy, in the Sentinel Distributed Database (SDD) From January 1, 2000 to September 30, 2015 (Matched, Aggregated), Ratio: 1:1, Caliper: 0.05

	Cohorts				Covariate Balance	
	Topiramate Pregnant Cohort		Unexposed Pregnant Cohort		Between Topiramate and Unexposed Pregnant Cohorts	
	Mean	Standard Deviation	Mean	Standard Deviation	Absolute Difference	Standardized Difference
Mean gestational age ³ at delivery	39.9	1.3	39.9	1.2	-0.013	-0.011
Exposure Characteristics						
Gestational age ³ of first exposure (weeks)	3.3	2.3	0.0	0.0	3.332	-
Mean number of dispensings in first trimester	1.4	0.7	0.0	0.0	1.358	-
Mean number of dispensings in second trimester	0.3	0.9	0.0	0.0	0.341	-
Mean number of dispensings in third trimester	0.3	0.8	0.0	0.0	0.291	-
	Number	Percent	Number	Percent		
Exposed during first trimester	1,725	100.0%	-	0.0%	100.000	-
Exposed during second trimester	276	16.0%	-	0.0%	16.000	-
Exposed during third trimester	232	13.4%	-	0.0%	13.449	-
Baseline⁴ Health Characteristics						
	Mean	Standard Deviation	Mean	Standard Deviation		
Combined comorbidity score ⁵	0.2	0.5	0.1	0.5	0.019	0.037
	Number	Percent	Number	Percent		
Epilepsy or seizures	147	8.5%	109	6.3%	2.203	0.084
Migraine or headache	984	57.0%	1,081	62.7%	-5.623	-0.115
Bipolar disorder	72	4.2%	98	5.7%	-1.507	-0.070
Neuropathic pain	136	7.9%	143	8.3%	-0.406	-0.015
Nonneuropathic pain	541	31.4%	547	31.7%	-0.348	-0.007
Obesity	121	7.0%	142	8.2%	-1.217	-0.046
Smoking	105	6.1%	109	6.3%	-0.232	-0.010
Depression	270	15.7%	282	16.3%	-0.696	-0.019
Anxiety	180	10.4%	215	12.5%	-2.029	-0.064
Psychotic conditions	8	0.5%	9	0.5%	-0.058	-0.008
Other psychiatric conditions	122	7.1%	119	6.9%	0.174	0.007
Sleep disorders	87	5.0%	75	4.3%	0.696	0.033
Fibromyalgia	95	5.5%	88	5.1%	0.406	0.018
Diabetes	49	2.8%	55	3.2%	-0.348	-0.020
Hypertension	104	6.0%	134	7.8%	-1.739	-0.069
Other pain conditions	41	2.4%	41	2.4%	0.000	0.000
ADHD	50	2.9%	41	2.4%	0.522	0.033
Drug or alcohol abuse	36	2.1%	37	2.1%	-0.058	-0.004
Chronic fatigue syndrome	12	0.7%	13	0.8%	-0.058	-0.007
Kidney disease	6	0.3%	13	0.8%	-0.406	-0.055
Migraine or bipolar disorder	1,036	60.1%	1,158	67.1%	-7.072	-0.147

Table 3c. Baseline Characteristics of the Topiramate Pregnancy Cohort and the Unexposed Pregnancy Cohort, Topiramate Monotherapy, in the Sentinel Distributed Database (SDD) From January 1, 2000 to September 30, 2015 (Matched, Aggregated), Ratio: 1:1, Caliper: 0.05

	Cohorts				Covariate Balance	
	Topiramate Pregnant Cohort		Unexposed Pregnant Cohort		Between Topiramate and Unexposed Pregnant Cohorts	
	Number	Percent	Number	Percent	Difference	Difference
Baseline⁴ Medical Product Use						
Valproate	-	0.0%	-	0.0%	0.000	-
Carbamazepine	-	0.0%	-	0.0%	0.000	-
Phenytoin	-	0.0%	-	0.0%	0.000	-
Benzodiazepines	163	9.4%	149	8.6%	0.812	0.028
Triptans	343	19.9%	294	17.0%	2.841	0.073
Antipsychotics	92	5.3%	88	5.1%	0.232	0.010
Antidepressants	643	37.3%	671	38.9%	-1.623	-0.033
Antihypertensives	185	10.7%	205	11.9%	-1.159	-0.037
Anxiolytics	196	11.4%	187	10.8%	0.522	0.017
Stimulants	71	4.1%	70	4.1%	0.058	0.003
Barbiturates	-	0.0%	-	0.0%	0.000	-
Insulin	19	1.1%	22	1.3%	-0.174	-0.016
Noninsulin antidiabetics	72	4.2%	96	5.6%	-1.391	-0.065
Opioids	448	26.0%	432	25.0%	0.928	0.021
Hypnotics	86	5.0%	77	4.5%	0.522	0.025
Buprenorphine	4	0.2%	3	0.2%	0.058	0.013
Methadone	5	0.3%	-	0.0%	0.290	-
Naloxone	-	0.0%	-	0.0%	0.000	-
Naltrexone	-	0.0%	-	0.0%	0.000	-
Suspected teratogens	130	7.5%	137	7.9%	-0.406	-0.015
NSAIDs	170	9.9%	150	8.7%	1.159	0.040
Other anticonvulsants	-	0.0%	-	0.0%	0.000	-
Baseline⁴ Health Service Utilization Intensity	Mean	Standard Deviation	Mean	Standard Deviation		
Mean number of ambulatory encounters	3.6	4.0	3.7	3.8	-0.073	-0.019
Mean number of inpatient hospital encounters	0.0	0.1	0.0	0.1	0.008	0.065
Mean number of unique generics dispensed	4.5	3.2	4.4	3.6	0.093	0.028

¹Preterm birth defined as a pregnancy duration less than 259 days

²Postterm birth defined as a pregnancy duration greater than 287 days

³Gestational age estimated using a claims-

⁴Related to user defined index date (pregnancy start, exposure date, or delivery date)

⁵The Charlson/Elixhauser Combined Comorbidity Score is calculated based on comorbidities observed during a requester-defined window around the exposure episode start date. (Gagne JJ, Glynn RJ, Avorn J, Levin R, Schneeweiss S. A combined comorbidity score predicted mortality in elderly patients better than existing scores. J Clin Epidemiol. 2011;64(7):749-759)

⁶Covariates in blue show a standardized difference greater than 0.1

Table 3d. Baseline Characteristics of the Topiramate Pregnancy Cohort and the Lamotrigine Pregnancy Cohort, Lamotrigine Comparator, in the Sentinel Distributed Database (SDD) From January 1, 2000 to September 30, 2015 (Matched, Aggregated), Ratio: 1:1, Caliper: 0.05

	Cohorts				Covariate Balance	
	Topiramate Pregnant Cohort		Lamotrigine Pregnant Cohort		Between Topiramate and Lamotrigine Pregnant Cohorts	
	Number	Percent	Number	Percent	Absolute Difference	Standardized Difference
Number of pregnant patients	1,281	55.2%	1,281	38.8%	-	-
Demographic Characteristics	Mean	Standard Deviation	Mean	Standard Deviation		
Mean maternal age at index date	29.2	5.2	29.2	5.2	0.010	0.002
Maternal age categories (years)	Number	Percent	Number	Percent		
12-20	136	10.6%	139	10.9%	-0.234	-0.008
21-30	639	49.9%	637	49.7%	0.156	0.003
31-40	486	37.9%	485	37.9%	0.078	0.002
41-54	20	1.6%	20	1.6%	0.000	0.000
Year of index date						
2001	3	0.2%	-	0.0%	0.234	-
2002	6	0.5%	2	0.2%	0.312	0.056
2003	11	0.9%	2	0.2%	0.703	0.099
2004	44	3.4%	14	1.1%	2.342	0.158
2005	56	4.4%	17	1.3%	3.044	0.184
2006	21	1.6%	30	2.3%	-0.703	-0.050
2007	58	4.5%	80	6.2%	-1.717	-0.076
2008	65	5.1%	85	6.6%	-1.561	-0.067
2009	149	11.6%	199	15.5%	-3.903	-0.114
2010	166	13.0%	180	14.1%	-1.093	-0.032
2011	147	11.5%	145	11.3%	0.156	0.005
2012	142	11.1%	137	10.7%	0.390	0.013
2013	158	12.3%	158	12.3%	0.000	0.000
2014	175	13.7%	159	12.4%	1.249	0.037
2015	80	6.2%	73	5.7%	0.546	0.023
Race categories						
Race (American Indian or Alaska Native)	2	0.2%	-	0.0%	0.156	-
Race (Asian)	3	0.2%	5	0.4%	-0.156	-0.028
Race (Black or African American)	42	3.3%	28	2.2%	1.093	0.067
Race (Native Hawaiian or Other Pacific Islander)	-	0.0%	-	0.0%	0.000	-
Race (Unknown)	936	73.1%	956	74.6%	-1.561	-0.036
Race (White)	298	23.3%	292	22.8%	0.468	0.011
Hispanic	12	0.9%	11	0.9%	0.078	0.008
Pregnancy Characteristics						
Preterm ¹	79	6.2%	103	8.0%	-1.874	-0.073
Postterm ²	96	7.5%	132	10.3%	-2.810	-0.099
Unknown term (assigned 273 days duration, term)	1,106	86.3%	1,046	81.7%	4.684	0.128

Table 3d. Baseline Characteristics of the Topiramate Pregnancy Cohort and the Lamotrigine Pregnancy Cohort, Lamotrigine Comparator, in the Sentinel Distributed Database (SDD) From January 1, 2000 to September 30, 2015 (Matched, Aggregated), Ratio: 1:1, Caliper: 0.05

	Cohorts				Covariate Balance	
	Topiramate Pregnant Cohort		Lamotrigine Pregnant Cohort		Between Topiramate and Lamotrigine Pregnant Cohorts	
	Mean	Standard Deviation	Mean	Standard Deviation	Absolute Difference	Standardized Difference
Mean gestational age ³ at delivery	39.9	1.2	39.9	1.4	0.023	0.018
Exposure Characteristics						
Gestational age ³ of first exposure (weeks)	3.6	2.5	3.9	2.8	-0.258	-0.096
Mean number of dispensings in first trimester	1.5	0.8	1.8	1.0	-0.384	-0.410
Mean number of dispensings in second trimester	0.5	1.1	1.3	1.5	-0.763	-0.575
Mean number of dispensings in third trimester	0.5	1.1	1.3	1.6	-0.803	-0.585
	Number	Percent	Number	Percent		
Exposed during first trimester	1,281	100.0%	1,281	100.0%	0.000	-
Exposed during second trimester	299	23.3%	653	51.0%	-27.635	-0.597
Exposed during third trimester	254	19.8%	630	49.2%	-29.352	-0.649
	Mean	Standard Deviation	Mean	Standard Deviation		
Baseline⁴ Health Characteristics						
Combined comorbidity score ⁵	0.3	0.7	0.3	0.6	-0.016	-0.026
	Number	Percent	Number	Percent		
Epilepsy or seizures	256	20.0%	252	19.7%	0.312	0.008
Migraine or headache	521	40.7%	234	18.3%	22.404	0.507
Bipolar disorder	125	9.8%	480	37.5%	-27.713	-0.690
Neuropathic pain	87	6.8%	99	7.7%	-0.937	-0.036
Nonneuropathic pain	396	30.9%	411	32.1%	-1.171	-0.025
Obesity	85	6.6%	75	5.9%	0.781	0.032
Smoking	143	11.2%	138	10.8%	0.390	0.012
Depression	340	26.5%	345	26.9%	-0.390	-0.009
Anxiety	220	17.2%	204	15.9%	1.249	0.034
Psychotic conditions	11	0.9%	4	0.3%	0.546	0.072
Other psychiatric conditions	163	12.7%	162	12.6%	0.078	0.002
Sleep disorders	61	4.8%	61	4.8%	0.000	0.000
Fibromyalgia	76	5.9%	78	6.1%	-0.156	-0.007
Diabetes	35	2.7%	31	2.4%	0.312	0.020
Hypertension	75	5.9%	76	5.9%	-0.078	-0.003
Other pain conditions	39	3.0%	40	3.1%	-0.078	-0.005
ADHD	48	3.7%	64	5.0%	-1.249	-0.061
Drug or alcohol abuse	61	4.8%	62	4.8%	-0.078	-0.004
Chronic fatigue syndrome	11	0.9%	5	0.4%	0.468	0.059
Kidney disease	7	0.5%	10	0.8%	-0.234	-0.029
Migraine or bipolar disorder	601	46.9%	636	49.6%	-2.732	-0.055

Table 3d. Baseline Characteristics of the Topiramate Pregnancy Cohort and the Lamotrigine Pregnancy Cohort, Lamotrigine Comparator, in the Sentinel Distributed Database (SDD) From January 1, 2000 to September 30, 2015 (Matched, Aggregated), Ratio: 1:1, Caliper: 0.05

	Cohorts				Covariate Balance	
	Topiramate Pregnant Cohort		Lamotrigine Pregnant Cohort		Between Topiramate and Lamotrigine Pregnant Cohorts	
	Number	Percent	Number	Percent	Difference	Difference
Baseline⁴ Medical Product Use						
Valproate	23	1.8%	16	1.2%	0.546	0.045
Carbamazepine	14	1.1%	20	1.6%	-0.468	-0.041
Phenytoin	16	1.2%	19	1.5%	-0.234	-0.020
Benzodiazepines	163	12.7%	165	12.9%	-0.156	-0.005
Triptans	68	5.3%	71	5.5%	-0.234	-0.010
Antipsychotics	134	10.5%	147	11.5%	-1.015	-0.032
Antidepressants	589	46.0%	571	44.6%	1.405	0.028
Antihypertensives	99	7.7%	110	8.6%	-0.859	-0.031
Anxiolytics	266	20.8%	266	20.8%	0.000	0.000
Stimulants	73	5.7%	89	6.9%	-1.249	-0.051
Barbiturates	7	0.5%	6	0.5%	0.078	0.011
Insulin	15	1.2%	15	1.2%	0.000	0.000
Noninsulin antidiabetics	45	3.5%	46	3.6%	-0.078	-0.004
Opioids	284	22.2%	316	24.7%	-2.498	-0.059
Hypnotics	99	7.7%	105	8.2%	-0.468	-0.017
Buprenorphine	5	0.4%	2	0.2%	0.234	0.045
Methadone	1	0.1%	4	0.3%	-0.234	-0.053
Naloxone	-	0.0%	-	0.0%	0.000	-
Naltrexone	-	0.0%	-	0.0%	0.000	-
Suspected teratogens	113	8.8%	116	9.1%	-0.234	-0.008
NSAIDs	128	10.0%	135	10.5%	-0.546	-0.018
Other anticonvulsants	212	16.5%	230	18.0%	-1.405	-0.037
Baseline⁴ Health Service Utilization Intensity		Standard		Standard		
	Mean	Deviation	Mean	Deviation		
Mean number of ambulatory encounters	4.0	4.6	4.1	4.3	-0.094	-0.021
Mean number of inpatient hospital encounters	0.0	0.2	0.0	0.2	0.004	0.017
Mean number of unique generics dispensed	4.9	3.6	4.8	3.4	0.148	0.042

¹Preterm birth defined as a pregnancy duration less than 259 days

²Postterm birth defined as a pregnancy duration greater than 287 days

³Gestational age estimated using a claims-

⁴Related to user defined index date (pregnancy start, exposure date, or delivery date)

⁵The Charlson/Elixhauser Combined Comorbidity Score is calculated based on comorbidities observed during a requester-defined window around the exposure episode start date. (Gagne JJ, Glynn RJ, Avorn J, Levin R, Schneeweiss S. A combined comorbidity score predicted mortality in elderly patients better than existing scores. J Clin Epidemiol. 2011;64(7):749-759)

⁶Covariates in blue show a standardized difference greater than 0.1

Table 3e. Baseline Characteristics of the Topiramate Pregnancy Cohort and the Unexposed Pregnancy Cohort, Two Fills of Topiramate Required, in the Sentinel Distributed Database (SDD) From January 1, 2000 to September 30, 2015 (Matched, Aggregated), Ratio: 1:1, Caliper: 0.05

	Cohorts				Covariate Balance	
	Topiramate Pregnant Cohort		Unexposed Pregnant Cohort		Between Topiramate and Unexposed Pregnant Cohorts	
	Number	Percent	Number	Percent	Absolute Difference	Standardized Difference
Number of pregnant patients	941	98.5%	941	0.1%	-	-
Demographic Characteristics	Mean	Standard Deviation	Mean	Standard Deviation		
Mean maternal age at index date	30.3	5.1	30.5	5.2	-0.187	-0.037
Maternal age categories (years)	Number	Percent	Number	Percent		
12-20	64	6.8%	52	5.5%	1.275	0.053
21-30	430	45.7%	437	46.4%	-0.744	-0.015
31-40	431	45.8%	426	45.3%	0.531	0.011
41-54	16	1.7%	26	2.8%	-1.063	-0.072
Year of index date						
2001	2	0.2%	10	1.1%	-0.850	-0.107
2002	2	0.2%	14	1.5%	-1.275	-0.139
2003	2	0.2%	15	1.6%	-1.382	-0.146
2004	10	1.1%	18	1.9%	-0.850	-0.070
2005	28	3.0%	18	1.9%	1.063	0.069
2006	17	1.8%	10	1.1%	0.744	0.063
2007	50	5.3%	65	6.9%	-1.594	-0.067
2008	55	5.8%	61	6.5%	-0.638	-0.027
2009	126	13.4%	129	13.7%	-0.319	-0.009
2010	158	16.8%	134	14.2%	2.550	0.070
2011	136	14.5%	114	12.1%	2.338	0.069
2012	100	10.6%	108	11.5%	-0.850	-0.027
2013	94	10.0%	97	10.3%	-0.319	-0.011
2014	108	11.5%	90	9.6%	1.913	0.062
2015	53	5.6%	58	6.2%	-0.531	-0.023
Race categories						
Race (American Indian or Alaska Native)	2	0.2%	-	0.0%	0.213	-
Race (Asian)	1	0.1%	3	0.3%	-0.213	-0.046
Race (Black or African American)	18	1.9%	24	2.6%	-0.638	-0.043
Race (Native Hawaiian or Other Pacific Islander)	-	0.0%	-	0.0%	0.000	-
Race (Unknown)	775	82.4%	768	81.6%	0.744	0.019
Race (White)	145	15.4%	146	15.5%	-0.106	-0.003
Hispanic	9	1.0%	8	0.9%	0.106	0.011
Pregnancy Characteristics						
Preterm ¹	71	7.5%	78	8.3%	-0.744	-0.028
Postterm ²	92	9.8%	78	8.3%	1.488	0.052
Unknown term (assigned 273 days duration, term)	778	82.7%	785	83.4%	-0.744	-0.020

Table 3e. Baseline Characteristics of the Topiramate Pregnancy Cohort and the Unexposed Pregnancy Cohort, Two Fills of Topiramate Required, in the Sentinel Distributed Database (SDD) From January 1, 2000 to September 30, 2015 (Matched, Aggregated), Ratio: 1:1, Caliper: 0.05

	Cohorts				Covariate Balance	
	Topiramate Pregnant Cohort		Unexposed Pregnant Cohort		Between Topiramate and Unexposed Pregnant Cohorts	
	Mean	Standard Deviation	Mean	Standard Deviation	Absolute Difference	Standardized Difference
Mean gestational age ³ at delivery	39.9	1.3	39.8	1.4	0.064	0.048
Exposure Characteristics						
Gestational age ³ of first exposure (weeks)	3.1	1.9	0.0	0.8	3.032	2.060
Mean number of dispensings in first trimester	1.7	0.9	0.0	0.0	1.713	-
Mean number of dispensings in second trimester	0.6	1.2	0.0	0.0	0.596	-
Mean number of dispensings in third trimester	0.6	1.2	0.0	0.1	0.550	0.633
	Number	Percent	Number	Percent		
Exposed during first trimester	941	100.0%	-	0.0%	100.000	-
Exposed during second trimester	237	25.2%	-	0.0%	25.186	-
Exposed during third trimester	202	21.5%	1	0.1%	21.360	0.733
Baseline⁴ Health Characteristics						
	Mean	Standard Deviation	Mean	Standard Deviation		
Combined comorbidity score ⁵	0.2	0.6	0.2	0.6	-0.010	-0.016
	Number	Percent	Number	Percent		
Epilepsy or seizures	164	17.4%	133	14.1%	3.294	0.090
Migraine or headache	501	53.2%	576	61.2%	-7.970	-0.162
Bipolar disorder	72	7.7%	62	6.6%	1.063	0.041
Neuropathic pain	79	8.4%	69	7.3%	1.063	0.039
Nonneuropathic pain	317	33.7%	315	33.5%	0.213	0.005
Obesity	54	5.7%	59	6.3%	-0.531	-0.022
Smoking	69	7.3%	77	8.2%	-0.850	-0.032
Depression	177	18.8%	188	20.0%	-1.169	-0.030
Anxiety	113	12.0%	109	11.6%	0.425	0.013
Psychotic conditions	4	0.4%	6	0.6%	-0.213	-0.029
Other psychiatric conditions	105	11.2%	114	12.1%	-0.956	-0.030
Sleep disorders	45	4.8%	49	5.2%	-0.425	-0.020
Fibromyalgia	66	7.0%	85	9.0%	-2.019	-0.074
Diabetes	25	2.7%	29	3.1%	-0.425	-0.025
Hypertension	56	6.0%	59	6.3%	-0.319	-0.013
Other pain conditions	34	3.6%	26	2.8%	0.850	0.048
ADHD	22	2.3%	26	2.8%	-0.425	-0.027
Drug or alcohol abuse	25	2.7%	32	3.4%	-0.744	-0.043
Chronic fatigue syndrome	8	0.9%	6	0.6%	0.213	0.025
Kidney disease	4	0.4%	6	0.6%	-0.213	-0.029
Migraine or bipolar disorder	553	58.8%	626	66.5%	-7.758	-0.161

Table 3e. Baseline Characteristics of the Topiramate Pregnancy Cohort and the Unexposed Pregnancy Cohort, Two Fills of Topiramate Required, in the Sentinel Distributed Database (SDD) From January 1, 2000 to September 30, 2015 (Matched, Aggregated), Ratio: 1:1, Caliper: 0.05

	Cohorts				Covariate Balance	
	Topiramate Pregnant Cohort		Unexposed Pregnant Cohort		Between Topiramate and Unexposed Pregnant Cohorts	
	Number	Percent	Number	Percent	Difference	Difference
Baseline⁴ Medical Product Use						
Valproate	11	1.2%	-	0.0%	1.169	-
Carbamazepine	10	1.1%	-	0.0%	1.063	-
Phenytoin	4	0.4%	-	0.0%	0.425	-
Benzodiazepines	104	11.1%	80	8.5%	2.550	0.086
Triptans	181	19.2%	191	20.3%	-1.063	-0.027
Antipsychotics	72	7.7%	64	6.8%	0.850	0.033
Antidepressants	394	41.9%	455	48.4%	-6.482	-0.131
Antihypertensives	106	11.3%	98	10.4%	0.850	0.027
Anxiolytics	172	18.3%	146	15.5%	2.763	0.074
Stimulants	47	5.0%	34	3.6%	1.382	0.068
Barbiturates	5	0.5%	-	0.0%	0.531	-
Insulin	8	0.9%	13	1.4%	-0.531	-0.051
Noninsulin antidiabetics	42	4.5%	47	5.0%	-0.531	-0.025
Opioids	287	30.5%	272	28.9%	1.594	0.035
Hypnotics	72	7.7%	55	5.8%	1.807	0.072
Buprenorphine	5	0.5%	4	0.4%	0.106	0.015
Methadone	4	0.4%	1	0.1%	0.319	0.062
Naloxone	-	0.0%	-	0.0%	0.000	-
Naltrexone	-	0.0%	-	0.0%	0.000	-
Suspected teratogens	69	7.3%	66	7.0%	0.319	0.012
NSAIDs	92	9.8%	87	9.2%	0.531	0.018
Other anticonvulsants	141	15.0%	-	0.0%	14.984	-
Baseline⁴ Health Service Utilization Intensity		Standard		Standard		
	Mean	Deviation	Mean	Deviation		
Mean number of ambulatory encounters	4.1	4.3	4.2	4.3	-0.156	-0.036
Mean number of inpatient hospital encounters	0.0	0.2	0.0	0.2	0.001	0.006
Mean number of unique generics dispensed	5.3	3.4	5.4	4.3	-0.139	-0.036

¹Preterm birth defined as a pregnancy duration less than 259 days

²Postterm birth defined as a pregnancy duration greater than 287 days

³Gestational age estimated using a claims-

⁴Related to user defined index date (pregnancy start, exposure date, or delivery date)

⁵The Charlson/Elixhauser Combined Comorbidity Score is calculated based on comorbidities observed during a requester-defined window around the exposure episode start date. (Gagne JJ, Glynn RJ, Avorn J, Levin R, Schneeweiss S. A combined comorbidity score predicted mortality in elderly patients better than existing scores. J Clin Epidemiol. 2011;64(7):749-759)

⁶Covariates in blue show a standardized difference greater than 0.1

Table 3f. Baseline Characteristics of the Topiramate Pregnancy Cohort and the Unexposed Pregnancy Cohort, Exposure Defined by Overlapping Days Supply, in the Sentinel Distributed Database (SDD) From January 1, 2000 to September 30, 2015 (Matched, Aggregated), Ratio: 1:1, Caliper: 0.05

	Cohorts				Covariate Balance	
	Topiramate Pregnant Cohort		Unexposed Pregnant Cohort		Between Topiramate and Unexposed Pregnant Cohorts	
	Number	Percent	Number	Percent	Absolute Difference	Standardized Difference
Number of pregnant patients	3,463	99.0%	3,463	0.3%	-	-
Demographic Characteristics	Mean	Standard Deviation	Mean	Standard Deviation		
Mean maternal age at index date	29.9	5.1	29.9	5.2	-0.014	-0.003
Maternal age categories (years)	Number	Percent	Number	Percent		
12-20	255	7.4%	279	8.1%	-0.693	-0.026
21-30	1,722	49.7%	1,701	49.1%	0.606	0.012
31-40	1,423	41.1%	1,409	40.7%	0.404	0.008
41-54	63	1.8%	74	2.1%	-0.318	-0.023
Year of index date						
2001	5	0.1%	42	1.2%	-1.068	-0.130
2002	12	0.3%	64	1.8%	-1.502	-0.145
2003	21	0.6%	67	1.9%	-1.328	-0.119
2004	58	1.7%	40	1.2%	0.520	0.044
2005	86	2.5%	50	1.4%	1.040	0.075
2006	63	1.8%	51	1.5%	0.347	0.027
2007	175	5.1%	195	5.6%	-0.578	-0.026
2008	219	6.3%	209	6.0%	0.289	0.012
2009	464	13.4%	493	14.2%	-0.837	-0.024
2010	494	14.3%	467	13.5%	0.780	0.023
2011	477	13.8%	407	11.8%	2.021	0.061
2012	372	10.7%	371	10.7%	0.029	0.001
2013	376	10.9%	378	10.9%	-0.058	-0.002
2014	420	12.1%	408	11.8%	0.347	0.011
2015	221	6.4%	221	6.4%	0.000	0.000
Race categories						
Race (American Indian or Alaska Native)	4	0.1%	1	0.0%	0.087	0.032
Race (Asian)	5	0.1%	25	0.7%	-0.578	-0.088
Race (Black or African American)	75	2.2%	83	2.4%	-0.231	-0.015
Race (Native Hawaiian or Other Pacific Islander)	-	0.0%	2	0.1%	-0.058	-
Race (Unknown)	2,834	81.8%	2,841	82.0%	-0.202	-0.005
Race (White)	545	15.7%	511	14.8%	0.982	0.027
Hispanic	35	1.0%	39	1.1%	-0.116	-0.011
Pregnancy Characteristics						
Preterm ¹	277	8.0%	261	7.5%	0.462	0.017
Postterm ²	338	9.8%	345	10.0%	-0.202	-0.007
Unknown term (assigned 273 days duration, term)	2,848	82.2%	2,857	82.5%	-0.260	-0.007

Table 3f. Baseline Characteristics of the Topiramate Pregnancy Cohort and the Unexposed Pregnancy Cohort, Exposure Defined by Overlapping Days Supply, in the Sentinel Distributed Database (SDD) From January 1, 2000 to September 30, 2015 (Matched, Aggregated), Ratio: 1:1, Caliper: 0.05

	Cohorts				Covariate Balance	
	Topiramate Pregnant Cohort		Unexposed Pregnant Cohort		Between Topiramate and Unexposed Pregnant Cohorts	
	Mean	Standard Deviation	Mean	Standard Deviation	Absolute Difference	Standardized Difference
Mean gestational age ³ at delivery	39.9	1.3	39.9	1.3	-0.016	-0.012
Exposure Characteristics						
Gestational age ³ of first exposure (weeks)	-9.2	24.6	0.0	0.6	-9.268	-0.532
Mean number of dispensings in first trimester	1.7	0.9	0.0	0.0	1.699	-
Mean number of dispensings in second trimester	0.5	1.0	0.0	0.1	0.468	0.634
Mean number of dispensings in third trimester	0.4	1.0	0.0	0.1	0.369	0.516
	Number	Percent	Number	Percent		
Exposed during first trimester	3,463	100.0%	-	0.0%	100.000	-
Exposed during second trimester	752	21.7%	2	0.1%	21.658	0.742
Exposed during third trimester	507	14.6%	3	0.1%	14.554	0.580
	Mean	Standard Deviation	Mean	Standard Deviation		
Baseline⁴ Health Characteristics						
Combined comorbidity score ⁵	0.2	0.6	0.2	0.6	-0.002	-0.004
	Number	Percent	Number	Percent		
Epilepsy or seizures	371	10.7%	287	8.3%	2.426	0.083
Migraine or headache	1,949	56.3%	2,142	61.9%	-5.573	-0.114
Bipolar disorder	238	6.9%	188	5.4%	1.444	0.060
Neuropathic pain	291	8.4%	306	8.8%	-0.433	-0.015
Nonneuropathic pain	1,118	32.3%	1,204	34.8%	-2.483	-0.053
Obesity	254	7.3%	298	8.6%	-1.271	-0.047
Smoking	251	7.2%	253	7.3%	-0.058	-0.002
Depression	649	18.7%	663	19.1%	-0.404	-0.010
Anxiety	429	12.4%	432	12.5%	-0.087	-0.003
Psychotic conditions	14	0.4%	8	0.2%	0.173	0.031
Other psychiatric conditions	311	9.0%	309	8.9%	0.058	0.002
Sleep disorders	183	5.3%	172	5.0%	0.318	0.014
Fibromyalgia	221	6.4%	215	6.2%	0.173	0.007
Diabetes	100	2.9%	116	3.3%	-0.462	-0.027
Hypertension	196	5.7%	213	6.2%	-0.491	-0.021
Other pain conditions	94	2.7%	78	2.3%	0.462	0.030
ADHD	87	2.5%	94	2.7%	-0.202	-0.013
Drug or alcohol abuse	105	3.0%	91	2.6%	0.404	0.024
Chronic fatigue syndrome	20	0.6%	17	0.5%	0.087	0.012
Kidney disease	15	0.4%	28	0.8%	-0.375	-0.048
Migraine or bipolar disorder	2,109	60.9%	2,295	66.3%	-5.371	-0.112

Table 3f. Baseline Characteristics of the Topiramate Pregnancy Cohort and the Unexposed Pregnancy Cohort, Exposure Defined by Overlapping Days Supply, in the Sentinel Distributed Database (SDD) From January 1, 2000 to September 30, 2015 (Matched, Aggregated), Ratio: 1:1, Caliper: 0.05

	Cohorts				Covariate Balance	
	Topiramate Pregnant Cohort		Unexposed Pregnant Cohort		Between Topiramate and Unexposed Pregnant Cohorts	
	Number	Percent	Number	Percent	Difference	Difference
Baseline⁴ Medical Product Use						
Valproate	41	1.2%	-	0.0%	1.184	-
Carbamazepine	26	0.8%	-	0.0%	0.751	-
Phenytoin	20	0.6%	-	0.0%	0.578	-
Benzodiazepines	333	9.6%	328	9.5%	0.144	0.005
Triptans	646	18.7%	609	17.6%	1.068	0.028
Antipsychotics	227	6.6%	213	6.2%	0.404	0.017
Antidepressants	1,339	38.7%	1,392	40.2%	-1.530	-0.031
Antihypertensives	359	10.4%	359	10.4%	0.000	0.000
Anxiolytics	541	15.6%	513	14.8%	0.809	0.023
Stimulants	167	4.8%	183	5.3%	-0.462	-0.021
Barbiturates	8	0.2%	-	0.0%	0.231	-
Insulin	39	1.1%	55	1.6%	-0.462	-0.040
Noninsulin antidiabetics	147	4.2%	170	4.9%	-0.664	-0.032
Opioids	913	26.4%	916	26.5%	-0.087	-0.002
Hypnotics	217	6.3%	177	5.1%	1.155	0.050
Buprenorphine	12	0.3%	7	0.2%	0.144	0.028
Methadone	7	0.2%	2	0.1%	0.144	0.040
Naloxone	-	0.0%	-	0.0%	0.000	-
Naltrexone	-	0.0%	3	0.1%	-0.087	-
Suspected teratogens	260	7.5%	312	9.0%	-1.502	-0.055
NSAIDs	337	9.7%	361	10.4%	-0.693	-0.023
Other anticonvulsants	422	12.2%	-	0.0%	12.186	-
Baseline⁴ Health Service Utilization Intensity		Standard		Standard		
	Mean	Deviation	Mean	Deviation		
Mean number of ambulatory encounters	4.0	4.3	4.2	4.3	-0.179	-0.041
Mean number of inpatient hospital encounters	0.0	0.2	0.0	0.2	0.004	0.024
Mean number of unique generics dispensed	5.0	3.4	5.0	4.0	0.030	0.008

¹Preterm birth defined as a pregnancy duration less than 259 days

²Postterm birth defined as a pregnancy duration greater than 287 days

³Gestational age estimated using a claims-

⁴Related to user defined index date (pregnancy start, exposure date, or delivery date)

⁵The Charlson/Elixhauser Combined Comorbidity Score is calculated based on comorbidities observed during a requester-defined window around the exposure episode start date. (Gagne JJ, Glynn RJ, Avorn J, Levin R, Schneeweiss S. A combined comorbidity score predicted mortality in elderly patients better than existing scores. J Clin Epidemiol. 2011;64(7):749-759)

⁶Covariates in blue show a standardized difference greater than 0.1

Table 4a. Effect Estimates for Risk of Oral Clefts comparing the Topiramate Cohort to the Unexposed Cohort by Analysis Type, Main Analysis, in the Sentinel Distributed Database (SDD) From January 1, 2000 to September 30, 2015

	Number of Pregnant Patients	Number of Events	Risk per 1000 Pregnant Patients	Risk Difference per 1000 Pregnant Patients	Risk Ratio	Odds Ratio	95% Confidence Interval
Unmatched Analysis (Site-adjusted only)							
Topiramate Cohort	2,364	12	5.08	3.91	4.35	4.364	(2.469, 7.714)
Unexposed Cohort	1,235,734	1,443	1.17				
1:1 Matched Predefined Analysis; Caliper= 0.05							
Topiramate Cohort	2,330	12	5.15	4.29	6	6.026	(1.347, 26.954)
Unexposed Cohort	2,330	2	0.86				
Predefined Percentile Analysis							
Topiramate Cohort	2,364	12	5.08	3.91	4.35	3.966	(2.210, 7.115)
Unexposed Cohort	1,235,734	1,443	1.17				

Table 4b. Effect Estimates for Risk of Oral Clefts comparing the Topiramate Cohort to the Unexposed Cohort by Analysis Type, Excluding Epilepsy Cases, in the Sentinel Distributed Database (SDD) From January 1, 2000 to September 30, 2015

	Number of Pregnant Patients	Number of Events	Risk per 1000 Pregnant Patients	Risk Difference per 1000 Pregnant Patients	Risk Ratio	Odds Ratio	95% Confidence Interval
Unmatched Analysis (Site-adjusted only)							
Topiramate Cohort	1,988	8	4.02	2.85	3.42	3.434	(1.712, 6.891)
Unexposed Cohort	1,182,064	1,389	1.18				
1:1 Matched Predefined Analysis; Caliper= 0.05							
Topiramate Cohort	1,975	8	4.05	2.03	2	2.004	(0.602, 6.666)
Unexposed Cohort	1,975	4	2.03				
Predefined Percentile Analysis							
Topiramate Cohort	1,988	8	4.02	2.85	3.42	3.178	(1.564, 6.457)
Unexposed Cohort	1,182,064	1,389	1.18				

Table 4c. Effect Estimates for Risk of Oral Clefts comparing the Topiramate Cohort to the Unexposed Cohort by Analysis Type, Topiramate Monotherapy, in the Sentinel Distributed Database (SDD) From January 1, 2000 to September 30, 2015

	Number of Pregnant Patients	Number of Events	Risk per 1000 Pregnant Patients	Risk Difference per 1000 Pregnant Patients	Risk Ratio	Odds Ratio	95% Confidence Interval
Unmatched Analysis (Site-adjusted only)							
Topiramate Cohort	1,728	9	5.21	4.03	4.42	4.442	(2.302, 8.571)
Unexposed Cohort	1,144,212	1,347	1.18				
1:1 Matched Predefined Analysis; Caliper= 0.05							
Topiramate Cohort	1,725	9	5.22	4.64	9	9.042	(1.144, 71.446)
Unexposed Cohort	1,725	1	0.58				
Predefined Percentile Analysis							
Topiramate Cohort	1,728	9	5.21	4.03	4.42	4.048	(2.071, 7.914)
Unexposed Cohort	1,144,212	1,347	1.18				

Table 4d. Effect Estimates for Risk of Oral Clefts comparing the Topiramate Cohort to the Lamotrigine Cohort by Analysis Type, Lamotrigine Comparator, in the Sentinel Distributed Database (SDD) From January 1, 2000 to September 30, 2015

	Number of Pregnant Patients	Number of Events	Risk per 1000 Pregnant Patients	Risk Difference per 1000 Pregnant Patients	Risk Ratio	Odds Ratio	95% Confidence Interval
Unmatched Analysis (Site-adjusted only)							
Topiramate Cohort	2,321	11	4.74	2.62	2.23	2.239	(0.867, 5.785)
Lamotrigine Cohort	3,299	7	2.12				
1:1 Matched Predefined Analysis; Caliper= 0.05							
Topiramate Cohort	1,281	6	4.68	3.9	6	6.024	(0.724, 50.104)
Lamotrigine Cohort	1,281	1	0.78				
Predefined Percentile Analysis							
Topiramate Cohort	2,321	11	4.74	2.62	2.23	4.031	(1.242, 13.088)
Lamotrigine Cohort	3,299	7	2.12				

Table 4e. Effect Estimates for Risk of Oral Clefts comparing the Topiramate Cohort to the Unexposed Cohort by Analysis Type, Two Fills of Topiramate Required, in the Sentinel Distributed Database (SDD) From January 1, 2000 to September 30, 2015

	Number of Pregnant Patients	Number of Events	Risk per 1000 Pregnant Patients	Risk Difference per 1000 Pregnant Patients	Risk Ratio	Odds Ratio	95% Confidence Interval
Unmatched Analysis (Site-adjusted only)							
Topiramate Cohort	955	4	4.19	3.01	3.56	3.569	(1.335, 9.542)
Unexposed Cohort	1,144,271	1,347	1.18				
1:1 Matched Predefined Analysis; Caliper= 0.05							
Topiramate Cohort	941	4	4.25	3.19	4	4.013	(0.448, 35.969)
Unexposed Cohort	941	1	1.06				
Predefined Percentile Analysis							
Topiramate Cohort	955	4	4.19	3.01	3.56	3.189	(1.181, 8.611)
Unexposed Cohort	1,144,271	1,347	1.18				

Table 4f. Effect Estimates for Risk of Oral Clefts comparing the Topiramate Cohort to the Unexposed Cohort by Analysis Type, Exposure Defined by Overlapping Days Supply, in the Sentinel Distributed Database (SDD) From January 1, 2000 to September 30, 2015

	Number of Pregnant Patients	Number of Events	Risk per 1000 Pregnant Patients	Risk Difference per 1000 Pregnant Patients	Risk Ratio	Odds Ratio	95% Confidence Interval
Unmatched Analysis (Site-adjusted only)							
Topiramate Cohort	3,499	13	3.72	2.55	3.19	3.196	(1.849, 5.523)
Unexposed Cohort	1,234,695	1,439	1.17				
1:1 Matched Predefined Analysis; Caliper= 0.05							
Topiramate Cohort	3,463	13	3.75	3.47	13	13.045	(1.706, 99.775)
Unexposed Cohort	3,463	1	0.29				
Predefined Percentile Analysis							
Topiramate Cohort	3,499	13	3.72	2.55	3.19	2.914	(1.660, 5.116)
Unexposed Cohort	1,234,695	1,439	1.17				

Table 5a. Effect Estimates for Risk of Oral Clefts comparing the Topiramate Cohort to the Unexposed Cohort in the Sentinel Distributed Database (SDD) by Analysis Type and Subgroups by Epilepsy or Seizures, Main Analysis, From January 1, 2000 to September 30, 2015

	Number of Pregnant Patients	Number of Events	Risk per 1000 Pregnant Patients	Risk Difference per 1000 Pregnant Patients	Risk Ratio	Odds Ratio	95% Confidence Interval
No Epilepsy or Seizures							
Unmatched Analysis (Site-adjusted only)							
Topiramate Cohort	2,036	9	4.42	3.25	3.79	3.8	(1.970, 7.328)
Unexposed Cohort	1,233,736	1,440	1.17				
1:1 Matched Predefined Analysis; Caliper= 0.05							
Topiramate Cohort	2,024	9	4.45	3.46	4.5	4.516	(0.974, 20.925)
Unexposed Cohort	2,024	2	0.99				
Epilepsy or Seizures							
Unmatched Analysis (Site-adjusted only)							
Topiramate Cohort	328	3	9.15	7.64	6.09	6.138	(1.234, 30.544)
Unexposed Cohort	1,998	3	1.5				
1:1 Matched Predefined Analysis; Caliper= 0.05							
Topiramate Cohort	302	3	9.93	9.93	-	-	-
Unexposed Cohort	302	0	0				

Table 5b. Effect Estimates for Risk of Oral Clefts comparing the Topiramate Cohort to the Unexposed Cohort in the Sentinel Distributed Database (SDD) by Analysis Type and Subgroups by Migraine or Bipolar Disorder, Main Analysis, From January 1, 2000 to September 30, 2015

	Number of Pregnant Patients	Number of Events	Risk per 1000 Pregnant Patients	Risk Difference per 1000 Pregnant Patients	Risk Ratio	Odds Ratio	95% Confidence Interval
No Migraine or Bipolar Disorder							
Unmatched Analysis (Site-adjusted only)							
Topiramate Cohort	942	5	5.31	4.15	4.59	4.611	(1.912, 11.123)
Unexposed Cohort	1,168,012	1,350	1.16				
1:1 Matched Predefined Analysis; Caliper= 0.05							
Topiramate Cohort	934	5	5.35	5.35	-	-	-
Unexposed Cohort	934	0	0				
Migraine or Bipolar Disorder							
Unmatched Analysis (Site-adjusted only)							
Topiramate Cohort	1,422	7	4.92	3.55	3.58	3.597	(1.666, 7.769)
Unexposed Cohort	67,722	93	1.37				
1:1 Matched Predefined Analysis; Caliper= 0.05							
Topiramate Cohort	1,386	7	5.05	2.89	2.33	2.34	(0.604, 9.068)
Unexposed Cohort	1,386	3	2.16				

Table 5c. Effect Estimates for Risk of Oral Clefts comparing the Topiramate Cohort to the Unexposed Cohort in the Sentinel Distributed Database (SDD) by Analysis Type and Subgroups by Epilepsy or Seizures, Exposure Defined by Overlapping Days Supply, From January 1, 2000 to September 30, 2015

	Number of Pregnant Patients	Number of Events	Risk per 1000 Pregnant Patients	Risk Difference per 1000 Pregnant Patients	Risk Ratio	Odds Ratio	95% Confidence Interval
No Epilepsy or Seizures							
Unmatched Analysis (Site-adjusted only)							
Topiramate Cohort	3,104	10	3.22	2.06	2.77	2.771	(1.486, 5.167)
Unexposed Cohort	1,232,724	1,436	1.16				
1:1 Matched Predefined Analysis; Caliper= 0.05							
Topiramate Cohort	3,088	10	3.24	2.91	10	10.029	(1.283, 78.393)
Unexposed Cohort	3,088	1	0.32				
Epilepsy or Seizures							
Unmatched Analysis (Site-adjusted only)							
Topiramate Cohort	395	3	7.59	6.07	4.99	5.02	(1.010, 24.965)
Unexposed Cohort	1,971	3	1.52				
1:1 Matched Predefined Analysis; Caliper= 0.05							
Topiramate Cohort	358	3	8.38	8.38	-	-	-
Unexposed Cohort	358	0	0				

Table 5d. Effect Estimates for Risk of Oral Clefts comparing the Topiramate Cohort to the Unexposed Cohort in the Sentinel Distributed Database (SDD) by Analysis Type and Subgroups by Migraine or Bipolar Disorder, Exposure Defined by Overlapping Days Supply, From January 1, 2000 to September 30, 2015

	Number of Pregnant Patients	Number of Events	Risk per 1000 Pregnant Patients	Risk Difference per 1000 Pregnant Patients	Risk Ratio	Odds Ratio	95% Confidence Interval
No Migraine or Bipolar Disorder							
Unmatched Analysis (Site-adjusted only)							
Topiramate Cohort	1,355	5	3.69	2.54	3.2	3.204	(1.329, 7.722)
Unexposed Cohort	1,167,296	1,348	1.15				
1:1 Matched Predefined Analysis; Caliper= 0.05							
Topiramate Cohort	1,346	5	3.71	2.23	2.5	2.506	(0.485, 12.937)
Unexposed Cohort	1,346	2	1.49				
Migraine or Bipolar Disorder							
Unmatched Analysis (Site-adjusted only)							
Topiramate Cohort	2,144	8	3.73	2.38	2.76	2.77	(1.343, 5.714)
Unexposed Cohort	67,399	91	1.35				
1:1 Matched Predefined Analysis; Caliper= 0.05							
Topiramate Cohort	2,106	8	3.8	3.8	-	-	-
Unexposed Cohort	2,106	0	0				

Figure 1a. Distribution of Propensity Scores Before Matching, Main Analysis, From January 1, 2000 to September 30, 2015

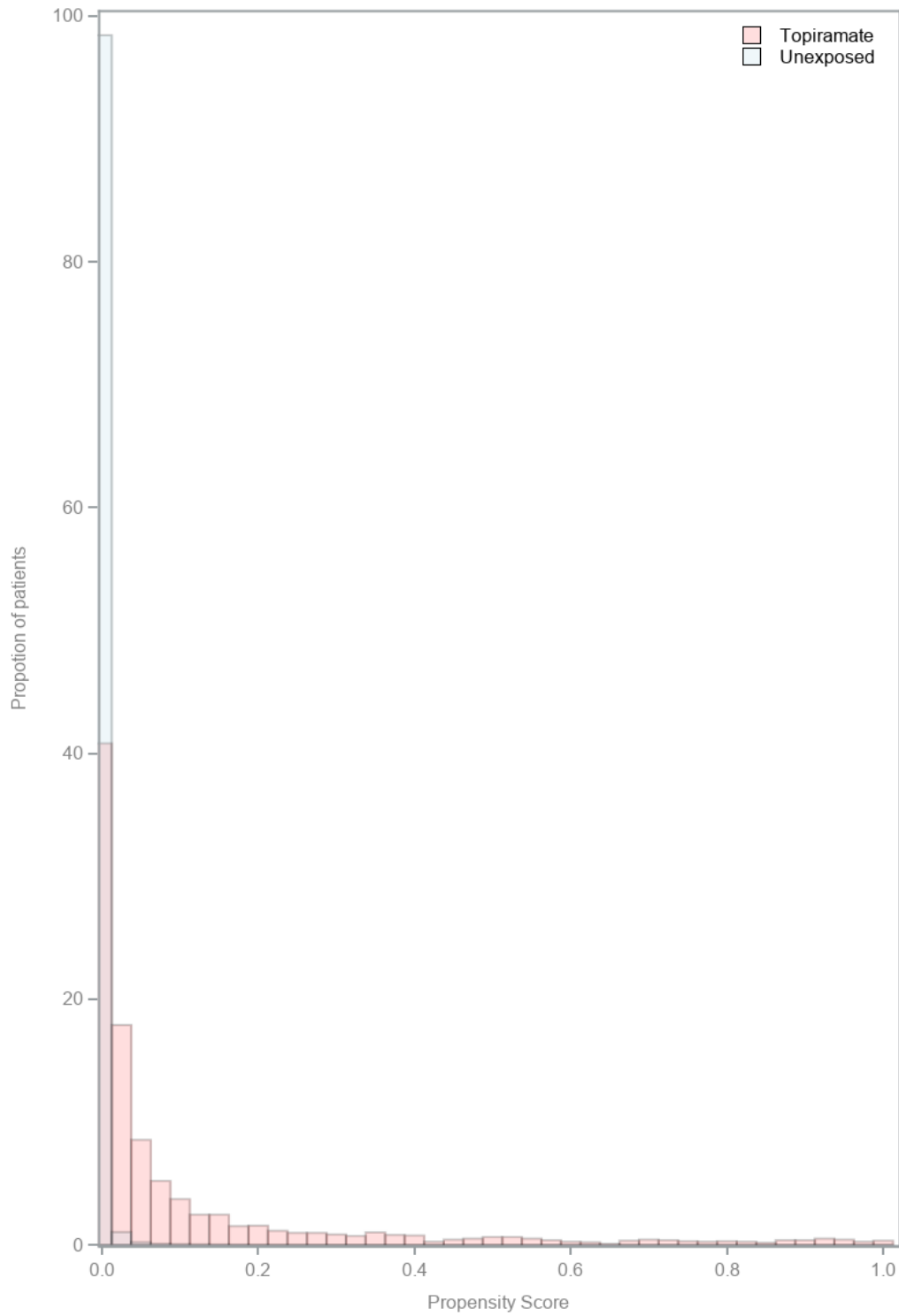


Figure 1b. Distribution of Propensity Scores Before Matching, Excluding Epilepsy Cases, From January 1, 2000 to September 30, 2015

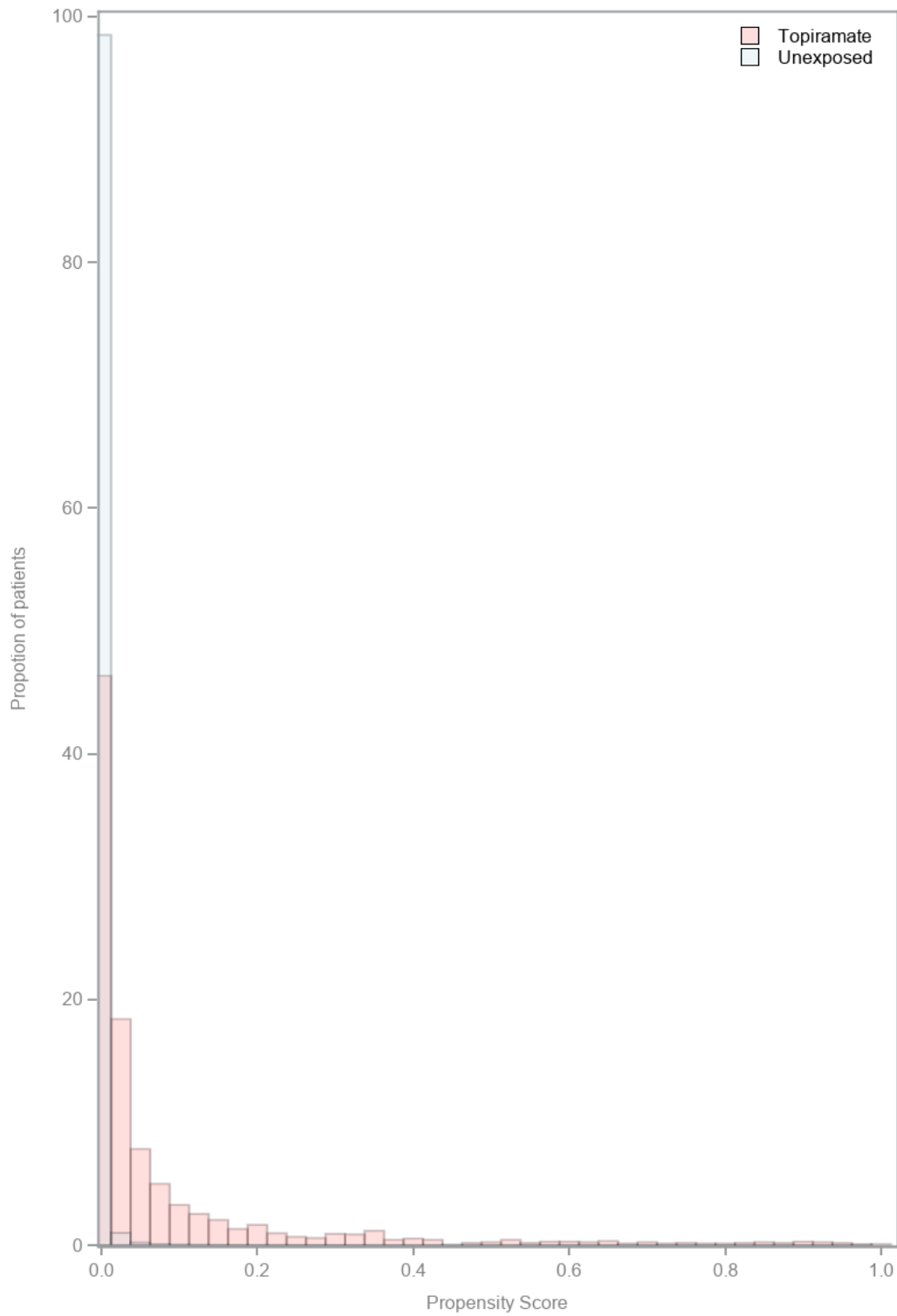


Figure 1c. Distribution of Propensity Scores Before Matching, Topiramate Monotherapy, From January 1, 2000 to September 30, 2015

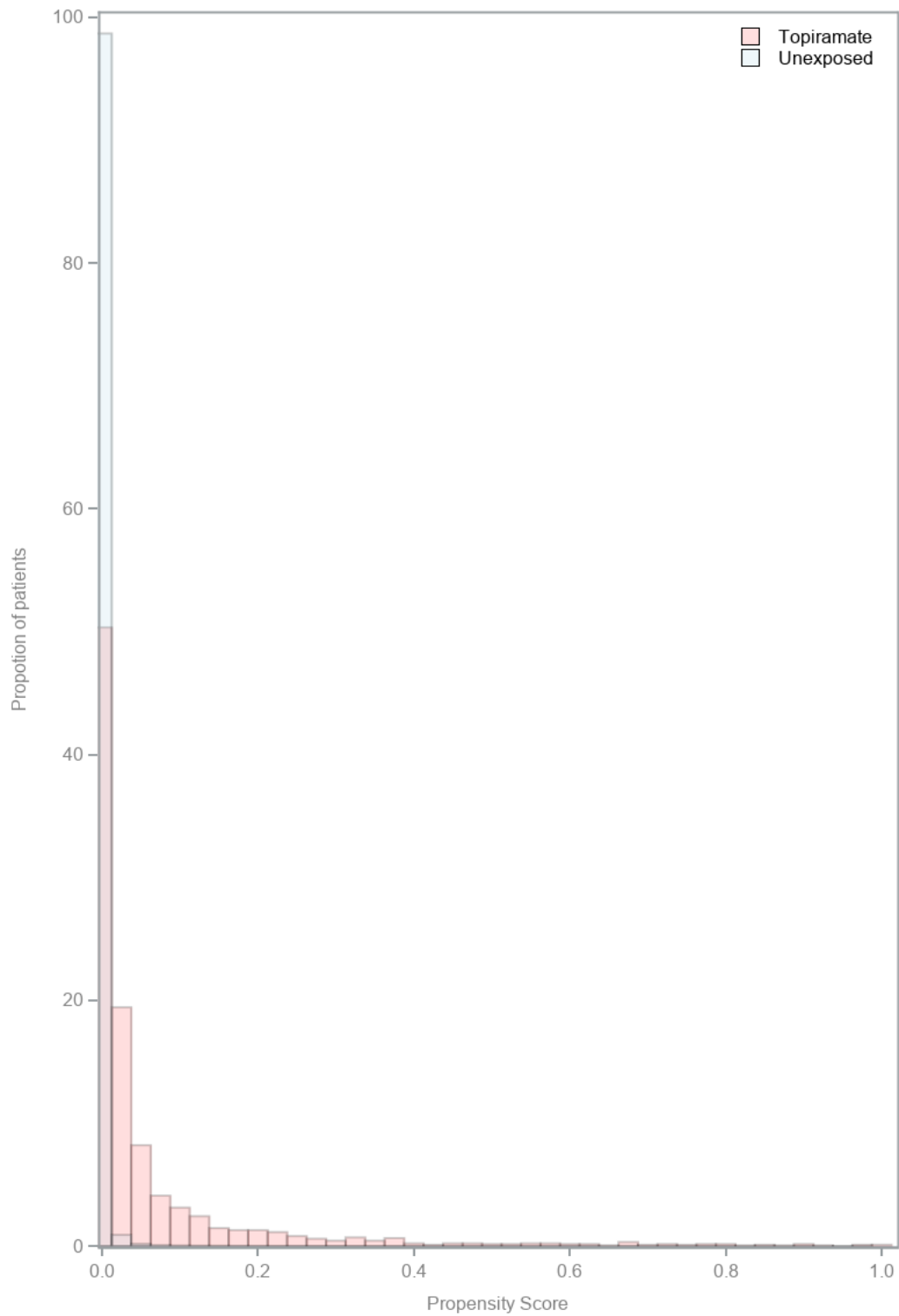


Figure 1d. Distribution of Propensity Scores Before Matching, Lamotrigine Comparator, From January 1, 2000 to September 30, 2015

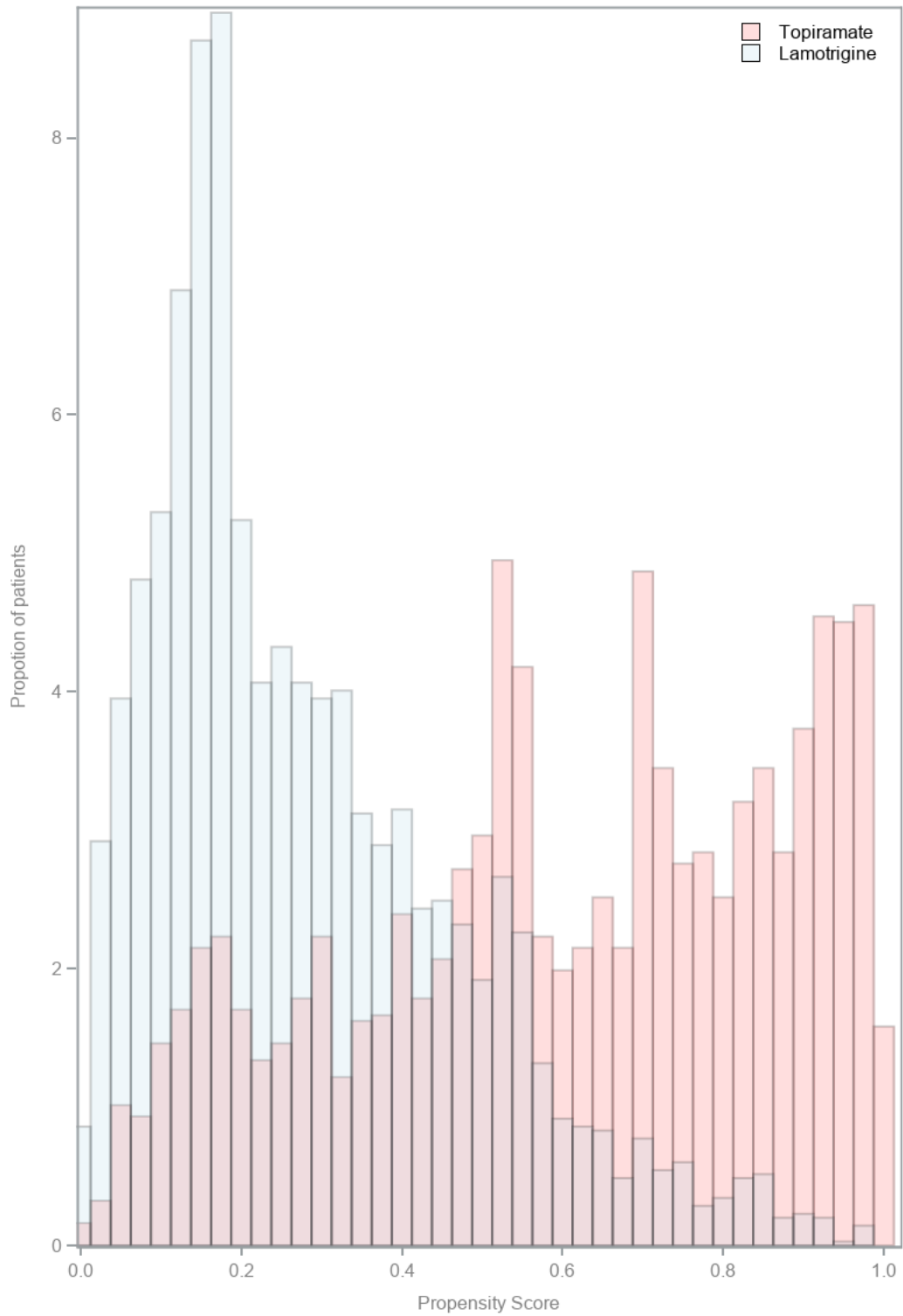


Figure 1e. Distribution of Propensity Scores Before Matching, Two Fills of Topiramate Required, From January 1, 2000 to September 30, 2015

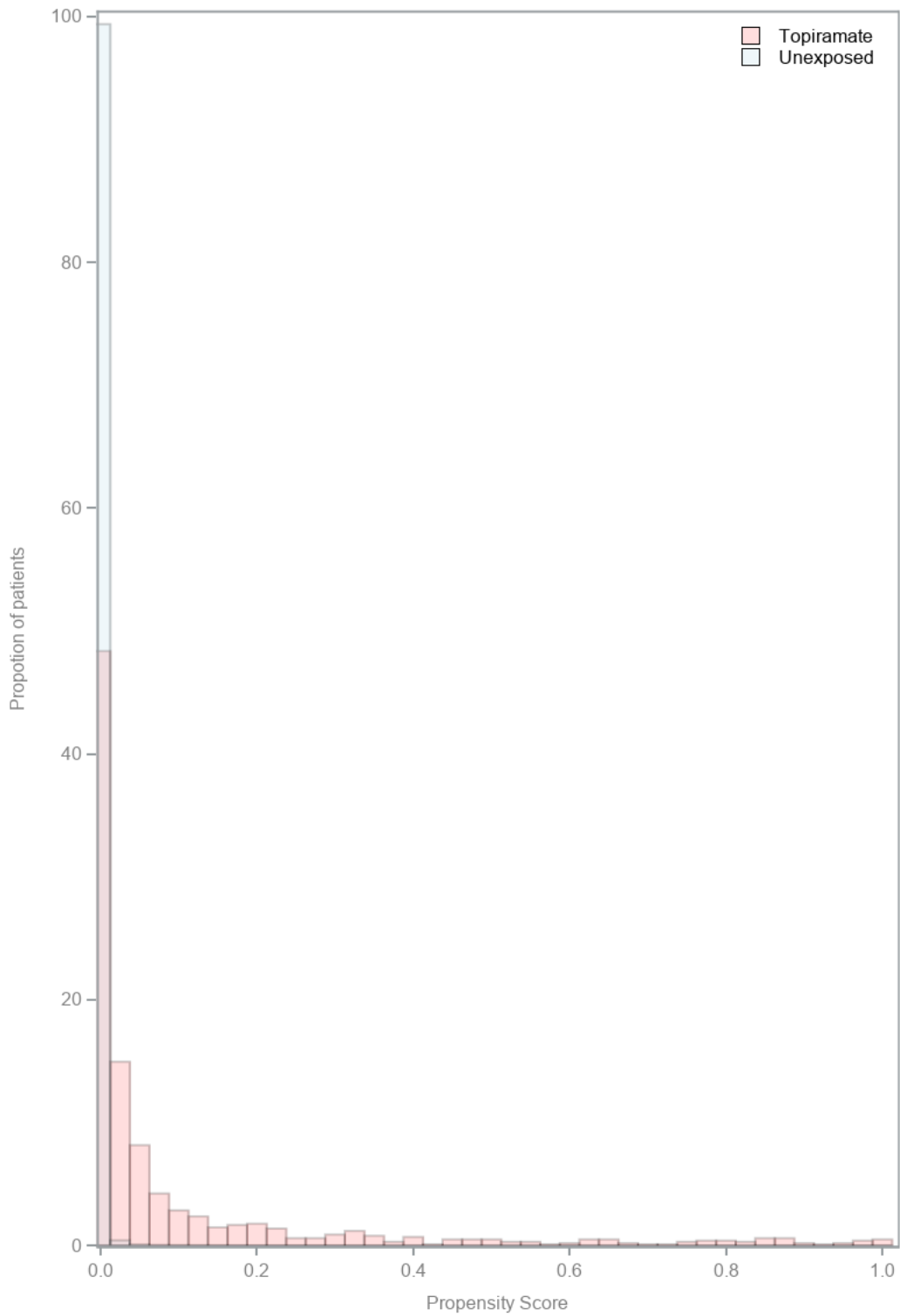


Figure 1f. Distribution of Propensity Scores Before Matching, Exposure Defined by Overlapping Days Supply, From January 1, 2000 to September 30, 2015

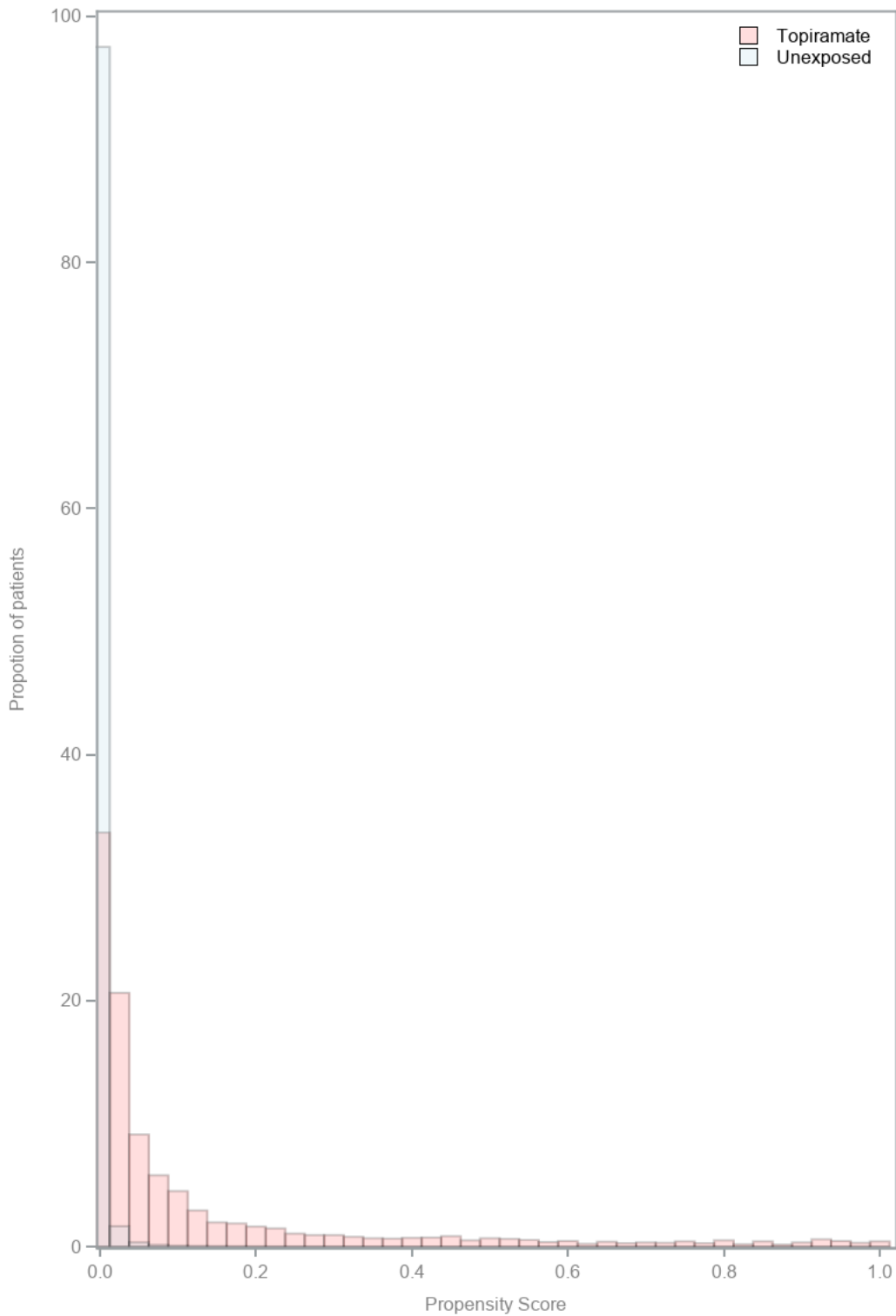


Figure 2a. Distribution of Propensity Scores After Matching, Main Analysis, From January 1, 2000 to September 30, 2015

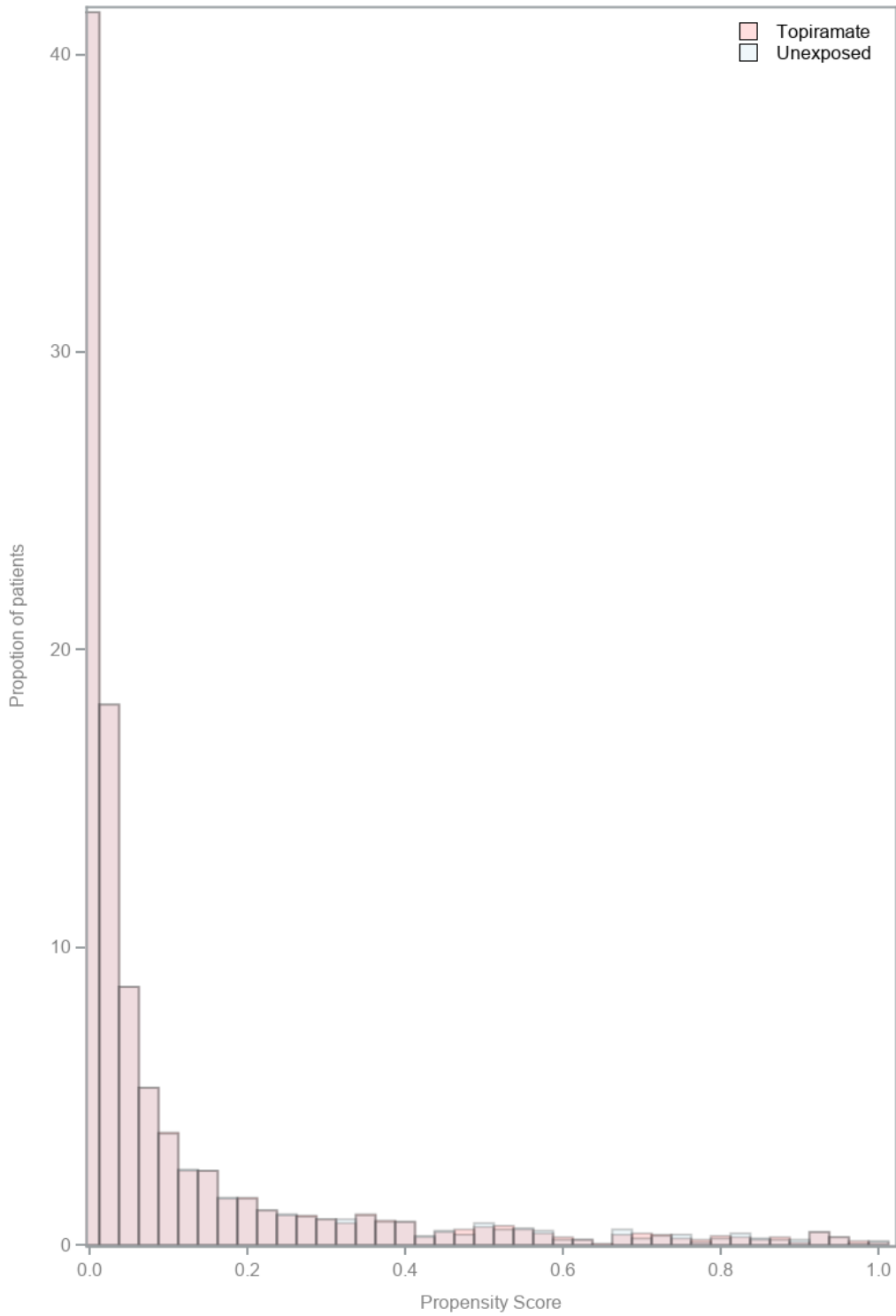


Figure 2b. Distribution of Propensity Scores After Matching, Excluding Epilepsy Cases, From January 1, 2000 to September 30, 2015

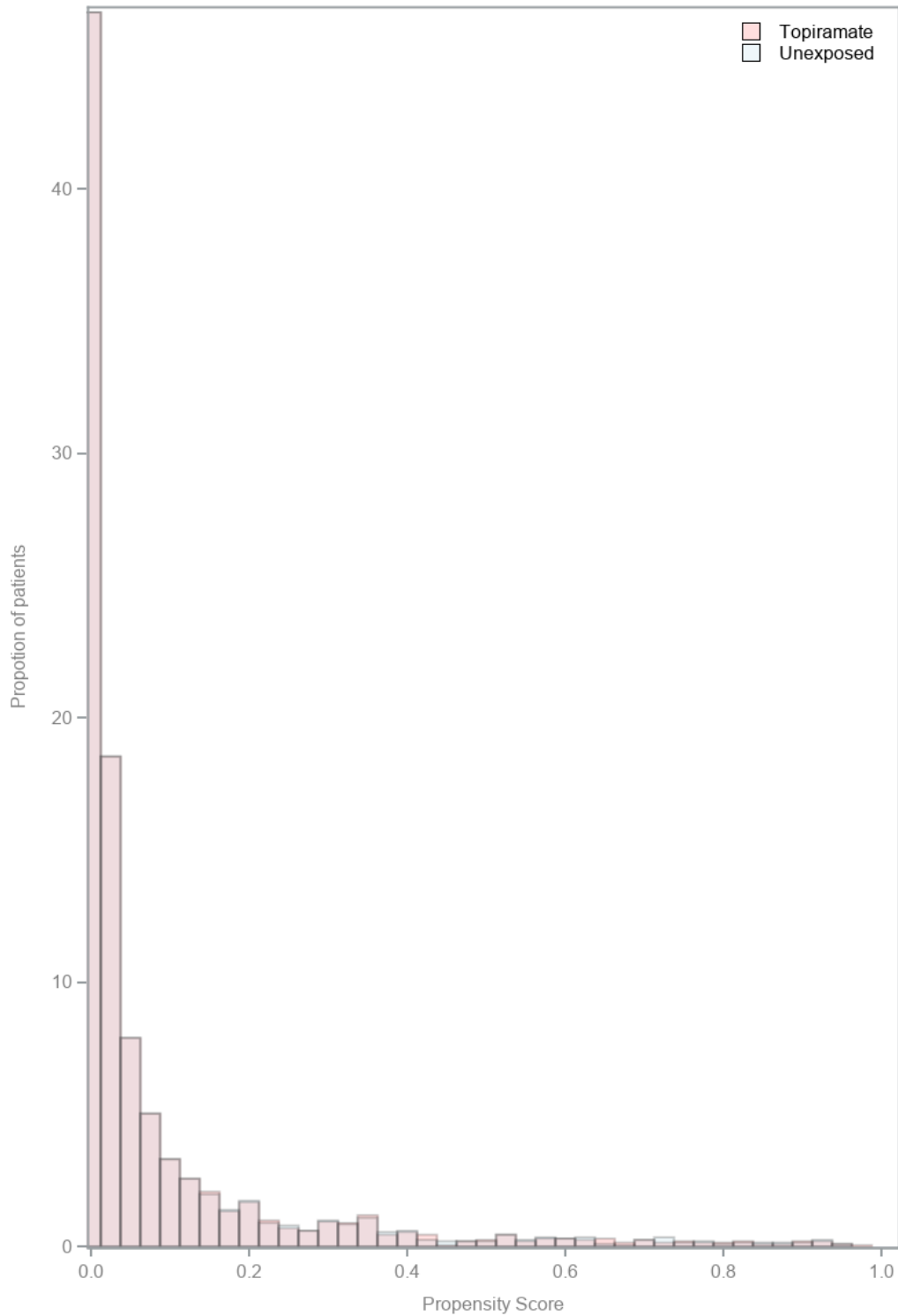


Figure 2c. Distribution of Propensity Scores After Matching, Topiramate Monotherapy, From January 1, 2000 to September 30, 2015

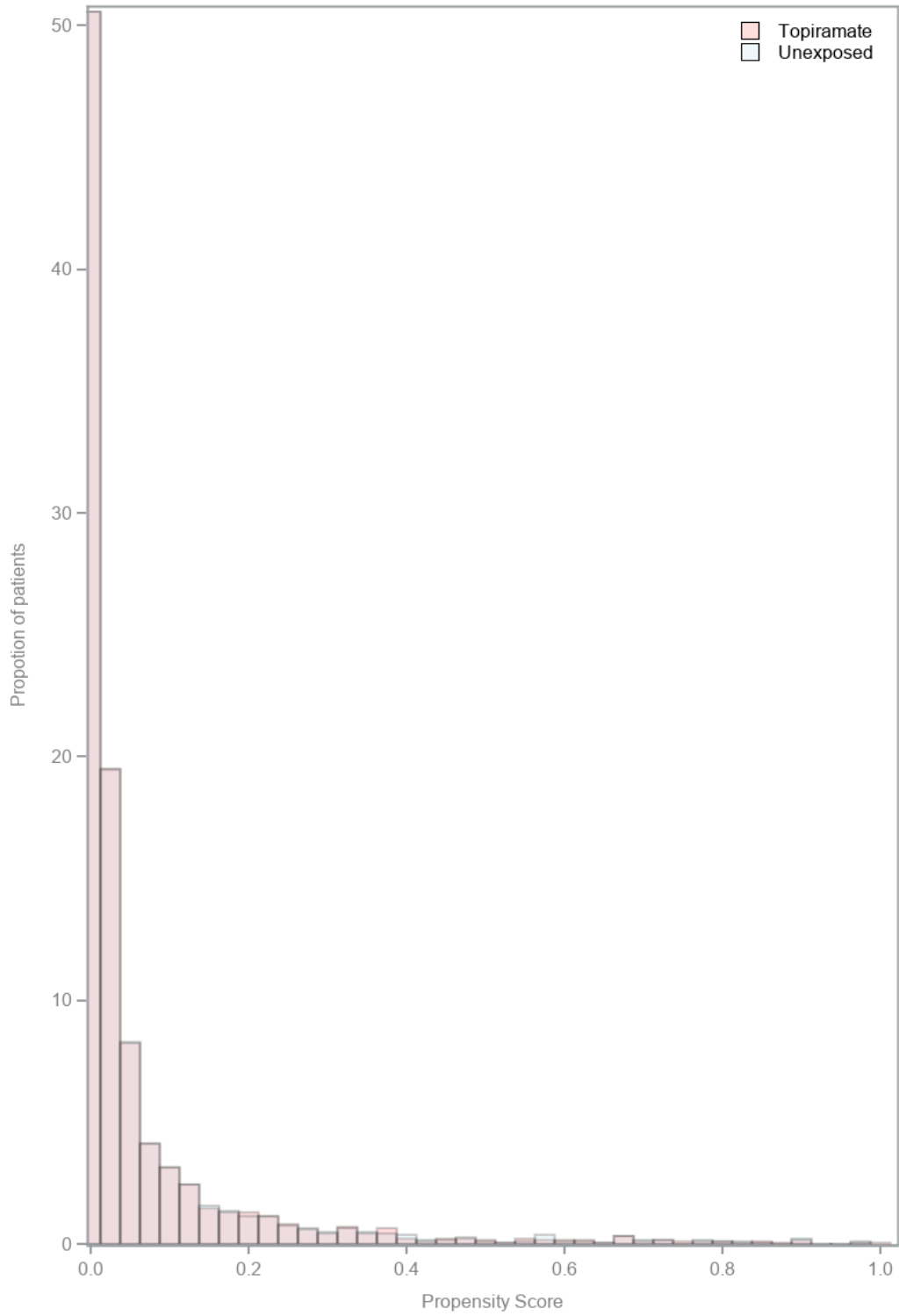


Figure 2d. Distribution of Propensity Scores After Matching, Lamotrigine Comparator, From January 1, 2000 to September 30, 2015

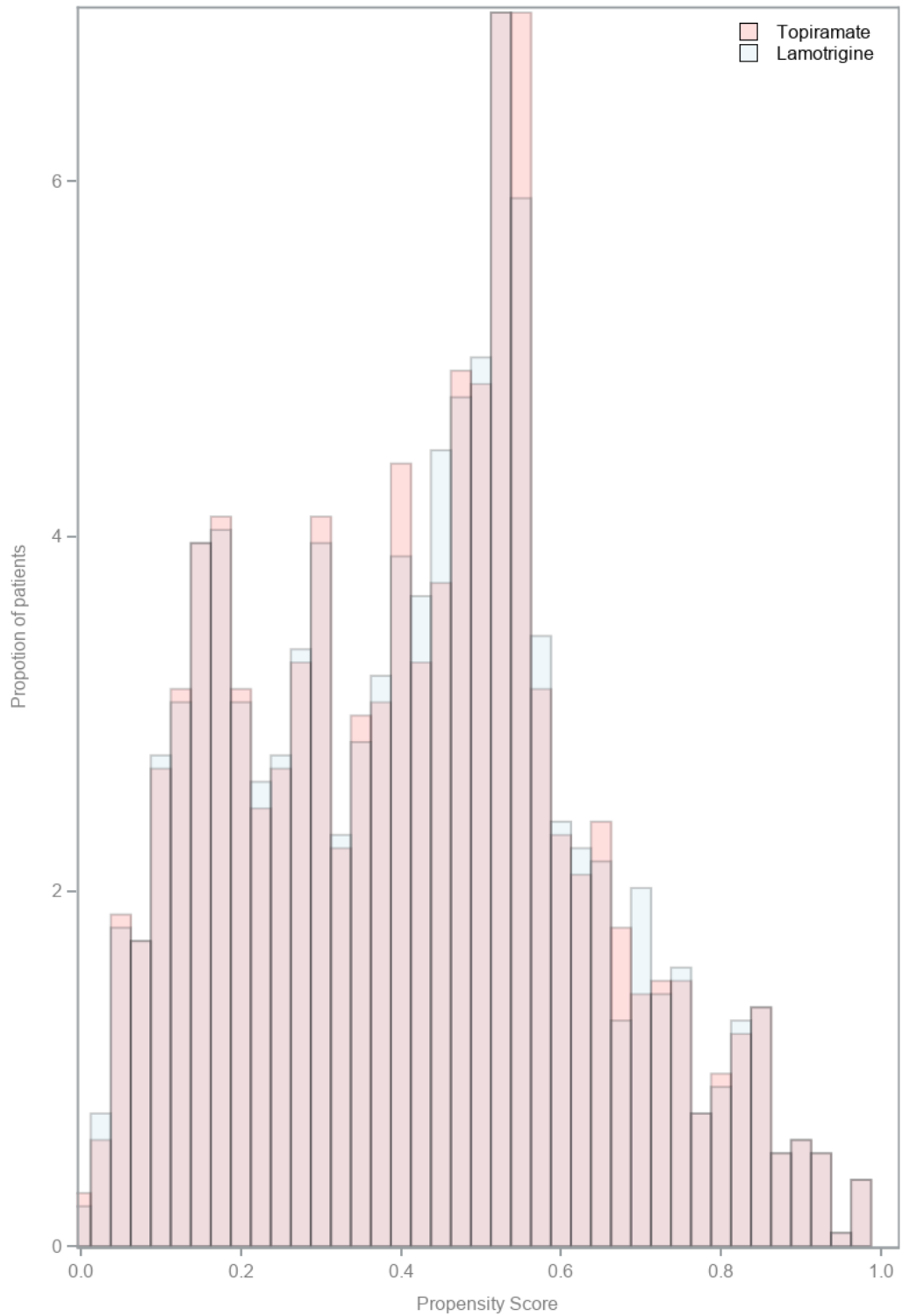


Figure 2e. Distribution of Propensity Scores After Matching, Two Fills of Topiramate Required, From January 1, 2000 to September 30, 2015

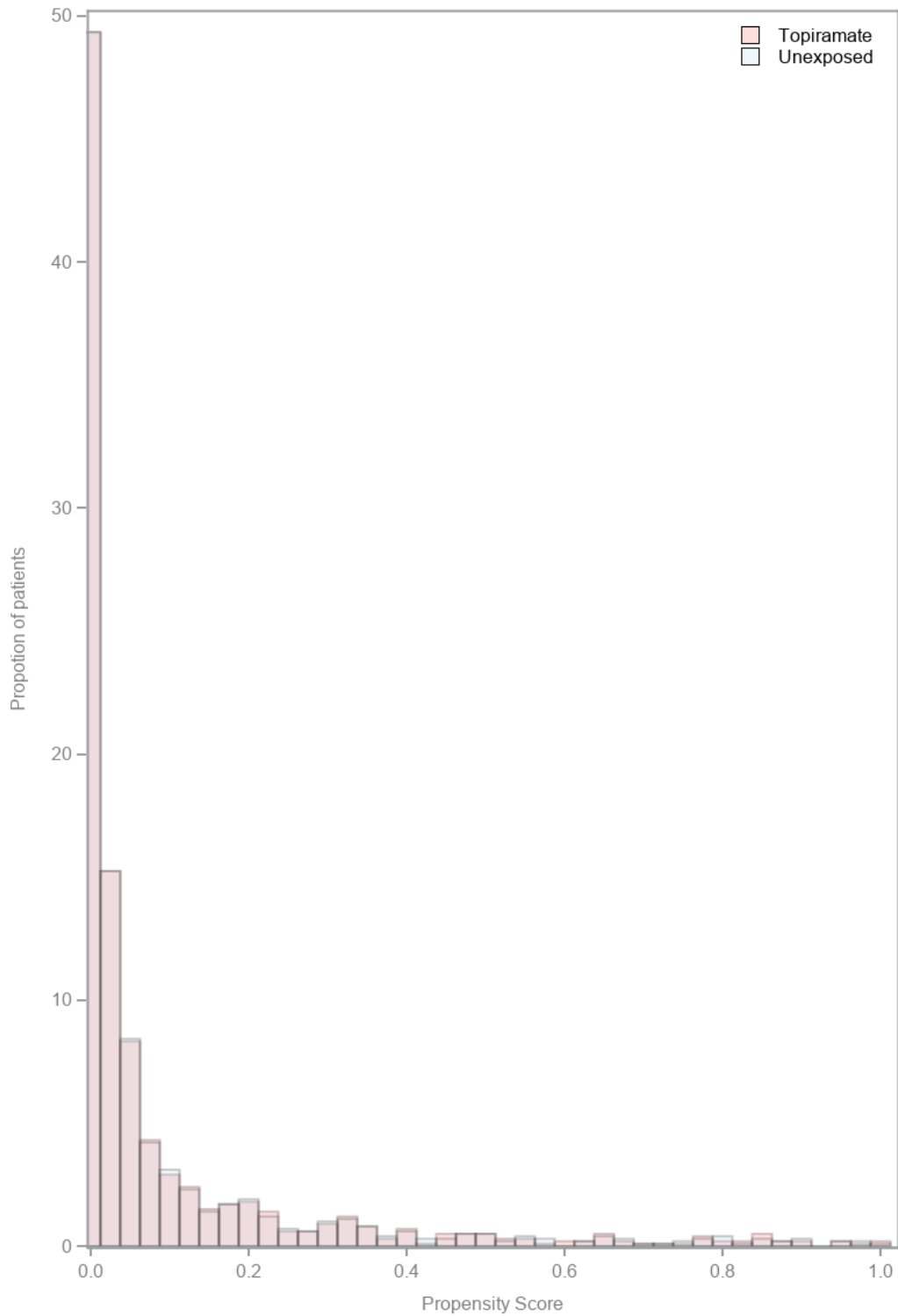


Figure 2f. Distribution of Propensity Scores After Matching, Exposure Defined by Overlapping Days Supply, From January 1, 2000 to September 30, 2015

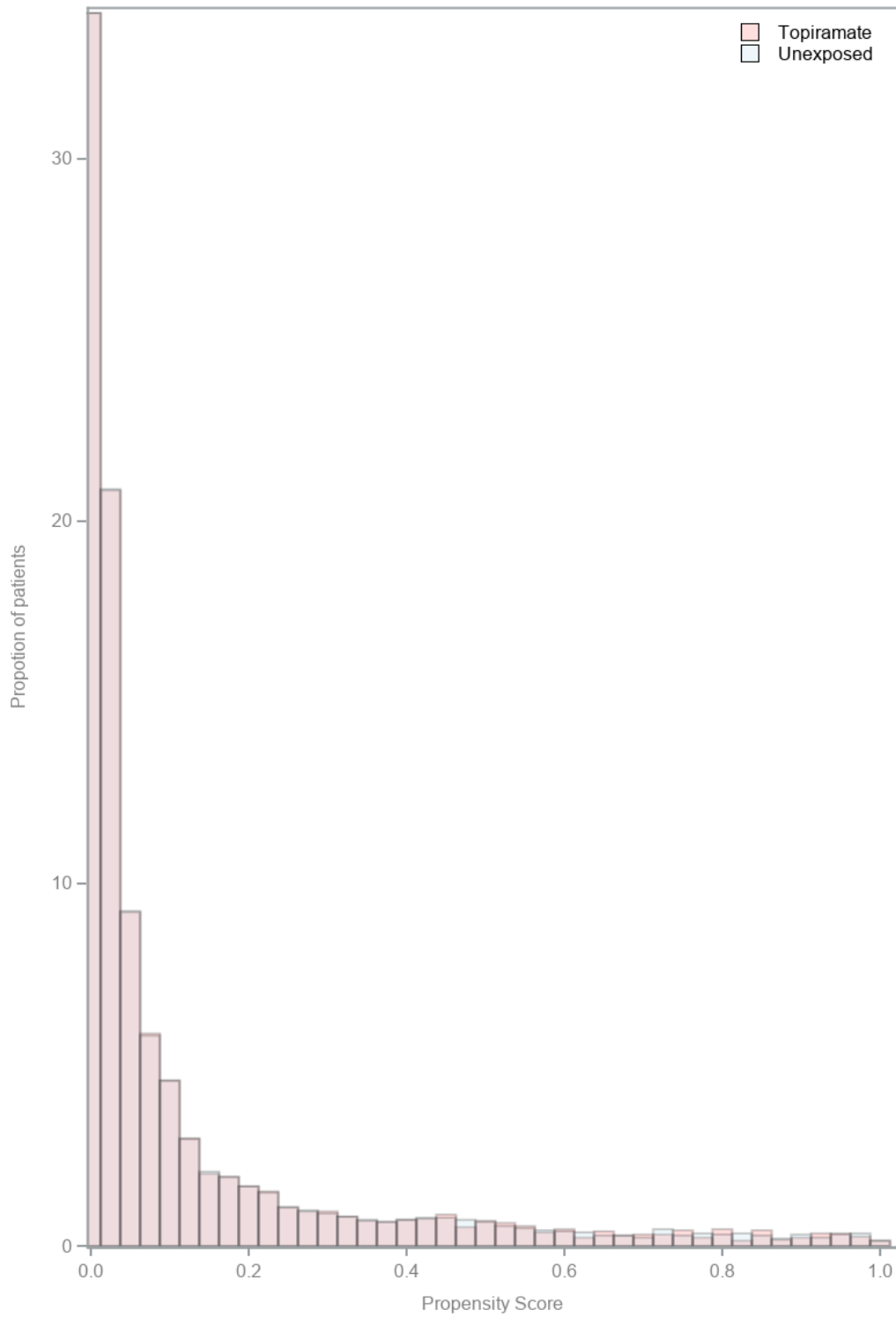
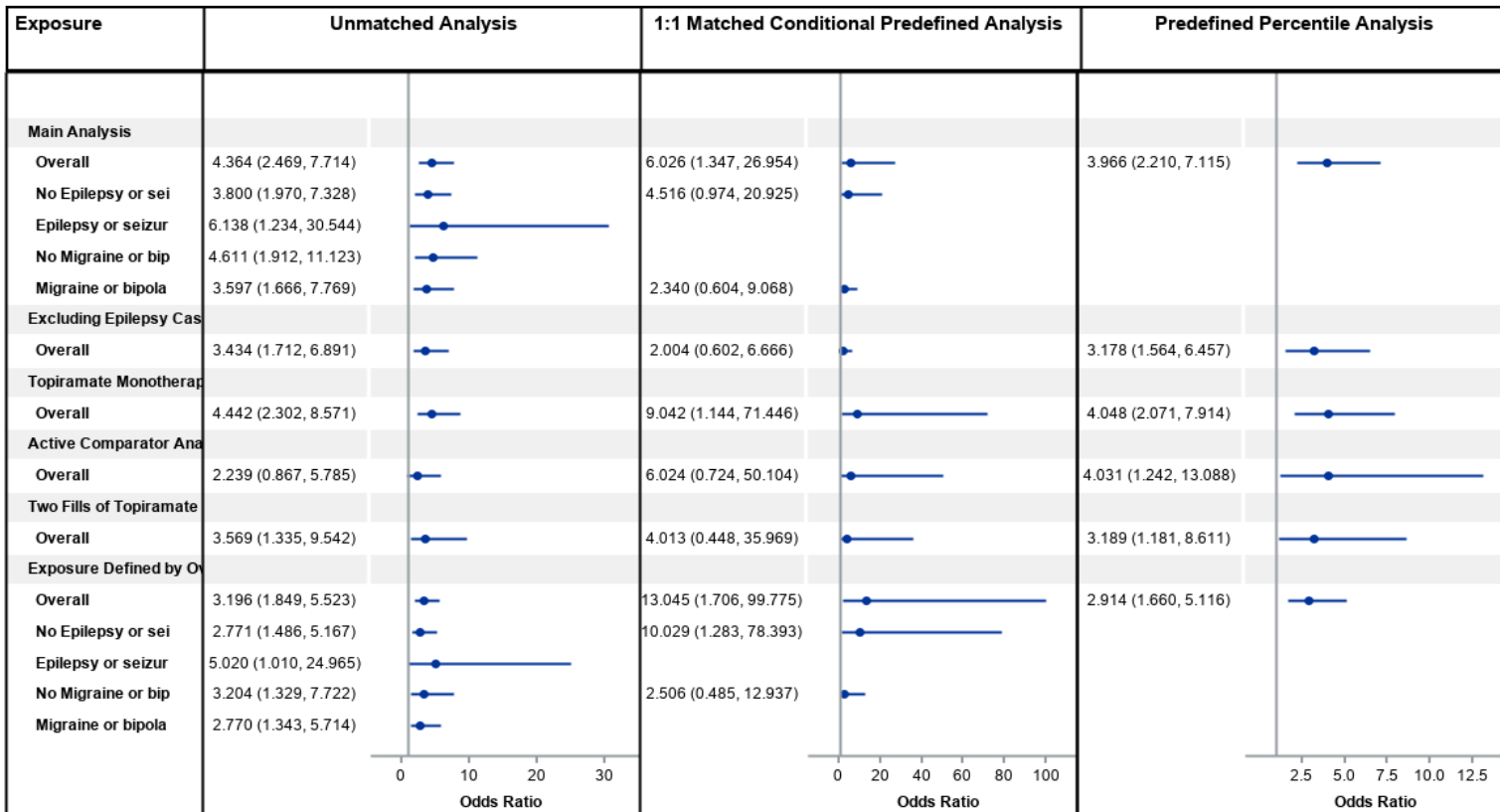


Figure 3a. Forest Plot of Odds Ratios and 95% Confidence Intervals Comparing the Risk of Oral Clefts in the Topiramate Pregnancy Cohort to the Referent Pregnancy Cohort in the Sentinel Distributed Database (SDD) from January 1, 2000 to September 30, 2015



Appendix A. Dates of Available Data for Each Data Partner (DP) as of Request Distribution Date (June 19, 2020)

DP ID	Start Date¹	End Date¹
DP01	1/1/2008	9/30/2015
DP02	1/1/2006	9/30/2015
DP03	1/1/2000	9/30/2015
DP04	6/1/2007	9/30/2015
DP05	1/1/2008	9/30/2015
DP06	1/1/2000	9/30/2015

¹The start and end dates are based on the minimum and maximum dates within each DP. The month with the maximum date must have at least 80% of the number of records in the previous month.

Appendix B. Generic and Brand Names of Medical Products Used to Define Exposures in this Request

Generic Name	Brand Name
Topiramate	
Topiramate	Qudexy XR
Topiramate	Topamax
Topiramate	Topiragen
Topiramate	Topiramate
Topiramate	Trokendi XR
Lamotrigine	
Lamotrigine	Lamictal
Lamotrigine	Lamictal ODT
Lamotrigine	Lamictal ODT Starter (Blue)
Lamotrigine	Lamictal ODT Starter (Green)
Lamotrigine	Lamictal ODT Starter (Orange)
Lamotrigine	Lamictal Starter (Blue) Kit
Lamotrigine	Lamictal Starter (Green) Kit
Lamotrigine	Lamictal Starter (Orange) Kit
Lamotrigine	Lamictal XR
Lamotrigine	Lamictal XR Starter (Blue)
Lamotrigine	Lamictal XR Starter (Green)
Lamotrigine	Lamictal XR Starter (Orange)
Lamotrigine	lamotrigine
Lamotrigine	Subvenite
Lamotrigine	Subvenite Starter (Blue) Kit
Lamotrigine	Subvenite Starter (Green) Kit
Lamotrigine	Subvenite Starter (Orange) Kit

Appendix C. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) and Current Procedural Terminology, 4th Edition (CPT-4) Diagnosis and Procedure Codes Used to Define Outcomes in this Request

Code	Description	Code Type	Code Category
Oral Clefts			
749	Cleft palate and cleft lip	ICD-9-CM	Diagnosis
749.0	Cleft palate	ICD-9-CM	Diagnosis
749.00	Unspecified cleft palate	ICD-9-CM	Diagnosis
749.01	Unilateral cleft palate, complete	ICD-9-CM	Diagnosis
749.02	Unilateral cleft palate, incomplete	ICD-9-CM	Diagnosis
749.03	Bilateral cleft palate, complete	ICD-9-CM	Diagnosis
749.04	Bilateral cleft palate, incomplete	ICD-9-CM	Diagnosis
749.1	Cleft lip	ICD-9-CM	Diagnosis
749.10	Unspecified cleft lip	ICD-9-CM	Diagnosis
749.11	Unilateral cleft lip, complete	ICD-9-CM	Diagnosis
749.12	Unilateral cleft lip, incomplete	ICD-9-CM	Diagnosis
749.13	Bilateral cleft lip, complete	ICD-9-CM	Diagnosis
749.14	Bilateral cleft lip, incomplete	ICD-9-CM	Diagnosis
749.2	Cleft palate with cleft lip	ICD-9-CM	Diagnosis
749.20	Unspecified cleft palate with cleft lip	ICD-9-CM	Diagnosis
749.21	Unilateral cleft palate with cleft lip, complete	ICD-9-CM	Diagnosis
749.22	Unilateral cleft palate with cleft lip, incomplete	ICD-9-CM	Diagnosis
749.23	Bilateral cleft palate with cleft lip, complete	ICD-9-CM	Diagnosis
749.24	Bilateral cleft palate with cleft lip, incomplete	ICD-9-CM	Diagnosis
749.25	Other combinations of cleft palate with cleft lip	ICD-9-CM	Diagnosis
27.62	Correction of cleft palate	ICD-9-CM	Procedure
27.54	Repair of cleft lip	ICD-9-CM	Procedure
27.63	Revision of cleft palate repair	ICD-9-CM	Procedure
00172	Anesthesia for intraoral procedures, including biopsy; repair of cleft palate	CPT-4	Procedure
00102	Anesthesia for procedures involving plastic repair of cleft lip	CPT-4	Procedure
42225	Palatoplasty for cleft palate; attachment pharyngeal flap	CPT-4	Procedure
42200	Palatoplasty for cleft palate, soft and/or hard palate only	CPT-4	Procedure
42210	Palatoplasty for cleft palate, with closure of alveolar ridge; with bone graft to alveolar ridge (includes obtaining graft)	CPT-4	Procedure
42215	Palatoplasty for cleft palate; major revision	CPT-4	Procedure
42220	Palatoplasty for cleft palate; secondary lengthening procedure	CPT-4	Procedure
42205	Palatoplasty for cleft palate, with closure of alveolar ridge; soft tissue only	CPT-4	Procedure
42226	Lengthening of palate, and pharyngeal flap	CPT-4	Procedure
42227	Lengthening of palate, with island flap	CPT-4	Procedure
42235	Repair of anterior palate, including vomer flap	CPT-4	Procedure
42260	Repair of nasolabial fistula	CPT-4	Procedure
40740	Plastic Repair Of Cleft Lip	CPT-4	Procedure
40702	Plastic repair of cleft lip/nasal deformity; primary bilateral, 1 of 2 stages	CPT-4	Procedure
40701	Plastic repair of cleft lip/nasal deformity; primary bilateral, 1-stage procedure	CPT-4	Procedure
40700	Plastic repair of cleft lip/nasal deformity; primary, partial or complete, unilateral	CPT-4	Procedure

Appendix C. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) and Current Procedural Terminology, 4th Edition (CPT-4) Diagnosis and Procedure Codes Used to Define Outcomes in this Request

Code	Description	Code Type	Code Category
40720	Plastic repair of cleft lip/nasal deformity; secondary, by recreation of defect and reclosure	CPT-4	Procedure
40761	Plastic repair of cleft lip/nasal deformity; with cross lip pedicle flap (Abbe-Estlander type), including sectioning and inserting of pedicle	CPT-4	Procedure
40799	Unlisted procedure, lips	CPT-4	Procedure

Appendix D. Generic and Brand Names of Medical Products Used to Define Exclusions in this Request

Generic Name	Brand Name
Antineoplastic Agents	
Abarelix	Plenaxis
Abemaciclib	Verzenio
Abiraterone acetate	Abiraterone
Abiraterone acetate	Zytiga
Abiraterone acetate, submicronized	Yonsa
Acalabrutinib	Calquence
Ado-trastuzumab emtansine	Kadcyla
Afatinib dimaleate	Gilotrif
Aldesleukin	Proleukin
Alectinib HCl	Alecensa
Alemtuzumab	Campath
Alpelisib	Piqray
Altretamine	Hexalen
Aminoglutethimide	Cytadren
Anastrozole	Anastrozole
Anastrozole	Anastrozole (bulk)
Anastrozole	Arimidex
Anastrozole	Arimidex 30-Day Pack
Apalutamide	Erleada
Arsenic trioxide	Arsenic Trioxide
Arsenic trioxide	Trisenox
Asparaginase	Elspar
Asparaginase (Erwinia chrysanthemi)	Erwinaze
Atezolizumab	Tecentriq
Avelumab	Bavencio
Axicabtagene ciloleuce	Yescarta
Axitinib	Inlyta
Azacitidine	Azacitidine
Azacitidine	Vidaza
BCG live	Theracys
BCG live	Tice BCG
Belinostat	Beleodaq
Bendamustine HCl	Belrapzo
Bendamustine HCl	Bendamustine
Bendamustine HCl	Bendeka
Bendamustine HCl	Treanda
Bevacizumab	Avastin
Bevacizumab-awwb	Mvasi
Bexarotene	Bexarotene
Bexarotene	Targretin
Bicalutamide	Bicalutamide
Bicalutamide	Casodex
Binimetinib	Mektovi
Bleomycin sulfate	Blenoxane
Bleomycin sulfate	Bleo 15K

Appendix D. Generic and Brand Names of Medical Products Used to Define Exclusions in this Request

Generic Name	Brand Name
Bleomycin sulfate	Bleomycin
Blinatumomab	Blincyto
Bortezomib	Bortezomib
Bortezomib	Velcade
Bosutinib	Bosulif
Brentuximab vedotin	Adcetris
Brigatinib	Alunbrig
Busulfan	Busulfan
Busulfan	Busulfex
Busulfan	Myleran
Cabazitaxel	Jevtana
Cabozantinib s-malate	Cabometyx
Cabozantinib s-malate	Cometriq
Capecitabine	Capecitabine
Capecitabine	Xeloda
Carboplatin	Carboplatin
Carboplatin	Paraplatin
Carfilzomib	Kyprolis
Carmustine	Bicnu
Carmustine	Carmustine
Carmustine in polifeprosan 20	Gliadel Wafer
Cemiplimab-rwlc	Libtayo
Ceritinib	Zykadia
Cetuximab	Erbitux
Chlorambucil	Leukeran
Cisplatin	Cisplatin
Cisplatin	Cisplatin (bulk)
Cisplatin	Platinol AQ
Cladribine	Cladribine
Cladribine	Leustatin
Clofarabine	Clofarabine
Clofarabine	Clolar
Cobimetinib fumarate	Cotellic
Copanlisib di-HCl	Aliqopa
Crizotinib	Xalkori
Cromolyn sodium	Cromolyn
Cromolyn sodium	Gastrocrom
Cyclophosphamide	Cyclophosphamide
Cyclophosphamide	Cyclophosphamide (bulk)
Cyclophosphamide	Cytoxan
Cyclophosphamide	Cytoxan Lyophilized
Cyclophosphamide	Neosar
Cytarabine	Cytarabine
Cytarabine	Cytosar-U
Cytarabine	Tarabine Pfs
Cytarabine liposome/PF	Depocyt (PF)

Appendix D. Generic and Brand Names of Medical Products Used to Define Exclusions in this Request

Generic Name	Brand Name
Cytarabine/PF	Cytarabine (PF)
Dabrafenib mesylate	Tafinlar
Dacarbazine	Dacarbazine
Dacarbazine	Dacarbazine (bulk)
Dacarbazine	Dtic-Dome
Dacomitinib	Vizimpro
Dactinomycin	Cosmegen
Dactinomycin	Dactinomycin
Daratumumab	Darzalex
Darolutamide	Nubeqa
Dasatinib	Sprycel
Daunorubicin citrate liposomal	Daunoxome
Daunorubicin HCl	Cerubidine
Daunorubicin HCl	Daunorubicin
Daunorubicin/cytarabine liposomal	Vyxeos
Decitabine	Dacogen
Decitabine	Decitabine
Degarelix acetate	Firmagon
Degarelix acetate	Firmagon Kit W Diluent Syringe
Denileukin diftitox	Ontak
Dinutuximab	Unituxin
Docetaxel	Docefrez
Docetaxel	Docetaxel
Docetaxel	Taxotere
Doxorubicin HCl	Adriamycin
Doxorubicin HCl	Adriamycin PFS
Doxorubicin HCl	Adriamycin RDF
Doxorubicin HCl	Doxorubicin
Doxorubicin HCl	Rubex
Doxorubicin HCl pegylated liposomal	Doxil
Doxorubicin HCl pegylated liposomal	Doxorubicin, Peg-Liposomal
Doxorubicin HCl pegylated liposomal	Lipodox
Doxorubicin HCl pegylated liposomal	Lipodox 50
Durvalumab	Imfinzi
Duvelisib	Copiktra
Elotuzumab	Empliciti
Enasidenib mesylate	Idhifa
Encorafenib	Braftovi
Enzalutamide	Xtandi
Epirubicin HCl	Ellence
Epirubicin HCl	Epirubicin
Erdafitinib	Balversa
Eribulin mesylate	Halaven
Erlotinib HCl	Erlotinib
Erlotinib HCl	Tarceva
Estramustine phosphate sodium	Emcyt

Appendix D. Generic and Brand Names of Medical Products Used to Define Exclusions in this Request

Generic Name	Brand Name
Etoposide	Etoposide
Etoposide	Etoposide (bulk)
Etoposide	Toposar
Etoposide	Vepesid
Etoposide phosphate	Etopophos
Everolimus	Afinitor
Everolimus	Afinitor Disperz
Exemestane	Aromasin
Exemestane	Exemestane
Floxuridine	Floxuridine
Floxuridine	Floxuridine (bulk)
Floxuridine	Fudr
Fludarabine phosphate	Fludara
Fludarabine phosphate	Fludarabine
Fludarabine phosphate	Oforta
Fluorouracil	Adrucil
Fluorouracil	Fluorouracil
Fluorouracil	Fluorouracil (bulk)
Flutamide	Eulexin
Flutamide	Flutamide
Fulvestrant	Faslodex
Fulvestrant	Fulvestrant
Gefitinib	Iressa
Gemcitabine HCl	Gemcitabine
Gemcitabine HCl	Gemzar
Gemcitabine HCl in 0.9 % sodium chloride	Infugem
Gemtuzumab ozogamicin	Mylotarg
Gilteritinib fumarate	Xospata
Glasdegib maleate	Daurismo
Goserelin acetate	Zoladex
Histrelin acetate	Vantas
Hydroxyurea	Hydrea
Hydroxyurea	Hydroxyurea
Hydroxyurea	Hydroxyurea (bulk)
Hydroxyurea	Mylocel
Ibrutinib	Imbruvica
Idarubicin HCl	Idamycin
Idarubicin HCl	Idamycin PFS
Idarubicin HCl	Idarubicin
Idelalisib	Zydelig
Ifosfamide	Ifex
Ifosfamide	Ifosfamide
Ifosfamide/mesna	Ifex/Mesnex
Ifosfamide/mesna	Ifosfamide-Mesna
Imatinib mesylate	Gleevec
Imatinib mesylate	Imatinib

Appendix D. Generic and Brand Names of Medical Products Used to Define Exclusions in this Request

Generic Name	Brand Name
Inotuzumab ozogamicin	Besponsa
Interferon alfa-2a,recomb.	Roferon-A
Interferon alfa-2b,recomb.	Intron A
lobenguane iodine-131	Azedra Dosimetric
lobenguane iodine-131	Azedra Therapeutic
Ipilimumab	Yervoy
Irinotecan HCl	Camptosar
Irinotecan HCl	Irinotecan
Irinotecan liposomal	Onivyde
Ivosidenib	Tibsovo
Ixabepilone	Ixempra
Ixazomib citrate	Ninlaro
Kit for prep indium-111/ibritumomab tiuxetan/albumin human	Zevalin (In-111)
Kit for prep yttrium-90/ibritumomab tiuxetan/albumin human	Zevalin (Y-90)
Lapatinib ditosylate	Tykerb
Larotrectinib sulfate	Vitrakvi
Lenalidomide	Revlimid
Lenvatinib mesylate	Lenvima
Letrozole	Femara
Letrozole	Letrozole
Letrozole	Letrozole (bulk)
Leuprolide acetate	Eligard
Leuprolide acetate	Eligard (3 Month)
Leuprolide acetate	Eligard (4 Month)
Leuprolide acetate	Eligard (6 Month)
Leuprolide acetate	Leuprolide
Leuprolide acetate	Leuprolide (bulk)
Leuprolide acetate	Lupron
Leuprolide acetate	Lupron Depot
Leuprolide acetate	Lupron Depot (3 Month)
Leuprolide acetate	Lupron Depot (4 Month)
Leuprolide acetate	Lupron Depot (6 Month)
Leuprolide acetate/lidocaine HCl	Viadur
Levamisole HCl	Ergamisol
Lomustine	Ceenu
Lomustine	Gleostine
Lomustine	Lomustine
Lorlatinib	Lorbrena
Lutetium Lu 177 dotatate	Lutathera
Mechlorethamine HCl	Mechlorethamine (bulk)
Mechlorethamine HCl	Mustargen
Medroxyprogesterone acetate	Depo-Provera
Megestrol acetate	Megace
Megestrol acetate	Megestrol

Appendix D. Generic and Brand Names of Medical Products Used to Define Exclusions in this Request

Generic Name	Brand Name
Megestrol acetate,micronized	Megestrol Acetate,Micro (bulk)
Melphalan	Alkeran
Melphalan	Melphalan
Melphalan HCl	Alkeran (as HCl)
Melphalan HCl	Melphalan HCl
Melphalan HCl/betadex sulfobutyl ether sodium	Evomela
Mercaptopurine	Mercaptopurine
Mercaptopurine	Mercaptopurine (bulk)
Mercaptopurine	Purinethol
Mercaptopurine	Purixan
Methotrexate	Methotrexate (bulk)
Methotrexate	Xatmep
Methotrexate sodium	Methotrexate Sodium
Methotrexate sodium	Trexall
Methotrexate sodium/PF	Methotrexate LPF
Methotrexate sodium/PF	Methotrexate Sodium (PF)
Methoxsalen	Methoxsalen (bulk)
Methoxsalen	Uvadex
Midostaurin	Rydapt
Mitomycin	Mitomycin
Mitomycin	Mitomycin (bulk)
Mitomycin	Mutamycin
Mitotane	Lysodren
Mitotane	Mitotane (bulk)
Mitoxantrone HCl	Mitoxantrone
Mitoxantrone HCl	Novantrone
Mogamulizumab-kpkc	Poteligeo
Moxetumomab pasudotox-tdfk	Lumoxiti
Necitumumab	Portrazza
Nelarabine	Arranon
Neratinib maleate	Nerlynx
Nilotinib HCl	Tasigna
Nilutamide	Nilandron
Nilutamide	Nilutamide
Nintedanib esylate	Ofev
Niraparib tosylate	Zejula
Nivolumab	Opdivo
Obinutuzumab	Gazyva
Ofatumumab	Arzerra
Olaparib	Lynparza
Olaratumab	Lartruvo
Omacetaxine mepesuccinate	Synribo
Osimertinib mesylate	Tagrisso
Oxaliplatin	Eloxatin
Oxaliplatin	Oxaliplatin
Paclitaxel	Onxol

Appendix D. Generic and Brand Names of Medical Products Used to Define Exclusions in this Request

Generic Name	Brand Name
Paclitaxel	Paclitaxel
Paclitaxel	Taxol
Paclitaxel protein-bound	Abraxane
Palbociclib	Ibrance
Panitumumab	Vectibix
Panobinostat lactate	Farydak
Pazopanib HCl	Votrient
Pegaspargase	Oncaspar
Peginterferon alfa-2b	Sylatron
Peginterferon alfa-2b	Sylatron 4-Pack
Pembrolizumab	Keytruda
Pemetrexed disodium	Alimta
Pentostatin	Nipent
Pentostatin	Pentostatin
Pertuzumab	Perjeta
Plicamycin	Mithracin
Polatuzumab vedotin-piiq	Polivy
Pomalidomide	Pomalyst
Ponatinib HCl	Iclusig
Porfimer sodium	Photofrin
Pralatrexate	Folotyn
Procarbazine HCl	Matulane
Procarbazine HCl	Procarbazine HCl (bulk)
Radium-223 dichloride	Xofigo
Ramucirumab	Cyramza
Regorafenib	Stivarga
Ribociclib succinate	Kisqali
Ribociclib succinate/letrozole	Kisqali Femara Co-Pack
Rituximab	Rituxan
Rituximab/hyaluronidase, human recombinant	Rituxan Hycela
Romidepsin	Istodax
Romidepsin	Romidepsin
Rucaparib camsylate	Rubraca
Ruxolitinib phosphate	Jakafi
Samarium Sm 153 lexitronam	Quadramet
Selinexor	Xpovio
Siltuximab	Sylvant
Sipuleucel-T/lactated ringers solution	Provenge
Sodium iodide-131	Hicon
Sonidegib phosphate	Odomzo
Sorafenib tosylate	Nexavar
Streptozocin	Zanosar
Strontium-89 chloride	Metastron
Strontium-89 chloride	Strontium-89 Chloride
Sunitinib malate	Sutent
Tagraxofusp-erzs	Elzonris

Appendix D. Generic and Brand Names of Medical Products Used to Define Exclusions in this Request

Generic Name	Brand Name
Talazoparib tosylate	Talzenna
Talimogene laherparepvec	Imlygic
Tamoxifen citrate	Nolvadex
Tamoxifen citrate	Soltamox
Tamoxifen citrate	Tamoxifen
Temozolomide	Temodar
Temozolomide	Temozolomide
Temsirolimus	Temsirolimus
Temsirolimus	Torisel
Teniposide	Teniposide
Teniposide	Vumon
Testolactone	Teslac
Thalidomide	Thalomid
Thioguanine	Tabloid
Thioguanine	Thioguanine (bulk)
Thiotepa	Tepadina
Thiotepa	Thioplex
Thiotepa	Thiotepa
Thiotepa	Thiotepa (bulk)
Tisagenlecleucel	Kymriah
Topotecan HCl	Hycamtin
Topotecan HCl	Topotecan
Toremifene citrate	Fareston
Toremifene citrate	Toremifene
Tositumomab (with maltose)	Bexxar Dosimetric
Tositumomab (with maltose)	Bexxar Therapeutic
Tositumomab Iodine-131 (with Maltose)	Bexxar 131 Iodine
Trabectedin	Yondelis
Trametinib dimethyl sulfoxide	Mekinist
Trastuzumab	Herceptin
Trastuzumab-anns	Kanjinti
Trastuzumab-hyaluronidase-oysk	Herceptin Hylecta
Tretinoin	Tretinoin (Chemotherapy)
Tretinoin	Vesanoid
Trifluridine/tipiracil HCl	Lonsurf
Triptorelin pamoate	Trelstar
Triptorelin pamoate	Trelstar Depot
Triptorelin pamoate	Trelstar LA
Valrubicin	Valrubicin
Valrubicin	Valstar
Vandetanib	Caprelsa
Vandetanib	Vandetanib
Vemurafenib	Zelboraf
Venetoclax	Venclexta
Venetoclax	Venclexta Starting Pack
Vinblastine sulfate	Velban

Appendix D. Generic and Brand Names of Medical Products Used to Define Exclusions in this Request

Generic Name	Brand Name
Vinblastine sulfate	Vinblastine
Vincristine sulfate	Oncovin
Vincristine sulfate	Vincasar PFS
Vincristine sulfate	Vincristine
Vincristine sulfate liposomal	Marqibo
Vinorelbine tartrate	Navelbine
Vinorelbine tartrate	Vinorelbine
Vismodegib	Erivedge
Vorinostat	Zolinza
Ziv-aflibercept	Zaltrap
Isotretinoin	
Isotretinoin	Absorica
Isotretinoin	Accutane
Isotretinoin	Amnesteem
Isotretinoin	Claravis
Isotretinoin	Isotretinoin
Isotretinoin	Isotretinoin (bulk)
Isotretinoin	Myorisan
Isotretinoin	Sotret
Isotretinoin	Zenatane
Lithium	
Lithium carbonate	Eskalith
Lithium carbonate	Eskalith CR
Lithium carbonate	Lithium Carbonate
Lithium carbonate	Lithium Carbonate (bulk)
Lithium carbonate	Lithobid
Lithium citrate	Lithium Citrate
Lithium citrate tetrahydrate	Lithium Citrate Tetrahyd (bulk)
Misoprostol	
Diclofenac sodium/misoprostol	Arthrotec 50
Diclofenac sodium/misoprostol	Arthrotec 75
Diclofenac sodium/misoprostol	Diclofenac-Misoprostol
Misoprostol	Cytotec
Misoprostol	Misoprostol
Misoprostol	Misoprostol (bulk)
Thalidomide	
Thalidomide	Thalomid
Warfarin	
Warfarin sodium	Coumadin
Warfarin sodium	Jantoven
Warfarin sodium	Warfarin
Warfarin sodium	Warfarin (bulk)

Appendix E. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) Diagnosis Codes Used to Define Exclusions in this Request

Code	Description	Code Type	Code Category
Chromosomal Abnormalities			
758.0	Down's syndrome	ICD-9-CM	Diagnosis
758.1	Patau's syndrome	ICD-9-CM	Diagnosis
758.2	Edwards' syndrome	ICD-9-CM	Diagnosis
758.3	Autosomal deletion syndromes	ICD-9-CM	Diagnosis
758.31	Cri-du-chat syndrome	ICD-9-CM	Diagnosis
758.32	Velo-cardio-facial syndrome	ICD-9-CM	Diagnosis
758.33	Autosomal deletion syndromes, other microdeletions	ICD-9-CM	Diagnosis
758.39	Autosomal deletion syndromes, other autosomal deletions	ICD-9-CM	Diagnosis
758.4	Balanced autosomal translocation in normal individual	ICD-9-CM	Diagnosis
758.5	Other conditions due to autosomal anomalies	ICD-9-CM	Diagnosis
758.6	Gonadal dysgenesis	ICD-9-CM	Diagnosis
758.7	Klinefelter's syndrome	ICD-9-CM	Diagnosis
758.8	Other conditions due to chromosome anomalies	ICD-9-CM	Diagnosis
758.81	Other conditions due to sex chromosome anomalies	ICD-9-CM	Diagnosis
758.89	Other conditions due to chromosome anomalies	ICD-9-CM	Diagnosis
758.9	Conditions due to anomaly of unspecified chromosome	ICD-9-CM	Diagnosis
759.81	Prader-Willi syndrome	ICD-9-CM	Diagnosis
759.82	Marfan's syndrome	ICD-9-CM	Diagnosis
759.83	Fragile X syndrome	ICD-9-CM	Diagnosis

Appendix F. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) Diagnosis Codes Used to Define Gestational Age in this Request

Gestational Age Look Up							
Code	Code Type	Code Category	Duration	Description	Priority Group 1	Priority Group 2	Priority
O481	Diagnosis	ICD-10-CM	294	Prolonged pregnancy	0	1	1
P0822	Diagnosis	ICD-10-CM	294	Prolonged gestation of newborn	0	1	1
Z3A49	Diagnosis	ICD-10-CM	301	Greater than 42 weeks gestation of pregnancy	1	0	1
O480	Diagnosis	ICD-10-CM	287	Post-term pregnancy	0	1	2
P0821	Diagnosis	ICD-10-CM	287	Post-term newborn	0	1	2
Z3A42	Diagnosis	ICD-10-CM	298	42 weeks gestation of pregnancy	1	0	2
Z3A41	Diagnosis	ICD-10-CM	291	41 weeks gestation of pregnancy	1	0	3
Z3A40	Diagnosis	ICD-10-CM	284	40 weeks gestation of pregnancy	1	0	4
Z3A39	Diagnosis	ICD-10-CM	277	39 weeks gestation of pregnancy	1	0	5
Z3A38	Diagnosis	ICD-10-CM	270	38 weeks gestation of pregnancy	1	0	6
Z3A37	Diagnosis	ICD-10-CM	263	37 weeks gestation of pregnancy	1	0	7
P0739	Diagnosis	ICD-10-CM	256	Preterm newborn, gestational age 36 completed weeks	1	0	8
Z3A36	Diagnosis	ICD-10-CM	256	36 weeks gestation of pregnancy	1	0	8
P0738	Diagnosis	ICD-10-CM	249	Preterm newborn, gestational age 35 completed weeks	1	0	9
Z3A35	Diagnosis	ICD-10-CM	249	35 weeks gestation of pregnancy	1	0	9
P0737	Diagnosis	ICD-10-CM	242	Preterm newborn, gestational age 34 completed weeks	1	0	10
Z3A34	Diagnosis	ICD-10-CM	242	34 weeks gestation of pregnancy	1	0	10
P0736	Diagnosis	ICD-10-CM	235	Preterm newborn, gestational age 33 completed weeks	1	0	11
Z3A33	Diagnosis	ICD-10-CM	235	33 weeks gestation of pregnancy	1	0	11
P0735	Diagnosis	ICD-10-CM	228	Preterm newborn, gestational age 32 completed weeks	1	0	12
Z3A32	Diagnosis	ICD-10-CM	228	32 weeks gestation of pregnancy	1	0	12
P0734	Diagnosis	ICD-10-CM	221	Preterm newborn, gestational age 31 completed weeks	1	0	13
Z3A31	Diagnosis	ICD-10-CM	221	31 weeks gestation of pregnancy	1	0	13
P0733	Diagnosis	ICD-10-CM	214	Preterm newborn, gestational age 30 completed weeks	1	0	14
Z3A30	Diagnosis	ICD-10-CM	214	30 weeks gestation of pregnancy	1	0	14
P0732	Diagnosis	ICD-10-CM	207	Preterm newborn, gestational age 29 completed weeks	1	0	15
Z3A29	Diagnosis	ICD-10-CM	207	29 weeks gestation of pregnancy	1	0	15
P0731	Diagnosis	ICD-10-CM	200	Preterm newborn, gestational age 28 completed weeks	1	0	16
Z3A28	Diagnosis	ICD-10-CM	200	28 weeks gestation of pregnancy	1	0	16
P0726	Diagnosis	ICD-10-CM	193	Extreme immaturity of newborn, gestational age 27 completed weeks	1	0	17

Appendix F. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) Diagnosis Codes Used to Define Gestational Age in this Request

Gestational Age Look Up							
Code	Code Type	Code Category	Duration	Description	Priority Group 1	Priority Group 2	Priority
Z3A27	Diagnosis	ICD-10-CM	193	27 weeks gestation of pregnancy	1	0	17
P0725	Diagnosis	ICD-10-CM	186	Extreme immaturity of newborn, gestational age 26 completed weeks	1	0	18
Z3A26	Diagnosis	ICD-10-CM	186	26 weeks gestation of pregnancy	1	0	18
P0724	Diagnosis	ICD-10-CM	179	Extreme immaturity of newborn, gestational age 25 completed weeks	1	0	19
Z3A25	Diagnosis	ICD-10-CM	179	25 weeks gestation of pregnancy	1	0	19
P0723	Diagnosis	ICD-10-CM	172	Extreme immaturity of newborn, gestational age 24 completed weeks	1	0	20
Z3A24	Diagnosis	ICD-10-CM	172	24 weeks gestation of pregnancy	1	0	20
P0722	Diagnosis	ICD-10-CM	165	Extreme immaturity of newborn, gestational age 23 completed weeks	1	0	21
Z3A23	Diagnosis	ICD-10-CM	165	23 weeks gestation of pregnancy	1	0	21
P0721	Diagnosis	ICD-10-CM	158	Extreme immaturity of newborn, gestational age less than 23 completed weeks	1	0	22
Z3A22	Diagnosis	ICD-10-CM	158	22 weeks gestation of pregnancy	1	0	22
Z3A21	Diagnosis	ICD-10-CM	151	21 weeks gestation of pregnancy	1	0	23
Z3A20	Diagnosis	ICD-10-CM	144	20 weeks gestation of pregnancy	1	0	24
P0720	Diagnosis	ICD-10-CM	196	Extreme immaturity of newborn, unspecified weeks of gestation	1	0	25
O6013X0	Diagnosis	ICD-10-CM	245	Preterm labor second trimester with preterm delivery third trimester	1	0	26
O6013X1	Diagnosis	ICD-10-CM	245	Preterm labor second trimester with preterm delivery third trimester	1	0	26
O6013X2	Diagnosis	ICD-10-CM	245	Preterm labor second trimester with preterm delivery third trimester	1	0	26
O6013X3	Diagnosis	ICD-10-CM	245	Preterm labor second trimester with preterm delivery third trimester	1	0	26
O6013X4	Diagnosis	ICD-10-CM	245	Preterm labor second trimester with preterm delivery third trimester	1	0	26
O6013X5	Diagnosis	ICD-10-CM	245	Preterm labor second trimester with preterm delivery third trimester	1	0	26
O6013X9	Diagnosis	ICD-10-CM	245	Preterm labor second trimester with preterm delivery third trimester	1	0	26
O6014X0	Diagnosis	ICD-10-CM	245	Preterm labor third trimester with preterm delivery third trimester	1	0	26
O6014X1	Diagnosis	ICD-10-CM	245	Preterm labor third trimester with preterm delivery third trimester	1	0	26
O6014X2	Diagnosis	ICD-10-CM	245	Preterm labor third trimester with preterm delivery third trimester	1	0	26
O6014X3	Diagnosis	ICD-10-CM	245	Preterm labor third trimester with preterm delivery third trimester	1	0	26
O6014X4	Diagnosis	ICD-10-CM	245	Preterm labor third trimester with preterm delivery third trimester	1	0	26
O6014X5	Diagnosis	ICD-10-CM	245	Preterm labor third trimester with preterm delivery third trimester	1	0	26
O6014X9	Diagnosis	ICD-10-CM	245	Preterm labor third trimester with preterm delivery third trimester	1	0	26
P0730	Diagnosis	ICD-10-CM	245	Preterm newborn, unspecified weeks of gestation	1	0	26

Appendix F. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) Diagnosis Codes Used to Define Gestational Age in this Request

Gestational Age Look Up								
Code	Code Type	Code Category	Duration	Description	Priority Group 1	Priority Group 2	Priority	
O6012X0	Diagnosis	ICD-10-CM	168	Preterm labor second trimester with preterm delivery second trimester	1	0	27	
O6012X1	Diagnosis	ICD-10-CM	168	Preterm labor second trimester with preterm delivery second trimester	1	0	27	
O6012X2	Diagnosis	ICD-10-CM	168	Preterm labor second trimester with preterm delivery second trimester	1	0	27	
O6012X3	Diagnosis	ICD-10-CM	168	Preterm labor second trimester with preterm delivery second trimester	1	0	27	
O6012X4	Diagnosis	ICD-10-CM	168	Preterm labor second trimester with preterm delivery second trimester	1	0	27	
O6012X5	Diagnosis	ICD-10-CM	168	Preterm labor second trimester with preterm delivery second trimester	1	0	27	
O6012X9	Diagnosis	ICD-10-CM	168	Preterm labor second trimester with preterm delivery second trimester	1	0	27	
64520	Diagnosis	ICD-9-CM	294	Prolonged pregnancy	0	1	28	
64521	Diagnosis	ICD-9-CM	294	Prolonged pregnancy	0	1	28	
64523	Diagnosis	ICD-9-CM	294	Prolonged pregnancy	0	1	28	
76528	Diagnosis	ICD-9-CM	252	35-36 completed weeks of gestation	1	0	28	
76622	Diagnosis	ICD-9-CM	294	Prolonged gestation of infant	0	1	28	
64510	Diagnosis	ICD-9-CM	287	Post term pregnancy	0	1	29	
64511	Diagnosis	ICD-9-CM	287	Post term pregnancy	0	1	29	
64513	Diagnosis	ICD-9-CM	287	Post term pregnancy	0	1	29	
76527	Diagnosis	ICD-9-CM	238	33-34 completed weeks of gestation	1	0	29	
76621	Diagnosis	ICD-9-CM	287	Post-term infant	0	1	29	
76526	Diagnosis	ICD-9-CM	224	31-32 completed weeks of gestation	1	0	30	
76525	Diagnosis	ICD-9-CM	210	29-30 completed weeks of gestation	1	0	31	
76524	Diagnosis	ICD-9-CM	196	27-28 completed weeks of gestation	1	0	32	
76523	Diagnosis	ICD-9-CM	182	25-26 completed weeks of gestation	1	0	33	
76521	Diagnosis	ICD-9-CM	168	Less than 24 completed weeks of gestation	1	0	34	
76522	Diagnosis	ICD-9-CM	168	24 completed weeks of gestation	1	0	34	
76500	Diagnosis	ICD-9-CM	196	Extreme immaturity, by weight	1	0	35	
76501	Diagnosis	ICD-9-CM	196	Extreme immaturity, by weight	1	0	35	
76502	Diagnosis	ICD-9-CM	196	Extreme immaturity, by weight	1	0	35	
76503	Diagnosis	ICD-9-CM	196	Extreme immaturity, by weight	1	0	35	
76504	Diagnosis	ICD-9-CM	196	Extreme immaturity, by weight	1	0	35	
76505	Diagnosis	ICD-9-CM	196	Extreme immaturity, by weight	1	0	35	
76506	Diagnosis	ICD-9-CM	196	Extreme immaturity, by weight	1	0	35	

Appendix F. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) Diagnosis Codes Used to Define Gestational Age in this Request

Gestational Age Look Up							
Code	Code Type	Code Category	Duration	Description	Priority Group 1	Priority Group 2	Priority
76507	Diagnosis	ICD-9-CM	196	Extreme immaturity, by weight	1	0	35
76508	Diagnosis	ICD-9-CM	196	Extreme immaturity, by weight	1	0	35
76509	Diagnosis	ICD-9-CM	196	Extreme immaturity, by weight	1	0	35
64421	Diagnosis	ICD-9-CM	245	Early onset of delivery, delivered, with or without mention of antepartum condition	1	0	36
76510	Diagnosis	ICD-9-CM	245	Other preterm infants, by weight	1	0	36
76511	Diagnosis	ICD-9-CM	245	Other preterm infants, by weight	1	0	36
76512	Diagnosis	ICD-9-CM	245	Other preterm infants, by weight	1	0	36
76513	Diagnosis	ICD-9-CM	245	Other preterm infants, by weight	1	0	36
76514	Diagnosis	ICD-9-CM	245	Other preterm infants, by weight	1	0	36
76515	Diagnosis	ICD-9-CM	245	Other preterm infants, by weight	1	0	36
76516	Diagnosis	ICD-9-CM	245	Other preterm infants, by weight	1	0	36
76517	Diagnosis	ICD-9-CM	245	Other preterm infants, by weight	1	0	36
76518	Diagnosis	ICD-9-CM	245	Other preterm infants, by weight	1	0	36
76519	Diagnosis	ICD-9-CM	245	Other preterm infants, by weight	1	0	36
76520	Diagnosis	ICD-9-CM	245	Unspecified weeks of gestation	1	0	36

If multiple codes for specific weeks of gestation (Z codes), preterm delivery, and/or post-term delivery are available, the ICD-10 algorithm for gestational age prioritizes the following codes:

- (1) **Codes that specify weeks of gestation, including all Z codes ranging from 20 weeks through >=42 weeks of gestation in one week increments, and codes that indicate preterm delivery with weeks of gestation specified in one week increments (other than Z codes).** If multiple codes are observed, codes indicating longer gestational age are prioritized over those indicating shorter gestational age. We assumed the approximate mid-point of the specified gestational age [e.g., assumption of 263 days (37 weeks and 4 days) for 37 weeks gestation].
- (2) **Codes that indicate preterm delivery without specifying weeks of gestation.** If multiple codes are observed, codes with more specificity (e.g., preterm delivery, 2nd trimester of pregnancy or 'extreme immaturity') are prioritized over those with less specificity (e.g., preterm newborn, unspecified weeks of gestation). Further, codes indicating longer gestational age are prioritized over those indicating shorter gestational age.
- (3) **Codes that indicate post-term delivery without specifying weeks of gestation.** If multiple codes are observed, codes indicating longer gestational age are prioritized over those indicating shorter gestational age.

If no codes for preterm or post-term delivery are observed, then the default assumption for gestational age is 273 days. However, this assumption is user specified and can be modified.

Appendix G. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) Healthcare Common Procedure Coding System (HCPCS), Current Procedural Terminology, Second Edition (CPT-2), and Current Procedural Terminology, Fourth Edition (CPT-4), Diagnosis and Procedure Codes Used to Define Baseline Characteristics in this Request

Code	Description	Code Type	Code Category
Epilepsy or Seizures			
345	Epilepsy and recurrent seizures	ICD-9-CM	Diagnosis
345.0	Generalized nonconvulsive epilepsy	ICD-9-CM	Diagnosis
345.00	Generalized nonconvulsive epilepsy without mention of intractable epilepsy	ICD-9-CM	Diagnosis
345.01	Generalized nonconvulsive epilepsy with intractable epilepsy	ICD-9-CM	Diagnosis
345.1	Generalized convulsive epilepsy	ICD-9-CM	Diagnosis
345.10	Generalized convulsive epilepsy without mention of intractable epilepsy	ICD-9-CM	Diagnosis
345.11	Generalized convulsive epilepsy with intractable epilepsy	ICD-9-CM	Diagnosis
345.2	Epileptic petit mal status	ICD-9-CM	Diagnosis
345.3	Epileptic grand mal status	ICD-9-CM	Diagnosis
345.4	Localization-related (focal) (partial) epilepsy and epileptic syndromes with complex partial seizures	ICD-9-CM	Diagnosis
345.40	Localization-related (focal) (partial) epilepsy and epileptic syndromes with complex partial seizures, without mention of intractable epilepsy	ICD-9-CM	Diagnosis
345.41	Localization-related (focal) (partial) epilepsy and epileptic syndromes with complex partial seizures, with intractable epilepsy	ICD-9-CM	Diagnosis
345.5	Localization-related (focal) (partial) epilepsy and epileptic syndromes with simple partial seizures	ICD-9-CM	Diagnosis
345.50	Localization-related (focal) (partial) epilepsy and epileptic syndromes with simple partial seizures, without mention of intractable epilepsy	ICD-9-CM	Diagnosis
345.51	Localization-related (focal) (partial) epilepsy and epileptic syndromes with simple partial seizures, with intractable epilepsy	ICD-9-CM	Diagnosis
345.6	Infantile spasms	ICD-9-CM	Diagnosis
345.60	Infantile spasms without mention of intractable epilepsy	ICD-9-CM	Diagnosis
345.61	Infantile spasms with intractable epilepsy	ICD-9-CM	Diagnosis
345.7	Epilepsia partialis continua	ICD-9-CM	Diagnosis
345.70	Epilepsia partialis continua without mention of intractable epilepsy	ICD-9-CM	Diagnosis
345.71	Epilepsia partialis continua with intractable epilepsy	ICD-9-CM	Diagnosis
345.8	Other forms of epilepsy and recurrent seizures	ICD-9-CM	Diagnosis
345.80	Other forms of epilepsy and recurrent seizures, without mention of intractable epilepsy	ICD-9-CM	Diagnosis
345.81	Other forms of epilepsy and recurrent seizures, with intractable epilepsy	ICD-9-CM	Diagnosis
345.9	Unspecified epilepsy	ICD-9-CM	Diagnosis
345.90	Unspecified epilepsy without mention of intractable epilepsy	ICD-9-CM	Diagnosis
345.91	Unspecified epilepsy with intractable epilepsy	ICD-9-CM	Diagnosis
649.4	Epilepsy complicating pregnancy, childbirth, or the puerperium	ICD-9-CM	Diagnosis
649.40	Epilepsy complicating pregnancy, childbirth, or the puerperium, unspecified as to episode of care or not applicable	ICD-9-CM	Diagnosis
649.41	Epilepsy complicating pregnancy, childbirth, or the puerperium, delivered, with or without mention of antepartum condition	ICD-9-CM	Diagnosis
649.42	Epilepsy complicating pregnancy, childbirth, or the puerperium, delivered, with mention of postpartum complication	ICD-9-CM	Diagnosis

Appendix G. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) Healthcare Common Procedure Coding System (HCPCS), Current Procedural Terminology, Second Edition (CPT-2), and Current Procedural Terminology, Fourth Edition (CPT-4), Diagnosis and Procedure Codes Used to Define Baseline Characteristics in this Request

Code	Description	Code Type	Code Category
649.43	Epilepsy complicating pregnancy, childbirth, or the puerperium, antepartum condition or complication	ICD-9-CM	Diagnosis
649.44	Epilepsy complicating pregnancy, childbirth, or the puerperium, postpartum condition or complication	ICD-9-CM	Diagnosis
780.3	Convulsions	ICD-9-CM	Diagnosis
780.31	Febrile convulsions (simple), unspecified	ICD-9-CM	Diagnosis
780.32	Complex febrile convulsions	ICD-9-CM	Diagnosis
780.33	Post traumatic seizures	ICD-9-CM	Diagnosis
780.39	Other convulsions	ICD-9-CM	Diagnosis
Migraine or Headache			
307.81	Tension headache	ICD-9-CM	Diagnosis
339	Other headache syndromes	ICD-9-CM	Diagnosis
339.0	Cluster headaches and other trigeminal autonomic cephalgias	ICD-9-CM	Diagnosis
339.00	Cluster headache syndrome, unspecified	ICD-9-CM	Diagnosis
339.01	Episodic cluster headache	ICD-9-CM	Diagnosis
339.02	Chronic cluster headache	ICD-9-CM	Diagnosis
339.03	Episodic paroxysmal hemicrania	ICD-9-CM	Diagnosis
339.04	Chronic paroxysmal hemicrania	ICD-9-CM	Diagnosis
339.05	Short lasting unilateral neuralgiform headache with conjunctival injection and tearing	ICD-9-CM	Diagnosis
339.09	Other trigeminal autonomic cephalgias	ICD-9-CM	Diagnosis
339.1	Tension type headache	ICD-9-CM	Diagnosis
339.10	Tension type headache, unspecified	ICD-9-CM	Diagnosis
339.11	Episodic tension type headache	ICD-9-CM	Diagnosis
339.12	Chronic tension type headache	ICD-9-CM	Diagnosis
339.2	Post-traumatic headache	ICD-9-CM	Diagnosis
339.20	Post-traumatic headache, unspecified	ICD-9-CM	Diagnosis
339.21	Acute post-traumatic headache	ICD-9-CM	Diagnosis
339.22	Chronic post-traumatic headache	ICD-9-CM	Diagnosis
339.3	Drug induced headache, not elsewhere classified	ICD-9-CM	Diagnosis
339.4	Complicated headache syndromes	ICD-9-CM	Diagnosis
339.41	Hemicrania continua	ICD-9-CM	Diagnosis
339.42	New daily persistent headache	ICD-9-CM	Diagnosis
339.43	Primary thunderclap headache	ICD-9-CM	Diagnosis
339.44	Other complicated headache syndrome	ICD-9-CM	Diagnosis
339.8	Other specified headache syndromes	ICD-9-CM	Diagnosis
339.81	Hypnic headache	ICD-9-CM	Diagnosis
339.82	Headache associated with sexual activity	ICD-9-CM	Diagnosis
339.83	Primary cough headache	ICD-9-CM	Diagnosis
339.84	Primary exertional headache	ICD-9-CM	Diagnosis
339.85	Primary stabbing headache	ICD-9-CM	Diagnosis
339.89	Other specified headache syndromes	ICD-9-CM	Diagnosis

Appendix G. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) Healthcare Common Procedure Coding System (HCPCS), Current Procedural Terminology, Second Edition (CPT-2), and Current Procedural Terminology, Fourth Edition (CPT-4), Diagnosis and Procedure Codes Used to Define Baseline Characteristics in this Request

Code	Description	Code Type	Code Category
346	Migraine	ICD-9-CM	Diagnosis
346.0	Migraine with aura	ICD-9-CM	Diagnosis
346.00	Migraine with aura, without mention of intractable migraine without mention of status migrainosus	ICD-9-CM	Diagnosis
346.01	Migraine with aura, with intractable migraine, so stated, without mention of status migrainosus	ICD-9-CM	Diagnosis
346.02	Migraine with aura, without mention of intractable migraine with status migrainosus	ICD-9-CM	Diagnosis
346.03	Migraine with aura, with intractable migraine, so stated, with status migrainosus	ICD-9-CM	Diagnosis
346.1	Migraine without aura	ICD-9-CM	Diagnosis
346.10	Migraine without aura, without mention of intractable migraine without mention of status migrainosus	ICD-9-CM	Diagnosis
346.11	Migraine without aura, with intractable migraine, so stated, without mention of status migrainosus	ICD-9-CM	Diagnosis
346.12	Migraine without aura, without mention of intractable migraine with status migrainosus	ICD-9-CM	Diagnosis
346.13	Migraine without aura, with intractable migraine, so stated, with status migrainosus	ICD-9-CM	Diagnosis
346.2	Variants of migraine, not elsewhere classified	ICD-9-CM	Diagnosis
346.20	Variants of migraine, not elsewhere classified, without mention of intractable migraine without mention of status migrainosus	ICD-9-CM	Diagnosis
346.21	Variants of migraine, not elsewhere classified, with intractable migraine, so stated, without mention of status migrainosus	ICD-9-CM	Diagnosis
346.22	Variants of migraine, not elsewhere classified, without mention of intractable migraine with status migrainosus	ICD-9-CM	Diagnosis
346.23	Variants of migraine, not elsewhere classified, with intractable migraine, so stated, with status migrainosus	ICD-9-CM	Diagnosis
346.3	Hemiplegic migraine	ICD-9-CM	Diagnosis
346.30	Hemiplegic migraine, without mention of intractable migraine without mention of status migrainosus	ICD-9-CM	Diagnosis
346.31	Hemiplegic migraine, with intractable migraine, so stated, without mention of status migrainosus	ICD-9-CM	Diagnosis
346.32	Hemiplegic migraine, without mention of intractable migraine with status migrainosus	ICD-9-CM	Diagnosis
346.33	Hemiplegic migraine, with intractable migraine, so stated, with status migrainosus	ICD-9-CM	Diagnosis
346.4	Menstrual migraine	ICD-9-CM	Diagnosis
346.40	Menstrual migraine, without mention of intractable migraine without mention of status migrainosus	ICD-9-CM	Diagnosis
346.41	Menstrual migraine, with intractable migraine, so stated, without mention of status migrainosus	ICD-9-CM	Diagnosis

Appendix G. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) Healthcare Common Procedure Coding System (HCPCS), Current Procedural Terminology, Second Edition (CPT-2), and Current Procedural Terminology, Fourth Edition (CPT-4), Diagnosis and Procedure Codes Used to Define Baseline Characteristics in this Request

Code	Description	Code Type	Code Category
346.42	Menstrual migraine, without mention of intractable migraine with status migrainosus	ICD-9-CM	Diagnosis
346.43	Menstrual migraine, with intractable migraine, so stated, with status migrainosus	ICD-9-CM	Diagnosis
346.5	Persistent migraine aura without cerebral infarction	ICD-9-CM	Diagnosis
346.50	Persistent migraine aura without cerebral infarction, without mention of intractable migraine without mention of status migrainosus	ICD-9-CM	Diagnosis
346.51	Persistent migraine aura without cerebral infarction, with intractable migraine, so stated, without mention of status migrainosus	ICD-9-CM	Diagnosis
346.52	Persistent migraine aura without cerebral infarction, without mention of intractable migraine with status migrainosus	ICD-9-CM	Diagnosis
346.53	Persistent migraine aura without cerebral infarction, with intractable migraine, so stated, with status migrainosus	ICD-9-CM	Diagnosis
346.6	Persistent migraine aura with cerebral infarction	ICD-9-CM	Diagnosis
346.60	Persistent migraine aura with cerebral infarction, without mention of intractable migraine without mention of status migrainosus	ICD-9-CM	Diagnosis
346.61	Persistent migraine aura with cerebral infarction, with intractable migraine, so stated, without mention of status migrainosus	ICD-9-CM	Diagnosis
346.62	Persistent migraine aura with cerebral infarction, without mention of intractable migraine with status migrainosus	ICD-9-CM	Diagnosis
346.63	Persistent migraine aura with cerebral infarction, with intractable migraine, so stated, with status migrainosus	ICD-9-CM	Diagnosis
346.7	Chronic migraine without aura	ICD-9-CM	Diagnosis
346.70	Chronic migraine without aura, without mention of intractable migraine without mention of status migrainosus	ICD-9-CM	Diagnosis
346.71	Chronic migraine without aura, with intractable migraine, so stated, without mention of status migrainosus	ICD-9-CM	Diagnosis
346.72	Chronic migraine without aura, without mention of intractable migraine with status migrainosus	ICD-9-CM	Diagnosis
346.73	Chronic migraine without aura, with intractable migraine, so stated, with status migrainosus	ICD-9-CM	Diagnosis
346.8	Other forms of migraine	ICD-9-CM	Diagnosis
346.80	Other forms of migraine, without mention of intractable migraine without mention of status migrainosus	ICD-9-CM	Diagnosis
346.81	Other forms of migraine, with intractable migraine, so stated, without mention of status migrainosus	ICD-9-CM	Diagnosis
346.82	Other forms of migraine, without mention of intractable migraine with status migrainosus	ICD-9-CM	Diagnosis
346.83	Other forms of migraine, with intractable migraine, so stated, with status migrainosus	ICD-9-CM	Diagnosis
346.9	Migraine, unspecified	ICD-9-CM	Diagnosis
346.90	Migraine, unspecified without mention of intractable migraine without mention of status migrainosus	ICD-9-CM	Diagnosis

Appendix G. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) Healthcare Common Procedure Coding System (HCPCS), Current Procedural Terminology, Second Edition (CPT-2), and Current Procedural Terminology, Fourth Edition (CPT-4), Diagnosis and Procedure Codes Used to Define Baseline Characteristics in this Request

Code	Description	Code Type	Code Category
346.91	Migraine, unspecified, with intractable migraine, so stated, without mention of status migrainosus	ICD-9-CM	Diagnosis
346.92	Migraine, unspecified, without mention of intractable migraine with status migrainosus	ICD-9-CM	Diagnosis
346.93	Migraine, unspecified, with intractable migraine, so stated, with status migrainosus	ICD-9-CM	Diagnosis
784.0	Headache	ICD-9-CM	Diagnosis
Bipolar Disorder			
296.0	Bipolar I disorder, single manic episode	ICD-9-CM	Diagnosis
296.00	Bipolar I disorder, single manic episode, unspecified	ICD-9-CM	Diagnosis
296.01	Bipolar I disorder, single manic episode, mild	ICD-9-CM	Diagnosis
296.02	Bipolar I disorder, single manic episode, moderate	ICD-9-CM	Diagnosis
296.03	Bipolar I disorder, single manic episode, severe, without mention of psychotic behavior	ICD-9-CM	Diagnosis
296.04	Bipolar I disorder, single manic episode, severe, specified as with psychotic behavior	ICD-9-CM	Diagnosis
296.05	Bipolar I disorder, single manic episode, in partial or unspecified remission	ICD-9-CM	Diagnosis
296.06	Bipolar I disorder, single manic episode, in full remission	ICD-9-CM	Diagnosis
296.1	Manic disorder, recurrent episode	ICD-9-CM	Diagnosis
296.10	Manic disorder, recurrent episode, unspecified	ICD-9-CM	Diagnosis
296.11	Manic disorder, recurrent episode, mild	ICD-9-CM	Diagnosis
296.12	Manic disorder, recurrent episode, moderate	ICD-9-CM	Diagnosis
296.13	Manic disorder, recurrent episode, severe, without mention of psychotic behavior	ICD-9-CM	Diagnosis
296.14	Manic disorder, recurrent episode, severe, specified as with psychotic behavior	ICD-9-CM	Diagnosis
296.15	Manic disorder, recurrent episode, in partial or unspecified remission	ICD-9-CM	Diagnosis
296.16	Manic disorder, recurrent episode, in full remission	ICD-9-CM	Diagnosis
296.4	Bipolar I disorder, most recent episode (or current) manic	ICD-9-CM	Diagnosis
296.40	Bipolar I disorder, most recent episode (or current) manic, unspecified	ICD-9-CM	Diagnosis
296.41	Bipolar I disorder, most recent episode (or current) manic, mild	ICD-9-CM	Diagnosis
296.42	Bipolar I disorder, most recent episode (or current) manic, moderate	ICD-9-CM	Diagnosis
296.43	Bipolar I disorder, most recent episode (or current) manic, severe, without mention of psychotic behavior	ICD-9-CM	Diagnosis
296.44	Bipolar I disorder, most recent episode (or current) manic, severe, specified as with psychotic behavior	ICD-9-CM	Diagnosis
296.45	Bipolar I disorder, most recent episode (or current) manic, in partial or unspecified remission	ICD-9-CM	Diagnosis
296.46	Bipolar I disorder, most recent episode (or current) manic, in full remission	ICD-9-CM	Diagnosis
296.5	Bipolar I disorder, most recent episode (or current), depressed	ICD-9-CM	Diagnosis
296.50	Bipolar I disorder, most recent episode (or current) depressed, unspecified	ICD-9-CM	Diagnosis
296.51	Bipolar I disorder, most recent episode (or current) depressed, mild	ICD-9-CM	Diagnosis
296.52	Bipolar I disorder, most recent episode (or current) depressed, moderate	ICD-9-CM	Diagnosis

Appendix G. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) Healthcare Common Procedure Coding System (HCPCS), Current Procedural Terminology, Second Edition (CPT-2), and Current Procedural Terminology, Fourth Edition (CPT-4), Diagnosis and Procedure Codes Used to Define Baseline Characteristics in this Request

Code	Description	Code Type	Code Category
296.53	Bipolar I disorder, most recent episode (or current) depressed, severe, without mention of psychotic behavior	ICD-9-CM	Diagnosis
296.54	Bipolar I disorder, most recent episode (or current) depressed, severe, specified as with psychotic behavior	ICD-9-CM	Diagnosis
296.55	Bipolar I disorder, most recent episode (or current) depressed, in partial or unspecified remission	ICD-9-CM	Diagnosis
296.56	Bipolar I disorder, most recent episode (or current) depressed, in full remission	ICD-9-CM	Diagnosis
296.6	Bipolar I disorder, most recent episode (or current), mixed	ICD-9-CM	Diagnosis
296.60	Bipolar I disorder, most recent episode (or current) mixed, unspecified	ICD-9-CM	Diagnosis
296.61	Bipolar I disorder, most recent episode (or current) mixed, mild	ICD-9-CM	Diagnosis
296.62	Bipolar I disorder, most recent episode (or current) mixed, moderate	ICD-9-CM	Diagnosis
296.63	Bipolar I disorder, most recent episode (or current) mixed, severe, without mention of psychotic behavior	ICD-9-CM	Diagnosis
296.64	Bipolar I disorder, most recent episode (or current) mixed, severe, specified as with psychotic behavior	ICD-9-CM	Diagnosis
296.65	Bipolar I disorder, most recent episode (or current) mixed, in partial or unspecified remission	ICD-9-CM	Diagnosis
296.66	Bipolar I disorder, most recent episode (or current) mixed, in full remission	ICD-9-CM	Diagnosis
296.7	Bipolar I disorder, most recent episode (or current) unspecified	ICD-9-CM	Diagnosis
296.8	Other and unspecified bipolar disorders	ICD-9-CM	Diagnosis
296.80	Bipolar disorder, unspecified	ICD-9-CM	Diagnosis
296.81	Atypical manic disorder	ICD-9-CM	Diagnosis
296.82	Atypical depressive disorder	ICD-9-CM	Diagnosis
296.89	Other and unspecified bipolar disorders	ICD-9-CM	Diagnosis
296.99	Other specified episodic mood disorder	ICD-9-CM	Diagnosis
Neuropathic Pain			
053.1	Herpes zoster with other nervous system complications	ICD-9-CM	Diagnosis
053.10	Herpes zoster with unspecified nervous system complication	ICD-9-CM	Diagnosis
053.11	Geniculate herpes zoster	ICD-9-CM	Diagnosis
053.12	Postherpetic trigeminal neuralgia	ICD-9-CM	Diagnosis
053.13	Postherpetic polyneuropathy	ICD-9-CM	Diagnosis
053.14	Herpes zoster myelitis	ICD-9-CM	Diagnosis
053.19	Other herpes zoster with nervous system complications	ICD-9-CM	Diagnosis
250.6	Diabetes with neurological manifestations	ICD-9-CM	Diagnosis
250.60	Diabetes with neurological manifestations, type II or unspecified type, not stated as uncontrolled	ICD-9-CM	Diagnosis
250.61	Diabetes with neurological manifestations, type I [juvenile type], not stated as uncontrolled	ICD-9-CM	Diagnosis
250.62	Diabetes with neurological manifestations, type II or unspecified type, uncontrolled	ICD-9-CM	Diagnosis
250.63	Diabetes with neurological manifestations, type I [juvenile type], uncontrolled	ICD-9-CM	Diagnosis
337.1	Peripheral autonomic neuropathy in disorders classified elsewhere	ICD-9-CM	Diagnosis

Appendix G. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) Healthcare Common Procedure Coding System (HCPCS), Current Procedural Terminology, Second Edition (CPT-2), and Current Procedural Terminology, Fourth Edition (CPT-4), Diagnosis and Procedure Codes Used to Define Baseline Characteristics in this Request

Code	Description	Code Type	Code Category
337.2	Reflex sympathetic dystrophy	ICD-9-CM	Diagnosis
337.20	Unspecified reflex sympathetic dystrophy	ICD-9-CM	Diagnosis
337.21	Reflex sympathetic dystrophy of the upper limb	ICD-9-CM	Diagnosis
337.22	Reflex sympathetic dystrophy of the lower limb	ICD-9-CM	Diagnosis
337.29	Reflex sympathetic dystrophy of other specified site	ICD-9-CM	Diagnosis
350.1	Trigeminal neuralgia	ICD-9-CM	Diagnosis
350.2	Atypical face pain	ICD-9-CM	Diagnosis
352.1	Glossopharyngeal neuralgia	ICD-9-CM	Diagnosis
353.0	Brachial plexus lesions	ICD-9-CM	Diagnosis
353.1	Lumbosacral plexus lesions	ICD-9-CM	Diagnosis
353.2	Cervical root lesions, not elsewhere classified	ICD-9-CM	Diagnosis
353.3	Thoracic root lesions, not elsewhere classified	ICD-9-CM	Diagnosis
353.4	Lumbosacral root lesions, not elsewhere classified	ICD-9-CM	Diagnosis
353.5	Neuralgic amyotrophy	ICD-9-CM	Diagnosis
353.6	Phantom limb (syndrome)	ICD-9-CM	Diagnosis
353.8	Other nerve root and plexus disorders	ICD-9-CM	Diagnosis
353.9	Unspecified nerve root and plexus disorder	ICD-9-CM	Diagnosis
354.0	Carpal tunnel syndrome	ICD-9-CM	Diagnosis
354.1	Other lesion of median nerve	ICD-9-CM	Diagnosis
354.2	Lesion of ulnar nerve	ICD-9-CM	Diagnosis
354.3	Lesion of radial nerve	ICD-9-CM	Diagnosis
354.4	Causalgia of upper limb	ICD-9-CM	Diagnosis
354.5	Mononeuritis multiplex	ICD-9-CM	Diagnosis
354.8	Other mononeuritis of upper limb	ICD-9-CM	Diagnosis
354.9	Unspecified mononeuritis of upper limb	ICD-9-CM	Diagnosis
355.0	Lesion of sciatic nerve	ICD-9-CM	Diagnosis
355.1	Meralgia paresthetica	ICD-9-CM	Diagnosis
355.2	Other lesion of femoral nerve	ICD-9-CM	Diagnosis
355.3	Lesion of lateral popliteal nerve	ICD-9-CM	Diagnosis
355.4	Lesion of medial popliteal nerve	ICD-9-CM	Diagnosis
355.5	Tarsal tunnel syndrome	ICD-9-CM	Diagnosis
355.6	Lesion of plantar nerve	ICD-9-CM	Diagnosis
355.7	Other mononeuritis of lower limb	ICD-9-CM	Diagnosis
355.71	Causalgia of lower limb	ICD-9-CM	Diagnosis
355.79	Other mononeuritis of lower limb	ICD-9-CM	Diagnosis
355.8	Unspecified mononeuritis of lower limb	ICD-9-CM	Diagnosis
355.9	Mononeuritis of unspecified site	ICD-9-CM	Diagnosis
357.0	Acute infective polyneuritis	ICD-9-CM	Diagnosis
357.1	Polyneuropathy in collagen vascular disease	ICD-9-CM	Diagnosis
357.2	Polyneuropathy in diabetes	ICD-9-CM	Diagnosis
357.3	Polyneuropathy in malignant disease	ICD-9-CM	Diagnosis
357.4	Polyneuropathy in other diseases classified elsewhere	ICD-9-CM	Diagnosis

Appendix G. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) Healthcare Common Procedure Coding System (HCPCS), Current Procedural Terminology, Second Edition (CPT-2), and Current Procedural Terminology, Fourth Edition (CPT-4), Diagnosis and Procedure Codes Used to Define Baseline Characteristics in this Request

Code	Description	Code Type	Code Category
357.5	Alcoholic polyneuropathy	ICD-9-CM	Diagnosis
357.6	Polyneuropathy due to drugs	ICD-9-CM	Diagnosis
357.7	Polyneuropathy due to other toxic agents	ICD-9-CM	Diagnosis
357.8	Other inflammatory and toxic neuropathy	ICD-9-CM	Diagnosis
357.81	Chronic inflammatory demyelinating polyneuritis	ICD-9-CM	Diagnosis
357.82	Critical illness polyneuropathy	ICD-9-CM	Diagnosis
357.89	Other inflammatory and toxic neuropathy	ICD-9-CM	Diagnosis
357.9	Unspecified inflammatory and toxic neuropathy	ICD-9-CM	Diagnosis
721.1	Cervical spondylosis with myelopathy	ICD-9-CM	Diagnosis
721.41	Spondylosis with myelopathy, thoracic region	ICD-9-CM	Diagnosis
721.42	Spondylosis with myelopathy, lumbar region	ICD-9-CM	Diagnosis
721.91	Spondylosis of unspecified site with myelopathy	ICD-9-CM	Diagnosis
722.7	Intervertebral disc disorder with myelopathy	ICD-9-CM	Diagnosis
722.70	Intervertebral disc disorder with myelopathy, unspecified region	ICD-9-CM	Diagnosis
722.71	Intervertebral cervical disc disorder with myelopathy, cervical region	ICD-9-CM	Diagnosis
722.72	Intervertebral thoracic disc disorder with myelopathy, thoracic region	ICD-9-CM	Diagnosis
722.73	Intervertebral lumbar disc disorder with myelopathy, lumbar region	ICD-9-CM	Diagnosis
723.4	Brachial neuritis or radiculitis NOS	ICD-9-CM	Diagnosis
724.3	Sciatica	ICD-9-CM	Diagnosis
724.4	Thoracic or lumbosacral neuritis or radiculitis, unspecified	ICD-9-CM	Diagnosis
729.2	Unspecified neuralgia, neuritis, and radiculitis	ICD-9-CM	Diagnosis
Non-neuropathic Pain			
710.0	Systemic lupus erythematosus	ICD-9-CM	Diagnosis
710.1	Systemic sclerosis	ICD-9-CM	Diagnosis
710.2	Sicca syndrome	ICD-9-CM	Diagnosis
710.3	Dermatomyositis	ICD-9-CM	Diagnosis
710.4	Polymyositis	ICD-9-CM	Diagnosis
710.5	Eosinophilia myalgia syndrome	ICD-9-CM	Diagnosis
710.8	Other specified diffuse disease of connective tissue	ICD-9-CM	Diagnosis
710.9	Unspecified diffuse connective tissue disease	ICD-9-CM	Diagnosis
711.0	Pyogenic arthritis	ICD-9-CM	Diagnosis
711.00	Pyogenic arthritis, site unspecified	ICD-9-CM	Diagnosis
711.01	Pyogenic arthritis, shoulder region	ICD-9-CM	Diagnosis
711.02	Pyogenic arthritis, upper arm	ICD-9-CM	Diagnosis
711.03	Pyogenic arthritis, forearm	ICD-9-CM	Diagnosis
711.04	Pyogenic arthritis, hand	ICD-9-CM	Diagnosis
711.05	Pyogenic arthritis, pelvic region and thigh	ICD-9-CM	Diagnosis
711.06	Pyogenic arthritis, lower leg	ICD-9-CM	Diagnosis
711.07	Pyogenic arthritis, ankle and foot	ICD-9-CM	Diagnosis
711.08	Pyogenic arthritis, other specified sites	ICD-9-CM	Diagnosis
711.09	Pyogenic arthritis, multiple sites	ICD-9-CM	Diagnosis
711.1	Arthropathy associated with Reiter's disease and nonspecific urethritis	ICD-9-CM	Diagnosis

Appendix G. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) Healthcare Common Procedure Coding System (HCPCS), Current Procedural Terminology, Second Edition (CPT-2), and Current Procedural Terminology, Fourth Edition (CPT-4), Diagnosis and Procedure Codes Used to Define Baseline Characteristics in this Request

Code	Description	Code Type	Code Category
711.10	Arthropathy associated with Reiter's disease and nonspecific urethritis, site unspecified	ICD-9-CM	Diagnosis
711.11	Arthropathy associated with Reiter's disease and nonspecific urethritis, shoulder region	ICD-9-CM	Diagnosis
711.12	Arthropathy associated with Reiter's disease and nonspecific urethritis, upper arm	ICD-9-CM	Diagnosis
711.13	Arthropathy associated with Reiter's disease and nonspecific urethritis, forearm	ICD-9-CM	Diagnosis
711.14	Arthropathy associated with Reiter's disease and nonspecific urethritis, hand	ICD-9-CM	Diagnosis
711.15	Arthropathy associated with Reiter's disease and nonspecific urethritis, pelvic region and thigh	ICD-9-CM	Diagnosis
711.16	Arthropathy associated with Reiter's disease and nonspecific urethritis, lower leg	ICD-9-CM	Diagnosis
711.17	Arthropathy associated with Reiter's disease and nonspecific urethritis, ankle and foot	ICD-9-CM	Diagnosis
711.18	Arthropathy associated with Reiter's disease and nonspecific urethritis, other specified site	ICD-9-CM	Diagnosis
711.19	Arthropathy associated with Reiter's disease and nonspecific urethritis, multiple sites	ICD-9-CM	Diagnosis
711.2	Arthropathy in Behcet's syndrome	ICD-9-CM	Diagnosis
711.20	Arthropathy in Behcet's syndrome, site unspecified	ICD-9-CM	Diagnosis
711.21	Arthropathy in Behcet's syndrome, shoulder region	ICD-9-CM	Diagnosis
711.22	Arthropathy in Behcet's syndrome, upper arm	ICD-9-CM	Diagnosis
711.23	Arthropathy in Behcet's syndrome, forearm	ICD-9-CM	Diagnosis
711.24	Arthropathy in Behcet's syndrome, hand	ICD-9-CM	Diagnosis
711.25	Arthropathy in Behcet's syndrome, pelvic region and thigh	ICD-9-CM	Diagnosis
711.26	Arthropathy in Behcet's syndrome, lower leg	ICD-9-CM	Diagnosis
711.27	Arthropathy in Behcet's syndrome, ankle and foot	ICD-9-CM	Diagnosis
711.28	Arthropathy in Behcet's syndrome, other specified sites	ICD-9-CM	Diagnosis
711.29	Arthropathy in Behcet's syndrome, multiple sites	ICD-9-CM	Diagnosis
711.3	Postdysenteric arthropathy	ICD-9-CM	Diagnosis
711.30	Postdysenteric arthropathy, site unspecified	ICD-9-CM	Diagnosis
711.31	Postdysenteric arthropathy, shoulder region	ICD-9-CM	Diagnosis
711.32	Postdysenteric arthropathy, upper arm	ICD-9-CM	Diagnosis
711.33	Postdysenteric arthropathy, forearm	ICD-9-CM	Diagnosis
711.34	Postdysenteric arthropathy, hand	ICD-9-CM	Diagnosis
711.35	Postdysenteric arthropathy, pelvic region and thigh	ICD-9-CM	Diagnosis
711.36	Postdysenteric arthropathy, lower leg	ICD-9-CM	Diagnosis
711.37	Postdysenteric arthropathy, ankle and foot	ICD-9-CM	Diagnosis
711.38	Postdysenteric arthropathy, other specified sites	ICD-9-CM	Diagnosis
711.39	Postdysenteric arthropathy, multiple sites	ICD-9-CM	Diagnosis
711.4	Arthropathy associated with other bacterial diseases	ICD-9-CM	Diagnosis
711.40	Arthropathy associated with other bacterial diseases, site unspecified	ICD-9-CM	Diagnosis

Appendix G. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) Healthcare Common Procedure Coding System (HCPCS), Current Procedural Terminology, Second Edition (CPT-2), and Current Procedural Terminology, Fourth Edition (CPT-4), Diagnosis and Procedure Codes Used to Define Baseline Characteristics in this Request

Code	Description	Code Type	Code Category
711.41	Arthropathy associated with other bacterial diseases, shoulder region	ICD-9-CM	Diagnosis
711.42	Arthropathy associated with other bacterial diseases, upper arm	ICD-9-CM	Diagnosis
711.43	Arthropathy associated with other bacterial diseases, forearm	ICD-9-CM	Diagnosis
711.44	Arthropathy, associated with other bacterial diseases, hand	ICD-9-CM	Diagnosis
711.45	Arthropathy associated with other bacterial diseases, pelvic region and thigh	ICD-9-CM	Diagnosis
711.46	Arthropathy associated with other bacterial diseases, lower leg	ICD-9-CM	Diagnosis
711.47	Arthropathy associated with other bacterial disease, ankle and foot	ICD-9-CM	Diagnosis
711.48	Arthropathy associated with other bacterial diseases, other specific sites	ICD-9-CM	Diagnosis
711.49	Arthropathy associated with other bacterial diseases, multiple sites	ICD-9-CM	Diagnosis
711.5	Arthropathy associated with other viral diseases	ICD-9-CM	Diagnosis
711.50	Arthropathy associated with other viral diseases, site unspecified	ICD-9-CM	Diagnosis
711.51	Arthropathy associated with other viral diseases, shoulder region	ICD-9-CM	Diagnosis
711.52	Arthropathy associated with other viral diseases, upper arm	ICD-9-CM	Diagnosis
711.53	Arthropathy associated with other viral diseases, forearm	ICD-9-CM	Diagnosis
711.54	Arthropathy associated with other viral diseases, hand	ICD-9-CM	Diagnosis
711.55	Arthropathy associated with other viral diseases, pelvic region and thigh	ICD-9-CM	Diagnosis
711.56	Arthropathy associated with other viral diseases, lower leg	ICD-9-CM	Diagnosis
711.57	Arthropathy associated with other viral diseases, ankle and foot	ICD-9-CM	Diagnosis
711.58	Arthropathy associated with other viral diseases, other specified sites	ICD-9-CM	Diagnosis
711.59	Arthropathy associated with other viral diseases, of multiple sites	ICD-9-CM	Diagnosis
711.6	Arthropathy associated with mycoses	ICD-9-CM	Diagnosis
711.60	Arthropathy associated with mycoses, site unspecified	ICD-9-CM	Diagnosis
711.61	Arthropathy associated with mycoses, shoulder region	ICD-9-CM	Diagnosis
711.62	Arthropathy associated with mycoses, upper arm	ICD-9-CM	Diagnosis
711.63	Arthropathy associated with mycoses, forearm	ICD-9-CM	Diagnosis
711.64	Arthropathy associated with mycoses, hand	ICD-9-CM	Diagnosis
711.65	Arthropathy associated with mycoses, pelvic region and thigh	ICD-9-CM	Diagnosis
711.66	Arthropathy associated with mycoses, lower leg	ICD-9-CM	Diagnosis
711.67	Arthropathy associated with mycoses, ankle and foot	ICD-9-CM	Diagnosis
711.68	Arthropathy associated with mycoses, other specified site	ICD-9-CM	Diagnosis
711.69	Arthropathy associated with mycoses, multiple sites	ICD-9-CM	Diagnosis
711.7	Arthropathy associated with helminthiasis	ICD-9-CM	Diagnosis
711.70	Arthropathy associated with helminthiasis, site unspecified	ICD-9-CM	Diagnosis
711.71	Arthropathy associated with helminthiasis, shoulder region	ICD-9-CM	Diagnosis
711.72	Arthropathy associated with helminthiasis, upper arm	ICD-9-CM	Diagnosis
711.73	Arthropathy associated with helminthiasis, forearm	ICD-9-CM	Diagnosis
711.74	Arthropathy associated with helminthiasis, hand	ICD-9-CM	Diagnosis
711.75	Arthropathy associated with helminthiasis, pelvic region and thigh	ICD-9-CM	Diagnosis
711.76	Arthropathy associated with helminthiasis, lower leg	ICD-9-CM	Diagnosis
711.77	Arthropathy associated with helminthiasis, ankle and foot	ICD-9-CM	Diagnosis
711.78	Arthropathy associated with helminthiasis, other specified site	ICD-9-CM	Diagnosis

Appendix G. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) Healthcare Common Procedure Coding System (HCPCS), Current Procedural Terminology, Second Edition (CPT-2), and Current Procedural Terminology, Fourth Edition (CPT-4), Diagnosis and Procedure Codes Used to Define Baseline Characteristics in this Request

Code	Description	Code Type	Code Category
711.79	Arthropathy associated with helminthiasis, multiple sites	ICD-9-CM	Diagnosis
711.8	Arthropathy associated with other infectious and parasitic diseases	ICD-9-CM	Diagnosis
711.80	Arthropathy associated with other infectious and parasitic diseases, site unspecified	ICD-9-CM	Diagnosis
711.81	Arthropathy associated with other infectious and parasitic diseases, shoulder region	ICD-9-CM	Diagnosis
711.82	Arthropathy associated with other infectious and parasitic diseases, upper arm	ICD-9-CM	Diagnosis
711.83	Arthropathy associated with other infectious and parasitic diseases, forearm	ICD-9-CM	Diagnosis
711.84	Arthropathy associated with other infectious and parasitic diseases, hand	ICD-9-CM	Diagnosis
711.85	Arthropathy associated with other infectious and parasitic diseases, pelvic region and thigh	ICD-9-CM	Diagnosis
711.86	Arthropathy associated with other infectious and parasitic diseases, lower leg	ICD-9-CM	Diagnosis
711.87	Arthropathy associated with other infectious and parasitic diseases, ankle and foot	ICD-9-CM	Diagnosis
711.88	Arthropathy associated with other infectious and parasitic diseases, other specific site	ICD-9-CM	Diagnosis
711.89	Arthropathy associated with other infectious and parasitic diseases, multiple sites	ICD-9-CM	Diagnosis
711.9	Unspecified infective arthritis	ICD-9-CM	Diagnosis
711.90	Unspecified infective arthritis, site unspecified	ICD-9-CM	Diagnosis
711.91	Unspecified infective arthritis, shoulder region	ICD-9-CM	Diagnosis
711.92	Unspecified infective arthritis, upper arm	ICD-9-CM	Diagnosis
711.93	Unspecified infective arthritis, forearm	ICD-9-CM	Diagnosis
711.94	Unspecified infective arthritis, hand	ICD-9-CM	Diagnosis
711.95	Unspecified infective arthritis, pelvic region and thigh	ICD-9-CM	Diagnosis
711.96	Unspecified infective arthritis, lower leg	ICD-9-CM	Diagnosis
711.97	Unspecified infective arthritis, ankle and foot	ICD-9-CM	Diagnosis
711.98	Unspecified infective arthritis, other specified sites	ICD-9-CM	Diagnosis
711.99	Unspecified infective arthritis, multiple sites	ICD-9-CM	Diagnosis
712.1	Chondrocalcinosis due to dicalcium phosphate crystals	ICD-9-CM	Diagnosis
712.10	Chondrocalcinosis due to dicalcium phosphate crystals, unspecified site	ICD-9-CM	Diagnosis
712.11	Chondrocalcinosis due to dicalcium phosphate crystals, shoulder region	ICD-9-CM	Diagnosis
712.12	Chondrocalcinosis due to dicalcium phosphate crystals, upper arm	ICD-9-CM	Diagnosis
712.13	Chondrocalcinosis due to dicalcium phosphate crystals, forearm	ICD-9-CM	Diagnosis
712.14	Chondrocalcinosis due to dicalcium phosphate crystals, hand	ICD-9-CM	Diagnosis
712.15	Chondrocalcinosis due to dicalcium phosphate crystals, pelvic region and thigh	ICD-9-CM	Diagnosis
712.16	Chondrocalcinosis due to dicalcium phosphate crystals, lower leg	ICD-9-CM	Diagnosis
712.17	Chondrocalcinosis due to dicalcium phosphate crystals, ankle and foot	ICD-9-CM	Diagnosis
712.18	Chondrocalcinosis due to dicalcium phosphate crystals, other specified sites	ICD-9-CM	Diagnosis
712.19	Chondrocalcinosis due to dicalcium phosphate crystals, multiple sites	ICD-9-CM	Diagnosis
712.2	Chondrocalcinosis due to pyrophosphate crystals	ICD-9-CM	Diagnosis
712.20	Chondrocalcinosis due to pyrophosphate crystals, unspecified site	ICD-9-CM	Diagnosis

Appendix G. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) Healthcare Common Procedure Coding System (HCPCS), Current Procedural Terminology, Second Edition (CPT-2), and Current Procedural Terminology, Fourth Edition (CPT-4), Diagnosis and Procedure Codes Used to Define Baseline Characteristics in this Request

Code	Description	Code Type	Code Category
712.21	Chondrocalcinosis due to pyrophosphate crystals, shoulder region	ICD-9-CM	Diagnosis
712.22	Chondrocalcinosis due to pyrophosphate crystals, upper arm	ICD-9-CM	Diagnosis
712.23	Chondrocalcinosis due to pyrophosphate crystals, forearm	ICD-9-CM	Diagnosis
712.24	Chondrocalcinosis due to pyrophosphate crystals, hand	ICD-9-CM	Diagnosis
712.25	Chondrocalcinosis due to pyrophosphate crystals, pelvic region and thigh	ICD-9-CM	Diagnosis
712.26	Chondrocalcinosis due to pyrophosphate crystals, lower leg	ICD-9-CM	Diagnosis
712.27	Chondrocalcinosis due to pyrophosphate crystals, ankle and foot	ICD-9-CM	Diagnosis
712.28	Chondrocalcinosis due to pyrophosphate crystals, other specified sites	ICD-9-CM	Diagnosis
712.29	Chondrocalcinosis due to pyrophosphate crystals, multiple sites	ICD-9-CM	Diagnosis
712.3	Chondrocalcinosis, cause unspecified	ICD-9-CM	Diagnosis
712.30	Chondrocalcinosis, cause unspecified, involving unspecified site	ICD-9-CM	Diagnosis
712.31	Chondrocalcinosis, cause unspecified, involving shoulder region	ICD-9-CM	Diagnosis
712.32	Chondrocalcinosis, cause unspecified, involving upper arm	ICD-9-CM	Diagnosis
712.33	Chondrocalcinosis, cause unspecified, involving forearm	ICD-9-CM	Diagnosis
712.34	Chondrocalcinosis, cause unspecified, involving hand	ICD-9-CM	Diagnosis
712.35	Chondrocalcinosis, cause unspecified, involving pelvic region and thigh	ICD-9-CM	Diagnosis
712.36	Chondrocalcinosis, cause unspecified, involving lower leg	ICD-9-CM	Diagnosis
712.37	Chondrocalcinosis, cause unspecified, involving ankle and foot	ICD-9-CM	Diagnosis
712.38	Chondrocalcinosis, cause unspecified, involving other specified sites	ICD-9-CM	Diagnosis
712.39	Chondrocalcinosis, cause unspecified, involving multiple sites	ICD-9-CM	Diagnosis
712.8	Other specified crystal arthropathies	ICD-9-CM	Diagnosis
712.80	Other specified crystal arthropathies, site unspecified	ICD-9-CM	Diagnosis
712.81	Other specified crystal arthropathies, shoulder region	ICD-9-CM	Diagnosis
712.82	Other specified crystal arthropathies, upper arm	ICD-9-CM	Diagnosis
712.83	Other specified crystal arthropathies, forearm	ICD-9-CM	Diagnosis
712.84	Other specified crystal arthropathies, hand	ICD-9-CM	Diagnosis
712.85	Other specified crystal arthropathies, pelvic region and thigh	ICD-9-CM	Diagnosis
712.86	Other specified crystal arthropathies, lower leg	ICD-9-CM	Diagnosis
712.87	Other specified crystal arthropathies, ankle and foot	ICD-9-CM	Diagnosis
712.88	Other specified crystal arthropathies, other specified sites	ICD-9-CM	Diagnosis
712.89	Other specified crystal arthropathies, multiple sites	ICD-9-CM	Diagnosis
712.9	Unspecified crystal arthropathy	ICD-9-CM	Diagnosis
712.90	Unspecified crystal arthropathy, site unspecified	ICD-9-CM	Diagnosis
712.91	Unspecified crystal arthropathy, shoulder region	ICD-9-CM	Diagnosis
712.92	Unspecified crystal arthropathy, upper arm	ICD-9-CM	Diagnosis
712.93	Unspecified crystal arthropathy, forearm	ICD-9-CM	Diagnosis
712.94	Unspecified crystal arthropathy, hand	ICD-9-CM	Diagnosis
712.95	Unspecified crystal arthropathy, pelvic region and thigh	ICD-9-CM	Diagnosis
712.96	Unspecified crystal arthropathy, lower leg	ICD-9-CM	Diagnosis
712.97	Unspecified crystal arthropathy, ankle and foot	ICD-9-CM	Diagnosis
712.98	Unspecified crystal arthropathy, other specified sites	ICD-9-CM	Diagnosis
712.99	Unspecified crystal arthropathy, multiple sites	ICD-9-CM	Diagnosis

Appendix G. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) Healthcare Common Procedure Coding System (HCPCS), Current Procedural Terminology, Second Edition (CPT-2), and Current Procedural Terminology, Fourth Edition (CPT-4), Diagnosis and Procedure Codes Used to Define Baseline Characteristics in this Request

Code	Description	Code Type	Code Category
713.0	Arthropathy associated with other endocrine and metabolic disorders	ICD-9-CM	Diagnosis
713.1	Arthropathy associated with gastrointestinal conditions other than infections	ICD-9-CM	Diagnosis
713.2	Arthropathy associated with hematological disorders	ICD-9-CM	Diagnosis
713.3	Arthropathy associated with dermatological disorders	ICD-9-CM	Diagnosis
713.4	Arthropathy associated with respiratory disorders	ICD-9-CM	Diagnosis
713.5	Arthropathy associated with neurological disorders	ICD-9-CM	Diagnosis
713.6	Arthropathy associated with hypersensitivity reaction	ICD-9-CM	Diagnosis
713.7	Other general diseases with articular involvement	ICD-9-CM	Diagnosis
713.8	Arthropathy associated with other conditions classifiable elsewhere	ICD-9-CM	Diagnosis
714	Rheumatoid arthritis and other inflammatory polyarthropathies	ICD-9-CM	Diagnosis
714.0	Rheumatoid arthritis	ICD-9-CM	Diagnosis
714.1	Felty's syndrome	ICD-9-CM	Diagnosis
714.2	Other rheumatoid arthritis with visceral or systemic involvement	ICD-9-CM	Diagnosis
714.3	Juvenile chronic polyarthritis	ICD-9-CM	Diagnosis
714.30	Polyarticular juvenile rheumatoid arthritis, chronic or unspecified	ICD-9-CM	Diagnosis
714.31	Polyarticular juvenile rheumatoid arthritis, acute	ICD-9-CM	Diagnosis
714.32	Pauciarticular juvenile rheumatoid arthritis	ICD-9-CM	Diagnosis
714.33	Monoarticular juvenile rheumatoid arthritis	ICD-9-CM	Diagnosis
714.4	Chronic postrheumatic arthropathy	ICD-9-CM	Diagnosis
714.8	Other specified inflammatory polyarthropathies	ICD-9-CM	Diagnosis
714.81	Rheumatoid lung	ICD-9-CM	Diagnosis
714.89	Other specified inflammatory polyarthropathies	ICD-9-CM	Diagnosis
714.9	Unspecified inflammatory polyarthropathy	ICD-9-CM	Diagnosis
715.0	Osteoarthritis, generalized	ICD-9-CM	Diagnosis
715.00	Generalized osteoarthritis, unspecified site	ICD-9-CM	Diagnosis
715.04	Generalized osteoarthritis, involving hand	ICD-9-CM	Diagnosis
715.09	Generalized osteoarthritis, involving multiple sites	ICD-9-CM	Diagnosis
715.1	Osteoarthritis, localized, primary	ICD-9-CM	Diagnosis
715.10	Primary localized osteoarthritis, unspecified site	ICD-9-CM	Diagnosis
715.11	Primary localized osteoarthritis, shoulder region	ICD-9-CM	Diagnosis
715.12	Primary localized osteoarthritis, upper arm	ICD-9-CM	Diagnosis
715.13	Primary localized osteoarthritis, forearm	ICD-9-CM	Diagnosis
715.14	Primary localized osteoarthritis, hand	ICD-9-CM	Diagnosis
715.15	Primary localized osteoarthritis, pelvic region and thigh	ICD-9-CM	Diagnosis
715.16	Primary localized osteoarthritis, lower leg	ICD-9-CM	Diagnosis
715.17	Primary localized osteoarthritis, ankle and foot	ICD-9-CM	Diagnosis
715.18	Primary localized osteoarthritis, other specified sites	ICD-9-CM	Diagnosis
715.2	Osteoarthritis, localized, secondary	ICD-9-CM	Diagnosis
715.20	Secondary localized osteoarthritis, unspecified site	ICD-9-CM	Diagnosis
715.21	Secondary localized osteoarthritis, shoulder region	ICD-9-CM	Diagnosis
715.22	Secondary localized osteoarthritis, upper arm	ICD-9-CM	Diagnosis

Appendix G. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) Healthcare Common Procedure Coding System (HCPCS), Current Procedural Terminology, Second Edition (CPT-2), and Current Procedural Terminology, Fourth Edition (CPT-4), Diagnosis and Procedure Codes Used to Define Baseline Characteristics in this Request

Code	Description	Code Type	Code Category
715.23	Secondary localized osteoarthritis, forearm	ICD-9-CM	Diagnosis
715.24	Secondary localized osteoarthritis, involving hand	ICD-9-CM	Diagnosis
715.25	Secondary localized osteoarthritis, pelvic region and thigh	ICD-9-CM	Diagnosis
715.26	Secondary localized osteoarthritis, lower leg	ICD-9-CM	Diagnosis
715.27	Secondary localized osteoarthritis, ankle and foot	ICD-9-CM	Diagnosis
715.28	Secondary localized osteoarthritis, other specified site	ICD-9-CM	Diagnosis
715.3	Osteoarthritis, localized, not specified whether primary or secondary	ICD-9-CM	Diagnosis
715.30	Localized osteoarthritis not specified whether primary or secondary, unspecified site	ICD-9-CM	Diagnosis
715.31	Localized osteoarthritis not specified whether primary or secondary, shoulder region	ICD-9-CM	Diagnosis
715.32	Localized osteoarthritis not specified whether primary or secondary, upper arm	ICD-9-CM	Diagnosis
715.33	Localized osteoarthritis not specified whether primary or secondary, forearm	ICD-9-CM	Diagnosis
715.34	Localized osteoarthritis not specified whether primary or secondary, hand	ICD-9-CM	Diagnosis
715.35	Localized osteoarthritis not specified whether primary or secondary, pelvic region and thigh	ICD-9-CM	Diagnosis
715.36	Localized osteoarthritis not specified whether primary or secondary, lower leg	ICD-9-CM	Diagnosis
715.37	Localized osteoarthritis not specified whether primary or secondary, ankle and foot	ICD-9-CM	Diagnosis
715.38	Localized osteoarthritis not specified whether primary or secondary, other specified sites	ICD-9-CM	Diagnosis
715.8	Osteoarthritis involving or with mention of more than one site, but not specified as generalized	ICD-9-CM	Diagnosis
715.80	Osteoarthritis involving more than one site, but not specified as generalized, unspecified site	ICD-9-CM	Diagnosis
715.89	Osteoarthritis involving multiple sites, but not specified as generalized	ICD-9-CM	Diagnosis
715.9	Osteoarthritis, unspecified whether generalized or localized	ICD-9-CM	Diagnosis
715.90	Osteoarthritis, unspecified whether generalized or localized, unspecified site	ICD-9-CM	Diagnosis
715.91	Osteoarthritis, unspecified whether generalized or localized, shoulder region	ICD-9-CM	Diagnosis
715.92	Osteoarthritis, unspecified whether generalized or localized, upper arm	ICD-9-CM	Diagnosis
715.93	Osteoarthritis, unspecified whether generalized or localized, forearm	ICD-9-CM	Diagnosis
715.94	Osteoarthritis, unspecified whether generalized or localized, hand	ICD-9-CM	Diagnosis
715.95	Osteoarthritis, unspecified whether generalized or localized, pelvic region and thigh	ICD-9-CM	Diagnosis
715.96	Osteoarthritis, unspecified whether generalized or localized, lower leg	ICD-9-CM	Diagnosis
715.97	Osteoarthritis, unspecified whether generalized or localized, ankle and foot	ICD-9-CM	Diagnosis
715.98	Osteoarthritis, unspecified whether generalized or localized, other specified sites	ICD-9-CM	Diagnosis
716	Other and unspecified arthropathies	ICD-9-CM	Diagnosis
716.0	Kaschin-Beck disease	ICD-9-CM	Diagnosis
716.00	Kaschin-Beck disease, site unspecified	ICD-9-CM	Diagnosis

Appendix G. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) Healthcare Common Procedure Coding System (HCPCS), Current Procedural Terminology, Second Edition (CPT-2), and Current Procedural Terminology, Fourth Edition (CPT-4), Diagnosis and Procedure Codes Used to Define Baseline Characteristics in this Request

Code	Description	Code Type	Code Category
716.01	Kaschin-Beck disease, shoulder region	ICD-9-CM	Diagnosis
716.02	Kaschin-Beck disease, upper arm	ICD-9-CM	Diagnosis
716.03	Kaschin-Beck disease, forearm	ICD-9-CM	Diagnosis
716.04	Kaschin-Beck disease, hand	ICD-9-CM	Diagnosis
716.05	Kaschin-Beck disease pelvic, region and thigh	ICD-9-CM	Diagnosis
716.06	Kaschin-Beck disease, lower leg	ICD-9-CM	Diagnosis
716.07	Kaschin-Beck disease, ankle and foot	ICD-9-CM	Diagnosis
716.08	Kaschin-Beck disease, other specified sites	ICD-9-CM	Diagnosis
716.09	Kaschin-Beck disease, multiple sites	ICD-9-CM	Diagnosis
716.1	Traumatic arthropathy	ICD-9-CM	Diagnosis
716.10	Traumatic arthropathy, site unspecified	ICD-9-CM	Diagnosis
716.11	Traumatic arthropathy, shoulder region	ICD-9-CM	Diagnosis
716.12	Traumatic arthropathy, upper arm	ICD-9-CM	Diagnosis
716.13	Traumatic arthropathy, forearm	ICD-9-CM	Diagnosis
716.14	Traumatic arthropathy, hand	ICD-9-CM	Diagnosis
716.15	Traumatic arthropathy, pelvic region and thigh	ICD-9-CM	Diagnosis
716.16	Traumatic arthropathy, lower leg	ICD-9-CM	Diagnosis
716.17	Traumatic arthropathy, ankle and foot	ICD-9-CM	Diagnosis
716.18	Traumatic arthropathy, other specified sites	ICD-9-CM	Diagnosis
716.19	Traumatic arthropathy, multiple sites	ICD-9-CM	Diagnosis
716.2	Allergic arthritis	ICD-9-CM	Diagnosis
716.20	Allergic arthritis, site unspecified	ICD-9-CM	Diagnosis
716.21	Allergic arthritis, shoulder region	ICD-9-CM	Diagnosis
716.22	Allergic arthritis, upper arm	ICD-9-CM	Diagnosis
716.23	Allergic arthritis, forearm	ICD-9-CM	Diagnosis
716.24	Allergic arthritis, hand	ICD-9-CM	Diagnosis
716.25	Allergic arthritis, pelvic region and thigh	ICD-9-CM	Diagnosis
716.26	Allergic arthritis, lower leg	ICD-9-CM	Diagnosis
716.27	Allergic arthritis, ankle and foot	ICD-9-CM	Diagnosis
716.28	Allergic arthritis, other specified sites	ICD-9-CM	Diagnosis
716.29	Allergic arthritis, multiple sites	ICD-9-CM	Diagnosis
716.3	Climacteric arthritis	ICD-9-CM	Diagnosis
716.30	Climacteric arthritis, site unspecified	ICD-9-CM	Diagnosis
716.31	Climacteric arthritis, shoulder region	ICD-9-CM	Diagnosis
716.32	Climacteric arthritis, upper arm	ICD-9-CM	Diagnosis
716.33	Climacteric arthritis, forearm	ICD-9-CM	Diagnosis
716.34	Climacteric arthritis, hand	ICD-9-CM	Diagnosis
716.35	Climacteric arthritis, pelvic region and thigh	ICD-9-CM	Diagnosis
716.36	Climacteric arthritis, lower leg	ICD-9-CM	Diagnosis
716.37	Climacteric arthritis involving ankle and foot	ICD-9-CM	Diagnosis
716.38	Climacteric arthritis involving other specified sites	ICD-9-CM	Diagnosis
716.39	Climacteric arthritis involving multiple sites	ICD-9-CM	Diagnosis

Appendix G. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) Healthcare Common Procedure Coding System (HCPCS), Current Procedural Terminology, Second Edition (CPT-2), and Current Procedural Terminology, Fourth Edition (CPT-4), Diagnosis and Procedure Codes Used to Define Baseline Characteristics in this Request

Code	Description	Code Type	Code Category
716.4	Transient arthropathy	ICD-9-CM	Diagnosis
716.40	Transient arthropathy, site unspecified	ICD-9-CM	Diagnosis
716.41	Transient arthropathy, shoulder region	ICD-9-CM	Diagnosis
716.42	Transient arthropathy, upper arm	ICD-9-CM	Diagnosis
716.43	Transient arthropathy, forearm	ICD-9-CM	Diagnosis
716.44	Transient arthropathy, hand	ICD-9-CM	Diagnosis
716.45	Transient arthropathy, pelvic region and thigh	ICD-9-CM	Diagnosis
716.46	Transient arthropathy, lower leg	ICD-9-CM	Diagnosis
716.47	Transient arthropathy, ankle and foot	ICD-9-CM	Diagnosis
716.48	Transient arthropathy, other specified site	ICD-9-CM	Diagnosis
716.49	Transient arthropathy, multiple sites	ICD-9-CM	Diagnosis
716.5	Unspecified polyarthropathy or polyarthritis	ICD-9-CM	Diagnosis
716.50	Unspecified polyarthropathy or polyarthritis, site unspecified	ICD-9-CM	Diagnosis
716.51	Unspecified polyarthropathy or polyarthritis, shoulder region	ICD-9-CM	Diagnosis
716.52	Unspecified polyarthropathy or polyarthritis, upper arm	ICD-9-CM	Diagnosis
716.53	Unspecified polyarthropathy or polyarthritis, forearm	ICD-9-CM	Diagnosis
716.54	Unspecified polyarthropathy or polyarthritis, hand	ICD-9-CM	Diagnosis
716.55	Unspecified polyarthropathy or polyarthritis, pelvic region and thigh	ICD-9-CM	Diagnosis
716.56	Unspecified polyarthropathy or polyarthritis, lower leg	ICD-9-CM	Diagnosis
716.57	Unspecified polyarthropathy or polyarthritis, ankle and foot	ICD-9-CM	Diagnosis
716.58	Unspecified polyarthropathy or polyarthritis, other specified sites	ICD-9-CM	Diagnosis
716.59	Unspecified polyarthropathy or polyarthritis, multiple sites	ICD-9-CM	Diagnosis
716.6	Unspecified monoarthritis	ICD-9-CM	Diagnosis
716.60	Unspecified monoarthritis, site unspecified	ICD-9-CM	Diagnosis
716.61	Unspecified monoarthritis, shoulder region	ICD-9-CM	Diagnosis
716.62	Unspecified monoarthritis, upper arm	ICD-9-CM	Diagnosis
716.63	Unspecified monoarthritis, forearm	ICD-9-CM	Diagnosis
716.64	Unspecified monoarthritis, hand	ICD-9-CM	Diagnosis
716.65	Unspecified monoarthritis, pelvic region and thigh	ICD-9-CM	Diagnosis
716.66	Unspecified monoarthritis, lower leg	ICD-9-CM	Diagnosis
716.67	Unspecified monoarthritis, ankle and foot	ICD-9-CM	Diagnosis
716.68	Unspecified monoarthritis, other specified sites	ICD-9-CM	Diagnosis
716.8	Other specified arthropathy	ICD-9-CM	Diagnosis
716.80	Other specified arthropathy, site unspecified	ICD-9-CM	Diagnosis
716.81	Other specified arthropathy, shoulder region	ICD-9-CM	Diagnosis
716.82	Other specified arthropathy, upper arm	ICD-9-CM	Diagnosis
716.83	Other specified arthropathy, forearm	ICD-9-CM	Diagnosis
716.84	Other specified arthropathy, hand	ICD-9-CM	Diagnosis
716.85	Other specified arthropathy, pelvic region and thigh	ICD-9-CM	Diagnosis
716.86	Other specified arthropathy, lower leg	ICD-9-CM	Diagnosis
716.87	Other specified arthropathy, ankle and foot	ICD-9-CM	Diagnosis
716.88	Other specified arthropathy, other specified sites	ICD-9-CM	Diagnosis

Appendix G. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) Healthcare Common Procedure Coding System (HCPCS), Current Procedural Terminology, Second Edition (CPT-2), and Current Procedural Terminology, Fourth Edition (CPT-4), Diagnosis and Procedure Codes Used to Define Baseline Characteristics in this Request

Code	Description	Code Type	Code Category
716.89	Other specified arthropathy, multiple sites	ICD-9-CM	Diagnosis
716.9	Unspecified arthropathy	ICD-9-CM	Diagnosis
716.90	Unspecified arthropathy, site unspecified	ICD-9-CM	Diagnosis
716.91	Unspecified arthropathy, shoulder region	ICD-9-CM	Diagnosis
716.92	Unspecified arthropathy, upper arm	ICD-9-CM	Diagnosis
716.93	Unspecified arthropathy, forearm	ICD-9-CM	Diagnosis
716.94	Unspecified arthropathy, hand	ICD-9-CM	Diagnosis
716.95	Unspecified arthropathy, pelvic region and thigh	ICD-9-CM	Diagnosis
716.96	Unspecified arthropathy, lower leg	ICD-9-CM	Diagnosis
716.97	Unspecified arthropathy, ankle and foot	ICD-9-CM	Diagnosis
716.98	Unspecified arthropathy, other specified sites	ICD-9-CM	Diagnosis
716.99	Unspecified arthropathy, multiple sites	ICD-9-CM	Diagnosis
717	Internal derangement of knee	ICD-9-CM	Diagnosis
717.0	Old bucket handle tear of medial meniscus	ICD-9-CM	Diagnosis
717.1	Derangement of anterior horn of medial meniscus	ICD-9-CM	Diagnosis
717.2	Derangement of posterior horn of medial meniscus	ICD-9-CM	Diagnosis
717.3	Other and unspecified derangement of medial meniscus	ICD-9-CM	Diagnosis
717.4	Derangement of lateral meniscus	ICD-9-CM	Diagnosis
717.40	Unspecified derangement of lateral meniscus	ICD-9-CM	Diagnosis
717.41	Bucket handle tear of lateral meniscus	ICD-9-CM	Diagnosis
717.42	Derangement of anterior horn of lateral meniscus	ICD-9-CM	Diagnosis
717.43	Derangement of posterior horn of lateral meniscus	ICD-9-CM	Diagnosis
717.49	Other derangement of lateral meniscus	ICD-9-CM	Diagnosis
717.5	Derangement of meniscus, not elsewhere classified	ICD-9-CM	Diagnosis
717.6	Loose body in knee	ICD-9-CM	Diagnosis
717.7	Chondromalacia of patella	ICD-9-CM	Diagnosis
717.8	Other internal derangement of knee	ICD-9-CM	Diagnosis
717.81	Old disruption of lateral collateral ligament	ICD-9-CM	Diagnosis
717.82	Old disruption of medial collateral ligament	ICD-9-CM	Diagnosis
717.83	Old disruption of anterior cruciate ligament	ICD-9-CM	Diagnosis
717.84	Old disruption of posterior cruciate ligament	ICD-9-CM	Diagnosis
717.85	Old disruption of other ligament of knee	ICD-9-CM	Diagnosis
717.89	Other internal derangement of knee	ICD-9-CM	Diagnosis
717.9	Unspecified internal derangement of knee	ICD-9-CM	Diagnosis
718	Other derangement of joint	ICD-9-CM	Diagnosis
718.0	Articular cartilage disorder	ICD-9-CM	Diagnosis
718.00	Articular cartilage disorder, site unspecified	ICD-9-CM	Diagnosis
718.01	Articular cartilage disorder, shoulder region	ICD-9-CM	Diagnosis
718.02	Articular cartilage disorder, upper arm	ICD-9-CM	Diagnosis
718.03	Articular cartilage disorder, forearm	ICD-9-CM	Diagnosis
718.04	Articular cartilage disorder, hand	ICD-9-CM	Diagnosis
718.05	Articular cartilage disorder, pelvic region and thigh	ICD-9-CM	Diagnosis

Appendix G. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) Healthcare Common Procedure Coding System (HCPCS), Current Procedural Terminology, Second Edition (CPT-2), and Current Procedural Terminology, Fourth Edition (CPT-4), Diagnosis and Procedure Codes Used to Define Baseline Characteristics in this Request

Code	Description	Code Type	Code Category
718.07	Articular cartilage disorder, ankle and foot	ICD-9-CM	Diagnosis
718.08	Articular cartilage disorder, other specified site	ICD-9-CM	Diagnosis
718.09	Articular cartilage disorder, multiple sites	ICD-9-CM	Diagnosis
718.1	Loose body in joint	ICD-9-CM	Diagnosis
718.10	Loose body in joint, site unspecified	ICD-9-CM	Diagnosis
718.11	Loose body in shoulder joint	ICD-9-CM	Diagnosis
718.12	Loose body in upper arm joint	ICD-9-CM	Diagnosis
718.13	Loose body in forearm joint	ICD-9-CM	Diagnosis
718.14	Loose body in hand joint	ICD-9-CM	Diagnosis
718.15	Loose body in pelvic joint	ICD-9-CM	Diagnosis
718.17	Loose body in ankle and foot joint	ICD-9-CM	Diagnosis
718.18	Loose body in joint of other specified site	ICD-9-CM	Diagnosis
718.19	Loose body in joint of multiple sites	ICD-9-CM	Diagnosis
718.2	Pathological dislocation	ICD-9-CM	Diagnosis
718.20	Pathological dislocation of joint, site unspecified	ICD-9-CM	Diagnosis
718.21	Pathological dislocation of shoulder joint	ICD-9-CM	Diagnosis
718.22	Pathological dislocation of upper arm joint	ICD-9-CM	Diagnosis
718.23	Pathological dislocation of forearm joint	ICD-9-CM	Diagnosis
718.24	Pathological dislocation of hand joint	ICD-9-CM	Diagnosis
718.25	Pathological dislocation of pelvic region and thigh joint	ICD-9-CM	Diagnosis
718.26	Pathological dislocation of lower leg joint	ICD-9-CM	Diagnosis
718.27	Pathological dislocation of ankle and foot joint	ICD-9-CM	Diagnosis
718.28	Pathological dislocation of joint of other specified site	ICD-9-CM	Diagnosis
718.29	Pathological dislocation of joint of multiple sites	ICD-9-CM	Diagnosis
718.3	Recurrent dislocation of joint	ICD-9-CM	Diagnosis
718.30	Recurrent dislocation of joint, site unspecified	ICD-9-CM	Diagnosis
718.31	Recurrent dislocation of shoulder joint	ICD-9-CM	Diagnosis
718.32	Recurrent dislocation of upper arm joint	ICD-9-CM	Diagnosis
718.33	Recurrent dislocation of forearm joint	ICD-9-CM	Diagnosis
718.34	Recurrent dislocation of hand joint	ICD-9-CM	Diagnosis
718.35	Recurrent dislocation of pelvic region and thigh joint	ICD-9-CM	Diagnosis
718.36	Recurrent dislocation of lower leg joint	ICD-9-CM	Diagnosis
718.37	Recurrent dislocation of ankle and foot joint	ICD-9-CM	Diagnosis
718.38	Recurrent dislocation of joint of other specified site	ICD-9-CM	Diagnosis
718.39	Recurrent dislocation of joint of multiple sites	ICD-9-CM	Diagnosis
718.4	Contracture of joint	ICD-9-CM	Diagnosis
718.40	Contracture of joint, site unspecified	ICD-9-CM	Diagnosis
718.41	Contracture of shoulder joint	ICD-9-CM	Diagnosis
718.42	Contracture of upper arm joint	ICD-9-CM	Diagnosis
718.43	Contracture of forearm joint	ICD-9-CM	Diagnosis
718.44	Contracture of hand joint	ICD-9-CM	Diagnosis
718.45	Contracture of pelvic joint	ICD-9-CM	Diagnosis

Appendix G. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) Healthcare Common Procedure Coding System (HCPCS), Current Procedural Terminology, Second Edition (CPT-2), and Current Procedural Terminology, Fourth Edition (CPT-4), Diagnosis and Procedure Codes Used to Define Baseline Characteristics in this Request

Code	Description	Code Type	Code Category
718.46	Contracture of lower leg joint	ICD-9-CM	Diagnosis
718.47	Contracture of ankle and foot joint	ICD-9-CM	Diagnosis
718.48	Contracture of joint of other specified site	ICD-9-CM	Diagnosis
718.49	Contracture of joint of multiple sites	ICD-9-CM	Diagnosis
718.5	Ankylosis of joint	ICD-9-CM	Diagnosis
718.50	Ankylosis of joint, site unspecified	ICD-9-CM	Diagnosis
718.51	Ankylosis of joint of shoulder region	ICD-9-CM	Diagnosis
718.52	Ankylosis of upper arm joint	ICD-9-CM	Diagnosis
718.53	Ankylosis of forearm joint	ICD-9-CM	Diagnosis
718.54	Ankylosis of hand joint	ICD-9-CM	Diagnosis
718.55	Ankylosis of pelvic region and thigh joint	ICD-9-CM	Diagnosis
718.56	Ankylosis of lower leg joint	ICD-9-CM	Diagnosis
718.57	Ankylosis of ankle and foot joint	ICD-9-CM	Diagnosis
718.58	Ankylosis of joint of other specified site	ICD-9-CM	Diagnosis
718.59	Ankylosis of joint of multiple sites	ICD-9-CM	Diagnosis
718.6	Unspecified intrapelvic protrusion of acetabulum	ICD-9-CM	Diagnosis
718.60	Unspecified intrapelvic protrusion of acetabulum, site unspecified	ICD-9-CM	Diagnosis
718.65	Unspecified intrapelvic protrusion acetabulum, pelvic region and thigh	ICD-9-CM	Diagnosis
718.7	Developmental dislocation of joint	ICD-9-CM	Diagnosis
718.70	Developmental dislocation of joint, site unspecified	ICD-9-CM	Diagnosis
718.71	Developmental dislocation of joint, shoulder region	ICD-9-CM	Diagnosis
718.72	Developmental dislocation of joint, upper arm	ICD-9-CM	Diagnosis
718.73	Developmental dislocation of joint, forearm	ICD-9-CM	Diagnosis
718.74	Developmental dislocation of joint, hand	ICD-9-CM	Diagnosis
718.75	Developmental dislocation of joint, pelvic region and thigh	ICD-9-CM	Diagnosis
718.76	Developmental dislocation of joint, lower leg	ICD-9-CM	Diagnosis
718.77	Developmental dislocation of joint, ankle and foot	ICD-9-CM	Diagnosis
718.78	Developmental dislocation of joint, other specified sites	ICD-9-CM	Diagnosis
718.79	Developmental dislocation of joint, multiple sites	ICD-9-CM	Diagnosis
718.8	Other joint derangement, not elsewhere classified	ICD-9-CM	Diagnosis
718.80	Other joint derangement, not elsewhere classified, unspecified site	ICD-9-CM	Diagnosis
718.81	Other joint derangement, not elsewhere classified, shoulder region	ICD-9-CM	Diagnosis
718.82	Other joint derangement, not elsewhere classified, upper arm	ICD-9-CM	Diagnosis
718.83	Other joint derangement, not elsewhere classified, forearm	ICD-9-CM	Diagnosis
718.84	Other joint derangement, not elsewhere classified, hand	ICD-9-CM	Diagnosis
718.85	Other joint derangement, not elsewhere classified, pelvic region and thigh	ICD-9-CM	Diagnosis
718.86	Other joint derangement, not elsewhere classified, lower leg	ICD-9-CM	Diagnosis
718.87	Other joint derangement, not elsewhere classified, ankle and foot	ICD-9-CM	Diagnosis
718.88	Other joint derangement, not elsewhere classified, other specified site	ICD-9-CM	Diagnosis
718.89	Other joint derangement, not elsewhere classified, multiple sites	ICD-9-CM	Diagnosis
718.9	Unspecified derangement of joint	ICD-9-CM	Diagnosis
718.90	Unspecified derangement, joint, site unspecified	ICD-9-CM	Diagnosis

Appendix G. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) Healthcare Common Procedure Coding System (HCPCS), Current Procedural Terminology, Second Edition (CPT-2), and Current Procedural Terminology, Fourth Edition (CPT-4), Diagnosis and Procedure Codes Used to Define Baseline Characteristics in this Request

Code	Description	Code Type	Code Category
718.91	Unspecified derangement, shoulder region	ICD-9-CM	Diagnosis
718.92	Unspecified derangement, upper arm joint	ICD-9-CM	Diagnosis
718.93	Unspecified derangement, forearm joint	ICD-9-CM	Diagnosis
718.94	Unspecified derangement of hand joint	ICD-9-CM	Diagnosis
718.95	Unspecified pelvic joint derangement	ICD-9-CM	Diagnosis
718.97	Unspecified ankle and foot joint derangement	ICD-9-CM	Diagnosis
718.98	Unspecified derangement of joint, other specified sites	ICD-9-CM	Diagnosis
718.99	Unspecified derangement of joint, multiple sites	ICD-9-CM	Diagnosis
719	Other and unspecified disorders of joint	ICD-9-CM	Diagnosis
719.0	Effusion of joint	ICD-9-CM	Diagnosis
719.00	Effusion of joint, site unspecified	ICD-9-CM	Diagnosis
719.01	Effusion of shoulder joint	ICD-9-CM	Diagnosis
719.02	Effusion of upper arm joint	ICD-9-CM	Diagnosis
719.03	Effusion of forearm joint	ICD-9-CM	Diagnosis
719.04	Effusion of hand joint	ICD-9-CM	Diagnosis
719.05	Effusion of pelvic joint	ICD-9-CM	Diagnosis
719.06	Effusion of lower leg joint	ICD-9-CM	Diagnosis
719.07	Effusion of ankle and foot joint	ICD-9-CM	Diagnosis
719.08	Effusion of joint, other specified site	ICD-9-CM	Diagnosis
719.09	Effusion of joint, multiple sites	ICD-9-CM	Diagnosis
719.1	Hemarthrosis	ICD-9-CM	Diagnosis
719.10	Hemarthrosis, site unspecified	ICD-9-CM	Diagnosis
719.11	Hemarthrosis, shoulder region	ICD-9-CM	Diagnosis
719.12	Hemarthrosis, upper arm	ICD-9-CM	Diagnosis
719.13	Hemarthrosis, forearm	ICD-9-CM	Diagnosis
719.14	Hemarthrosis, hand	ICD-9-CM	Diagnosis
719.15	Hemarthrosis, pelvic region and thigh	ICD-9-CM	Diagnosis
719.16	Hemarthrosis, lower leg	ICD-9-CM	Diagnosis
719.17	Hemarthrosis, ankle and foot	ICD-9-CM	Diagnosis
719.18	Hemarthrosis, other specified site	ICD-9-CM	Diagnosis
719.19	Hemarthrosis, multiple sites	ICD-9-CM	Diagnosis
719.2	Villonodular synovitis	ICD-9-CM	Diagnosis
719.20	Villonodular synovitis, site unspecified	ICD-9-CM	Diagnosis
719.21	Villonodular synovitis, shoulder region	ICD-9-CM	Diagnosis
719.22	Villonodular synovitis, upper arm	ICD-9-CM	Diagnosis
719.23	Villonodular synovitis, forearm	ICD-9-CM	Diagnosis
719.24	Villonodular synovitis, hand	ICD-9-CM	Diagnosis
719.25	Villonodular synovitis, pelvic region and thigh	ICD-9-CM	Diagnosis
719.26	Villonodular synovitis, lower leg	ICD-9-CM	Diagnosis
719.27	Villonodular synovitis, ankle and foot	ICD-9-CM	Diagnosis
719.28	Villonodular synovitis, other specified sites	ICD-9-CM	Diagnosis
719.29	Villonodular synovitis, multiple sites	ICD-9-CM	Diagnosis

Appendix G. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) Healthcare Common Procedure Coding System (HCPCS), Current Procedural Terminology, Second Edition (CPT-2), and Current Procedural Terminology, Fourth Edition (CPT-4), Diagnosis and Procedure Codes Used to Define Baseline Characteristics in this Request

Code	Description	Code Type	Code Category
719.3	Palindromic rheumatism	ICD-9-CM	Diagnosis
719.30	Palindromic rheumatism, site unspecified	ICD-9-CM	Diagnosis
719.31	Palindromic rheumatism, shoulder region	ICD-9-CM	Diagnosis
719.32	Palindromic rheumatism, upper arm	ICD-9-CM	Diagnosis
719.33	Palindromic rheumatism, forearm	ICD-9-CM	Diagnosis
719.34	Palindromic rheumatism, hand	ICD-9-CM	Diagnosis
719.35	Palindromic rheumatism, pelvic region and thigh	ICD-9-CM	Diagnosis
719.36	Palindromic rheumatism, lower leg	ICD-9-CM	Diagnosis
719.37	Palindromic rheumatism, ankle and foot	ICD-9-CM	Diagnosis
719.38	Palindromic rheumatism, other specified sites	ICD-9-CM	Diagnosis
719.39	Palindromic rheumatism, multiple sites	ICD-9-CM	Diagnosis
719.4	Pain in joint	ICD-9-CM	Diagnosis
719.40	Pain in joint, site unspecified	ICD-9-CM	Diagnosis
719.41	Pain in joint, shoulder region	ICD-9-CM	Diagnosis
719.42	Pain in joint, upper arm	ICD-9-CM	Diagnosis
719.43	Pain in joint, forearm	ICD-9-CM	Diagnosis
719.44	Pain in joint, hand	ICD-9-CM	Diagnosis
719.45	Pain in joint, pelvic region and thigh	ICD-9-CM	Diagnosis
719.46	Pain in joint, lower leg	ICD-9-CM	Diagnosis
719.47	Pain in joint, ankle and foot	ICD-9-CM	Diagnosis
719.48	Pain in joint, other specified sites	ICD-9-CM	Diagnosis
719.49	Pain in joint, multiple sites	ICD-9-CM	Diagnosis
719.5	Stiffness of joint, not elsewhere classified	ICD-9-CM	Diagnosis
719.50	Stiffness of joint, not elsewhere classified, unspecified site	ICD-9-CM	Diagnosis
719.51	Stiffness of joint, not elsewhere classified, shoulder region	ICD-9-CM	Diagnosis
719.52	Stiffness of joint, not elsewhere classified, upper arm	ICD-9-CM	Diagnosis
719.53	Stiffness of joint, not elsewhere classified, forearm	ICD-9-CM	Diagnosis
719.54	Stiffness of joint, not elsewhere classified, hand	ICD-9-CM	Diagnosis
719.55	Stiffness of joint, not elsewhere classified, pelvic region and thigh	ICD-9-CM	Diagnosis
719.56	Stiffness of joint, not elsewhere classified, lower leg	ICD-9-CM	Diagnosis
719.57	Stiffness of joint, not elsewhere classified, ankle and foot	ICD-9-CM	Diagnosis
719.58	Stiffness of joint, not elsewhere classified, other specified site	ICD-9-CM	Diagnosis
719.59	Stiffness of joints, not elsewhere classified, multiple sites	ICD-9-CM	Diagnosis
719.6	Other symptoms referable to joint	ICD-9-CM	Diagnosis
719.60	Other symptoms referable to joint, site unspecified	ICD-9-CM	Diagnosis
719.61	Other symptoms referable to shoulder joint	ICD-9-CM	Diagnosis
719.62	Other symptoms referable to upper arm joint	ICD-9-CM	Diagnosis
719.63	Other symptoms referable to forearm joint	ICD-9-CM	Diagnosis
719.64	Other symptoms referable to hand joint	ICD-9-CM	Diagnosis
719.65	Other symptoms referable to pelvic joint	ICD-9-CM	Diagnosis
719.66	Other symptoms referable to lower leg joint	ICD-9-CM	Diagnosis
719.67	Other symptoms referable to ankle and foot joint	ICD-9-CM	Diagnosis

Appendix G. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) Healthcare Common Procedure Coding System (HCPCS), Current Procedural Terminology, Second Edition (CPT-2), and Current Procedural Terminology, Fourth Edition (CPT-4), Diagnosis and Procedure Codes Used to Define Baseline Characteristics in this Request

Code	Description	Code Type	Code Category
719.68	Other symptoms referable to joint of other specified site	ICD-9-CM	Diagnosis
719.69	Other symptoms referable to joints of multiple sites	ICD-9-CM	Diagnosis
719.7	Difficulty in walking	ICD-9-CM	Diagnosis
719.70	Difficulty in walking involving joint, site unspecified	ICD-9-CM	Diagnosis
719.75	Difficulty in walking involving pelvic joint	ICD-9-CM	Diagnosis
719.76	Difficulty in walking involving lower leg joint	ICD-9-CM	Diagnosis
719.77	Difficulty in walking involving ankle and foot joint	ICD-9-CM	Diagnosis
719.78	Difficulty in walking involving joint of other specified site	ICD-9-CM	Diagnosis
719.79	Difficulty in walking involving joints of multiple sites	ICD-9-CM	Diagnosis
719.8	Other specified disorders of joint	ICD-9-CM	Diagnosis
719.80	Other specified disorders of joint, site unspecified	ICD-9-CM	Diagnosis
719.81	Other specified disorders of shoulder joint	ICD-9-CM	Diagnosis
719.82	Other specified disorders of upper arm joint	ICD-9-CM	Diagnosis
719.83	Other specified disorders of forearm joint	ICD-9-CM	Diagnosis
719.84	Other specified disorders of hand joint	ICD-9-CM	Diagnosis
719.85	Other specified disorders of pelvic joint	ICD-9-CM	Diagnosis
719.86	Other specified disorders of lower leg joint	ICD-9-CM	Diagnosis
719.87	Other specified disorders of ankle and foot joint	ICD-9-CM	Diagnosis
719.88	Other specified disorders of joint of other specified site	ICD-9-CM	Diagnosis
719.89	Other specified disorders of joints of multiple sites	ICD-9-CM	Diagnosis
719.9	Unspecified disorder of joint	ICD-9-CM	Diagnosis
719.90	Unspecified disorder of joint, site unspecified	ICD-9-CM	Diagnosis
719.91	Unspecified disorder of shoulder joint	ICD-9-CM	Diagnosis
719.92	Unspecified disorder of upper arm joint	ICD-9-CM	Diagnosis
719.93	Unspecified disorder of forearm joint	ICD-9-CM	Diagnosis
719.94	Unspecified disorder of hand joint	ICD-9-CM	Diagnosis
719.95	Unspecified disorder of joint of pelvic region and thigh	ICD-9-CM	Diagnosis
719.96	Unspecified disorder of lower leg joint	ICD-9-CM	Diagnosis
719.97	Unspecified disorder of ankle and foot joint	ICD-9-CM	Diagnosis
719.98	Unspecified joint disorder of other specified site	ICD-9-CM	Diagnosis
719.99	Unspecified joint disorder of multiple sites	ICD-9-CM	Diagnosis
720.0	Ankylosing spondylitis	ICD-9-CM	Diagnosis
720.1	Spinal enthesopathy	ICD-9-CM	Diagnosis
720.2	Sacroiliitis, not elsewhere classified	ICD-9-CM	Diagnosis
720.81	Inflammatory spondylopathies in diseases classified elsewhere	ICD-9-CM	Diagnosis
720.89	Other inflammatory spondylopathies	ICD-9-CM	Diagnosis
720.9	Unspecified inflammatory spondylopathy	ICD-9-CM	Diagnosis
721.0	Cervical spondylosis without myelopathy	ICD-9-CM	Diagnosis
721.2	Thoracic spondylosis without myelopathy	ICD-9-CM	Diagnosis
721.3	Lumbosacral spondylosis without myelopathy	ICD-9-CM	Diagnosis
721.5	Kissing spine	ICD-9-CM	Diagnosis
721.6	Ankylosing vertebral hyperostosis	ICD-9-CM	Diagnosis

Appendix G. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) Healthcare Common Procedure Coding System (HCPCS), Current Procedural Terminology, Second Edition (CPT-2), and Current Procedural Terminology, Fourth Edition (CPT-4), Diagnosis and Procedure Codes Used to Define Baseline Characteristics in this Request

Code	Description	Code Type	Code Category
721.7	Traumatic spondylopathy	ICD-9-CM	Diagnosis
721.8	Other allied disorders of spine	ICD-9-CM	Diagnosis
721.90	Spondylosis of unspecified site without mention of myelopathy	ICD-9-CM	Diagnosis
722.10	Displacement of lumbar intervertebral disc without myelopathy	ICD-9-CM	Diagnosis
722.11	Displacement of thoracic intervertebral disc without myelopathy	ICD-9-CM	Diagnosis
722.30	Schmorl's nodes, unspecified region	ICD-9-CM	Diagnosis
722.31	Schmorl's nodes, thoracic region	ICD-9-CM	Diagnosis
722.32	Schmorl's nodes, lumbar region	ICD-9-CM	Diagnosis
722.39	Schmorl's nodes, other spinal region	ICD-9-CM	Diagnosis
722.4	Degeneration of cervical intervertebral disc	ICD-9-CM	Diagnosis
722.5	Degeneration of thoracic or lumbar intervertebral disc	ICD-9-CM	Diagnosis
722.51	Degeneration of thoracic or thoracolumbar intervertebral disc	ICD-9-CM	Diagnosis
722.52	Degeneration of lumbar or lumbosacral intervertebral disc	ICD-9-CM	Diagnosis
722.6	Degeneration of intervertebral disc, site unspecified	ICD-9-CM	Diagnosis
722.80	Postlaminectomy syndrome, unspecified region	ICD-9-CM	Diagnosis
722.81	Postlaminectomy syndrome, cervical region	ICD-9-CM	Diagnosis
722.82	Postlaminectomy syndrome, thoracic region	ICD-9-CM	Diagnosis
722.83	Postlaminectomy syndrome, lumbar region	ICD-9-CM	Diagnosis
722.90	Other and unspecified disc disorder of unspecified region	ICD-9-CM	Diagnosis
722.91	Other and unspecified disc disorder of cervical region	ICD-9-CM	Diagnosis
722.92	Other and unspecified disc disorder of thoracic region	ICD-9-CM	Diagnosis
722.93	Other and unspecified disc disorder of lumbar region	ICD-9-CM	Diagnosis
723	Other disorders of cervical region	ICD-9-CM	Diagnosis
723.0	Spinal stenosis in cervical region	ICD-9-CM	Diagnosis
723.1	Cervicalgia	ICD-9-CM	Diagnosis
723.2	Cervicocranial syndrome	ICD-9-CM	Diagnosis
723.3	Cervicobrachial syndrome (diffuse)	ICD-9-CM	Diagnosis
723.5	Torticollis, unspecified	ICD-9-CM	Diagnosis
723.6	Panniculitis specified as affecting neck	ICD-9-CM	Diagnosis
723.7	Ossification of posterior longitudinal ligament in cervical region	ICD-9-CM	Diagnosis
723.8	Other syndromes affecting cervical region	ICD-9-CM	Diagnosis
723.9	Unspecified musculoskeletal disorders and symptoms referable to neck	ICD-9-CM	Diagnosis
724.00	Spinal stenosis, unspecified region other than cervical	ICD-9-CM	Diagnosis
724.01	Spinal stenosis of thoracic region	ICD-9-CM	Diagnosis
724.02	Spinal stenosis of lumbar region, without neurogenic claudication	ICD-9-CM	Diagnosis
724.1	Pain in thoracic spine	ICD-9-CM	Diagnosis
724.2	Lumbago	ICD-9-CM	Diagnosis
724.5	Unspecified backache	ICD-9-CM	Diagnosis
724.6	Disorders of sacrum	ICD-9-CM	Diagnosis
724.70	Unspecified disorder of coccyx	ICD-9-CM	Diagnosis
724.71	Hypermobility of coccyx	ICD-9-CM	Diagnosis
724.79	Other disorder of coccyx	ICD-9-CM	Diagnosis

Appendix G. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) Healthcare Common Procedure Coding System (HCPCS), Current Procedural Terminology, Second Edition (CPT-2), and Current Procedural Terminology, Fourth Edition (CPT-4), Diagnosis and Procedure Codes Used to Define Baseline Characteristics in this Request

Code	Description	Code Type	Code Category
724.8	Other symptoms referable to back	ICD-9-CM	Diagnosis
724.9	Other unspecified back disorder	ICD-9-CM	Diagnosis
725	Polymyalgia rheumatica	ICD-9-CM	Diagnosis
726	Peripheral enthesopathies and allied syndromes	ICD-9-CM	Diagnosis
726.0	Adhesive capsulitis of shoulder	ICD-9-CM	Diagnosis
726.1	Rotator cuff syndrome of shoulder and allied disorders	ICD-9-CM	Diagnosis
726.10	Unspecified disorders of bursae and tendons in shoulder region	ICD-9-CM	Diagnosis
726.11	Calcifying tendinitis of shoulder	ICD-9-CM	Diagnosis
726.12	Bicipital tenosynovitis	ICD-9-CM	Diagnosis
726.13	Partial tear of rotator cuff	ICD-9-CM	Diagnosis
726.19	Other specified disorders of rotator cuff syndrome of shoulder and allied disorders	ICD-9-CM	Diagnosis
726.2	Other affections of shoulder region, not elsewhere classified	ICD-9-CM	Diagnosis
726.3	Enthesopathy of elbow region	ICD-9-CM	Diagnosis
726.30	Unspecified enthesopathy of elbow	ICD-9-CM	Diagnosis
726.31	Medial epicondylitis of elbow	ICD-9-CM	Diagnosis
726.32	Lateral epicondylitis of elbow	ICD-9-CM	Diagnosis
726.33	Olecranon bursitis	ICD-9-CM	Diagnosis
726.39	Other enthesopathy of elbow region	ICD-9-CM	Diagnosis
726.4	Enthesopathy of wrist and carpus	ICD-9-CM	Diagnosis
726.5	Enthesopathy of hip region	ICD-9-CM	Diagnosis
726.6	Enthesopathy of knee	ICD-9-CM	Diagnosis
726.60	Unspecified enthesopathy of knee	ICD-9-CM	Diagnosis
726.61	Pes anserinus tendinitis or bursitis	ICD-9-CM	Diagnosis
726.62	Tibial collateral ligament bursitis	ICD-9-CM	Diagnosis
726.63	Fibular collateral ligament bursitis	ICD-9-CM	Diagnosis
726.64	Patellar tendinitis	ICD-9-CM	Diagnosis
726.65	Prepatellar bursitis	ICD-9-CM	Diagnosis
726.69	Other enthesopathy of knee	ICD-9-CM	Diagnosis
726.7	Enthesopathy of ankle and tarsus	ICD-9-CM	Diagnosis
726.70	Unspecified enthesopathy of ankle and tarsus	ICD-9-CM	Diagnosis
726.71	Achilles bursitis or tendinitis	ICD-9-CM	Diagnosis
726.72	Tibialis tendinitis	ICD-9-CM	Diagnosis
726.73	Calcaneal spur	ICD-9-CM	Diagnosis
726.79	Other enthesopathy of ankle and tarsus	ICD-9-CM	Diagnosis
726.8	Other peripheral enthesopathies	ICD-9-CM	Diagnosis
726.9	Unspecified enthesopathy	ICD-9-CM	Diagnosis
726.90	Enthesopathy of unspecified site	ICD-9-CM	Diagnosis
726.91	Exostosis of unspecified site	ICD-9-CM	Diagnosis
727	Other disorders of synovium, tendon, and bursa	ICD-9-CM	Diagnosis
727.0	Synovitis and tenosynovitis	ICD-9-CM	Diagnosis
727.00	Unspecified synovitis and tenosynovitis	ICD-9-CM	Diagnosis

Appendix G. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) Healthcare Common Procedure Coding System (HCPCS), Current Procedural Terminology, Second Edition (CPT-2), and Current Procedural Terminology, Fourth Edition (CPT-4), Diagnosis and Procedure Codes Used to Define Baseline Characteristics in this Request

Code	Description	Code Type	Code Category
727.01	Synovitis and tenosynovitis in diseases classified elsewhere	ICD-9-CM	Diagnosis
727.02	Giant cell tumor of tendon sheath	ICD-9-CM	Diagnosis
727.03	Trigger finger (acquired)	ICD-9-CM	Diagnosis
727.04	Radial styloid tenosynovitis	ICD-9-CM	Diagnosis
727.05	Other tenosynovitis of hand and wrist	ICD-9-CM	Diagnosis
727.06	Tenosynovitis of foot and ankle	ICD-9-CM	Diagnosis
727.09	Other synovitis and tenosynovitis	ICD-9-CM	Diagnosis
727.1	Bunion	ICD-9-CM	Diagnosis
727.2	Specific bursitides often of occupational origin	ICD-9-CM	Diagnosis
727.3	Other bursitis disorders	ICD-9-CM	Diagnosis
727.4	Ganglion and cyst of synovium, tendon, and bursa	ICD-9-CM	Diagnosis
727.40	Unspecified synovial cyst	ICD-9-CM	Diagnosis
727.41	Ganglion of joint	ICD-9-CM	Diagnosis
727.42	Ganglion of tendon sheath	ICD-9-CM	Diagnosis
727.43	Unspecified ganglion	ICD-9-CM	Diagnosis
727.49	Other ganglion and cyst of synovium, tendon, and bursa	ICD-9-CM	Diagnosis
727.5	Rupture of synovium	ICD-9-CM	Diagnosis
727.50	Unspecified rupture of synovium	ICD-9-CM	Diagnosis
727.51	Synovial cyst of popliteal space	ICD-9-CM	Diagnosis
727.59	Other rupture of synovium	ICD-9-CM	Diagnosis
727.6	Rupture of tendon, nontraumatic	ICD-9-CM	Diagnosis
727.60	Nontraumatic rupture of unspecified tendon	ICD-9-CM	Diagnosis
727.61	Complete rupture of rotator cuff	ICD-9-CM	Diagnosis
727.62	Nontraumatic rupture of tendons of biceps (long head)	ICD-9-CM	Diagnosis
727.63	Nontraumatic rupture of extensor tendons of hand and wrist	ICD-9-CM	Diagnosis
727.64	Nontraumatic rupture of flexor tendons of hand and wrist	ICD-9-CM	Diagnosis
727.65	Nontraumatic rupture of quadriceps tendon	ICD-9-CM	Diagnosis
727.66	Nontraumatic rupture of patellar tendon	ICD-9-CM	Diagnosis
727.67	Nontraumatic rupture of Achilles tendon	ICD-9-CM	Diagnosis
727.68	Nontraumatic rupture of other tendons of foot and ankle	ICD-9-CM	Diagnosis
727.69	Nontraumatic rupture of other tendon	ICD-9-CM	Diagnosis
727.8	Other disorders of synovium, tendon, and bursa	ICD-9-CM	Diagnosis
727.81	Contracture of tendon (sheath)	ICD-9-CM	Diagnosis
727.82	Calcium deposits in tendon and bursa	ICD-9-CM	Diagnosis
727.83	Plica syndrome	ICD-9-CM	Diagnosis
727.89	Other disorders of synovium, tendon, and bursa	ICD-9-CM	Diagnosis
727.9	Unspecified disorder of synovium, tendon, and bursa	ICD-9-CM	Diagnosis
728	Disorders of muscle, ligament, and fascia	ICD-9-CM	Diagnosis
728.0	Infective myositis	ICD-9-CM	Diagnosis
728.1	Muscular calcification and ossification	ICD-9-CM	Diagnosis
728.10	Unspecified calcification and ossification	ICD-9-CM	Diagnosis
728.11	Progressive myositis ossificans	ICD-9-CM	Diagnosis

Appendix G. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) Healthcare Common Procedure Coding System (HCPCS), Current Procedural Terminology, Second Edition (CPT-2), and Current Procedural Terminology, Fourth Edition (CPT-4), Diagnosis and Procedure Codes Used to Define Baseline Characteristics in this Request

Code	Description	Code Type	Code Category
728.12	Traumatic myositis ossificans	ICD-9-CM	Diagnosis
728.13	Postoperative heterotopic calcification	ICD-9-CM	Diagnosis
728.19	Other muscular calcification and ossification	ICD-9-CM	Diagnosis
728.2	Muscular wasting and disuse atrophy, not elsewhere classified	ICD-9-CM	Diagnosis
728.3	Other specific muscle disorders	ICD-9-CM	Diagnosis
728.4	Laxity of ligament	ICD-9-CM	Diagnosis
728.5	Hypermobility syndrome	ICD-9-CM	Diagnosis
728.6	Contracture of palmar fascia	ICD-9-CM	Diagnosis
728.7	Other fibromatoses of muscle, ligament, and fascia	ICD-9-CM	Diagnosis
728.71	Plantar fascial fibromatosis	ICD-9-CM	Diagnosis
728.79	Other fibromatoses of muscle, ligament, and fascia	ICD-9-CM	Diagnosis
728.8	Other disorders of muscle, ligament, and fascia	ICD-9-CM	Diagnosis
728.81	Interstitial myositis	ICD-9-CM	Diagnosis
728.82	Foreign body granuloma of muscle	ICD-9-CM	Diagnosis
728.83	Rupture of muscle, nontraumatic	ICD-9-CM	Diagnosis
728.84	Diastasis of muscle	ICD-9-CM	Diagnosis
728.85	Spasm of muscle	ICD-9-CM	Diagnosis
728.86	Necrotizing fasciitis	ICD-9-CM	Diagnosis
728.87	Muscle weakness (generalized)	ICD-9-CM	Diagnosis
728.88	Rhabdomyolysis	ICD-9-CM	Diagnosis
728.89	Other disorder of muscle, ligament, and fascia	ICD-9-CM	Diagnosis
728.9	Unspecified disorder of muscle, ligament, and fascia	ICD-9-CM	Diagnosis
729	Other disorders of soft tissues	ICD-9-CM	Diagnosis
729.0	Rheumatism, unspecified and fibrositis	ICD-9-CM	Diagnosis
729.3	Unspecified panniculitis	ICD-9-CM	Diagnosis
729.30	Panniculitis, unspecified site	ICD-9-CM	Diagnosis
729.31	Hypertrophy of fat pad, knee	ICD-9-CM	Diagnosis
729.39	Panniculitis of other sites	ICD-9-CM	Diagnosis
729.4	Unspecified fasciitis	ICD-9-CM	Diagnosis
729.5	Pain in soft tissues of limb	ICD-9-CM	Diagnosis
729.6	Residual foreign body in soft tissue	ICD-9-CM	Diagnosis
729.7	Nontraumatic compartment syndrome	ICD-9-CM	Diagnosis
729.71	Nontraumatic compartment syndrome of upper extremity	ICD-9-CM	Diagnosis
729.72	Nontraumatic compartment syndrome of lower extremity	ICD-9-CM	Diagnosis
729.73	Nontraumatic compartment syndrome of abdomen	ICD-9-CM	Diagnosis
729.79	Nontraumatic compartment syndrome of other sites	ICD-9-CM	Diagnosis
729.8	Other musculoskeletal symptoms referable to limbs	ICD-9-CM	Diagnosis
729.81	Swelling of limb	ICD-9-CM	Diagnosis
729.82	Cramp of limb	ICD-9-CM	Diagnosis
729.89	Other musculoskeletal symptoms referable to limbs	ICD-9-CM	Diagnosis
729.9	Other and unspecified disorders of soft tissue	ICD-9-CM	Diagnosis
729.90	Disorders of soft tissue, unspecified	ICD-9-CM	Diagnosis

Appendix G. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) Healthcare Common Procedure Coding System (HCPCS), Current Procedural Terminology, Second Edition (CPT-2), and Current Procedural Terminology, Fourth Edition (CPT-4), Diagnosis and Procedure Codes Used to Define Baseline Characteristics in this Request

Code	Description	Code Type	Code Category
729.91	Post-traumatic seroma	ICD-9-CM	Diagnosis
729.92	Nontraumatic hematoma of soft tissue	ICD-9-CM	Diagnosis
729.99	Other disorders of soft tissue	ICD-9-CM	Diagnosis
Obesity			
278.00	Obesity, unspecified	ICD-9-CM	Diagnosis
278.01	Morbid obesity	ICD-9-CM	Diagnosis
278.03	Obesity hypoventilation syndrome	ICD-9-CM	Diagnosis
539.0	Complications of gastric band procedure	ICD-9-CM	Diagnosis
539.01	Infection due to gastric band procedure	ICD-9-CM	Diagnosis
539.09	Other complications of gastric band procedure	ICD-9-CM	Diagnosis
539.8	Complications of other bariatric procedure	ICD-9-CM	Diagnosis
539.81	Infection due to other bariatric procedure	ICD-9-CM	Diagnosis
539.89	Other complications of other bariatric procedure	ICD-9-CM	Diagnosis
649.1	Obesity complicating pregnancy, childbirth, or the puerperium	ICD-9-CM	Diagnosis
649.10	Obesity complicating pregnancy, childbirth, or the puerperium, unspecified as to episode of care or not applicable	ICD-9-CM	Diagnosis
649.11	Obesity complicating pregnancy, childbirth, or the puerperium, delivered, with or without mention of antepartum condition	ICD-9-CM	Diagnosis
649.12	Obesity complicating pregnancy, childbirth, or the puerperium, delivered, with mention of postpartum complication	ICD-9-CM	Diagnosis
649.13	Obesity complicating pregnancy, childbirth, or the puerperium, antepartum condition or complication	ICD-9-CM	Diagnosis
649.14	Obesity complicating pregnancy, childbirth, or the puerperium, postpartum condition or complication	ICD-9-CM	Diagnosis
649.2	Bariatric surgery status complicating pregnancy, childbirth, or the puerperium	ICD-9-CM	Diagnosis
649.20	Bariatric surgery status complicating pregnancy, childbirth, or the puerperium, unspecified as to episode of care or not applicable	ICD-9-CM	Diagnosis
649.21	Bariatric surgery status complicating pregnancy, childbirth, or the puerperium, delivered, with or without mention of antepartum condition	ICD-9-CM	Diagnosis
649.22	Bariatric surgery status complicating pregnancy, childbirth, or the puerperium, delivered, with mention of postpartum complication	ICD-9-CM	Diagnosis
649.23	Bariatric surgery status complicating pregnancy, childbirth, or the puerperium, antepartum condition or complication	ICD-9-CM	Diagnosis
649.24	Bariatric surgery status complicating pregnancy, childbirth, or the puerperium, postpartum condition or complication	ICD-9-CM	Diagnosis
V85.3	Body Mass Index between 30-39, adult	ICD-9-CM	Diagnosis
V85.30	Body Mass Index 30.0-30.9, adult	ICD-9-CM	Diagnosis
V85.31	Body Mass Index 31.0-31.9, adult	ICD-9-CM	Diagnosis
V85.32	Body Mass Index 32.0-32.9, adult	ICD-9-CM	Diagnosis
V85.33	Body Mass Index 33.0-33.9, adult	ICD-9-CM	Diagnosis
V85.34	Body Mass Index 34.0-34.9, adult	ICD-9-CM	Diagnosis
V85.35	Body Mass Index 35.0-35.9, adult	ICD-9-CM	Diagnosis

Appendix G. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) Healthcare Common Procedure Coding System (HCPCS), Current Procedural Terminology, Second Edition (CPT-2), and Current Procedural Terminology, Fourth Edition (CPT-4), Diagnosis and Procedure Codes Used to Define Baseline Characteristics in this Request

Code	Description	Code Type	Code Category
V85.36	Body Mass Index 36.0-36.9, adult	ICD-9-CM	Diagnosis
V85.37	Body Mass Index 37.0-37.9, adult	ICD-9-CM	Diagnosis
V85.38	Body Mass Index 38.0-38.9, adult	ICD-9-CM	Diagnosis
V85.39	Body Mass Index 39.0-39.9, adult	ICD-9-CM	Diagnosis
V85.4	Body Mass Index 40 and over, adult	ICD-9-CM	Diagnosis
V85.41	Body Mass Index 40.0-44.9, adult	ICD-9-CM	Diagnosis
V85.42	Body Mass Index 45.0-49.9, adult	ICD-9-CM	Diagnosis
V85.43	Body Mass Index 50.0-59.9, adult	ICD-9-CM	Diagnosis
V85.44	Body Mass Index 60.0-69.9, adult	ICD-9-CM	Diagnosis
V85.45	Body Mass Index 70 and over, adult	ICD-9-CM	Diagnosis
43.89	Open and other partial gastrectomy	ICD-9-CM	Procedure
44.38	Laparoscopic gastroenterostomy	ICD-9-CM	Procedure
44.39	Other gastroenterostomy without gastrectomy	ICD-9-CM	Procedure
44.68	Laparoscopic gastroplasty	ICD-9-CM	Procedure
44.95	Laparoscopic gastric restrictive procedure	ICD-9-CM	Procedure
45.51	Isolation of segment of small intestine	ICD-9-CM	Procedure
45.91	Small-to-small intestinal anastomosis	ICD-9-CM	Procedure
43644	Laparoscopy, surgical, gastric restrictive procedure; with gastric bypass and Roux-en-Y gastroenterostomy (roux limb 150 cm or less)	CPT-4	Procedure
43645	Laparoscopy, surgical, gastric restrictive procedure; with gastric bypass and small intestine reconstruction to limit absorption	CPT-4	Procedure
43770	Laparoscopy, surgical, gastric restrictive procedure; placement of adjustable gastric restrictive device (eg, gastric band and subcutaneous port components)	CPT-4	Procedure
43842	Gastric restrictive procedure, without gastric bypass, for morbid obesity; vertical-banded gastroplasty	CPT-4	Procedure
43843	Gastric restrictive procedure, without gastric bypass, for morbid obesity; other than vertical-banded gastroplasty	CPT-4	Procedure
43845	Gastric restrictive procedure with partial gastrectomy, pylorus-preserving duodenoileostomy and ileoileostomy (50 to 100 cm common channel) to limit absorption (biliopancreatic diversion with duodenal switch)	CPT-4	Procedure
43846	Gastric restrictive procedure, with gastric bypass for morbid obesity; with short limb (150 cm or less) Roux-en-Y gastroenterostomy	CPT-4	Procedure
43847	Gastric restrictive procedure, with gastric bypass for morbid obesity; with small intestine reconstruction to limit absorption	CPT-4	Procedure
Smoking			
292.0	Drug withdrawal	ICD-9-CM	Diagnosis
292.89	Other specified drug-induced mental disorder	ICD-9-CM	Diagnosis
292.9	Unspecified drug-induced mental disorder	ICD-9-CM	Diagnosis
305.1	Nondependent tobacco use disorder	ICD-9-CM	Diagnosis
649.0	Tobacco use disorder complicating pregnancy, childbirth, or the puerperium	ICD-9-CM	Diagnosis
649.00	Tobacco use disorder complicating pregnancy, childbirth, or the puerperium, unspecified as to episode of care or not applicable	ICD-9-CM	Diagnosis

Appendix G. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) Healthcare Common Procedure Coding System (HCPCS), Current Procedural Terminology, Second Edition (CPT-2), and Current Procedural Terminology, Fourth Edition (CPT-4), Diagnosis and Procedure Codes Used to Define Baseline Characteristics in this Request

Code	Description	Code Type	Code Category
649.01	Tobacco use disorder complicating pregnancy, childbirth, or the puerperium, delivered, with or without mention of antepartum condition	ICD-9-CM	Diagnosis
649.02	Tobacco use disorder complicating pregnancy, childbirth, or the puerperium, delivered, with mention of postpartum complication	ICD-9-CM	Diagnosis
649.03	Tobacco use disorder complicating pregnancy, childbirth, or the puerperium, antepartum condition or complication	ICD-9-CM	Diagnosis
649.04	Tobacco use disorder complicating pregnancy, childbirth, or the puerperium, postpartum condition or complication	ICD-9-CM	Diagnosis
989.84	Toxic effect of tobacco	ICD-9-CM	Diagnosis
E866.8	Accidental poisoning by other specified solid or liquid substances	ICD-9-CM	Diagnosis
E950.9	Suicide and self-inflicted poisoning by other and unspecified solid and liquid substances	ICD-9-CM	Diagnosis
E962.1	Assault by other solid and liquid substances	ICD-9-CM	Diagnosis
E980.9	Poisoning by other and unspecified solid and liquid substances, undetermined whether accidentally or purposely inflicted	ICD-9-CM	Diagnosis
V15.82	Personal history of tobacco use, presenting hazards to health	ICD-9-CM	Diagnosis
V69.8	Other problems related to lifestyle	ICD-9-CM	Diagnosis
C9801	Smoking and tobacco cessation counseling visit for the asymptomatic patient; intermediate, greater than 3 minutes, up to 10 minutes	HCPCS	Procedure
C9802	Smoking and tobacco cessation counseling visit for the asymptomatic patient; intensive, greater than 10 minutes	HCPCS	Procedure
D1320	tobacco counseling for the control and prevention of oral disease	HCPCS	Procedure
G0375	Smoking and tobacco use cessation counseling visit; intermediate, greater than 3 minutes up to 10 minutes	HCPCS	Procedure
G0376	Smoking and tobacco use cessation counseling visit; intensive, greater than 10 minutes	HCPCS	Procedure
G0436	Smoking and tobacco cessation counseling visit for the asymptomatic patient; intermediate, greater than 3 minutes, up to 10 minutes	HCPCS	Procedure
G0437	Smoking and tobacco cessation counseling visit for the asymptomatic patient; intensive, greater than 10 minutes	HCPCS	Procedure
G8093	Newly diagnosed chronic obstructive pulmonary disease (COPD) patient documented to have received smoking cessation intervention, within 3 months of diagnosis	HCPCS	Procedure
G8094	Newly diagnosed chronic obstructive pulmonary disease (COPD) patient not documented to have received smoking cessation intervention, within 3 months of diagnosis	HCPCS	Procedure
G8402	Tobacco (smoke) use cessation intervention, counseling	HCPCS	Procedure
G8403	Tobacco (smoke) use cessation intervention not counseled	HCPCS	Procedure
G8453	Tobacco use cessation intervention, counseling	HCPCS	Procedure
G8454	Tobacco use cessation intervention not counseled, reason not specified	HCPCS	Procedure
G8455	Current tobacco smoker	HCPCS	Procedure
G8456	Current smokeless tobacco user	HCPCS	Procedure

Appendix G. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) Healthcare Common Procedure Coding System (HCPCS), Current Procedural Terminology, Second Edition (CPT-2), and Current Procedural Terminology, Fourth Edition (CPT-4), Diagnosis and Procedure Codes Used to Define Baseline Characteristics in this Request

Code	Description	Code Type	Code Category
G8688	Currently a smokeless tobacco user (e.g., chew, snuff) and no exposure to secondhand smoke	HCPCS	Procedure
G8690	Current tobacco smoker or current exposure to secondhand smoke	HCPCS	Procedure
G8692	Current smokeless tobacco user (e.g., chew, snuff) and no exposure to secondhand smoke	HCPCS	Procedure
G9016	Smoking cessation counseling, individual, in the absence of or in addition to any other evaluation and management service, per session (6-10 minutes) [demo project code only]	HCPCS	Procedure
G9276	Documentation that patient is a current tobacco user	HCPCS	Procedure
G9458	Patient documented as tobacco user and received tobacco cessation intervention (must include at least one of the following: advice given to quit smoking or tobacco use, counseling on the benefits of quitting smoking or tobacco use, assistance with or referral to external smoking or tobacco cessation support programs, or current enrollment in smoking or tobacco use cessation program) if identified as a tobacco user	HCPCS	Procedure
S4990	Nicotine patches, legend	HCPCS	Procedure
S4991	Nicotine patches, non-legend	HCPCS	Procedure
S4995	Smoking cessation gum	HCPCS	Procedure
S9075	Smoking cessation treatment	HCPCS	Procedure
S9453	Smoking cessation classes, nonphysician provider, per session	HCPCS	Procedure
83887	Nicotine	CPT-4	Procedure
99406	Smoking and tobacco use cessation counseling visit; intermediate, greater than 3 minutes up to 10 minutes	CPT-4	Procedure
99407	Smoking and tobacco use cessation counseling visit; intensive, greater than 10 minutes	CPT-4	Procedure
1034F	Current tobacco smoker (CAD, CAP, COPD, PV) (DM)	CPT-2	Procedure
1035F	Current smokeless tobacco user (eg, chew, snuff) (PV)	CPT-2	Procedure
4000F	Tobacco use cessation intervention, counseling (COPD, CAP, CAD, Asthma) (DM) (PV)	CPT-2	Procedure
4001F	Tobacco use cessation intervention, pharmacologic therapy (COPD, CAD, CAP, PV, Asthma) (DM) (PV)	CPT-2	Procedure
4004F	Patient screened for tobacco use and received tobacco cessation intervention (counseling, pharmacotherapy, or both), if identified as a tobacco user (PV, CAD)	CPT-2	Procedure

Depression

311	Depressive disorder, not elsewhere classified	ICD-9-CM	Diagnosis
296.2	Major depressive disorder, single episode	ICD-9-CM	Diagnosis
296.20	Major depressive disorder, single episode, unspecified	ICD-9-CM	Diagnosis
296.21	Major depressive disorder, single episode, mild	ICD-9-CM	Diagnosis
296.22	Major depressive disorder, single episode, moderate	ICD-9-CM	Diagnosis
296.23	Major depressive disorder, single episode, severe, without mention of psychotic behavior	ICD-9-CM	Diagnosis

Appendix G. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) Healthcare Common Procedure Coding System (HCPCS), Current Procedural Terminology, Second Edition (CPT-2), and Current Procedural Terminology, Fourth Edition (CPT-4), Diagnosis and Procedure Codes Used to Define Baseline Characteristics in this Request

Code	Description	Code Type	Code Category
296.24	Major depressive disorder, single episode, severe, specified as with psychotic behavior	ICD-9-CM	Diagnosis
296.25	Major depressive disorder, single episode, in partial or unspecified remission	ICD-9-CM	Diagnosis
296.26	Major depressive disorder, single episode in full remission	ICD-9-CM	Diagnosis
296.3	Major depressive disorder, recurrent episode	ICD-9-CM	Diagnosis
296.30	Major depressive disorder, recurrent episode, unspecified	ICD-9-CM	Diagnosis
296.31	Major depressive disorder, recurrent episode, mild	ICD-9-CM	Diagnosis
296.32	Major depressive disorder, recurrent episode, moderate	ICD-9-CM	Diagnosis
296.33	Major depressive disorder, recurrent episode, severe, without mention of psychotic behavior	ICD-9-CM	Diagnosis
296.34	Major depressive disorder, recurrent episode, severe, specified as with psychotic behavior	ICD-9-CM	Diagnosis
296.35	Major depressive disorder, recurrent episode, in partial or unspecified remission	ICD-9-CM	Diagnosis
296.36	Major depressive disorder, recurrent episode, in full remission	ICD-9-CM	Diagnosis
296.90	Unspecified episodic mood disorder	ICD-9-CM	Diagnosis
300.4	Dysthymic disorder	ICD-9-CM	Diagnosis
309.0	Adjustment disorder with depressed mood	ICD-9-CM	Diagnosis
309.1	Prolonged depressive reaction as adjustment reaction	ICD-9-CM	Diagnosis
Anxiety			
300.02	Generalized anxiety disorder	ICD-9-CM	Diagnosis
300.0	Anxiety states	ICD-9-CM	Diagnosis
300.00	Anxiety state, unspecified	ICD-9-CM	Diagnosis
300.09	Other anxiety states	ICD-9-CM	Diagnosis
300.2	Phobic disorders	ICD-9-CM	Diagnosis
300.20	Phobia, unspecified	ICD-9-CM	Diagnosis
300.22	Agoraphobia without mention of panic attacks	ICD-9-CM	Diagnosis
300.29	Other isolated or specific phobias	ICD-9-CM	Diagnosis
300.01	Panic disorder without agoraphobia	ICD-9-CM	Diagnosis
300.21	Agoraphobia with panic disorder	ICD-9-CM	Diagnosis
Psychotic Conditions			
290.8	Other specified senile psychotic conditions	ICD-9-CM	Diagnosis
290.9	Unspecified senile psychotic condition	ICD-9-CM	Diagnosis
297	Delusional disorders	ICD-9-CM	Diagnosis
297.0	Paranoid state, simple	ICD-9-CM	Diagnosis
297.1	Delusional disorders	ICD-9-CM	Diagnosis
297.2	Paraphrenia	ICD-9-CM	Diagnosis
297.3	Shared psychotic disorder	ICD-9-CM	Diagnosis
297.8	Other specified paranoid states	ICD-9-CM	Diagnosis
297.9	unspecified paranoid state	ICD-9-CM	Diagnosis
298	Other nonorganic psychosis	ICD-9-CM	Diagnosis
298.0	Depressive type psychosis	ICD-9-CM	Diagnosis

Appendix G. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) Healthcare Common Procedure Coding System (HCPCS), Current Procedural Terminology, Second Edition (CPT-2), and Current Procedural Terminology, Fourth Edition (CPT-4), Diagnosis and Procedure Codes Used to Define Baseline Characteristics in this Request

Code	Description	Code Type	Code Category
298.1	Excitative type psychosis	ICD-9-CM	Diagnosis
298.2	Reactive confusion	ICD-9-CM	Diagnosis
298.3	Acute paranoid reaction	ICD-9-CM	Diagnosis
298.4	Psychogenic paranoid psychosis	ICD-9-CM	Diagnosis
298.8	Other and unspecified reactive psychosis	ICD-9-CM	Diagnosis
298.9	Unspecified psychosis	ICD-9-CM	Diagnosis
Other Psychiatric Disorders			
291.0	Alcohol withdrawal delirium	ICD-9-CM	Diagnosis
292.81	Drug-induced delirium	ICD-9-CM	Diagnosis
293	Transient mental disorders due to conditions classified elsewhere	ICD-9-CM	Diagnosis
293.0	Delirium due to conditions classified elsewhere	ICD-9-CM	Diagnosis
293.1	Subacute delirium	ICD-9-CM	Diagnosis
293.8	Other specified transient mental disorders due to conditions classified elsewhere	ICD-9-CM	Diagnosis
293.81	Psychotic disorder with delusions in conditions classified elsewhere	ICD-9-CM	Diagnosis
293.82	Psychotic disorder with hallucinations in conditions classified elsewhere	ICD-9-CM	Diagnosis
293.83	Mood disorder in conditions classified elsewhere	ICD-9-CM	Diagnosis
293.84	Anxiety disorder in conditions classified elsewhere	ICD-9-CM	Diagnosis
293.89	Other specified transient mental disorders due to conditions classified elsewhere	ICD-9-CM	Diagnosis
293.9	Unspecified transient mental disorder in conditions classified elsewhere	ICD-9-CM	Diagnosis
294	Persistent mental disorders due to conditions classified elsewhere	ICD-9-CM	Diagnosis
294.0	Amnestic disorder in conditions classified elsewhere	ICD-9-CM	Diagnosis
294.1	Dementia in conditions classified elsewhere	ICD-9-CM	Diagnosis
294.10	Dementia in conditions classified elsewhere without behavioral disturbance	ICD-9-CM	Diagnosis
294.11	Dementia in conditions classified elsewhere with behavioral disturbance	ICD-9-CM	Diagnosis
294.2	Dementia, unspecified	ICD-9-CM	Diagnosis
294.20	Dementia, unspecified, without behavioral disturbance	ICD-9-CM	Diagnosis
294.21	Dementia, unspecified, with behavioral disturbance	ICD-9-CM	Diagnosis
294.8	Other persistent mental disorders due to conditions classified elsewhere	ICD-9-CM	Diagnosis
294.9	Unspecified persistent mental disorders due to conditions classified elsewhere	ICD-9-CM	Diagnosis
295	Schizophrenic disorders	ICD-9-CM	Diagnosis
295.0	Simple type schizophrenia	ICD-9-CM	Diagnosis
295.00	Simple schizophrenia, unspecified condition	ICD-9-CM	Diagnosis
295.01	Simple schizophrenia, subchronic condition	ICD-9-CM	Diagnosis
295.02	Simple schizophrenia, chronic condition	ICD-9-CM	Diagnosis
295.03	Simple schizophrenia, subchronic condition with acute exacerbation	ICD-9-CM	Diagnosis
295.04	Simple schizophrenia, chronic condition with acute exacerbation	ICD-9-CM	Diagnosis
295.05	Simple schizophrenia, in remission	ICD-9-CM	Diagnosis
295.1	Disorganized type schizophrenia	ICD-9-CM	Diagnosis
295.10	Disorganized schizophrenia, unspecified condition	ICD-9-CM	Diagnosis
295.11	Disorganized schizophrenia, subchronic condition	ICD-9-CM	Diagnosis

Appendix G. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) Healthcare Common Procedure Coding System (HCPCS), Current Procedural Terminology, Second Edition (CPT-2), and Current Procedural Terminology, Fourth Edition (CPT-4), Diagnosis and Procedure Codes Used to Define Baseline Characteristics in this Request

Code	Description	Code Type	Code Category
295.12	Disorganized schizophrenia, chronic condition	ICD-9-CM	Diagnosis
295.13	Disorganized schizophrenia, subchronic condition with acute exacerbation	ICD-9-CM	Diagnosis
295.14	Disorganized schizophrenia, chronic condition with acute exacerbation	ICD-9-CM	Diagnosis
295.15	Disorganized schizophrenia, in remission	ICD-9-CM	Diagnosis
295.2	Catatonic type schizophrenia	ICD-9-CM	Diagnosis
295.20	Catatonic schizophrenia, unspecified condition	ICD-9-CM	Diagnosis
295.21	Catatonic schizophrenia, subchronic condition	ICD-9-CM	Diagnosis
295.22	Catatonic schizophrenia, chronic condition	ICD-9-CM	Diagnosis
295.23	Catatonic schizophrenia, subchronic condition with acute exacerbation	ICD-9-CM	Diagnosis
295.24	Catatonic schizophrenia, chronic condition with acute exacerbation	ICD-9-CM	Diagnosis
295.25	Catatonic schizophrenia, in remission	ICD-9-CM	Diagnosis
295.3	Paranoid type schizophrenia	ICD-9-CM	Diagnosis
295.30	Paranoid schizophrenia, unspecified condition	ICD-9-CM	Diagnosis
295.31	Paranoid schizophrenia, subchronic condition	ICD-9-CM	Diagnosis
295.32	Paranoid schizophrenia, chronic condition	ICD-9-CM	Diagnosis
295.33	Paranoid schizophrenia, subchronic condition with acute exacerbation	ICD-9-CM	Diagnosis
295.34	Paranoid schizophrenia, chronic condition with acute exacerbation	ICD-9-CM	Diagnosis
295.35	Paranoid schizophrenia, in remission	ICD-9-CM	Diagnosis
295.4	Schizophreniform disorder	ICD-9-CM	Diagnosis
295.40	Schizophreniform disorder, unspecified	ICD-9-CM	Diagnosis
295.41	Schizophreniform disorder, subchronic	ICD-9-CM	Diagnosis
295.42	Schizophreniform disorder, chronic	ICD-9-CM	Diagnosis
295.43	Schizophreniform disorder, subchronic with acute exacerbation	ICD-9-CM	Diagnosis
295.44	Schizophreniform disorder, chronic with acute exacerbation	ICD-9-CM	Diagnosis
295.45	Schizophreniform disorder, in remission	ICD-9-CM	Diagnosis
295.5	Latent schizophrenia	ICD-9-CM	Diagnosis
295.50	Latent schizophrenia, unspecified condition	ICD-9-CM	Diagnosis
295.51	Latent schizophrenia, subchronic condition	ICD-9-CM	Diagnosis
295.52	Latent schizophrenia, chronic condition	ICD-9-CM	Diagnosis
295.53	Latent schizophrenia, subchronic condition with acute exacerbation	ICD-9-CM	Diagnosis
295.54	Latent schizophrenia, chronic condition with acute exacerbation	ICD-9-CM	Diagnosis
295.55	Latent schizophrenia, in remission	ICD-9-CM	Diagnosis
295.6	Schizophrenic disorders, residual type	ICD-9-CM	Diagnosis
295.60	Schizophrenic disorders, residual type, unspecified	ICD-9-CM	Diagnosis
295.61	Schizophrenic disorders, residual type, subchronic	ICD-9-CM	Diagnosis
295.62	Schizophrenic disorders, residual type, chronic	ICD-9-CM	Diagnosis
295.63	Schizophrenic disorders, residual type, subchronic with acute exacerbation	ICD-9-CM	Diagnosis
295.64	Schizophrenic disorders, residual type, chronic with acute exacerbation	ICD-9-CM	Diagnosis
295.65	Schizophrenic disorders, residual type, in remission	ICD-9-CM	Diagnosis
295.7	Schizoaffective disorder	ICD-9-CM	Diagnosis
295.70	Schizoaffective disorder, unspecified	ICD-9-CM	Diagnosis
295.71	Schizoaffective disorder, subchronic	ICD-9-CM	Diagnosis

Appendix G. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) Healthcare Common Procedure Coding System (HCPCS), Current Procedural Terminology, Second Edition (CPT-2), and Current Procedural Terminology, Fourth Edition (CPT-4), Diagnosis and Procedure Codes Used to Define Baseline Characteristics in this Request

Code	Description	Code Type	Code Category
295.72	Schizoaffective disorder, chronic	ICD-9-CM	Diagnosis
295.73	Schizoaffective disorder, subchronic with acute exacerbation	ICD-9-CM	Diagnosis
295.74	Schizoaffective disorder, chronic with acute exacerbation	ICD-9-CM	Diagnosis
295.75	Schizoaffective disorder, in remission	ICD-9-CM	Diagnosis
295.8	Other specified types of schizophrenia	ICD-9-CM	Diagnosis
295.80	Other specified types of schizophrenia, unspecified condition	ICD-9-CM	Diagnosis
295.81	Other specified types of schizophrenia, subchronic condition	ICD-9-CM	Diagnosis
295.82	Other specified types of schizophrenia, chronic condition	ICD-9-CM	Diagnosis
295.83	Other specified types of schizophrenia, subchronic condition with acute exacerbation	ICD-9-CM	Diagnosis
295.84	Other specified types of schizophrenia, chronic condition with acute exacerbation	ICD-9-CM	Diagnosis
295.85	Other specified types of schizophrenia, in remission	ICD-9-CM	Diagnosis
295.9	Unspecified schizophrenia	ICD-9-CM	Diagnosis
295.90	Unspecified schizophrenia, unspecified condition	ICD-9-CM	Diagnosis
295.91	Unspecified schizophrenia, subchronic condition	ICD-9-CM	Diagnosis
295.92	Unspecified schizophrenia, chronic condition	ICD-9-CM	Diagnosis
295.93	Unspecified schizophrenia, subchronic condition with acute exacerbation	ICD-9-CM	Diagnosis
295.94	Unspecified schizophrenia, chronic condition with acute exacerbation	ICD-9-CM	Diagnosis
295.95	Unspecified schizophrenia, in remission	ICD-9-CM	Diagnosis
299	Pervasive developmental disorders	ICD-9-CM	Diagnosis
299.0	Autistic disorder	ICD-9-CM	Diagnosis
299.00	Autistic disorder, current or active state	ICD-9-CM	Diagnosis
299.01	Autistic disorder, residual state	ICD-9-CM	Diagnosis
299.1	Childhood disintegrative disorder	ICD-9-CM	Diagnosis
299.10	Childhood disintegrative disorder, current or active state	ICD-9-CM	Diagnosis
299.11	Childhood disintegrative disorder, residual state	ICD-9-CM	Diagnosis
299.8	Other specified pervasive developmental disorders	ICD-9-CM	Diagnosis
299.80	Other specified pervasive developmental disorders, current or active state	ICD-9-CM	Diagnosis
299.81	Other specified pervasive developmental disorders, residual state	ICD-9-CM	Diagnosis
299.9	Unspecified pervasive developmental disorder	ICD-9-CM	Diagnosis
299.90	Unspecified pervasive developmental disorder, current or active state	ICD-9-CM	Diagnosis
299.91	Unspecified pervasive developmental disorder, residual state	ICD-9-CM	Diagnosis
300.1	Dissociative, conversion and factitious disorders	ICD-9-CM	Diagnosis
300.10	Hysteria unspecified	ICD-9-CM	Diagnosis
300.11	conversion disorder	ICD-9-CM	Diagnosis
300.12	Dissociative amnesia	ICD-9-CM	Diagnosis
300.13	Dissociative fugue	ICD-9-CM	Diagnosis
300.14	Dissociative identity disorder	ICD-9-CM	Diagnosis
300.15	Dissociative disorder or reaction, unspecified	ICD-9-CM	Diagnosis
300.16	Factitious disorder with predominantly psychological signs and symptoms	ICD-9-CM	Diagnosis
300.19	Other and unspecified factitious illness	ICD-9-CM	Diagnosis

Appendix G. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) Healthcare Common Procedure Coding System (HCPCS), Current Procedural Terminology, Second Edition (CPT-2), and Current Procedural Terminology, Fourth Edition (CPT-4), Diagnosis and Procedure Codes Used to Define Baseline Characteristics in this Request

Code	Description	Code Type	Code Category
300.23	Social phobia	ICD-9-CM	Diagnosis
300.3	Obsessive-compulsive disorders	ICD-9-CM	Diagnosis
300.5	Neurasthenia	ICD-9-CM	Diagnosis
300.6	Depersonalization disorder	ICD-9-CM	Diagnosis
300.7	Hypochondriasis	ICD-9-CM	Diagnosis
300.8	Somatoform disorders	ICD-9-CM	Diagnosis
300.81	Somatization disorder	ICD-9-CM	Diagnosis
300.82	Undifferentiated somatoform disorder	ICD-9-CM	Diagnosis
300.89	Other somatoform disorders	ICD-9-CM	Diagnosis
300.9	Unspecified nonpsychotic mental disorder	ICD-9-CM	Diagnosis
301	Personality disorders	ICD-9-CM	Diagnosis
301.0	Paranoid personality disorder	ICD-9-CM	Diagnosis
301.1	Affective personality disorder	ICD-9-CM	Diagnosis
301.10	Affective personality disorder, unspecified	ICD-9-CM	Diagnosis
301.11	Chronic hypomanic personality disorder	ICD-9-CM	Diagnosis
301.12	Chronic depressive personality disorder	ICD-9-CM	Diagnosis
301.13	Cyclothymic disorder	ICD-9-CM	Diagnosis
301.2	Schizoid personality disorder	ICD-9-CM	Diagnosis
301.20	Schizoid personality disorder, unspecified	ICD-9-CM	Diagnosis
301.21	Introverted personality	ICD-9-CM	Diagnosis
301.22	Schizotypal personality disorder	ICD-9-CM	Diagnosis
301.3	Explosive personality disorder	ICD-9-CM	Diagnosis
301.4	Obsessive-compulsive personality disorder	ICD-9-CM	Diagnosis
301.5	Histrionic personality disorder	ICD-9-CM	Diagnosis
301.50	Histrionic personality disorder, unspecified	ICD-9-CM	Diagnosis
301.51	Chronic factitious illness with physical symptoms	ICD-9-CM	Diagnosis
301.59	Other histrionic personality disorder	ICD-9-CM	Diagnosis
301.6	Dependent personality disorder	ICD-9-CM	Diagnosis
301.7	Antisocial personality disorder	ICD-9-CM	Diagnosis
301.8	Other personality disorders	ICD-9-CM	Diagnosis
301.81	Narcissistic personality disorder	ICD-9-CM	Diagnosis
301.82	Avoidant personality disorder	ICD-9-CM	Diagnosis
301.83	Borderline personality disorder	ICD-9-CM	Diagnosis
301.84	Passive-aggressive personality	ICD-9-CM	Diagnosis
301.89	Other personality disorders	ICD-9-CM	Diagnosis
301.9	Unspecified personality disorder	ICD-9-CM	Diagnosis
302	Sexual and gender identity disorders	ICD-9-CM	Diagnosis
302.0	Ego-dystonic sexual orientation	ICD-9-CM	Diagnosis
302.1	Zoophilia	ICD-9-CM	Diagnosis
302.2	Pedophilia	ICD-9-CM	Diagnosis
302.3	Transvestic fetishism	ICD-9-CM	Diagnosis
302.4	Exhibitionism	ICD-9-CM	Diagnosis

Appendix G. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) Healthcare Common Procedure Coding System (HCPCS), Current Procedural Terminology, Second Edition (CPT-2), and Current Procedural Terminology, Fourth Edition (CPT-4), Diagnosis and Procedure Codes Used to Define Baseline Characteristics in this Request

Code	Description	Code Type	Code Category
302.5	Trans-sexualism	ICD-9-CM	Diagnosis
302.50	Trans-sexualism with unspecified sexual history	ICD-9-CM	Diagnosis
302.51	Trans-sexualism with asexual history	ICD-9-CM	Diagnosis
302.52	Trans-sexualism with homosexual history	ICD-9-CM	Diagnosis
302.53	Trans-sexualism with heterosexual history	ICD-9-CM	Diagnosis
302.6	Gender identity disorder in children	ICD-9-CM	Diagnosis
302.7	Psychosexual dysfunction	ICD-9-CM	Diagnosis
302.70	Psychosexual dysfunction, unspecified	ICD-9-CM	Diagnosis
302.71	Hypoactive sexual desire disorder	ICD-9-CM	Diagnosis
302.72	Psychosexual dysfunction with inhibited sexual excitement	ICD-9-CM	Diagnosis
302.73	Female orgasmic disorder	ICD-9-CM	Diagnosis
302.74	Male orgasmic disorder	ICD-9-CM	Diagnosis
302.75	Premature ejaculation	ICD-9-CM	Diagnosis
302.76	Dyspareunia, psychogenic	ICD-9-CM	Diagnosis
302.79	Psychosexual dysfunction with other specified psychosexual dsyfunctions	ICD-9-CM	Diagnosis
302.8	Other specified psychosexual disorders	ICD-9-CM	Diagnosis
302.81	Fetishism	ICD-9-CM	Diagnosis
302.82	Voyeurism	ICD-9-CM	Diagnosis
302.83	Sexual masochism	ICD-9-CM	Diagnosis
302.84	Sexual sadism	ICD-9-CM	Diagnosis
302.85	Gender identity disorder in adolescents or adults	ICD-9-CM	Diagnosis
302.89	Other specified psychosexual disorders	ICD-9-CM	Diagnosis
302.9	Unspecified psychosexual disorders	ICD-9-CM	Diagnosis
306	Physiological malfunction arising from mental factors	ICD-9-CM	Diagnosis
306.0	Musculoskeletal malfunction arising from mental factors	ICD-9-CM	Diagnosis
306.1	Respiratory malfunction arising from mental factors	ICD-9-CM	Diagnosis
306.2	Cardiovascular malfunction arising from mental factors	ICD-9-CM	Diagnosis
306.3	Skin disorder arising from mental factors	ICD-9-CM	Diagnosis
306.4	Gastrointestinal malfunction arising from mental factors	ICD-9-CM	Diagnosis
306.5	Genitourinary malfunction arising from mental factors	ICD-9-CM	Diagnosis
306.50	Psychogenic genitourinary malfunction, unspecified	ICD-9-CM	Diagnosis
306.51	psychogenic vaginismus	ICD-9-CM	Diagnosis
306.52	psychogenic dysmenorrhea	ICD-9-CM	Diagnosis
306.53	psychogenic dysuria	ICD-9-CM	Diagnosis
306.59	Other genitourinary malfunction arising from mental factors	ICD-9-CM	Diagnosis
306.6	Endocrine disorder arising from mental factors	ICD-9-CM	Diagnosis
306.7	Disorder of organs of special sense arising from mental factors	ICD-9-CM	Diagnosis
306.8	Other specified psychophysiological malfunction	ICD-9-CM	Diagnosis
306.9	Unspecified psychophysiological malfunction	ICD-9-CM	Diagnosis
307	Special symptoms or syndromes not elsewhere classified	ICD-9-CM	Diagnosis
307.0	Adult onset fluency disorder	ICD-9-CM	Diagnosis
307.1	Anorexia nervosa	ICD-9-CM	Diagnosis

Appendix G. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) Healthcare Common Procedure Coding System (HCPCS), Current Procedural Terminology, Second Edition (CPT-2), and Current Procedural Terminology, Fourth Edition (CPT-4), Diagnosis and Procedure Codes Used to Define Baseline Characteristics in this Request

Code	Description	Code Type	Code Category
307.2	Tics	ICD-9-CM	Diagnosis
307.20	Tic disorder, unspecified	ICD-9-CM	Diagnosis
307.21	Transient tic disorder	ICD-9-CM	Diagnosis
307.22	Chronic motor or vocal tic disorder	ICD-9-CM	Diagnosis
307.23	Tourette's disorder	ICD-9-CM	Diagnosis
307.3	Stereotypic movement disorder	ICD-9-CM	Diagnosis
307.5	Other unspecified disorder of eating	ICD-9-CM	Diagnosis
307.50	Eating disorder, unspecified	ICD-9-CM	Diagnosis
307.51	Bulimia nervosa	ICD-9-CM	Diagnosis
307.52	Pica	ICD-9-CM	Diagnosis
307.53	Rumination disorder	ICD-9-CM	Diagnosis
307.54	Psychogenic vomiting	ICD-9-CM	Diagnosis
307.59	Other disorders of eating	ICD-9-CM	Diagnosis
307.6	Enuresis	ICD-9-CM	Diagnosis
307.7	Encopresis	ICD-9-CM	Diagnosis
307.8	pain disorder related to psychological factors	ICD-9-CM	Diagnosis
307.80	psychogenic pain, site unspecified	ICD-9-CM	Diagnosis
307.89	Other pain disorders related to psychological factors	ICD-9-CM	Diagnosis
307.9	Other and unspecified special symptoms or syndromes, not elsewhere classified	ICD-9-CM	Diagnosis
308	Acute reaction to stress	ICD-9-CM	Diagnosis
308.0	Predominant disturbance of emotions	ICD-9-CM	Diagnosis
308.1	Predominant disturbance of consciousness	ICD-9-CM	Diagnosis
308.2	Predominant psychomotor disturbance	ICD-9-CM	Diagnosis
308.3	Other acute reactions to stress	ICD-9-CM	Diagnosis
308.4	Mixed disorders as reaction to stress	ICD-9-CM	Diagnosis
308.9	Unspecified acute reaction to stress	ICD-9-CM	Diagnosis
309.2	Adjustment reaction with predominant disturbance of other emotions	ICD-9-CM	Diagnosis
309.21	Separation anxiety disorder	ICD-9-CM	Diagnosis
309.22	Emancipation disorder of adolescence and early adult life	ICD-9-CM	Diagnosis
309.23	Specific academic or work inhibition	ICD-9-CM	Diagnosis
309.24	Adjustment disorder with anxiety	ICD-9-CM	Diagnosis
309.28	Adjustment disorder with mixed anxiety and depressed mo	ICD-9-CM	Diagnosis
309.29	Other adjustment reactions with predominant disturbance of other emotions	ICD-9-CM	Diagnosis
309.3	Adjustment disorder with disturbance of conduct	ICD-9-CM	Diagnosis
309.4	Adjustment disorder with mixed disturbance of emotions and conduct	ICD-9-CM	Diagnosis
309.8	Other specified adjustment reactions	ICD-9-CM	Diagnosis
309.81	Posttraumatic stress disorder	ICD-9-CM	Diagnosis
309.82	Adjustment reaction with physical symptoms	ICD-9-CM	Diagnosis
309.83	Adjustment reaction with withdrawal	ICD-9-CM	Diagnosis
309.89	Other specified adjustment reactions	ICD-9-CM	Diagnosis
309.9	Unspecified adjustment reaction	ICD-9-CM	Diagnosis

Appendix G. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) Healthcare Common Procedure Coding System (HCPCS), Current Procedural Terminology, Second Edition (CPT-2), and Current Procedural Terminology, Fourth Edition (CPT-4), Diagnosis and Procedure Codes Used to Define Baseline Characteristics in this Request

Code	Description	Code Type	Code Category
310	Specific nonpsychotic mental disorders due to brain damage	ICD-9-CM	Diagnosis
310.0	Frontal lobe syndrome	ICD-9-CM	Diagnosis
310.1	Personality change due to conditions classified elsewhere	ICD-9-CM	Diagnosis
310.2	Postconcussion syndrome	ICD-9-CM	Diagnosis
310.8	Other specified nonpsychotic mental disorders following organic brain damage	ICD-9-CM	Diagnosis
310.81	Pseudobulbar affect	ICD-9-CM	Diagnosis
310.89	Other specified nonpsychotic mental disorders following organic brain damage	ICD-9-CM	Diagnosis
310.9	Unspecified nonpsychotic mental disorder following organic brain damage	ICD-9-CM	Diagnosis
312	Disturbance of conduct not elsewhere classified	ICD-9-CM	Diagnosis
312.0	Undersocialized conduct disorder aggressive type	ICD-9-CM	Diagnosis
312.00	Undersocialized conduct disorder aggressive type, unspecified	ICD-9-CM	Diagnosis
312.01	Undersocialized conduct disorder aggressive type, mild	ICD-9-CM	Diagnosis
312.02	Undersocialized conduct disorder aggressive type, moderate	ICD-9-CM	Diagnosis
312.03	Undersocialized conduct disorder aggressive, severe	ICD-9-CM	Diagnosis
312.1	Undersocialized conduct disorder unaggressive type	ICD-9-CM	Diagnosis
312.10	Undersocialized conduct disorder unaggressive type, unspecified	ICD-9-CM	Diagnosis
312.11	Undersocialized conduct disorder unaggressive type, mild	ICD-9-CM	Diagnosis
312.12	Undersocialized conduct disorder unaggressive type, moderate	ICD-9-CM	Diagnosis
312.13	Undersocialized conduct disorder unaggressive, severe	ICD-9-CM	Diagnosis
312.2	Socialized conduct disorder	ICD-9-CM	Diagnosis
312.20	Socialized conduct disorder, unspecified	ICD-9-CM	Diagnosis
312.21	Socialized conduct disorder, mild	ICD-9-CM	Diagnosis
312.22	Socialized conduct disorder, moderate	ICD-9-CM	Diagnosis
312.23	Socialized conduct disorder, severe	ICD-9-CM	Diagnosis
312.3	Disorders of impulse control not elsewhere classified	ICD-9-CM	Diagnosis
312.30	Impulse control disorder, unspecified	ICD-9-CM	Diagnosis
312.31	Pathological gambling	ICD-9-CM	Diagnosis
312.32	Kleptomania	ICD-9-CM	Diagnosis
312.33	Pyromania	ICD-9-CM	Diagnosis
312.34	Intermittent explosive disorder	ICD-9-CM	Diagnosis
312.35	Isolated explosive disorder	ICD-9-CM	Diagnosis
312.39	Other disorders of impulse control	ICD-9-CM	Diagnosis
312.4	Mixed disturbance of conduct and emotions	ICD-9-CM	Diagnosis
312.8	Other specified disturbances of conduct not elsewhere classified	ICD-9-CM	Diagnosis
312.81	Conduct disorder, childhood onset type	ICD-9-CM	Diagnosis
312.82	Conduct disorder, adolescent onset type	ICD-9-CM	Diagnosis
312.89	Other conduct disorder	ICD-9-CM	Diagnosis
312.9	Unspecified disturbance of conduct	ICD-9-CM	Diagnosis
313	Disturbance of emotions specific to childhood and adolescence	ICD-9-CM	Diagnosis
313.0	Overanxious disorder specific to childhood and adolescence	ICD-9-CM	Diagnosis
313.1	Misery and unhappiness disorder specific to childhood and adolescence	ICD-9-CM	Diagnosis

Appendix G. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) Healthcare Common Procedure Coding System (HCPCS), Current Procedural Terminology, Second Edition (CPT-2), and Current Procedural Terminology, Fourth Edition (CPT-4), Diagnosis and Procedure Codes Used to Define Baseline Characteristics in this Request

Code	Description	Code Type	Code Category
313.2	Sensitivity shyness and social withdrawal disorder specific to childhood and adolescence	ICD-9-CM	Diagnosis
313.21	Shyness disorder of childhood	ICD-9-CM	Diagnosis
313.22	Introverted disorder of childhood	ICD-9-CM	Diagnosis
313.23	Selective mutism	ICD-9-CM	Diagnosis
313.3	Relationship problems specific to childhood and adolescence	ICD-9-CM	Diagnosis
313.8	Other or mixed emotional disturbances of childhood or adolescence	ICD-9-CM	Diagnosis
313.81	Oppositional defiant disorder	ICD-9-CM	Diagnosis
313.82	Identity disorder of childhood or adolescence	ICD-9-CM	Diagnosis
313.83	Academic underachievement disorder of childhood or adolescence	ICD-9-CM	Diagnosis
313.89	Other emotional disturbances of childhood or adolescence	ICD-9-CM	Diagnosis
313.9	Unspecified emotional disturbance of childhood or adolescence	ICD-9-CM	Diagnosis
315	Specific delays in development	ICD-9-CM	Diagnosis
315.0	Developmental reading disorder	ICD-9-CM	Diagnosis
315.00	Developmental reading disorder, unspecified	ICD-9-CM	Diagnosis
315.01	Alexia	ICD-9-CM	Diagnosis
315.02	Developmental dyslexia	ICD-9-CM	Diagnosis
315.09	Other specific developmental reading disorder	ICD-9-CM	Diagnosis
315.1	Mathematics disorder	ICD-9-CM	Diagnosis
315.2	Other specific developmental learning difficulties	ICD-9-CM	Diagnosis
315.3	Developmental speech or language disorder	ICD-9-CM	Diagnosis
315.31	Expressive language disorder	ICD-9-CM	Diagnosis
315.32	Mixed receptive-expressive language disorder	ICD-9-CM	Diagnosis
315.34	Speech and language developmental delay due to hearing loss	ICD-9-CM	Diagnosis
315.35	Childhood onset fluency disorder	ICD-9-CM	Diagnosis
315.39	Other developmental speech or language disorder	ICD-9-CM	Diagnosis
315.4	Developmental coordination disorder	ICD-9-CM	Diagnosis
315.5	Mixed development disorder	ICD-9-CM	Diagnosis
315.8	Other specified delays in development	ICD-9-CM	Diagnosis
315.9	Unspecified delay in development	ICD-9-CM	Diagnosis
316	Psychic factors associated with diseases classified elsewhere	ICD-9-CM	Diagnosis
330	Cerebral degenerations usually manifest in childhood	ICD-9-CM	Diagnosis
330.0	Leukodystrophy	ICD-9-CM	Diagnosis
330.1	Cerebral lipidoses	ICD-9-CM	Diagnosis
330.2	Cerebral degeneration in generalized lipidoses	ICD-9-CM	Diagnosis
330.3	Cerebral degeneration of childhood in other diseases classified elsewhere	ICD-9-CM	Diagnosis
330.8	Other specified cerebral degenerations in childhood	ICD-9-CM	Diagnosis
330.9	Unspecified cerebral degeneration in childhood	ICD-9-CM	Diagnosis
331	Other cerebral degenerations	ICD-9-CM	Diagnosis
331.0	Alzheimer's disease	ICD-9-CM	Diagnosis
331.1	Frontotemporal dementia	ICD-9-CM	Diagnosis
331.11	Pick's disease	ICD-9-CM	Diagnosis

Appendix G. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) Healthcare Common Procedure Coding System (HCPCS), Current Procedural Terminology, Second Edition (CPT-2), and Current Procedural Terminology, Fourth Edition (CPT-4), Diagnosis and Procedure Codes Used to Define Baseline Characteristics in this Request

Code	Description	Code Type	Code Category
331.19	Other frontotemporal dementia	ICD-9-CM	Diagnosis
331.2	Senile degeneration of brain	ICD-9-CM	Diagnosis
331.3	Communicating hydrocephalus	ICD-9-CM	Diagnosis
331.4	Obstructive hydrocephalus	ICD-9-CM	Diagnosis
331.5	Idiopathic normal pressure hydrocephalus (INPH)	ICD-9-CM	Diagnosis
331.6	Corticobasal degeneration	ICD-9-CM	Diagnosis
331.7	Cerebral degeneration in diseases classified elsewhere	ICD-9-CM	Diagnosis
331.8	Other cerebral degeneration	ICD-9-CM	Diagnosis
331.81	Reye's syndrome	ICD-9-CM	Diagnosis
331.82	Dementia with lewy bodies	ICD-9-CM	Diagnosis
331.83	Mild cognitive impairment, so stated	ICD-9-CM	Diagnosis
331.89	Other cerebral degeneration	ICD-9-CM	Diagnosis
331.9	Cerebral degeneration, unspecified	ICD-9-CM	Diagnosis
333.99	Other extrapyramidal disease and abnormal movement disorder	ICD-9-CM	Diagnosis
348.3	Encephalopathy, not elsewhere classified	ICD-9-CM	Diagnosis
348.30	Encephalopathy, unspecified	ICD-9-CM	Diagnosis
348.31	Metabolic encephalopathy	ICD-9-CM	Diagnosis
348.39	Other encephalopathy	ICD-9-CM	Diagnosis
780.1	Hallucinations	ICD-9-CM	Diagnosis
L8679	Implantable neurostimulator, pulse generator, any type	HCPCS	Procedure
L8680	Implantable neurostimulator electrode, each	HCPCS	Procedure
L8681	Patient programmer (external) for use with implantable programmable neurostimulator pulse generator, replacement only	HCPCS	Procedure
L8682	Implantable neurostimulator radiofrequency receiver	HCPCS	Procedure
L8683	Radiofrequency transmitter (external) for use with implantable neurostimulator radiofrequency receiver	HCPCS	Procedure
L8685	Implantable neurostimulator pulse generator, single array, rechargeable, includes extension	HCPCS	Procedure
L8686	Implantable neurostimulator pulse generator, single array, nonrechargeable, includes extension	HCPCS	Procedure
L8687	Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension	HCPCS	Procedure
L8688	Implantable neurostimulator pulse generator, dual array, nonrechargeable, includes extension	HCPCS	Procedure
L8689	External recharging system for battery (internal) for use with implantable neurostimulator, replacement only	HCPCS	Procedure
61885	Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to a single electrode array	CPT-4	Procedure
61886	Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to 2 or more electrode arrays	CPT-4	Procedure
61888	Revision or removal of cranial neurostimulator pulse generator or receiver	CPT-4	Procedure
64553	Percutaneous implantation of neurostimulator electrode array; cranial nerve	CPT-4	Procedure

Appendix G. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) Healthcare Common Procedure Coding System (HCPCS), Current Procedural Terminology, Second Edition (CPT-2), and Current Procedural Terminology, Fourth Edition (CPT-4), Diagnosis and Procedure Codes Used to Define Baseline Characteristics in this Request

Code	Description	Code Type	Code Category
64568	Incision for implantation of cranial nerve (eg, vagus nerve) neurostimulator electrode array and pulse generator	CPT-4	Procedure
64569	Revision or replacement of cranial nerve (eg, vagus nerve) neurostimulator electrode array, including connection to existing pulse generator	CPT-4	Procedure
64570	Removal of cranial nerve (eg, vagus nerve) neurostimulator electrode array and pulse generator	CPT-4	Procedure
64585	Revision or removal of peripheral neurostimulator electrode array	CPT-4	Procedure
90867	Therapeutic repetitive transcranial magnetic stimulation (TMS) treatment; initial, including cortical mapping, motor threshold determination, delivery and management	CPT-4	Procedure
90868	Therapeutic repetitive transcranial magnetic stimulation (TMS) treatment; subsequent delivery and management, per session	CPT-4	Procedure
90869	Therapeutic repetitive transcranial magnetic stimulation (TMS) treatment; subsequent motor threshold re-determination with delivery and management	CPT-4	Procedure
90870	Electroconvulsive therapy (includes necessary monitoring)	CPT-4	Procedure
90871	Electroconvulsive therapy (includes necessary monitoring); multiple seizures, per day	CPT-4	Procedure
95970	Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude, pulse duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); simple or complex brain, spinal cord, or peripheral (ie, cranial nerve, peripheral nerve, sacral nerve, neuromuscular) neurostimulator pulse generator/transmitter, without reprogramming	CPT-4	Procedure
95971	Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude, pulse duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); simple spinal cord, or peripheral (ie, peripheral nerve, sacral nerve, neuromuscular) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming	CPT-4	Procedure
95974	Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude, pulse duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); complex cranial nerve neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming, with or without nerve interface testing, first hour	CPT-4	Procedure
95975	Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude, pulse duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); complex cranial nerve neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming, each additional 30 minutes after first hour (List separately in addition to code for primary procedure)	CPT-4	Procedure

Sleep Disorders

Appendix G. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) Healthcare Common Procedure Coding System (HCPCS), Current Procedural Terminology, Second Edition (CPT-2), and Current Procedural Terminology, Fourth Edition (CPT-4), Diagnosis and Procedure Codes Used to Define Baseline Characteristics in this Request

Code	Description	Code Type	Code Category
307.4	Specific disorders of sleep of nonorganic origin	ICD-9-CM	Diagnosis
307.40	Nonorganic sleep disorder, unspecified	ICD-9-CM	Diagnosis
307.41	Transient disorder of initiating or maintaining sleep	ICD-9-CM	Diagnosis
307.42	Persistent disorder of initiating or maintaining sleep	ICD-9-CM	Diagnosis
307.43	Transient disorder of initiating or maintaining wakefulness	ICD-9-CM	Diagnosis
307.44	Persistent disorder of initiating or maintaining wakefulness	ICD-9-CM	Diagnosis
307.45	Circadian rhythm sleep disorder of nonorganic origin	ICD-9-CM	Diagnosis
307.46	Sleep arousal disorder	ICD-9-CM	Diagnosis
307.47	Other dysfunctions of sleep stages or arousal from sleep	ICD-9-CM	Diagnosis
307.48	Repetitive intrusions of sleep	ICD-9-CM	Diagnosis
307.49	Other specific disorders of sleep of nonorganic origin	ICD-9-CM	Diagnosis
347	Cataplexy and narcolepsy	ICD-9-CM	Diagnosis
347.0	Narcolepsy	ICD-9-CM	Diagnosis
347.00	Narcolepsy, without cataplexy	ICD-9-CM	Diagnosis
347.01	Narcolepsy, with cataplexy	ICD-9-CM	Diagnosis
347.1	Narcolepsy in conditions classified elsewhere	ICD-9-CM	Diagnosis
347.10	Narcolepsy in conditions classified elsewhere, without cataplexy	ICD-9-CM	Diagnosis
347.11	Narcolepsy in conditions classified elsewhere, with cataplexy	ICD-9-CM	Diagnosis
780.5	Sleep disturbances	ICD-9-CM	Diagnosis
780.50	Sleep disturbances, unspecified	ICD-9-CM	Diagnosis
780.51	Insomnia with sleep apnea, unspecified	ICD-9-CM	Diagnosis
780.52	Insomnia, unspecified	ICD-9-CM	Diagnosis
780.53	Hypersomnia, with sleep apnea, unspecified	ICD-9-CM	Diagnosis
780.54	Hypersomnia, unspecified	ICD-9-CM	Diagnosis
780.55	Disruption of 24 hour sleep wake cycle, unspecified	ICD-9-CM	Diagnosis
780.56	Dysfunctions associated with sleep stages or arousal from sleep	ICD-9-CM	Diagnosis
780.57	Unspecified sleep apnea	ICD-9-CM	Diagnosis
780.58	Sleep related movement disorder, unspecified	ICD-9-CM	Diagnosis
780.59	Other sleep disturbances	ICD-9-CM	Diagnosis
Fibromyalgia			
307.80	Psychogenic pain, site unspecified	ICD-9-CM	Diagnosis
307.89	Other pain disorders related to psychological factors	ICD-9-CM	Diagnosis
712.97	Unspecified crystal arthropathy, ankle and foot	ICD-9-CM	Diagnosis
729.1	Myalgia and myositis, unspecified	ICD-9-CM	Diagnosis
780.96	Generalized pain	ICD-9-CM	Diagnosis
Diabetes			
249.00	Secondary diabetes mellitus without mention of complication, not stated as uncontrolled, or unspecified	ICD-9-CM	Diagnosis
249.01	Secondary diabetes mellitus without mention of complication, uncontrolled	ICD-9-CM	Diagnosis
249.10	Secondary diabetes mellitus with ketoacidosis, not stated as uncontrolled, or unspecified	ICD-9-CM	Diagnosis
249.11	Secondary diabetes mellitus with ketoacidosis, uncontrolled	ICD-9-CM	Diagnosis

Appendix G. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) Healthcare Common Procedure Coding System (HCPCS), Current Procedural Terminology, Second Edition (CPT-2), and Current Procedural Terminology, Fourth Edition (CPT-4), Diagnosis and Procedure Codes Used to Define Baseline Characteristics in this Request

Code	Description	Code Type	Code Category
249.20	Secondary diabetes mellitus with hyperosmolarity, not stated as uncontrolled, or unspecified	ICD-9-CM	Diagnosis
249.21	Secondary diabetes mellitus with hyperosmolarity, uncontrolled	ICD-9-CM	Diagnosis
249.30	Secondary diabetes mellitus with other coma, not stated as uncontrolled, or unspecified	ICD-9-CM	Diagnosis
249.31	Secondary diabetes mellitus with other coma, uncontrolled	ICD-9-CM	Diagnosis
249.40	Secondary diabetes mellitus with renal manifestations, not stated as uncontrolled, or unspecified	ICD-9-CM	Diagnosis
249.41	Secondary diabetes mellitus with renal manifestations, uncontrolled	ICD-9-CM	Diagnosis
249.50	Secondary diabetes mellitus with ophthalmic manifestations, not stated as uncontrolled, or unspecified	ICD-9-CM	Diagnosis
249.51	Secondary diabetes mellitus with ophthalmic manifestations, uncontrolled	ICD-9-CM	Diagnosis
249.60	Secondary diabetes mellitus with neurological manifestations, not stated as uncontrolled, or unspecified	ICD-9-CM	Diagnosis
249.61	Secondary diabetes mellitus with neurological manifestations, uncontrolled	ICD-9-CM	Diagnosis
249.70	Secondary diabetes mellitus with peripheral circulatory disorders, not stated as uncontrolled, or unspecified	ICD-9-CM	Diagnosis
249.71	Secondary diabetes mellitus with peripheral circulatory disorders, uncontrolled	ICD-9-CM	Diagnosis
249.80	Secondary diabetes mellitus with other specified manifestations, not stated as uncontrolled, or unspecified	ICD-9-CM	Diagnosis
249.81	Secondary diabetes mellitus with other specified manifestations, uncontrolled	ICD-9-CM	Diagnosis
249.90	Secondary diabetes mellitus with unspecified complication, not stated as uncontrolled, or unspecified	ICD-9-CM	Diagnosis
249.91	Secondary diabetes mellitus with unspecified complication, uncontrolled	ICD-9-CM	Diagnosis
250.00	Diabetes mellitus without mention of complication, type II or unspecified type, not stated as uncontrolled	ICD-9-CM	Diagnosis
250.01	Diabetes mellitus without mention of complication, type I [juvenile type], not stated as uncontrolled	ICD-9-CM	Diagnosis
250.02	Diabetes mellitus without mention of complication, type II or unspecified type, uncontrolled	ICD-9-CM	Diagnosis
250.03	Diabetes mellitus without mention of complication, type I [juvenile type], uncontrolled	ICD-9-CM	Diagnosis
250.10	Diabetes with ketoacidosis, type II or unspecified type, not stated as uncontrolled	ICD-9-CM	Diagnosis
250.11	Diabetes with ketoacidosis, type I [juvenile type], not stated as uncontrolled	ICD-9-CM	Diagnosis
250.12	Diabetes with ketoacidosis, type II or unspecified type, uncontrolled	ICD-9-CM	Diagnosis
250.13	Diabetes with ketoacidosis, type I [juvenile type], uncontrolled	ICD-9-CM	Diagnosis
250.20	Diabetes with hyperosmolarity, type II or unspecified type, not stated as uncontrolled	ICD-9-CM	Diagnosis
250.21	Diabetes with hyperosmolarity, type I [juvenile type], not stated as uncontrolled	ICD-9-CM	Diagnosis
250.22	Diabetes with hyperosmolarity, type II or unspecified type, uncontrolled	ICD-9-CM	Diagnosis
250.23	Diabetes with hyperosmolarity, type I [juvenile type], uncontrolled	ICD-9-CM	Diagnosis

Appendix G. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) Healthcare Common Procedure Coding System (HCPCS), Current Procedural Terminology, Second Edition (CPT-2), and Current Procedural Terminology, Fourth Edition (CPT-4), Diagnosis and Procedure Codes Used to Define Baseline Characteristics in this Request

Code	Description	Code Type	Code Category
250.30	Diabetes with other coma, type II or unspecified type, not stated as uncontrolled	ICD-9-CM	Diagnosis
250.31	Diabetes with other coma, type I [juvenile type], not stated as uncontrolled	ICD-9-CM	Diagnosis
250.32	Diabetes with other coma, type II or unspecified type, uncontrolled	ICD-9-CM	Diagnosis
250.33	Diabetes with other coma, type I [juvenile type], uncontrolled	ICD-9-CM	Diagnosis
250.40	Diabetes with renal manifestations, type II or unspecified type, not stated as uncontrolled	ICD-9-CM	Diagnosis
250.41	Diabetes with renal manifestations, type I [juvenile type], not stated as uncontrolled	ICD-9-CM	Diagnosis
250.42	Diabetes with renal manifestations, type II or unspecified type, uncontrolled	ICD-9-CM	Diagnosis
250.43	Diabetes with renal manifestations, type I [juvenile type], uncontrolled	ICD-9-CM	Diagnosis
250.50	Diabetes with ophthalmic manifestations, type II or unspecified type, not stated as uncontrolled	ICD-9-CM	Diagnosis
250.51	Diabetes with ophthalmic manifestations, type I [juvenile type], not stated as uncontrolled	ICD-9-CM	Diagnosis
250.52	Diabetes with ophthalmic manifestations, type II or unspecified type, uncontrolled	ICD-9-CM	Diagnosis
250.53	Diabetes with ophthalmic manifestations, type I [juvenile type], uncontrolled	ICD-9-CM	Diagnosis
250.60	Diabetes with neurological manifestations, type II or unspecified type, not stated as uncontrolled	ICD-9-CM	Diagnosis
250.61	Diabetes with neurological manifestations, type I [juvenile type], not stated as uncontrolled	ICD-9-CM	Diagnosis
250.62	Diabetes with neurological manifestations, type II or unspecified type, uncontrolled	ICD-9-CM	Diagnosis
250.63	Diabetes with neurological manifestations, type I [juvenile type], uncontrolled	ICD-9-CM	Diagnosis
250.70	Diabetes with peripheral circulatory disorders, type II or unspecified type, not stated as uncontrolled	ICD-9-CM	Diagnosis
250.71	Diabetes with peripheral circulatory disorders, type I [juvenile type], not stated as uncontrolled	ICD-9-CM	Diagnosis
250.72	Diabetes with peripheral circulatory disorders, type II or unspecified type, uncontrolled	ICD-9-CM	Diagnosis
250.73	Diabetes with peripheral circulatory disorders, type I [juvenile type], uncontrolled	ICD-9-CM	Diagnosis
250.80	Diabetes with other specified manifestations, type II or unspecified type, not stated as uncontrolled	ICD-9-CM	Diagnosis
250.81	Diabetes with other specified manifestations, type I [juvenile type], not stated as uncontrolled	ICD-9-CM	Diagnosis
250.82	Diabetes with other specified manifestations, type II or unspecified type, uncontrolled	ICD-9-CM	Diagnosis
250.83	Diabetes with other specified manifestations, type I [juvenile type], uncontrolled	ICD-9-CM	Diagnosis
250.90	Diabetes with unspecified complication, type II or unspecified type, not stated as uncontrolled	ICD-9-CM	Diagnosis

Appendix G. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) Healthcare Common Procedure Coding System (HCPCS), Current Procedural Terminology, Second Edition (CPT-2), and Current Procedural Terminology, Fourth Edition (CPT-4), Diagnosis and Procedure Codes Used to Define Baseline Characteristics in this Request

Code	Description	Code Type	Code Category
250.91	Diabetes with unspecified complication, type I [juvenile type], not stated as uncontrolled	ICD-9-CM	Diagnosis
250.92	Diabetes with unspecified complication, type II or unspecified type, uncontrolled	ICD-9-CM	Diagnosis
250.93	Diabetes with unspecified complication, type I [juvenile type], uncontrolled	ICD-9-CM	Diagnosis
362.01	Background diabetic retinopathy	ICD-9-CM	Diagnosis
362.02	Proliferative diabetic retinopathy	ICD-9-CM	Diagnosis
362.03	Nonproliferative diabetic retinopathy NOS	ICD-9-CM	Diagnosis
362.04	Mild nonproliferative diabetic retinopathy	ICD-9-CM	Diagnosis
362.05	Moderate nonproliferative diabetic retinopathy	ICD-9-CM	Diagnosis
362.06	Severe nonproliferative diabetic retinopathy	ICD-9-CM	Diagnosis
366.41	Diabetic cataract	ICD-9-CM	Diagnosis
Hypertension			
362.11	Hypertensive retinopathy	ICD-9-CM	Diagnosis
401.0	Essential hypertension, malignant	ICD-9-CM	Diagnosis
401.1	Essential hypertension, benign	ICD-9-CM	Diagnosis
401.9	Unspecified essential hypertension	ICD-9-CM	Diagnosis
402.00	Malignant hypertensive heart disease without heart failure	ICD-9-CM	Diagnosis
402.01	Malignant hypertensive heart disease with heart failure	ICD-9-CM	Diagnosis
402.10	Benign hypertensive heart disease without heart failure	ICD-9-CM	Diagnosis
402.11	Benign hypertensive heart disease with heart failure	ICD-9-CM	Diagnosis
402.90	Unspecified hypertensive heart disease without heart failure	ICD-9-CM	Diagnosis
402.91	Hypertensive heart disease, unspecified, with heart failure	ICD-9-CM	Diagnosis
403.00	Hypertensive chronic kidney disease, malignant, with chronic kidney disease stage I through stage IV, or unspecified	ICD-9-CM	Diagnosis
403.01	Hypertensive chronic kidney disease, malignant, with chronic kidney disease stage V or end stage renal disease	ICD-9-CM	Diagnosis
403.10	Hypertensive chronic kidney disease, benign, with chronic kidney disease stage I through stage IV, or unspecified	ICD-9-CM	Diagnosis
403.11	Hypertensive chronic kidney disease, benign, with chronic kidney disease stage V or end stage renal disease	ICD-9-CM	Diagnosis
403.90	Hypertensive chronic kidney disease, unspecified, with chronic kidney disease stage I through stage IV, or unspecified	ICD-9-CM	Diagnosis
403.91	Hypertensive chronic kidney disease, unspecified, with chronic kidney disease stage V or end stage renal disease	ICD-9-CM	Diagnosis
404.00	Hypertensive heart and chronic kidney disease, malignant, without heart failure and with chronic kidney disease stage I through stage IV, or unspecified	ICD-9-CM	Diagnosis
404.01	Hypertensive heart and chronic kidney disease, malignant, with heart failure and with chronic kidney disease stage I through stage IV, or unspecified	ICD-9-CM	Diagnosis
404.02	Hypertensive heart and chronic kidney disease, malignant, without heart failure and with chronic kidney disease stage V or end stage renal disease	ICD-9-CM	Diagnosis

Appendix G. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) Healthcare Common Procedure Coding System (HCPCS), Current Procedural Terminology, Second Edition (CPT-2), and Current Procedural Terminology, Fourth Edition (CPT-4), Diagnosis and Procedure Codes Used to Define Baseline Characteristics in this Request

Code	Description	Code Type	Code Category
404.03	Hypertensive heart and chronic kidney disease, malignant, with heart failure and with chronic kidney disease stage V or end stage renal disease	ICD-9-CM	Diagnosis
404.10	Hypertensive heart and chronic kidney disease, benign, without heart failure and with chronic kidney disease stage I through stage IV, or unspecified	ICD-9-CM	Diagnosis
404.11	Hypertensive heart and chronic kidney disease, benign, with heart failure and with chronic kidney disease stage I through stage IV, or unspecified	ICD-9-CM	Diagnosis
404.12	Hypertensive heart and chronic kidney disease, benign, without heart failure and with chronic kidney disease stage V or end stage renal disease	ICD-9-CM	Diagnosis
404.13	Hypertensive heart and chronic kidney disease, benign, with heart failure and chronic kidney disease stage V or end stage renal disease	ICD-9-CM	Diagnosis
404.90	Hypertensive heart and chronic kidney disease, unspecified, without heart failure and with chronic kidney disease stage I through stage IV, or unspecified	ICD-9-CM	Diagnosis
404.91	Hypertensive heart and chronic kidney disease, unspecified, with heart failure and with chronic kidney disease stage I through stage IV, or unspecified	ICD-9-CM	Diagnosis
404.92	Hypertensive heart and chronic kidney disease, unspecified, without heart failure and with chronic kidney disease stage V or end stage renal disease	ICD-9-CM	Diagnosis
404.93	Hypertensive heart and chronic kidney disease, unspecified, with heart failure and chronic kidney disease stage V or end stage renal disease	ICD-9-CM	Diagnosis
405.01	Secondary renovascular hypertension, malignant	ICD-9-CM	Diagnosis
405.09	Other secondary hypertension, malignant	ICD-9-CM	Diagnosis
405.11	Secondary renovascular hypertension, benign	ICD-9-CM	Diagnosis
405.19	Other secondary hypertension, benign	ICD-9-CM	Diagnosis
405.91	Secondary renovascular hypertension, unspecified	ICD-9-CM	Diagnosis
405.99	Other secondary hypertension, unspecified	ICD-9-CM	Diagnosis
437.2	Hypertensive encephalopathy	ICD-9-CM	Diagnosis
Other Pain Conditions			
338.0	Central pain syndrome	ICD-9-CM	Diagnosis
338.1	Acute pain	ICD-9-CM	Diagnosis
338.11	Acute pain due to trauma	ICD-9-CM	Diagnosis
338.12	Acute post-thoracotomy pain	ICD-9-CM	Diagnosis
338.18	Other acute postoperative pain	ICD-9-CM	Diagnosis
338.19	Other acute pain	ICD-9-CM	Diagnosis
338.2	Chronic pain	ICD-9-CM	Diagnosis
338.21	Chronic pain due to trauma	ICD-9-CM	Diagnosis
338.22	Chronic post-thoracotomy pain	ICD-9-CM	Diagnosis
338.28	Other chronic postoperative pain	ICD-9-CM	Diagnosis
338.29	Other chronic pain	ICD-9-CM	Diagnosis
338.3	Neoplasm related pain (acute) (chronic)	ICD-9-CM	Diagnosis
338.4	Chronic pain syndrome	ICD-9-CM	Diagnosis
Attention Deficit/Hyperactivity Disorder			
314	Hyperkinetic syndrome of childhood	ICD-9-CM	Diagnosis
314.0	Attention deficit disorder of childhood	ICD-9-CM	Diagnosis

Appendix G. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) Healthcare Common Procedure Coding System (HCPCS), Current Procedural Terminology, Second Edition (CPT-2), and Current Procedural Terminology, Fourth Edition (CPT-4), Diagnosis and Procedure Codes Used to Define Baseline Characteristics in this Request

Code	Description	Code Type	Code Category
314.00	Attention deficit disorder without mention of hyperactivity	ICD-9-CM	Diagnosis
314.01	Attention deficit disorder with hyperactivity	ICD-9-CM	Diagnosis
314.1	Hyperkinesis with developmental delay	ICD-9-CM	Diagnosis
314.2	Hyperkinetic conduct disorder	ICD-9-CM	Diagnosis
314.8	Other specified manifestations of hyperkinetic syndrome	ICD-9-CM	Diagnosis
314.9	Unspecified hyperkinetic syndrome	ICD-9-CM	Diagnosis
Alcohol or Drug Abuse/Dependence			
291	Alcohol-induced mental disorders	ICD-9-CM	Diagnosis
291.1	Alcohol-induced persisting amnesic disorder	ICD-9-CM	Diagnosis
291.2	Alcohol-induced persisting dementia	ICD-9-CM	Diagnosis
291.3	Alcohol-induced psychotic disorder with hallucinations	ICD-9-CM	Diagnosis
291.4	Idiosyncratic alcohol intoxication	ICD-9-CM	Diagnosis
291.5	Alcohol-induced psychotic disorder with delusions	ICD-9-CM	Diagnosis
291.8	Other specified alcohol-induced mental disorders	ICD-9-CM	Diagnosis
291.81	Alcohol withdrawal	ICD-9-CM	Diagnosis
291.82	Alcohol induced sleep disorders	ICD-9-CM	Diagnosis
291.89	Other specified alcohol-induced mental disorders	ICD-9-CM	Diagnosis
291.9	Unspecified alcohol-induced mental disorders	ICD-9-CM	Diagnosis
292	Drug-induced mental disorders	ICD-9-CM	Diagnosis
292.1	Drug-induced psychotic disorder	ICD-9-CM	Diagnosis
292.11	Drug-induced psychotic disorder with delusions	ICD-9-CM	Diagnosis
292.12	Drug-induced psychotic disorder with hallucinations	ICD-9-CM	Diagnosis
292.2	Pathological drug intoxication	ICD-9-CM	Diagnosis
292.8	Other specified drug-induced mental disorders	ICD-9-CM	Diagnosis
292.82	Drug-induced persisting dementia	ICD-9-CM	Diagnosis
292.83	Drug-induced persisting amnesic disorder	ICD-9-CM	Diagnosis
292.84	Drug-induced mood disorder	ICD-9-CM	Diagnosis
292.85	Drug induced sleep disorders	ICD-9-CM	Diagnosis
303	Alcohol dependence syndrome	ICD-9-CM	Diagnosis
303.0	Acute alcoholic intoxication	ICD-9-CM	Diagnosis
303.00	Acute alcoholic intoxication, unspecified	ICD-9-CM	Diagnosis
303.01	Acute alcoholic intoxication, continuous	ICD-9-CM	Diagnosis
303.02	Acute alcoholic intoxication, episodic	ICD-9-CM	Diagnosis
303.03	Acute alcoholic intoxication, in remission	ICD-9-CM	Diagnosis
303.9	Other and unspecified alcohol dependence	ICD-9-CM	Diagnosis
303.90	Other and unspecified alcohol dependence, unspecified	ICD-9-CM	Diagnosis
303.91	Other and unspecified alcohol dependence, continuous	ICD-9-CM	Diagnosis
303.92	Other and unspecified alcohol dependence, episodic	ICD-9-CM	Diagnosis
303.93	Other and unspecified alcohol dependence, in remission	ICD-9-CM	Diagnosis
304	Drug dependence	ICD-9-CM	Diagnosis
304.0	Opioid type dependence	ICD-9-CM	Diagnosis
304.00	Opioid type dependence, unspecified	ICD-9-CM	Diagnosis

Appendix G. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) Healthcare Common Procedure Coding System (HCPCS), Current Procedural Terminology, Second Edition (CPT-2), and Current Procedural Terminology, Fourth Edition (CPT-4), Diagnosis and Procedure Codes Used to Define Baseline Characteristics in this Request

Code	Description	Code Type	Code Category
304.01	Opioid type dependence, continuous	ICD-9-CM	Diagnosis
304.02	Opioid type dependence, episodic	ICD-9-CM	Diagnosis
304.03	Opioid type dependence, in remission	ICD-9-CM	Diagnosis
304.1	Sedative, hypnotic or anxiolytic dependence	ICD-9-CM	Diagnosis
304.10	Sedative, hypnotic or anxiolytic dependence, unspecified	ICD-9-CM	Diagnosis
304.11	Sedative, hypnotic or anxiolytic dependence, continuous	ICD-9-CM	Diagnosis
304.12	Sedative, hypnotic or anxiolytic dependence, episodic	ICD-9-CM	Diagnosis
304.13	Sedative, hypnotic or anxiolytic dependence, in remission	ICD-9-CM	Diagnosis
304.2	Cocaine dependence	ICD-9-CM	Diagnosis
304.20	Cocaine dependence, unspecified	ICD-9-CM	Diagnosis
304.21	Cocaine dependence, continuous	ICD-9-CM	Diagnosis
304.22	Cocaine dependence, episodic	ICD-9-CM	Diagnosis
304.23	Cocaine dependence, in remission	ICD-9-CM	Diagnosis
304.3	Cannabis dependence	ICD-9-CM	Diagnosis
304.30	Cannabis dependence, unspecified	ICD-9-CM	Diagnosis
304.31	Cannabis dependence, continuous	ICD-9-CM	Diagnosis
304.32	Cannabis dependence, episodic	ICD-9-CM	Diagnosis
304.33	Cannabis dependence, in remission	ICD-9-CM	Diagnosis
304.4	Amphetamine and other psychostimulant dependence	ICD-9-CM	Diagnosis
304.40	Amphetamine and other psychostimulant dependence, unspecified	ICD-9-CM	Diagnosis
304.41	Amphetamine and other psychostimulant dependence, continuous	ICD-9-CM	Diagnosis
304.42	Amphetamine and other psychostimulant dependence, episodic	ICD-9-CM	Diagnosis
304.43	Amphetamine and other psychostimulant dependence, in remission	ICD-9-CM	Diagnosis
304.5	Hallucinogen dependence	ICD-9-CM	Diagnosis
304.50	Hallucinogen dependence, unspecified	ICD-9-CM	Diagnosis
304.51	Hallucinogen dependence, continuous	ICD-9-CM	Diagnosis
304.52	Hallucinogen dependence, episodic	ICD-9-CM	Diagnosis
304.53	Hallucinogen dependence, in remission	ICD-9-CM	Diagnosis
304.6	Other specified drug dependence	ICD-9-CM	Diagnosis
304.60	Other specified drug dependence, unspecified	ICD-9-CM	Diagnosis
304.61	Other specified drug dependence, continuous	ICD-9-CM	Diagnosis
304.62	Other specified drug dependence, episodic	ICD-9-CM	Diagnosis
304.63	Other specified drug dependence, in remission	ICD-9-CM	Diagnosis
304.7	Combinations of opioid type drug with any other drug dependence	ICD-9-CM	Diagnosis
304.70	Combinations of opioid type drug with any other drug dependence, unspecified	ICD-9-CM	Diagnosis
304.71	Combinations of opioid type drug with any other drug dependence, continuous	ICD-9-CM	Diagnosis
304.72	Combinations of opioid type drug with any other drug dependence, episodic	ICD-9-CM	Diagnosis
304.73	Combinations of opioid type drug with any other drug dependence, in remission	ICD-9-CM	Diagnosis
304.8	Combinations of drug dependence excluding opioid type drug	ICD-9-CM	Diagnosis
304.80	Combinations of drug dependence excluding opioid type drug, unspecified	ICD-9-CM	Diagnosis
304.81	Combinations of drug dependence excluding opioid type drug, continuous	ICD-9-CM	Diagnosis

Appendix G. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) Healthcare Common Procedure Coding System (HCPCS), Current Procedural Terminology, Second Edition (CPT-2), and Current Procedural Terminology, Fourth Edition (CPT-4), Diagnosis and Procedure Codes Used to Define Baseline Characteristics in this Request

Code	Description	Code Type	Code Category
304.82	Combinations of drug dependence excluding opioid type drug, episodic	ICD-9-CM	Diagnosis
304.83	Combinations of drug dependence excluding opioid type drug, in remission	ICD-9-CM	Diagnosis
304.9	Unspecified drug dependence	ICD-9-CM	Diagnosis
304.90	Unspecified drug dependence, unspecified	ICD-9-CM	Diagnosis
304.91	Unspecified drug dependence, continuous	ICD-9-CM	Diagnosis
304.92	Unspecified drug dependence, episodic	ICD-9-CM	Diagnosis
304.93	Unspecified drug dependence, in remission	ICD-9-CM	Diagnosis
305	Nondependent abuse of drugs	ICD-9-CM	Diagnosis
305.0	Nondependent alcohol abuse	ICD-9-CM	Diagnosis
305.00	Nondependent alcohol abuse, unspecified	ICD-9-CM	Diagnosis
305.01	Nondependent alcohol abuse, continuous	ICD-9-CM	Diagnosis
305.02	Nondependent alcohol abuse, episodic	ICD-9-CM	Diagnosis
305.03	Nondependent alcohol abuse, in remission	ICD-9-CM	Diagnosis
305.2	Nondependent cannabis abuse	ICD-9-CM	Diagnosis
305.20	Nondependent cannabis abuse, unspecified	ICD-9-CM	Diagnosis
305.21	Nondependent cannabis abuse, continuous	ICD-9-CM	Diagnosis
305.22	Nondependent cannabis abuse, episodic	ICD-9-CM	Diagnosis
305.23	Nondependent cannabis abuse, in remission	ICD-9-CM	Diagnosis
305.3	Nondependent hallucinogen abuse	ICD-9-CM	Diagnosis
305.30	Nondependent hallucinogen abuse, unspecified	ICD-9-CM	Diagnosis
305.31	Nondependent hallucinogen abuse, continuous	ICD-9-CM	Diagnosis
305.32	Nondependent hallucinogen abuse, episodic	ICD-9-CM	Diagnosis
305.33	Nondependent hallucinogen abuse, in remission	ICD-9-CM	Diagnosis
305.4	Nondependent sedative, hypnotic or anxiolytic abuse	ICD-9-CM	Diagnosis
305.40	Nondependent sedative, hypnotic or anxiolytic abuse, unspecified	ICD-9-CM	Diagnosis
305.41	Nondependent sedative hypnotic or anxiolytic abuse, continuous	ICD-9-CM	Diagnosis
305.42	Nondependent sedative, hypnotic or anxiolytic abuse, episodic	ICD-9-CM	Diagnosis
305.43	Nondependent sedative, hypnotic or anxiolytic abuse, in remission	ICD-9-CM	Diagnosis
305.5	Nondependent opioid abuse	ICD-9-CM	Diagnosis
305.50	Nondependent opioid abuse, unspecified	ICD-9-CM	Diagnosis
305.51	Nondependent opioid abuse, continuous	ICD-9-CM	Diagnosis
305.52	Nondependent opioid abuse, episodic	ICD-9-CM	Diagnosis
305.53	Nondependent opioid abuse, in remission	ICD-9-CM	Diagnosis
305.6	Nondependent cocaine abuse	ICD-9-CM	Diagnosis
305.60	Nondependent cocaine abuse, unspecified	ICD-9-CM	Diagnosis
305.61	Nondependent cocaine abuse, continuous	ICD-9-CM	Diagnosis
305.62	Nondependent cocaine abuse, episodic	ICD-9-CM	Diagnosis
305.63	Nondependent cocaine abuse, in remission	ICD-9-CM	Diagnosis
305.7	Nondependent amphetamine or related acting sympathomimetic abuse	ICD-9-CM	Diagnosis
305.70	Nondependent amphetamine or related acting sympathomimetic abuse,	ICD-9-CM	Diagnosis
305.71	Nondependent amphetamine or related acting sympathomimetic abuse,	ICD-9-CM	Diagnosis
305.72	Nondependent amphetamine or related acting sympathomimetic abuse, episodic	ICD-9-CM	Diagnosis

Appendix G. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) Healthcare Common Procedure Coding System (HCPCS), Current Procedural Terminology, Second Edition (CPT-2), and Current Procedural Terminology, Fourth Edition (CPT-4), Diagnosis and Procedure Codes Used to Define Baseline Characteristics in this Request

Code	Description	Code Type	Code Category
305.73	Nondependent amphetamine or related acting sympathomimetic abuse, in remission	ICD-9-CM	Diagnosis
305.8	Nondependent antidepressant type abuse	ICD-9-CM	Diagnosis
305.80	Nondependent antidepressant type abuse, unspecified	ICD-9-CM	Diagnosis
305.81	Nondependent antidepressant type abuse, continuous	ICD-9-CM	Diagnosis
305.82	Nondependent antidepressant type abuse, episodic	ICD-9-CM	Diagnosis
305.83	Nondependent antidepressant type abuse, in remission	ICD-9-CM	Diagnosis
305.9	Other, mixed, or unspecified nondependent drug abuse	ICD-9-CM	Diagnosis
305.90	Other, mixed, or unspecified nondependent drug abuse, unspecified	ICD-9-CM	Diagnosis
305.91	Other, mixed, or unspecified nondependent drug abuse, continuous	ICD-9-CM	Diagnosis
305.92	Other, mixed, or unspecified nondependent drug abuse, episodic	ICD-9-CM	Diagnosis
305.93	Other, mixed, or unspecified nondependent drug abuse, in remission	ICD-9-CM	Diagnosis
571.0	Alcoholic fatty liver	ICD-9-CM	Diagnosis
571.1	Acute alcoholic hepatitis	ICD-9-CM	Diagnosis
571.2	Alcoholic cirrhosis of liver	ICD-9-CM	Diagnosis
571.3	Unspecified alcoholic liver damage	ICD-9-CM	Diagnosis
648.3	Maternal drug dependence complicating pregnancy, childbirth, or the puerperium	ICD-9-CM	Diagnosis
94.46	Alcoholism counseling	ICD-9-CM	Procedure
94.53	Referral for alcoholism rehabilitation	ICD-9-CM	Procedure
94.6	Alcohol and drug rehabilitation and detoxification	ICD-9-CM	Procedure
94.61	Alcohol rehabilitation	ICD-9-CM	Procedure
94.62	Alcohol detoxification	ICD-9-CM	Procedure
94.63	Alcohol rehabilitation and detoxification	ICD-9-CM	Procedure
94.67	Combined alcohol and drug rehabilitation	ICD-9-CM	Procedure
94.68	Combined alcohol and drug detoxification	ICD-9-CM	Procedure
94.69	Combined alcohol and drug rehabilitation and detoxification	ICD-9-CM	Procedure
H0005	Drug or Alcohol Abuse	HCPCS	Procedure
H0007	Drug or Alcohol Abuse	HCPCS	Procedure
H0008	Drug or Alcohol Abuse	HCPCS	Procedure
H0010	Drug or Alcohol Abuse	HCPCS	Procedure
H0011	Drug or Alcohol Abuse	HCPCS	Procedure
H0012	Drug or Alcohol Abuse	HCPCS	Procedure
H0013	Drug or Alcohol Abuse	HCPCS	Procedure
H0014	Drug or Alcohol Abuse	HCPCS	Procedure
H0015	Drug or Alcohol Abuse	HCPCS	Procedure
H0020	Drug or Alcohol Abuse	HCPCS	Procedure
H0022	Drug or Alcohol Abuse	HCPCS	Procedure
H2035	Drug or Alcohol Abuse	HCPCS	Procedure
H2036	Drug or Alcohol Abuse	HCPCS	Procedure
T1006	Drug or Alcohol Abuse	HCPCS	Procedure
T1007	Drug or Alcohol Abuse	HCPCS	Procedure

Appendix G. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) Healthcare Common Procedure Coding System (HCPCS), Current Procedural Terminology, Second Edition (CPT-2), and Current Procedural Terminology, Fourth Edition (CPT-4), Diagnosis and Procedure Codes Used to Define Baseline Characteristics in this Request

Code	Description	Code Type	Code Category
T1008	Drug or Alcohol Abuse	HCPCS	Procedure
T1010	Drug or Alcohol Abuse	HCPCS	Procedure
T1012	Drug or Alcohol Abuse	HCPCS	Procedure
4320F	Drug or Alcohol Abuse	CPT-2	Procedure
Chronic Fatigue Syndrome			
780.71	Chronic fatigue syndrome	ICD-9-CM	Diagnosis
Kidney Disease			
394.2	Mitral stenosis with insufficiency	ICD-9-CM	Diagnosis
580	Acute glomerulonephritis	ICD-9-CM	Diagnosis
581	Nephrotic syndrome	ICD-9-CM	Diagnosis
581.1	Nephrotic syndrome with lesion of membranous glomerulonephritis	ICD-9-CM	Diagnosis
581.2	Nephrotic syndrome with lesion of membranoproliferative glomerulonephritis	ICD-9-CM	Diagnosis
581.3	Nephrotic syndrome with lesion of minimal change glomerulonephritis	ICD-9-CM	Diagnosis
581.81	Nephrotic syndrome with other specified pathological lesion in kidney in diseases classified elsewhere	ICD-9-CM	Diagnosis
581.89	Other nephrotic syndrome with specified pathological lesion in kidney	ICD-9-CM	Diagnosis
581.9	Nephrotic syndrome with unspecified pathological lesion in kidney	ICD-9-CM	Diagnosis
582	Chronic glomerulonephritis	ICD-9-CM	Diagnosis
582.9	Chronic glomerulonephritis with unspecified pathological lesion in kidney	ICD-9-CM	Diagnosis
583	Nephritis and nephropathy, not specified as acute or chronic	ICD-9-CM	Diagnosis
583.81	Nephritis and nephropathy, not specified as acute or chronic, with other specified pathological lesion in kidney, in diseases classified elsewhere	ICD-9-CM	Diagnosis
584	Acute kidney failure	ICD-9-CM	Diagnosis
584.5	Acute kidney failure with lesion of tubular necrosis	ICD-9-CM	Diagnosis
584.6	Acute kidney failure with lesion of renal cortical necrosis	ICD-9-CM	Diagnosis
584.7	Acute kidney failure with lesion of medullary [papillary] necrosis	ICD-9-CM	Diagnosis
584.8	Acute kidney failure with other specified pathological lesion in kidney	ICD-9-CM	Diagnosis
584.9	Acute kidney failure, unspecified	ICD-9-CM	Diagnosis
585	Chronic kidney disease (CKD)	ICD-9-CM	Diagnosis
585.1	Chronic kidney disease, Stage I	ICD-9-CM	Diagnosis
585.2	Chronic kidney disease, Stage II (mild)	ICD-9-CM	Diagnosis
585.3	Chronic kidney disease, Stage III (moderate)	ICD-9-CM	Diagnosis
585.4	Chronic kidney disease, Stage IV (severe)	ICD-9-CM	Diagnosis
585.5	Chronic kidney disease, Stage V	ICD-9-CM	Diagnosis
585.6	End stage renal disease	ICD-9-CM	Diagnosis
585.9	Chronic kidney disease, unspecified	ICD-9-CM	Diagnosis
586	Unspecified renal failure	ICD-9-CM	Diagnosis
587	Unspecified renal sclerosis	ICD-9-CM	Diagnosis
588	Disorders resulting from impaired renal function	ICD-9-CM	Diagnosis
588.0	Renal osteodystrophy	ICD-9-CM	Diagnosis
588.1	Nephrogenic diabetes insipidus	ICD-9-CM	Diagnosis
588.9	Unspecified disorder resulting from impaired renal function	ICD-9-CM	Diagnosis

Appendix G. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) Healthcare Common Procedure Coding System (HCPCS), Current Procedural Terminology, Second Edition (CPT-2), and Current Procedural Terminology, Fourth Edition (CPT-4), Diagnosis and Procedure Codes Used to Define Baseline Characteristics in this Request

Code	Description	Code Type	Code Category
593	Other disorders of kidney and ureter	ICD-9-CM	Diagnosis
593.0	Nephroptosis	ICD-9-CM	Diagnosis
593.1	Hypertrophy of kidney	ICD-9-CM	Diagnosis
593.2	Acquired cyst of kidney	ICD-9-CM	Diagnosis
593.81	Vascular disorders of kidney	ICD-9-CM	Diagnosis
593.89	Other specified disorder of kidney and ureter	ICD-9-CM	Diagnosis
593.9	Unspecified disorder of kidney and ureter	ICD-9-CM	Diagnosis
646.2	Unspecified renal disease in pregnancy, without mention of hypertension	ICD-9-CM	Diagnosis
V42.0	Kidney replaced by transplant	ICD-9-CM	Diagnosis
V45.1	Renal dialysis status	ICD-9-CM	Diagnosis
V45.11	Renal dialysis status	ICD-9-CM	Diagnosis
V45.12	Noncompliance with renal dialysis	ICD-9-CM	Diagnosis
V56.0	Encounter for extracorporeal dialysis	ICD-9-CM	Diagnosis
V56.1	Fitting and adjustment of extracorporeal dialysis catheter	ICD-9-CM	Diagnosis
V56.2	Fitting and adjustment of peritoneal dialysis catheter	ICD-9-CM	Diagnosis
V56.31	Encounter for adequacy testing for hemodialysis	ICD-9-CM	Diagnosis
V56.32	Encounter for adequacy testing for peritoneal dialysis	ICD-9-CM	Diagnosis
V56.8	Encounter other dialysis	ICD-9-CM	Diagnosis
A4653	Peritoneal dialysis catheter anchoring device, belt, each	HCPCS	Procedure
A4671	Disposable cyclor set used with cyclor dialysis machine, each	HCPCS	Procedure
A4672	Drainage extension line, sterile, for dialysis, each	HCPCS	Procedure
A4673	Extension line with easy lock connectors, used with dialysis	HCPCS	Procedure
A4680	Activated carbon filter for hemodialysis, each	HCPCS	Procedure
A4690	Dialyzer (artificial kidneys), all types, all sizes, for hemodialysis, each	HCPCS	Procedure
A4714	Treated water (deionized, distilled, or reverse osmosis) for peritoneal dialysis, per gallon	HCPCS	Procedure
A4719	"Y set" tubing for peritoneal dialysis	HCPCS	Procedure
A4730	Fistula cannulation set for hemodialysis, each	HCPCS	Procedure
A4736	Topical anesthetic, for dialysis, per g	HCPCS	Procedure
A4737	Injectable anesthetic, for dialysis, per 10 ml	HCPCS	Procedure
A4740	Shunt accessory, for hemodialysis, any type, each	HCPCS	Procedure
A4750	Blood tubing, arterial or venous, for hemodialysis, each	HCPCS	Procedure
A4755	Blood tubing, arterial and venous combined, for hemodialysis, each	HCPCS	Procedure
A4760	Dialysate solution test kit, for peritoneal dialysis, any type, each	HCPCS	Procedure
A4765	Dialysate concentrate, powder, additive for peritoneal dialysis, per packet	HCPCS	Procedure
A4766	Dialysate concentrate, solution, additive for peritoneal dialysis, per 10 ml	HCPCS	Procedure
A4770	Blood collection tube, vacuum, for dialysis, per 50	HCPCS	Procedure
A4771	Serum clotting time tube, for dialysis, per 50	HCPCS	Procedure
A4772	Blood glucose test strips, for dialysis, per 50	HCPCS	Procedure
A4773	Occult blood test strips, for dialysis, per 50	HCPCS	Procedure
A4774	Ammonia test strips, for dialysis, per 50	HCPCS	Procedure
A4780	Sterilizing agent for dialysis equipment, per gallon	HCPCS	Procedure

Appendix G. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) Healthcare Common Procedure Coding System (HCPCS), Current Procedural Terminology, Second Edition (CPT-2), and Current Procedural Terminology, Fourth Edition (CPT-4), Diagnosis and Procedure Codes Used to Define Baseline Characteristics in this Request

Code	Description	Code Type	Code Category
A4801	Heparin, any type, for hemodialysis, per 1000 units	HCPCS	Procedure
A4802	Protamine sulfate, for hemodialysis, per 50 mg	HCPCS	Procedure
A4860	Disposable catheter tips for peritoneal dialysis, per 10	HCPCS	Procedure
A4880	Storage tanks utilized in connection with water purification system, replacement tanks for dialysis	HCPCS	Procedure
A4900	Continuous ambulatory peritoneal dialysis (capd) supply kit	HCPCS	Procedure
A4901	Continuous cycling peritoneal dialysis (ccpd) supply kit	HCPCS	Procedure
A4905	Intermittent peritoneal dialysis (ipd) supply kit	HCPCS	Procedure
A4910	Non-medical supplies for dialysis, (i.e., scale, scissors, stopwatch, etc.)	HCPCS	Procedure
A4911	Drain bag/bottle, for dialysis, each	HCPCS	Procedure
A4913	Miscellaneous dialysis supplies, not otherwise specified	HCPCS	Procedure
A4918	Venous pressure clamp, for hemodialysis, each	HCPCS	Procedure
A4929	Tourniquet for dialysis, each	HCPCS	Procedure
C1037	Catheter, vaxcel chronic dialysis catheter, medcomp bio flex tesio catheter, medcomp silicone tesio catheter, medcomp hemo-cath long term silicone catheter, bard niagara dual lumen catheter, bard opti-flow dual lumen catheter, medcomp ash split catheter	HCPCS	Procedure
C1152	Access system, dialysis, lifesite access system	HCPCS	Procedure
C1750	Catheter, hemodialysis/peritoneal, long-term	HCPCS	Procedure
C1752	Catheter, hemodialysis/peritoneal, short-term	HCPCS	Procedure
C1881	Dialysis access system (implantable)	HCPCS	Procedure
E1500	Centrifuge, for dialysis	HCPCS	Procedure
E1520	Heparin infusion pump for hemodialysis	HCPCS	Procedure
E1530	Air bubble detector for hemodialysis, each, replacement	HCPCS	Procedure
E1540	Pressure alarm for hemodialysis, each, replacement	HCPCS	Procedure
E1550	Bath conductivity meter for hemodialysis, each	HCPCS	Procedure
E1560	Blood leak detector for hemodialysis, each, replacement	HCPCS	Procedure
E1580	Unipuncture control system for hemodialysis	HCPCS	Procedure
E1590	Hemodialysis machine	HCPCS	Procedure
E1592	Automatic intermittent peritoneal dialysis system	HCPCS	Procedure
E1594	Cycler dialysis machine for peritoneal dialysis	HCPCS	Procedure
E1615	Deionizer water purification system, for hemodialysis	HCPCS	Procedure
E1620	Blood pump for hemodialysis, replacement	HCPCS	Procedure
E1625	Water softening system, for hemodialysis	HCPCS	Procedure
E1630	Reciprocating peritoneal dialysis system	HCPCS	Procedure
E1634	Peritoneal dialysis clamps, each	HCPCS	Procedure
E1636	Sorbent cartridges, for hemodialysis, per 10	HCPCS	Procedure
E1637	Hemostats, each	HCPCS	Procedure
E1638	Heating pad, for peritoneal dialysis, any size, each	HCPCS	Procedure
E1640	Replacement components for hemodialysis and/or peritoneal dialysis machines that are owned or being purchased by the patient	HCPCS	Procedure
E1699	Dialysis equipment, not otherwise specified	HCPCS	Procedure

Appendix G. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) Healthcare Common Procedure Coding System (HCPCS), Current Procedural Terminology, Second Edition (CPT-2), and Current Procedural Terminology, Fourth Edition (CPT-4), Diagnosis and Procedure Codes Used to Define Baseline Characteristics in this Request

Code	Description	Code Type	Code Category
G0257	Unscheduled or emergency dialysis treatment for an ESRD patient in a hospital outpatient department that is not certified as an ESRD facility	HCPCS	Procedure
G0320	ESRD related services for home dialysis patients per full month; for patients under 2 years of age to include monitoring for adequacy of nutrition, assessment of growth and development, and counseling of parents	HCPCS	Procedure
G0321	ESRD related services for home dialysis patients per full month; for patients 2 to 11 years of age to include monitoring for adequacy of nutrition, assessment of growth and development, and counseling of parents	HCPCS	Procedure
G0322	End Stage Renal disease (ESRD) related services for home dialysis patients per full month; for patients 12 to 19 years of age to include monitoring for adequacy of nutrition, assessment of growth and development, and counseling of parents	HCPCS	Procedure
G0323	End Stage Renal disease (ESRD) related services for home dialysis patients per full month; for patients 20 years of age and older	HCPCS	Procedure
G0324	ESRD related services for home dialysis (less than full month), per day; for patients under 2 years of age	HCPCS	Procedure
G0325	ESRD related services for home dialysis (less than full month), per day; for patients between 2 and 11 years of age	HCPCS	Procedure
G0326	ESRD related services for home dialysis (less than full month), per day; for patients between twelve and nineteen years of age	HCPCS	Procedure
G0327	ESRD related services for home dialysis (less than full month), per day; for patients twenty years of age and over	HCPCS	Procedure
G0365	Vessel mapping of vessels for hemodialysis access (services for preoperative vessel mapping prior to creation of hemodialysis access using an autogenous hemodialysis conduit, including arterial inflow and venous outflow)	HCPCS	Procedure
G8075	ESRD patient with documented dialysis dose of URR greater than or equal to 65% (or Kt/ V greater than or equal to 1.2)	HCPCS	Procedure
G8076	ESRD patient with documented dialysis dose of URR less than 65% (or Kt/V less than 1.2)	HCPCS	Procedure
G8575	Developed postoperative renal failure or required dialysis	HCPCS	Procedure
G8714	Hemodialysis treatment performed exactly 3 times per week > 90 days	HCPCS	Procedure
G8956	Patient receiving maintenance hemodialysis in an outpatient dialysis facility	HCPCS	Procedure
G9231	Documentation of end stage renal disease (ESRD), dialysis, renal transplant before or during the measurement period or pregnancy during the measurement period	HCPCS	Procedure
G9523	Patient discontinued from hemodialysis or peritoneal dialysis	HCPCS	Procedure
J0882	Injection, darbepoetin alfa, 1 mcg (for ESRD on dialysis)	HCPCS	Procedure
J0886	Injection, epoetin alfa, 1000 units (for ESRD on dialysis)	HCPCS	Procedure
K0610	Peritoneal dialysis clamp, each	HCPCS	Procedure
K0611	Disposable cyclor set used with cyclor dialysis machine, each	HCPCS	Procedure
K0612	Drainage extension line, sterile, for dialysis, each	HCPCS	Procedure
K0613	Extension line with easy lock connectors, used with dialysis	HCPCS	Procedure
K0614	Chemicals/antiseptic solution used to clean/sterilize dialysis equipment, per 8 oz	HCPCS	Procedure

Appendix G. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) Healthcare Common Procedure Coding System (HCPCS), Current Procedural Terminology, Second Edition (CPT-2), and Current Procedural Terminology, Fourth Edition (CPT-4), Diagnosis and Procedure Codes Used to Define Baseline Characteristics in this Request

Code	Description	Code Type	Code Category
Q4054	Injection, darbepoetin alfa, 1 mcg (for ESRD on dialysis)	HCPCS	Procedure
Q4055	Injection, epoetin alfa, 1000 units (for ESRD on dialysis)	HCPCS	Procedure
Q4081	Injection, epoetin alfa, 100 units (for ESRD on dialysis)	HCPCS	Procedure
S9339	Home therapy; peritoneal dialysis, administrative services, professional pharmacy services, care coordination and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem	HCPCS	Procedure
90740	Hepatitis B vaccine (HepB), dialysis or immunosuppressed patient dosage, 3 dose schedule, for intramuscular use	CPT-4	Procedure
90747	Hepatitis B vaccine (HepB), dialysis or immunosuppressed patient dosage, 4 dose schedule, for intramuscular use	CPT-4	Procedure
90921	End-stage renal disease (ESRD) related services per full month; for patients twenty years of age and older	CPT-4	Procedure
90922	End-stage renal disease (ESRD) related services (less than full month), per day; for patients younger than two years of age	CPT-4	Procedure
90923	End-stage renal disease (ESRD) related services (less than full month), per day; for patients between two and eleven years of age	CPT-4	Procedure
90924	End-stage renal disease (ESRD) related services (less than full month), per day; for patients between twelve and nineteen years of age	CPT-4	Procedure
90925	End-stage renal disease (ESRD) related services (less than full month), per day; for patients twenty years of age and older	CPT-4	Procedure
90935	Hemodialysis procedure with single evaluation by a physician or other qualified health care professional	CPT-4	Procedure
90937	Hemodialysis procedure requiring repeated evaluation(s) with or without substantial revision of dialysis prescription	CPT-4	Procedure
90939	Hemodialysis access flow study to determine blood flow in grafts and arteriovenous fistulae by an indicator dilution method, hook-up; transcutaneous measurement and disconnection	CPT-4	Procedure
90940	Hemodialysis access flow study to determine blood flow in grafts and arteriovenous fistulae by an indicator method	CPT-4	Procedure
90941	Hemodialysis, For Acute Renal Failure And Or Intoxication,	CPT-4	Procedure
90942	Hemodialysis, For Acute Renal Failure And Or Intoxication,	CPT-4	Procedure
90943	Hemodialysis, For Acute Renal Failure And Or Intoxication,	CPT-4	Procedure
90944	Hemodialysis, For Acute Renal Failure And Or Intoxication,	CPT-4	Procedure
90945	Dialysis procedure other than hemodialysis (eg, peritoneal dialysis, hemofiltration, or other continuous renal replacement therapies), with single evaluation by a physician or other qualified health care professional	CPT-4	Procedure
90947	Dialysis procedure other than hemodialysis (eg, peritoneal dialysis, hemofiltration, or other continuous renal replacement therapies) requiring repeated evaluations by a physician or other qualified health care professional, with or without substantial revision of dialysis prescription	CPT-4	Procedure

Appendix G. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) Healthcare Common Procedure Coding System (HCPCS), Current Procedural Terminology, Second Edition (CPT-2), and Current Procedural Terminology, Fourth Edition (CPT-4), Diagnosis and Procedure Codes Used to Define Baseline Characteristics in this Request

Code	Description	Code Type	Code Category
90957	End-stage renal disease (ESRD) related services monthly, for patients 12-19 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents; with 4 or more face-to-face visits by a physician or other qualified health care professional per month	CPT-4	Procedure
90958	End-stage renal disease (ESRD) related services monthly, for patients 12-19 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents; with 2-3 face-to-face visits by a physician or other qualified health care professional per month	CPT-4	Procedure
90959	End-stage renal disease (ESRD) related services monthly, for patients 12-19 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents; with 1 face-to-face visit by a physician or other qualified health care professional per month	CPT-4	Procedure
90960	End-stage renal disease (ESRD) related services monthly, for patients 20 years of age and older; with 4 or more face-to-face visits by a physician or other qualified health care professional per month	CPT-4	Procedure
90961	End-stage renal disease (ESRD) related services monthly, for patients 20 years of age and older; with 2-3 face-to-face visits by a physician or other qualified health care professional per month	CPT-4	Procedure
90962	End-stage renal disease (ESRD) related services monthly, for patients 20 years of age and older; with 1 face-to-face visit by a physician or other qualified health care professional per month	CPT-4	Procedure
90963	End-stage renal disease (ESRD) related services for home dialysis per full month, for patients younger than 2 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents	CPT-4	Procedure
90965	End-stage renal disease (ESRD) related services for home dialysis per full month, for patients 12-19 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents	CPT-4	Procedure
90966	End-stage renal disease (ESRD) related services for home dialysis per full month, for patients 20 years of age and older	CPT-4	Procedure
90969	End-stage renal disease (ESRD) related services for dialysis less than a full month of service, per day; for patients 12-19 years of age	CPT-4	Procedure
90970	End-stage renal disease (ESRD) related services for dialysis less than a full month of service, per day; for patients 20 years of age and older	CPT-4	Procedure
90976	Peritoneal Dialysis For End-stage Renal Disease (esrd),	CPT-4	Procedure
90977	Peritoneal Dialysis For End-stage Renal Disease (esrd),	CPT-4	Procedure
90978	Peritoneal Dialysis For End-stage Renal Disease (esrd),	CPT-4	Procedure
90979	Peritoneal Dialysis For End-stage Renal Disease (esrd),	CPT-4	Procedure
90982	Peritoneal Dialysis For End-stage Renal Disease (esrd),	CPT-4	Procedure
90983	Peritoneal Dialysis For End-stage Renal Disease (esrd),	CPT-4	Procedure
90984	Peritoneal Dialysis For End-stage Renal Disease (esrd),	CPT-4	Procedure
90985	Peritoneal Dialysis For End-stage Renal Disease (esrd),	CPT-4	Procedure

Appendix G. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) Healthcare Common Procedure Coding System (HCPCS), Current Procedural Terminology, Second Edition (CPT-2), and Current Procedural Terminology, Fourth Edition (CPT-4), Diagnosis and Procedure Codes Used to Define Baseline Characteristics in this Request

Code	Description	Code Type	Code Category
90988	Supervision Of Hemodialysis In Hospital Or Other Facility (excluding Home Dialysis), On Monthly Basis	CPT-4	Procedure
90989	Dialysis training, patient, including helper where applicable, any mode, completed course	CPT-4	Procedure
90990	Hemodialysis Training And/or Counseling	CPT-4	Procedure
90991	Home Hemodialysis Care, Outpatient, For Those Services Either Provided By The Physician Primarily Responsible	CPT-4	Procedure
90992	Peritoneal Dialysis Training And/or Counseling	CPT-4	Procedure
90993	Dialysis training, patient, including helper where applicable, any mode, course not completed, per training session	CPT-4	Procedure
90994	Supervision Of Chronic Ambulatory Peritoneal Dialysis (capd), Home Or Out-patient (monthly)	CPT-4	Procedure
90995	End Stage Renal Disease (esrd) Related Services, Per Full Month	CPT-4	Procedure
90996	Continuous Arteriovenous Hemofiltration (cavh) (per Day)	CPT-4	Procedure
90997	Hemoperfusion (eg, with activated charcoal or resin)	CPT-4	Procedure
90998	End Stage Renal Disease (esrd) Related Services (less Than Full Month), Per Day	CPT-4	Procedure
90999	Unlisted dialysis procedure, inpatient or outpatient	CPT-4	Procedure
93990	Duplex scan of hemodialysis access (including arterial inflow, body of access and venous outflow)	CPT-4	Procedure
99512	Home visit for hemodialysis	CPT-4	Procedure
99559	Home infusion of peritoneal dialysis, per visit	CPT-4	Procedure

Appendix H. Generic and Brand Names of Medical Products Used to Define Baseline Characteristics in this Request

Generic Name	Brand Name
Obesity	
Benzphetamine HCl	Benzphetamine
Benzphetamine HCl	Didrex
Benzphetamine HCl	Regimex
Diethylpropion HCl	Diethylpropion
Diethylpropion HCl	Diethylpropion HCl (bulk)
Diethylpropion HCl	Tenuate
Diethylpropion HCl	Tenuate Dospan
Lorcaserin HCl	Belviq
Lorcaserin HCl	Belviq XR
Orlistat	Alli
Orlistat	Xenical
Phendimetrazine tartrate	Bontril PDM
Phendimetrazine tartrate	Bontril Slow-Release
Phendimetrazine tartrate	Bontril SR
Phendimetrazine tartrate	Melfiat CR
Phendimetrazine tartrate	Phendimetrazine Tartrate
Phentermine HCl	Adipex-P
Phentermine HCl	Fastin (Phentermine)
Phentermine HCl	Lomaira
Phentermine HCl	Phentermine
Phentermine HCl	Phentermine HCl (bulk)
Phentermine HCl	Suprenza
Phentermine HCl/topiramate	Qsymia
Phentermine resin	Ionamin
Phentermine resin	Ionamin-15
Phentermine resin	Ionamin-30
Sibutramine HCl m-hydrate	Meridia
Smoking	
Bupropion HCl	Buproban
Bupropion HCl	Bupropion HCl (Smoking Deter)
Bupropion HCl	Zyban
Nicotine	Habitrol
Nicotine	Nicoderm CQ
Nicotine	Nicotrol
Nicotine	Nicotrol NS
Nicotine	Nts Step 1
Nicotine	Nts Step 2
Nicotine	Nts Step 3
Nicotine bitartrate	Nicotine Tartrate
Nicotine polacrilex	Commit
Nicotine polacrilex	Nicorelief
Nicotine polacrilex	Nicorette
Nicotine polacrilex	Nicorette Refill
Nicotine polacrilex	Nicorette Starter Kit

Appendix H. Generic and Brand Names of Medical Products Used to Define Baseline Characteristics in this Request

Generic Name	Brand Name
Nicotine polacrilex	Nicotine (Polacrilex)
Nicotine polacrilex	Nicotine Polacrilex (bulk)
Nicotine polacrilex	Quit 2
Nicotine polacrilex	Quit 4
Nicotine polacrilex	Stop Smoking Aid
Nicotine polacrilex	Thrive Nicotine
Silver nitrate	Silver Nitrate (bulk)
Varenicline tartrate	Chantix
Varenicline tartrate	Chantix Continuing Month Box
Varenicline tartrate	Chantix Continuing Month Pak
Varenicline tartrate	Chantix Starting Month Box
Varenicline tartrate	Chantix Starting Month Pak
Valproate	
Divalproex sodium	Depakote ER
Divalproex sodium	Depakote Sprinkles
Divalproex sodium	Depakote
Divalproex sodium	Divalproex
Valproic acid	Depakene
Valproic acid	Valproic Acid
Valproic acid	Valproic Acid (bulk)
Valproic acid	Stavzor
Valproic acid (as sodium salt) (valproate sodium)	Depacon
Valproic acid (as sodium salt) (valproate sodium)	Valproic Acid (As Sodium Salt)
Valproic acid (as sodium salt) (valproate sodium)	Valproate Sodium
Valproic acid (as sodium salt) (valproate sodium)	Valproate Sodium (bulk)
Carbamazepine	
Carbamazepine	Atretol
Carbamazepine	Carbamazepine
Carbamazepine	Carbamazepine (bulk)
Carbamazepine	Carbatrol
Carbamazepine	Epitol
Carbamazepine	Equetro
Carbamazepine	Tegretol
Carbamazepine	Tegretol XR
Phenytoin	
Fosphenytoin sodium	Cerebyx
Fosphenytoin sodium	Fosphenytoin
Phenytoin	Dilantin Infatabs
Phenytoin	Dilantin-125
Phenytoin	Phenytoin
Phenytoin sodium	Di-Phen
Phenytoin sodium	Phenytoin Sodium
Phenytoin sodium extended	Dilantin
Phenytoin sodium extended	Dilantin Extended
Phenytoin sodium extended	Dilantin Kapseal

Appendix H. Generic and Brand Names of Medical Products Used to Define Baseline Characteristics in this Request

Generic Name	Brand Name
Phenytoin sodium extended	Phenytek
Phenytoin sodium extended	Phenytoin Sodium Extended
Triptans	
5-hydroxy-L-tryptophan (oxitriptan)	5-Hydroxy-L-Tryptophan
5-hydroxy-L-tryptophan (oxitriptan)	5-Hydroxy-L-Tryptophan (bulk)
5-hydroxy-L-tryptophan (oxitriptan)	5hydroxytryptophan(Oxitriptan)
Almotriptan malate	Almotriptan Malate
Almotriptan malate	Axert
Eletriptan hydrobromide	Eletriptan
Eletriptan hydrobromide	Relpax
Frovatriptan succinate	Frova
Frovatriptan succinate	Frovatriptan
Naratriptan HCl	Amerge
Naratriptan HCl	Naratriptan
Rizatriptan benzoate	Maxalt
Rizatriptan benzoate	Maxalt-MLT
Rizatriptan benzoate	Rizatriptan
Sumatriptan	Sumatriptan
Sumatriptan	Sumatriptan (bulk)
Sumatriptan succinate	Alsuma
Sumatriptan succinate	Imitrex
Sumatriptan succinate	Imitrex Statdose Pen
Sumatriptan succinate	Imitrex Statdose Refill
Sumatriptan succinate	Onzetra Xsail
Sumatriptan succinate	Sumatriptan Succinate
Sumatriptan succinate	Sumatriptan Succinate (bulk)
Sumatriptan succinate	Sumavel Dosepro
Sumatriptan succinate	Zecuity
Sumatriptan succinate	Zembrace Symtouch
Sumatriptan succinate/menthol/camphor	Migranow
Sumatriptan succinate/naproxen sodium	Sumatriptan-Naproxen
Sumatriptan succinate/naproxen sodium	Treximet
Zolmitriptan	Zolmitriptan
Zolmitriptan	Zolmitriptan (bulk)
Zolmitriptan	Zomig
Zolmitriptan	Zomig ZMT
Antipsychotics	
Aripiprazole	Abilify
Aripiprazole	Abilify Discmelt
Aripiprazole	Abilify Maintena
Aripiprazole	Abilify Mycite
Aripiprazole	Aripiprazole
Aripiprazole lauroxil	Aristada
Aripiprazole lauroxil, submicronized	Aristada Initio
Asenapine maleate	Saphris
Asenapine maleate	Saphris (Black Cherry)

Appendix H. Generic and Brand Names of Medical Products Used to Define Baseline Characteristics in this Request

Generic Name	Brand Name
Brexipiprazole	Rexulti
Cariprazine HCl	Vraylar
Chlorpromazine HCl	Chlorpromazine
Chlorpromazine HCl	Chlorpromazine (bulk)
Chlorpromazine HCl	Thorazine
Clozapine	Clozapine
Clozapine	Clozaril
Clozapine	Fazaclo
Clozapine	Versacloz
Fluphenazine decanoate	Fluphenazine Decanoate
Fluphenazine decanoate	Fluphenazine Decanoate (bulk)
Fluphenazine decanoate	Prolixin Decanoate
Fluphenazine HCl	Fluphenazine HCl
Fluphenazine HCl	Permitil
Fluphenazine HCl	Prolixin
Haloperidol	Haloperidol
Haloperidol decanoate	Haldol Decanoate
Haloperidol decanoate	Haloperidol Decanoate
Haloperidol decanoate	Haloperidol Decanoate (bulk)
Haloperidol lactate	Haldol
Haloperidol lactate	Haloperidol Lactate
Iloperidone	Fanapt
Loxapine	Adasuve
Loxapine HCl	Loxitane-C
Loxapine succinate	Loxapine Succinate
Loxapine succinate	Loxapine Succinate (bulk)
Loxapine succinate	Loxitane
Lurasidone HCl	Latuda
Mesoridazine besylate	Serentil
Molindone HCl	Moban
Molindone HCl	Molindone
Olanzapine	Olanzapine
Olanzapine	Zyprexa
Olanzapine	Zyprexa Zydis
Olanzapine pamoate	Zyprexa Relprev
Olanzapine/fluoxetine HCl	Olanzapine-Fluoxetine
Olanzapine/fluoxetine HCl	Symbyax
Paliperidone	Invega
Paliperidone	Paliperidone
Paliperidone palmitate	Invega Sustenna
Paliperidone palmitate	Invega Trinza
Perphenazine	Perphenazine
Perphenazine	Perphenazine (bulk)
Perphenazine	Trilafon
Perphenazine/amitriptyline HCl	Duo-Vil 2-10
Perphenazine/amitriptyline HCl	Duo-Vil 2-25

Appendix H. Generic and Brand Names of Medical Products Used to Define Baseline Characteristics in this Request

Generic Name	Brand Name
Perphenazine/amitriptyline HCl	Etrafon 2-10
Perphenazine/amitriptyline HCl	Etrafon 2-25
Perphenazine/amitriptyline HCl	Etrafon Forte 4-25
Perphenazine/amitriptyline HCl	Perphenazine-Amitriptyline
Perphenazine/amitriptyline HCl	Triavil 2-10
Perphenazine/amitriptyline HCl	Triavil 2-25
Perphenazine/amitriptyline HCl	Triavil 4-25
Pimavanserin tartrate	Nuplazid
Pimozide	Orap
Pimozide	Pimozide
Prochlorperazine maleate	Compazine
Prochlorperazine maleate	Prochlorperazine Maleate
Quetiapine fumarate	Quetiapine
Quetiapine fumarate	Seroquel
Quetiapine fumarate	Seroquel XR
Risperidone	Perseris
Risperidone	Risperdal
Risperidone	Risperdal M-TAB
Risperidone	Risperidone
Risperidone microspheres	Risperdal Consta
Thioridazine HCl	Mellaril
Thioridazine HCl	Mellaril-S
Thioridazine HCl	Thioridazine
Thioridazine HCl	Thioridazine (bulk)
Thiothixene	Navane
Thiothixene	Thiothixene
Thiothixene HCl	Thiothixene HCl
Trifluoperazine HCl	Stelazine
Trifluoperazine HCl	Trifluoperazine
Triflupromazine HCl	Vesprin
Ziprasidone HCl	Geodon
Ziprasidone HCl	Ziprasidone HCl
Antidepressants	
Amitriptyline HCl	Amitriptyline
Amitriptyline HCl	Elavil
Amitriptyline HCl	Vanatrip
Amitriptyline HCl/chlordiazepoxide	Amitriptyline-Chlordiazepoxide
Amitriptyline HCl/chlordiazepoxide	Limbitrol
Amitriptyline HCl/chlordiazepoxide	Limbitrol DS
Amoxapine	Amoxapine
Benactyzine HCl	Benactyzine HCl (bulk)
Brexanolone	Zulresso
Bupropion hbr	Aplenzin
Bupropion HCl	Budeprion SR
Bupropion HCl	Budeprion XL
Bupropion HCl	Bupropion (bulk)

Appendix H. Generic and Brand Names of Medical Products Used to Define Baseline Characteristics in this Request

Generic Name	Brand Name
Bupropion HCl	Bupropion HCl
Bupropion HCl	Forfivo XL
Bupropion HCl	Wellbutrin
Bupropion HCl	Wellbutrin SR
Bupropion HCl	Wellbutrin XL
Bupropion HCl/dietary supplement combination no.15	Appbutamone-D
Bupropion HCl/dietary supplement combination no.16	Appbutamone
Citalopram hydrobromide	Celexa
Citalopram hydrobromide	Citalopram
Clomipramine HCl	Anafranil
Clomipramine HCl	Clomipramine
Clomipramine HCl	Clomipramine (bulk)
Desipramine HCl	Desipramine
Desipramine HCl	Norpramin
Desvenlafaxine	Desvenlafaxine
Desvenlafaxine	Khedezla
Desvenlafaxine fumarate	Desvenlafaxine Fumarate
Desvenlafaxine succinate	Desvenlafaxine Succinate
Desvenlafaxine succinate	Pristiq
Doxepin HCl	Doxepin
Doxepin HCl	Silenor
Doxepin HCl	Sinequan
Duloxetine HCl	Cymbalta
Duloxetine HCl	Duloxetine
Duloxetine HCl	Duloxetine HCl (bulk)
Duloxetine HCl	Irenka
Escitalopram oxalate	Escitalopram Oxalate
Escitalopram oxalate	Lexapro
Esketamine HCl	Spravato
Fluoxetine	Fluoxetine (bulk)
Fluoxetine HCl	Fluoxetine
Fluoxetine HCl	Prozac
Fluoxetine HCl	Prozac Weekly
Fluoxetine HCl	Rapiflux
Fluoxetine HCl	Sarafem
Fluoxetine HCl	Selfemra
Fluoxetine HCl/dietary supplement no.17	Gaboxetine
Fluoxetine HCl/dietary supplement no.8	Sentroxatine
Fluvoxamine maleate	Fluvoxamine
Fluvoxamine maleate	Luvox
Fluvoxamine maleate	Luvox CR
Imipramine HCl	Imipramine (bulk)
Imipramine HCl	Imipramine HCl
Imipramine HCl	Tofranil
Imipramine pamoate	Imipramine Pamoate
Imipramine pamoate	Tofranil-PM

Appendix H. Generic and Brand Names of Medical Products Used to Define Baseline Characteristics in this Request

Generic Name	Brand Name
Isocarboxazid	Marplan
Levomilnacipran HCl	Fetzima
Maprotiline HCl	Ludiomil
Maprotiline HCl	Maprotiline
Milnacipran HCl	Savella
Mirtazapine	Mirtazapine
Mirtazapine	Mirtazapine (bulk)
Mirtazapine	Remeron
Mirtazapine	Remeron Soltab
Nefazodone HCl	Nefazodone
Nefazodone HCl	Serzone
Nortriptyline HCl	Aventyl
Nortriptyline HCl	Nortriptyline
Nortriptyline HCl	Pamelor
Olanzapine/fluoxetine HCl	Olanzapine-Fluoxetine
Olanzapine/fluoxetine HCl	Symbyax
Paroxetine HCl	Paroxetine HCl
Paroxetine HCl	Paxil
Paroxetine HCl	Paxil CR
Paroxetine mesylate	Brisdelle
Paroxetine mesylate	Paroxetine Mesylate(Menop.Sym)
Paroxetine mesylate	Pexeva
Perphenazine/amitriptyline HCl	Duo-Vil 2-10
Perphenazine/amitriptyline HCl	Duo-Vil 2-25
Perphenazine/amitriptyline HCl	Etrafon 2-10
Perphenazine/amitriptyline HCl	Etrafon 2-25
Perphenazine/amitriptyline HCl	Etrafon Forte 4-25
Perphenazine/amitriptyline HCl	Perphenazine-Amitriptyline
Perphenazine/amitriptyline HCl	Triavil 2-10
Perphenazine/amitriptyline HCl	Triavil 2-25
Perphenazine/amitriptyline HCl	Triavil 4-25
Phenelzine sulfate	Nardil
Phenelzine sulfate	Phenelzine
Phenelzine sulfate	Phenelzine (bulk)
Protriptyline HCl	Protriptyline
Protriptyline HCl	Vivactil
Selegiline	Emsam
Sertraline HCl	Sertraline
Sertraline HCl	Sertraline (bulk)
Sertraline HCl	Zoloft
Tranylcypromine sulfate	Parnate
Tranylcypromine sulfate	Tranylcypromine
Trazodone HCl	Desyrel
Trazodone HCl	Oleptro ER
Trazodone HCl	Trazodone
Trazodone HCl/dietary supplement no.8	Trazamine

Appendix H. Generic and Brand Names of Medical Products Used to Define Baseline Characteristics in this Request

Generic Name	Brand Name
Trimipramine maleate	Surmontil
Trimipramine maleate	Trimipramine
Venlafaxine HCl	Effexor
Venlafaxine HCl	Effexor XR
Venlafaxine HCl	Venlafaxine
Vilazodone HCl	Viiibryd
Vortioxetine hydrobromide	Brintellix
Vortioxetine hydrobromide	Trintellix
Antihypertension medications	
Acebutolol HCl	Acebutolol
Acebutolol HCl	Sectral
Amiloride HCl	Amiloride
Amiloride HCl	Midamor
Amiloride HCl/hydrochlorothiazide	Amiloride-Hydrochlorothiazide
Amiloride HCl/hydrochlorothiazide	Moduretic
Amlodipine benzoate	Katerzia
Amlodipine besylate	Amlodipine
Amlodipine besylate	Amlodipine Besylate (bulk)
Amlodipine besylate	Norvasc
Amlodipine besylate/benazepril HCl	Amlodipine-Benazepril
Amlodipine besylate/benazepril HCl	Lotrel
Amlodipine besylate/olmesartan medoxomil	Amlodipine-Olmesartan
Amlodipine besylate/olmesartan medoxomil	Azor
Amlodipine besylate/valsartan	Amlodipine-Valsartan
Amlodipine besylate/valsartan	Exforge
Amlodipine besylate/valsartan/hydrochlorothiazide	Amlodipine-Valsartan-Hcthiazid
Amlodipine besylate/valsartan/hydrochlorothiazide	Exforge HCT
Atenolol	Atenolol
Atenolol	Atenolol (bulk)
Atenolol	Senormin
Atenolol	Tenormin
Atenolol/chlorthalidone	Atenolol-Chlorthalidone
Atenolol/chlorthalidone	Tenoretic 100
Atenolol/chlorthalidone	Tenoretic 50
Azilsartan medoxomil	Edarbi
Azilsartan medoxomil/chlorthalidone	Edarbyclor
Benazepril HCl	Benazepril
Benazepril HCl	Benazepril HCl (bulk)
Benazepril HCl	Lotensin
Benazepril HCl/hydrochlorothiazide	Benazepril-Hydrochlorothiazide
Benazepril HCl/hydrochlorothiazide	Lotensin HCT
Bendroflumethiazide	Naturetin
Bepidil HCl	Vascor
Betaxolol HCl	Betaxolol
Betaxolol HCl	Kerlone
Bisoprolol fumarate	Bisoprolol Fumarate

Appendix H. Generic and Brand Names of Medical Products Used to Define Baseline Characteristics in this Request

Generic Name	Brand Name
Bisoprolol fumarate	Zebeta
Bisoprolol fumarate/hydrochlorothiazide	Bisoprolol-Hydrochlorothiazide
Bisoprolol fumarate/hydrochlorothiazide	Ziac
Bumetanide	Bumetanide
Bumetanide	Bumex
Candesartan cilexetil	Atacand
Candesartan cilexetil	Candesartan
Candesartan cilexetil/hydrochlorothiazide	Atacand HCT
Candesartan cilexetil/hydrochlorothiazide	Candesartan-Hydrochlorothiazid
Captopril	Capoten
Captopril	Captopril
Captopril	Captopril (bulk)
Captopril/hydrochlorothiazide	Capozide
Captopril/hydrochlorothiazide	Captopril-Hydrochlorothiazide
Carteolol HCl	Cartrol
Carvedilol	Carvedilol
Carvedilol	Coreg
Carvedilol phosphate	Carvedilol Phosphate
Carvedilol phosphate	Coreg CR
Chlorothiazide	Chlorothiazide
Chlorothiazide	Diuril
Chlorothiazide sodium	Chlorothiazide Sodium
Chlorothiazide sodium	Diuril IV
Chlorthalidone	Chlorthalidone
Chlorthalidone	Thalitone
Clevidipine butyrate	Cleviprex
Deserpidine/methyclothiazide	Enduronyl
Deserpidine/methyclothiazide	Enduronyl Forte
Diazoxide	Diazoxide (bulk)
Diazoxide	Hyperstat
Diltiazem HCl	Cardizem
Diltiazem HCl	Cardizem CD
Diltiazem HCl	Cardizem LA
Diltiazem HCl	Cardizem SR
Diltiazem HCl	Cartia XT
Diltiazem HCl	Dilacor XR
Diltiazem HCl	Dilt-Cd
Diltiazem HCl	Diltia XT
Diltiazem HCl	Diltiazem HCl
Diltiazem HCl	Dilt-Xr
Diltiazem HCl	Diltzac ER
Diltiazem HCl	Matzim LA
Diltiazem HCl	Taztia XT
Diltiazem HCl	Tiazac
Diltiazem HCl in 0.9 % sodium chloride	Diltiazem HCl In 0.9% Nacl
Diltiazem HCl/dextrose 5 % in water	Diltiazem In Dextrose 5 %

Appendix H. Generic and Brand Names of Medical Products Used to Define Baseline Characteristics in this Request

Generic Name	Brand Name
Doxazosin mesylate	Cardura
Doxazosin mesylate	Cardura XL
Doxazosin mesylate	Doxazosin
Doxazosin mesylate	Doxazosin Mesylate (bulk)
Enalapril maleate	Enalapril Maleate
Enalapril maleate	Enalapril Maleate (bulk)
Enalapril maleate	Epaned
Enalapril maleate	Vasotec
Enalapril maleate/felodipine	Lexxel
Enalapril maleate/hydrochlorothiazide	Enalapril-Hydrochlorothiazide
Enalapril maleate/hydrochlorothiazide	Vaseretic
Enalaprilat dihydrate	Enalaprilat
Eplerenone	Eplerenone
Eplerenone	Inspra
Eprosartan mesylate	Eprosartan
Eprosartan mesylate	Teveten
Eprosartan mesylate/hydrochlorothiazide	Teveten HCT
Esmolol HCl	Brevibloc
Esmolol HCl	Esmolol
Esmolol HCl in sodium chloride, iso-osmotic	Brevibloc In Nacl (Iso-Osm)
Esmolol HCl in sodium chloride, iso-osmotic	Esmolol In Nacl (Iso-Osm)
Esmolol HCl in sterile water	Esmolol In Sterile Water
Ethacrynate sodium	Ethacrynate Sodium
Ethacrynate sodium	Sodium Edecrin
Ethacrynic acid	Edecrin
Ethacrynic acid	Ethacrynic Acid
Ethacrynic acid	Ethacrynic Acid (bulk)
Felodipine	Felodipine
Felodipine	Plendil
Fosinopril sodium	Fosinopril
Fosinopril sodium	Monopril
Fosinopril sodium/hydrochlorothiazide	Fosinopril-Hydrochlorothiazide
Fosinopril sodium/hydrochlorothiazide	Monopril HCT
Furosemide	Furosemide
Furosemide	Lasix
Furosemide in 0.9 % sodium chloride	Furosemide In 0.9 % Nacl
Furosemide/dextrose 5 % in water	Furosemide In Dextrose 5 %
Hydralazine HCl	Apresoline
Hydralazine HCl	Hydralazine
Hydrochlorothiazide	Aquazide-H
Hydrochlorothiazide	Carozide
Hydrochlorothiazide	Esidrix
Hydrochlorothiazide	Hydrochlorothiazide
Hydrochlorothiazide	Hydrochlorothiazide (bulk)
Hydrochlorothiazide	Hydrodiuril
Hydrochlorothiazide	Microzide

Appendix H. Generic and Brand Names of Medical Products Used to Define Baseline Characteristics in this Request

Generic Name	Brand Name
Hydrochlorothiazide	Oretic
Hydroflumethiazide	Diucardin
Indapamide	Indapamide
Indapamide	Lozol
Irbesartan	Avapro
Irbesartan	Irbesartan
Irbesartan/hydrochlorothiazide	Avalide
Irbesartan/hydrochlorothiazide	Irbesartan-Hydrochlorothiazide
Isradipine	Dynacirc
Isradipine	Dynacirc CR
Isradipine	Isradipine
Labetalol HCl	Labetalol
Labetalol HCl	Labetalol (bulk)
Labetalol HCl	Normodyne
Labetalol HCl	Trandate
Labetalol in dextrose 5 % in water	Labetalol In Dextrose 5 %
Lisinopril	Lisinopril
Lisinopril	Lisinopril (bulk)
Lisinopril	Prinivil
Lisinopril	Qbrelis
Lisinopril	Zestril
Lisinopril/dietary supplement,comb.10	Lytensopril
Lisinopril/dietary supplement,comb.10	Lytensopril-90
Lisinopril/hydrochlorothiazide	Lisinopril-Hydrochlorothiazide
Lisinopril/hydrochlorothiazide	Prinzide
Lisinopril/hydrochlorothiazide	Zestoretic
Losartan potassium	Cozaar
Losartan potassium	Losartan
Losartan potassium/hydrochlorothiazide	Hyzaar
Losartan potassium/hydrochlorothiazide	Losartan-Hydrochlorothiazide
Methyclothiazide	Aquatensen
Methyclothiazide	Enduron
Methyclothiazide	Methyclothiazide
Methyclothiazide	Methyclothiazide (bulk)
Metolazone	Metolazone
Metolazone	Mykrox
Metolazone	Zaroxolyn
Metoprolol succinate	Kapsargo Sprinkle
Metoprolol succinate	Metoprolol Succinate
Metoprolol succinate	Toprol XL
Metoprolol succinate/hydrochlorothiazide	Dutoprol
Metoprolol succinate/hydrochlorothiazide	Metoprolol Su-Hydrochlorothiaz
Metoprolol tartrate	Lopressor
Metoprolol tartrate	Metoprolol Tartrate
Metoprolol tartrate	Metoprolol Tartrate (bulk)
Metoprolol tartrate/dietary supplement,comb.10	Hypertensolol

Appendix H. Generic and Brand Names of Medical Products Used to Define Baseline Characteristics in this Request

Generic Name	Brand Name
Metoprolol tartrate/hydrochlorothiazide	Lopressor HCT
Metoprolol tartrate/hydrochlorothiazide	Metoprolol Ta-Hydrochlorothiaz
Minoxidil	Loniten
Minoxidil	Minoxidil
Moexipril HCl	Moexipril
Moexipril HCl	Univasc
Moexipril HCl/hydrochlorothiazide	Moexipril-Hydrochlorothiazide
Moexipril HCl/hydrochlorothiazide	Uniretic
Nadolol	Corgard
Nadolol	Nadolol
Nadolol	Nadolol (bulk)
Nadolol/bendroflumethiazide	Corzide
Nadolol/bendroflumethiazide	Nadolol-Bendroflumethiazide
Nebivolol HCl	Bystolic
Nebivolol HCl/valsartan	Byvalson
Nicardipine HCl	Cardene
Nicardipine HCl	Cardene IV
Nicardipine HCl	Cardene SR
Nicardipine HCl	Nicardipine
Nicardipine HCl in 0.9 % sodium chloride	Nicardipine In 0.9 % Nacl
Nicardipine in 5 % dextrose in water	Nicardipine In 5 % Dextrose
Nicardipine in dextrose, iso-osmotic	Cardene IV In Dextrose
Nicardipine in sodium chloride, iso-osmotic	Cardene IV In Sodium Chloride
Nifedipine	Adalat
Nifedipine	Adalat CC
Nifedipine	Afeditab CR
Nifedipine	Nifediac CC
Nifedipine	Nifedical XL
Nifedipine	Nifedipine
Nifedipine	Procardia
Nifedipine	Procardia XL
Nifedipine, micronized	Nifedipine, Micronized (bulk)
Nimodipine	Nimodipine
Nimodipine	Nimodipine (bulk)
Nimodipine	Nimotop
Nimodipine	Nymalize
Nisoldipine	Nisoldipine
Nisoldipine	Sular
Nitroprusside sodium	Nitropress
Nitroprusside sodium	Sodium Nitroprusside
Nitroprusside sodium in 0.9 % sodium chloride	Nipride RTU
Olmesartan medoxomil	Benicar
Olmesartan medoxomil	Olmesartan
Olmesartan medoxomil/amlodipine besylate/ hydrochlorothiazide	Olmesartan-Amlodipin-Hcthiazid

Appendix H. Generic and Brand Names of Medical Products Used to Define Baseline Characteristics in this Request

Generic Name	Brand Name
Olmesartan medoxomil/amlodipine besylate/ hydrochlorothiazide	Tribenzor
Olmesartan medoxomil/hydrochlorothiazide	Benicar HCT
Olmesartan medoxomil/hydrochlorothiazide	Olmesartan-Hydrochlorothiazide
Penbutolol sulfate	Levatol
Perindopril arginine/amlodipine besylate	Prestalia
Perindopril erbumine	Aceon
Perindopril erbumine	Perindopril Erbumine
Phenoxybenzamine HCl	Dibenzyline
Phenoxybenzamine HCl	Phenoxybenzamine
Phentolamine mesylate	Phentolamine
Phentolamine mesylate	Phentolamine Mesylate (bulk)
Phentolamine mesylate	Regitine
Pindolol	Pindolol
Pindolol	Pindolol (bulk)
Pindolol	Visken
Polythiazide	Renese
Prazosin HCl	Minipress
Prazosin HCl	Prazosin
Propranolol HCl	Hemangeol
Propranolol HCl	Inderal
Propranolol HCl	Inderal LA
Propranolol HCl	Inderal XL
Propranolol HCl	Innopran XL
Propranolol HCl	Propranolol
Propranolol HCl	Propranolol (bulk)
Propranolol HCl/hydrochlorothiazide	Inderide
Propranolol HCl/hydrochlorothiazide	Inderide LA
Propranolol HCl/hydrochlorothiazide	Propranolol-Hydrochlorothiazid
Quinapril HCl	Accupril
Quinapril HCl	Quinapril
Quinapril HCl/hydrochlorothiazide	Accuretic
Quinapril HCl/hydrochlorothiazide	Quinapril-Hydrochlorothiazide
Quinapril HCl/hydrochlorothiazide	Quinaretic
Ramipril	Altace
Ramipril	Ramipril
Rauwolfia serpentina/bendroflumethiazide	Flumezide
Rauwolfia serpentina/bendroflumethiazide	Rauzide
Rauwolfia serpentina/bendroflumethiazide	Rondameth
Reserpine/hydrochlorothiazide	Hydro-Reserp
Reserpine/hydrochlorothiazide	Reserpine-Hydrochlorothiazide
Reserpine/hydroflumethiazide	Salutensin
Reserpine/hydroflumethiazide	Salutensin-Demi
Reserpine/methyclothiazide	Diutensen-R
Reserpine/polythiazide	Renese-R
Sacubitril/valsartan	Entresto

Appendix H. Generic and Brand Names of Medical Products Used to Define Baseline Characteristics in this Request

Generic Name	Brand Name
Sotalol HCl	Betapace
Sotalol HCl	Betapace AF
Sotalol HCl	Sorine
Sotalol HCl	Sotalol
Sotalol HCl	Sotalol AF
Sotalol HCl	Sotylize
Spironolactone	Aldactone
Spironolactone	Carospir
Spironolactone	Spironolactone
Spironolactone	Spironolactone (bulk)
Spironolactone, micronized	Spironolactone Micro (bulk)
Spironolactone/hydrochlorothiazide	Aldactazide
Spironolactone/hydrochlorothiazide	Spironolacton-Hydrochlorothiaz
Telmisartan	Micardis
Telmisartan	Telmisartan
Telmisartan/amlodipine besylate	Telmisartan-Amlodipine
Telmisartan/amlodipine besylate	Twynsta
Telmisartan/hydrochlorothiazide	Micardis HCT
Telmisartan/hydrochlorothiazide	Telmisartan-Hydrochlorothiazid
Terazosin HCl	Hytrin
Terazosin HCl	Terazosin
Timolol maleate	Blocadren
Timolol maleate	Timolol Maleate
Timolol maleate	Timolol Maleate (bulk)
Timolol maleate/hydrochlorothiazide	Timolide
Tolazoline HCl	Priscoline
Tolazoline HCl	Tolazoline (bulk)
Torsemide	Demadex
Torsemide	Torsemide
Trandolapril	Mavik
Trandolapril	Trandolapril
Trandolapril/verapamil HCl	Tarka
Trandolapril/verapamil HCl	Trandolapril-Verapamil
Triamterene	Dyrenium
Triamterene/hydrochlorothiazide	Dyazide
Triamterene/hydrochlorothiazide	Maxzide
Triamterene/hydrochlorothiazide	Maxzide-25mg
Triamterene/hydrochlorothiazide	Triamterene-Hydrochlorothiazid
Trichlormethiazide	Aquazide
Trichlormethiazide	Naqua
Trichlormethiazide	Trichlormethiazide
Trichlormethiazide	Trichlormethiazide (bulk)
Valsartan	Diovan
Valsartan	Valsartan
Valsartan/hydrochlorothiazide	Diovan HCT
Valsartan/hydrochlorothiazide	Valsartan-Hydrochlorothiazide

Appendix H. Generic and Brand Names of Medical Products Used to Define Baseline Characteristics in this Request

Generic Name	Brand Name
Verapamil HCl	Calan
Verapamil HCl	Calan SR
Verapamil HCl	Covera-HS
Verapamil HCl	Isoptin SR
Verapamil HCl	Verapamil
Verapamil HCl	Verapamil (bulk)
Verapamil HCl	Verelan
Verapamil HCl	Verelan PM
Anxiolytics	
Alprazolam	Alprazolam
Alprazolam	Alprazolam (bulk)
Alprazolam	Alprazolam Intensol
Alprazolam	Niravam
Alprazolam	Xanax
Alprazolam	Xanax XR
Alprazolam/dietary supplement,misc combo no.17	Gabazolamine
Buspirone HCl	Buspar
Buspirone HCl	Buspirone
Buspirone HCl	Buspirone (bulk)
Buspirone HCl	Vanspar
Chlordiazepoxide HCl	Chlordiazepoxide HCl
Chlordiazepoxide HCl	Librium
Chlordiazepoxide HCl	Poxi
Clonazepam	Ceberclon
Clonazepam	Clonazepam
Clonazepam	Clonazepam (bulk)
Clonazepam	Klonopin
Clorazepate dipotassium	Clorazepate Dipotassium
Clorazepate dipotassium	Gen-XENE
Clorazepate dipotassium	Tranxene T-Tab
Clorazepate dipotassium	Tranxene-SD
Diazepam	Diazepam
Diazepam	Diazepam (bulk)
Diazepam	Diazepam Intensol
Diazepam	Valium
Diazepam (in soybean oil)	Dizac
Halazepam	Paxipam
Hydroxyzine HCl	Anx
Hydroxyzine HCl	Atarax
Hydroxyzine HCl	Hydroxyzine HCl
Hydroxyzine HCl	Hydroxyzine HCl (bulk)
Hydroxyzine HCl	Hyzine
Hydroxyzine HCl	Rezine
Hydroxyzine HCl	Vistacot
Hydroxyzine HCl	Vistaril IM (HCl Salt)
Hydroxyzine HCl	Vistazine

Appendix H. Generic and Brand Names of Medical Products Used to Define Baseline Characteristics in this Request

Generic Name	Brand Name
Hydroxyzine pamoate	Hydroxyzine Pamoate
Hydroxyzine pamoate	Hydroxyzine Pamoate (bulk)
Hydroxyzine pamoate	Vistaril
Lorazepam	Ativan
Lorazepam	Lorazepam
Lorazepam	Lorazepam (bulk)
Lorazepam	Lorazepam Intensol
Meprobamate	Equanil
Meprobamate	Mb-Tab
Meprobamate	Meprobamate
Meprobamate	Miltown
Oxazepam	Oxazepam
Oxazepam	Serax
Stimulants	
Ammonia	Ammonia Aromatic
Ammonia	Amoply
Amphetamine	Adzenys ER
Amphetamine	Adzenys XR-ODT
Amphetamine	Dyanavel XR
Amphetamine sulfate	Amphetamine Sulfate
Amphetamine sulfate	Evekeo
Amphetamine sulfate	Evekeo ODT
Armodafinil	Armodafinil
Armodafinil	Nuvigil
Caffeine	Alertness
Caffeine	Alertness Aid
Caffeine	Awake
Caffeine	Ban Drowz
Caffeine	Caffedrine
Caffeine	Caffeine
Caffeine	Caffeine (bulk)
Caffeine	Keep Alert
Caffeine	Kola Wine
Caffeine	Lucidex
Caffeine	No Doz
Caffeine	Pocion Jaccoud, Grandpa's
Caffeine	Stay Awake
Caffeine	Stay Awake Extra Strength
Caffeine	Stay Awake Maximum Strength
Caffeine	Verv
Caffeine	Vivarin
Caffeine	Wakespan
Caffeine citrate	Cafcit
Caffeine citrate	Caffeine Citrate
Caffeine/dextrose	Quick-Pep
Caffeine/ethyl alcohol	Kola Extract

Appendix H. Generic and Brand Names of Medical Products Used to Define Baseline Characteristics in this Request

Generic Name	Brand Name
Caffeine/sodium benzoate	Caffeine-Sodium Benzoate
Dexmethylphenidate HCl	Dexmethylphenidate
Dexmethylphenidate HCl	Focalin
Dexmethylphenidate HCl	Focalin XR
Dextroamphetamine sulfate	Dexedrine
Dextroamphetamine sulfate	Dexedrine Spansule
Dextroamphetamine sulfate	Dextroamphetamine
Dextroamphetamine sulfate	Dextroamphetamine (bulk)
Dextroamphetamine sulfate	Dextrostat
Dextroamphetamine sulfate	Liquadd
Dextroamphetamine sulfate	Procentra
Dextroamphetamine sulfate	Zenzedi
Dextroamphetamine sulf-saccharate/amphetamine sulf-aspartate	Adderall
Dextroamphetamine sulf-saccharate/amphetamine sulf-aspartate	Adderall XR
Dextroamphetamine sulf-saccharate/amphetamine sulf-aspartate	Dextroamphetamine-Amphetamine
Dextroamphetamine sulf-saccharate/amphetamine sulf-aspartate	Mydayis
Doxapram HCl	Dopram
Doxapram HCl	Doxapram
Lisdexamfetamine dimesylate	Vyvanse
Meclofenoxate HCl	Meclofenoxate HCl (bulk)
Methamphetamine HCl	Desoxyn
Methamphetamine HCl	Methamphetamine
Methylphenidate	Cotempla XR-ODT
Methylphenidate	Daytrana
Methylphenidate HCl	Adhansia XR
Methylphenidate HCl	Aptensio XR
Methylphenidate HCl	Concerta
Methylphenidate HCl	Jornay PM
Methylphenidate HCl	Metadate CD
Methylphenidate HCl	Metadate ER
Methylphenidate HCl	Methylin
Methylphenidate HCl	Methylin ER
Methylphenidate HCl	Methylphenidate HCl
Methylphenidate HCl	Methylphenidate HCl (bulk)
Methylphenidate HCl	Quillichew ER
Methylphenidate HCl	Quillivant XR
Methylphenidate HCl	Relexxii
Methylphenidate HCl	Ritalin
Methylphenidate HCl	Ritalin LA
Methylphenidate HCl	Ritalin SR
Modafinil	Modafinil
Modafinil	Provigil

Appendix H. Generic and Brand Names of Medical Products Used to Define Baseline Characteristics in this Request

Generic Name	Brand Name
Pemoline	Cylert
Pemoline	Pemoline
Pemoline	Pemoline (bulk)
Barbituates	
Amobarbital sodium	Amytal
Amobarbital sodium/secobarbital sodium	Tuinal
Butobarbital sodium	Butisol
Butalbital	Butalbital (bulk)
Mephobarbital	Mebaral
Mephobarbital	Mephobarbital
Methohexital sodium	Brevital
Methohexital sodium in sterile water for injection/PF	Methohexital In Water (PF)
Pentobarbital sodium	Nembutal
Pentobarbital sodium	Nembutal Sodium
Pentobarbital sodium	Pentobarbital Sodium
Pentobarbital sodium	Pentobarbital Sodium (bulk)
Phenobarbital	Phenobarbital
Phenobarbital	Phenobarbital (bulk)
Phenobarbital sodium	Luminal
Phenobarbital sodium	Phenobarbital Sodium
Phenobarbital sodium in 0.9 % sodium chloride	Phenobarbital In 0.9 % Sod Chl
Primidone	Mysoline
Primidone	Primidone
Primidone	Primidone (bulk)
Secobarbital sodium	Seconal
Secobarbital sodium	Seconal Sodium
Theophylline/ephedrine HCl/phenobarbital	Asthma
Theophylline/ephedrine HCl/phenobarbital	Theophylline-Ephed-Phenobarb
Thiopental sodium	Pentothal
Thiopental sodium	Thiopental Sodium
Insulin	
Insulin aspart	Novolog Flexpen U-100 Insulin
Insulin aspart	Novolog Penfill U-100 Insulin
Insulin aspart	Novolog U-100 Insulin Aspart
Insulin aspart (niacinamide)	Fiasp Flextouch U-100 Insulin
Insulin aspart (niacinamide)	Fiasp U-100 Insulin
Insulin aspart protamine human/insulin aspart	Novolog Mix 70-30 U-100 Insulin
Insulin aspart protamine human/insulin aspart	Novolog Mix 70-30flexpen U-100
Insulin degludec	Tresiba Flextouch U-100
Insulin degludec	Tresiba Flextouch U-200
Insulin degludec	Tresiba U-100 Insulin
Insulin degludec/liraglutide	Xultophy 100/3.6
Insulin detemir	Levemir Flexpen
Insulin detemir	Levemir Flextouch U-100 Insulin
Insulin detemir	Levemir U-100 Insulin
Insulin glargine, human recombinant analog	Basaglar Kwikpen U-100 Insulin

Appendix H. Generic and Brand Names of Medical Products Used to Define Baseline Characteristics in this Request

Generic Name	Brand Name
Insulin glargine,human recombinant analog	Lantus Solostar U-100 Insulin
Insulin glargine,human recombinant analog	Lantus U-100 Insulin
Insulin glargine,human recombinant analog	Toujeo Max U-300 Solostar
Insulin glargine,human recombinant analog	Toujeo Solostar U-300 Insulin
Insulin glargine,human recombinant analog/lixisenatide	Soliqua 100/33
Insulin glulisine	Apidra Solostar U-100 Insulin
Insulin glulisine	Apidra U-100 Insulin
Insulin lispro	Admelog Solostar U-100 Insulin
Insulin lispro	Admelog U-100 Insulin Lispro
Insulin lispro	Humalog Junior Kwikpen U-100
Insulin lispro	Humalog Kwikpen Insulin
Insulin lispro	Humalog Pen
Insulin lispro	Humalog U-100 Insulin
Insulin lispro	Insulin Lispro
Insulin lispro protamine and insulin lispro	Humalog Mix 50-50 Insulin U-100
Insulin lispro protamine and insulin lispro	Humalog Mix 50-50 Kwikpen
Insulin lispro protamine and insulin lispro	Humalog Mix 75-25 Kwikpen
Insulin lispro protamine and insulin lispro	Humalog Mix 75-25(U-100)Insulin
Insulin NPH human isophane	Humulin N NPH Insulin Kwikpen
Insulin NPH human isophane	Humulin N Nph U-100 Insulin
Insulin NPH human isophane	Humulin N Pen
Insulin NPH human isophane	Novolin N Innolet
Insulin NPH human isophane	Novolin N Nph U-100 Insulin
Insulin NPH human isophane	Novolin N Penfill
Insulin NPH human isophane/insulin regular, human	Humulin 50/50
Insulin NPH human isophane/insulin regular, human	Humulin 70/30 Insulin Pen
Insulin NPH human isophane/insulin regular, human	Humulin 70/30 U-100 Insulin
Insulin NPH human isophane/insulin regular, human	Humulin 70/30 U-100 Kwikpen
Insulin NPH human isophane/insulin regular, human	Novolin 70/30 Innolet Insulin
Insulin NPH human isophane/insulin regular, human	Novolin 70/30 Penfill
Insulin NPH human isophane/insulin regular, human	Novolin 70/30 U-100 Insulin
Insulin NPH human isophane/insulin regular, human	Novolin 70-30 Flexpen U-100
Insulin regular, human	Afrezza
Insulin regular, human	Humulin R Regular U-100 Insulin
Insulin regular, human	Humulin R U-500 (Conc) Insulin
Insulin regular, human	Humulin R U-500 (Conc) Kwikpen
Insulin regular, human	Novolin R Innolet
Insulin regular, human	Novolin R Penfill
Insulin regular, human	Novolin R Regular U-100 Insulin
Insulin regular,human buffered	Velosulin BR (Rdna)
Insulin regular,human buffered	Velosulin Human Br
Non-insulin antidiabetic medication	
Acarbose	Acarbose
Acarbose	Precose
Acetohexamide	Acetohexamide
Albiglutide	Tanzeum

Appendix H. Generic and Brand Names of Medical Products Used to Define Baseline Characteristics in this Request

Generic Name	Brand Name
Alogliptin benzoate	Alogliptin
Alogliptin benzoate	Nesina
Alogliptin benzoate/metformin HCl	Alogliptin-Metformin
Alogliptin benzoate/metformin HCl	Kazano
Alogliptin benzoate/pioglitazone HCl	Alogliptin-Pioglitazone
Alogliptin benzoate/pioglitazone HCl	Oseni
Bromocriptine mesylate	Cycloset
Canagliflozin	Invokana
Canagliflozin/metformin HCl	Invokamet
Canagliflozin/metformin HCl	Invokamet XR
Chlorpropamide	Chlorpropamide
Chlorpropamide	Diabinese
Dapagliflozin propanediol	Farxiga
Dapagliflozin propanediol/metformin HCl	Xigduo XR
Dapagliflozin propanediol/saxagliptin HCl	Qtern
Dulaglutide	Trulicity
Empagliflozin	Jardiance
Empagliflozin/linagliptin	Glyxambi
Empagliflozin/metformin HCl	Synjardy
Empagliflozin/metformin HCl	Synjardy XR
Ertugliflozin pidolate	Steglatro
Ertugliflozin pidolate/metformin HCl	Segluromet
Ertugliflozin pidolate/sitagliptin phosphate	Steglujan
Exenatide	Byetta
Exenatide microspheres	Bydureon
Exenatide microspheres	Bydureon Bcise
Glimepiride	Amaryl
Glimepiride	Glimepiride
Glipizide	Glipizide
Glipizide	Glucotrol
Glipizide	Glucotrol XL
Glipizide/metformin HCl	Glipizide-Metformin
Glipizide/metformin HCl	Metaglip
Glyburide	Diabeta
Glyburide	Glyburide
Glyburide	Micronase
Glyburide,micronized	Glyburide Micronized
Glyburide,micronized	Glycron
Glyburide,micronized	Glynase
Glyburide/metformin HCl	Glucovance
Glyburide/metformin HCl	Glyburide-Metformin
Linagliptin	Tradjenta
Linagliptin/metformin HCl	Jentadueto
Linagliptin/metformin HCl	Jentadueto XR
Liraglutide	Victoza 2-Pak
Liraglutide	Victoza 3-Pak

Appendix H. Generic and Brand Names of Medical Products Used to Define Baseline Characteristics in this Request

Generic Name	Brand Name
Lixisenatide	Adlyxin
Metformin HCl	Fortamet
Metformin HCl	Glucophage
Metformin HCl	Glucophage XR
Metformin HCl	Glumetza
Metformin HCl	Metformin
Metformin HCl	Metformin (bulk)
Metformin HCl	Riomet
Metformin HCl/blood sugar diagnostic	Dm2
Metformin/amino acids no.7/herbal cmb.125/choline bitartrate	Appformin-D
Metformin/caffeine/amino acids 7/herbal comb 125/choline bit	Appformin
Mifepristone	Korlym
Miglitol	Glyset
Miglitol	Miglitol
Nateglinide	Nateglinide
Nateglinide	Starlix
Pioglitazone HCl	Actos
Pioglitazone HCl	Pioglitazone
Pioglitazone HCl/glimepiride	Duetact
Pioglitazone HCl/glimepiride	Pioglitazone-Glimepiride
Pioglitazone HCl/metformin HCl	Actoplus MET
Pioglitazone HCl/metformin HCl	Actoplus Met Xr
Pioglitazone HCl/metformin HCl	Pioglitazone-Metformin
Pramlintide acetate	Symlin
Pramlintide acetate	Symlinpen 120
Pramlintide acetate	Symlinpen 60
Repaglinide	Prandin
Repaglinide	Repaglinide
Repaglinide/metformin HCl	Prandimet
Repaglinide/metformin HCl	Repaglinide-Metformin
Rosiglitazone maleate	Avandia
Rosiglitazone maleate/glimepiride	Avandaryl
Rosiglitazone maleate/metformin HCl	Avandamet
Saxagliptin HCl	Onglyza
Saxagliptin HCl/metformin HCl	Kombiglyze XR
Semaglutide	Ozempic
Sitagliptin phosphate	Januvia
Sitagliptin phosphate/metformin HCl	Janumet
Sitagliptin phosphate/metformin HCl	Janumet XR
Sitagliptin phosphate/simvastatin	Juvisync
Tolazamide	Tolazamide
Tolazamide	Tolinase
Tolbutamide	Orinase

Appendix H. Generic and Brand Names of Medical Products Used to Define Baseline Characteristics in this Request

Generic Name	Brand Name
Tolbutamide	Tolbutamide
Troglitazone	Rezulin
Opioids	
Acetaminophen with codeine phosphate	Acetaminophen-Codeine
Acetaminophen with codeine phosphate	Capital With Codeine
Acetaminophen with codeine phosphate	Cocet
Acetaminophen with codeine phosphate	Cocet Plus
Acetaminophen with codeine phosphate	Phenaphen/Codeine #3
Acetaminophen with codeine phosphate	Phenaphen/Codeine #4
Acetaminophen with codeine phosphate	Tylenol-Codeine #3
Acetaminophen with codeine phosphate	Tylenol-Codeine #4
Acetaminophen with codeine phosphate	Tylenol-Codeine Elixir
Acetaminophen with codeine phosphate	Vopac
Acetaminophen/caffeine/dihydrocodeine bitartrate	Acetaminophen-Caff-Dihydrocod
Acetaminophen/caffeine/dihydrocodeine bitartrate	Dhc Plus
Acetaminophen/caffeine/dihydrocodeine bitartrate	Dvorah
Acetaminophen/caffeine/dihydrocodeine bitartrate	Panlor DC
Acetaminophen/caffeine/dihydrocodeine bitartrate	Panlor SS
Acetaminophen/caffeine/dihydrocodeine bitartrate	Panlor(Acetam-Caff-Dihydrocod)
Acetaminophen/caffeine/dihydrocodeine bitartrate	Trezix
Acetaminophen/caffeine/dihydrocodeine bitartrate	Zerlor
Alfentanil HCl	Alfenta
Alfentanil HCl	Alfentanil
Aspirin/caffeine/dihydrocodeine bitartrate	Aspirin-Caffeine-Dihydrocodein
Aspirin/caffeine/dihydrocodeine bitartrate	Synalgos-DC
Aspirin/codeine phosphate	Aspirin-Codeine
Aspirin/codeine phosphate	Aspirin-Codeine #3
Aspirin/codeine phosphate	Aspirin-Codeine #4
Benzhydrocodone HCl/acetaminophen	Apadaz
Benzhydrocodone HCl/acetaminophen	Benzhydrocodone-Acetaminophen
Buprenorphine	Buprenorphine
Buprenorphine	Butrans
Buprenorphine HCl	Belbuca
Buprenorphine HCl	Buprenex
Buprenorphine HCl	Buprenorphine HCl
Buprenorphine HCl	Buprenorphine HCl (bulk)
Butalbital/acetaminophen/caffeine/codeine phosphate	Butalbital-Acetaminop-Caf-Cod
Butalbital/acetaminophen/caffeine/codeine phosphate	Fioricet With Codeine
Butalbital/acetaminophen/caffeine/codeine phosphate	Phrenilin W/Caffeine-Codeine
Butorphanol tartrate	Butorphanol Tartrate
Butorphanol tartrate	Butorphanol Tartrate (bulk)
Butorphanol tartrate	Stadol
Butorphanol tartrate	Stadol NS
Codeine phosphate	Codeine Phosphate
Codeine phosphate	Codeine Phosphate (bulk)
Codeine phosphate	Codeine Phosphate Soluble

Appendix H. Generic and Brand Names of Medical Products Used to Define Baseline Characteristics in this Request

Generic Name	Brand Name
Codeine phosphate/butalbital/aspirin/caffeine	Ascomp With Codeine
Codeine phosphate/butalbital/aspirin/caffeine	Butalbital Compound W/Codeine
Codeine phosphate/butalbital/aspirin/caffeine	Butalbital Compound-Codeine
Codeine phosphate/butalbital/aspirin/caffeine	Codeine-Butalbital-ASA-Caff
Codeine phosphate/butalbital/aspirin/caffeine	Fiorinal-Codeine #3
Codeine phosphate/butalbital/aspirin/caffeine	Fiortal/Codeine
Codeine sulfate	Codeine Sulfate
Codeine/aspirin/salicylamide/acetaminophen/caffeine	Rid-A-Pain
Codeine/aspirin/salicylamide/acetaminophen/caffeine	Rid-A-Pain W/Codeine
Fentanyl	Duragesic
Fentanyl	Fentanyl
Fentanyl	Fentanyl (bulk)
Fentanyl	Subsys
Fentanyl citrate	Abstral
Fentanyl citrate	Actiq
Fentanyl citrate	Fentanyl Citrate
Fentanyl citrate	Fentanyl Citrate (bulk)
Fentanyl citrate	Fentora
Fentanyl citrate	Lazanda
Fentanyl citrate	Onsolis
Fentanyl citrate in 0.9 % sodium chloride/PF	Fentanyl Citrate (PF)-0.9%Nacl
Fentanyl citrate in dextrose 5% in water/PF	Fentanyl Citrate In D5W (PF)
Fentanyl citrate/bupivacaine HCl in 0.9 % sodium chloride/PF	Fentanyl (PF)-Bupivacaine-NaCl
Fentanyl citrate/PF	Fentanyl Citrate (PF)
Fentanyl citrate/ropivacaine HCl/sodium chloride 0.9%/PF	Fentanyl-Ropivacaine-NaCl (PF)
Fentanyl HCl	lonsys
Hydrocodone bitartrate	Hydrocodone Bitartrate (bulk)
Hydrocodone bitartrate	Hysingla ER
Hydrocodone bitartrate	Zohydro ER
Hydrocodone bitartrate/acetaminophen	Anexsia
Hydrocodone bitartrate/acetaminophen	Bancap HC
Hydrocodone bitartrate/acetaminophen	Ceta Plus
Hydrocodone bitartrate/acetaminophen	Co-Gesic
Hydrocodone bitartrate/acetaminophen	Dolacet
Hydrocodone bitartrate/acetaminophen	Dolorex Forte
Hydrocodone bitartrate/acetaminophen	Duocet
Hydrocodone bitartrate/acetaminophen	Hycet
Hydrocodone bitartrate/acetaminophen	Hycomed
Hydrocodone bitartrate/acetaminophen	Hydrocet
Hydrocodone bitartrate/acetaminophen	Hydrocodone-Acetaminophen
Hydrocodone bitartrate/acetaminophen	Hydrogesic
Hydrocodone bitartrate/acetaminophen	Hy-Phen
Hydrocodone bitartrate/acetaminophen	Liquicet
Hydrocodone bitartrate/acetaminophen	Lorcet (Hydrocodone)
Hydrocodone bitartrate/acetaminophen	Lorcet 10/650
Hydrocodone bitartrate/acetaminophen	Lorcet HD

Appendix H. Generic and Brand Names of Medical Products Used to Define Baseline Characteristics in this Request

Generic Name	Brand Name
Hydrocodone bitartrate/acetaminophen	Lorcet Plus
Hydrocodone bitartrate/acetaminophen	Lortab
Hydrocodone bitartrate/acetaminophen	Lortab 10-325
Hydrocodone bitartrate/acetaminophen	Lortab 5-325
Hydrocodone bitartrate/acetaminophen	Lortab 7.5-325
Hydrocodone bitartrate/acetaminophen	Lortab Elixir
Hydrocodone bitartrate/acetaminophen	Margesic-H
Hydrocodone bitartrate/acetaminophen	Maxidone
Hydrocodone bitartrate/acetaminophen	Norco
Hydrocodone bitartrate/acetaminophen	Polygesic
Hydrocodone bitartrate/acetaminophen	Procet
Hydrocodone bitartrate/acetaminophen	Stagesic
Hydrocodone bitartrate/acetaminophen	Stagesic-10
Hydrocodone bitartrate/acetaminophen	Vanacet
Hydrocodone bitartrate/acetaminophen	Vendone
Hydrocodone bitartrate/acetaminophen	Verdrocet
Hydrocodone bitartrate/acetaminophen	Vicodin
Hydrocodone bitartrate/acetaminophen	Vicodin ES
Hydrocodone bitartrate/acetaminophen	Vicodin HP
Hydrocodone bitartrate/acetaminophen	Xodol 10/300
Hydrocodone bitartrate/acetaminophen	Xodol 5/300
Hydrocodone bitartrate/acetaminophen	Xodol 7.5/300
Hydrocodone bitartrate/acetaminophen	Zamicet
Hydrocodone bitartrate/acetaminophen	Zolvit
Hydrocodone bitartrate/acetaminophen	Zydone
Hydrocodone bitartrate/acetaminophen/dietary supplement #11	Theracodophen-325
Hydrocodone bitartrate/acetaminophen/dietary supplement #11	Theracodophen-650
Hydrocodone bitartrate/acetaminophen/dietary supplement #11	Theracodophen-Low-90
Hydrocodone bitartrate/aspirin	Alor
Hydrocodone bitartrate/aspirin	Damason-P
Hydrocodone bitartrate/aspirin	Lortab ASA
Hydrocodone/ibuprofen	Hydrocodone-Ibuprofen
Hydrocodone/ibuprofen	Ibudone
Hydrocodone/ibuprofen	Reprexain
Hydrocodone/ibuprofen	Vicoprofen
Hydrocodone/ibuprofen	Xylon 10
Hydromorphone HCl	Dilaudid
Hydromorphone HCl	Dilaudid-5
Hydromorphone HCl	Exalgo ER
Hydromorphone HCl	Hydromorphone
Hydromorphone HCl	Hydromorphone (bulk)
Hydromorphone HCl	Palladone
Hydromorphone HCl in 0.9 % sodium chloride	Hydromorphone In 0.9 % NaCl

Appendix H. Generic and Brand Names of Medical Products Used to Define Baseline Characteristics in this Request

Generic Name	Brand Name
Hydromorphone HCl in 0.9 % sodium chloride/PF	Hydromorphone (PF)-0.9 % Nacl
Hydromorphone HCl in dextrose 5 %-water/PF	Hydromorphone In D5W (PF)
Hydromorphone HCl in sterile water/PF	Hydromorphone (PF) In Water
Hydromorphone HCl/bupivacaine HCl in 0.9% sodium chloride/PF	Hydromorphone-Bupiv (PF)-Nacl
Hydromorphone HCl/PF	Dilaudid (PF)
Hydromorphone HCl/PF	Dilaudid-HP (PF)
Hydromorphone HCl/PF	Hydromorphone (PF)
Hydromorphone HCl/ropivacaine in 0.9 % sodium chloride/PF	Hydromorph(PF)-Ropiv-0.9% Nacl
Ibuprofen/oxycodone HCl	Combunox
Ibuprofen/oxycodone HCl	Ibuprofen-Oxycodone
Levomethadyl acetate HCl	Orlaam
Levorphanol tartrate	Levo-Dromoran
Levorphanol tartrate	Levorphanol Tartrate
Levorphanol tartrate	Levorphanol Tartrate (bulk)
Meperidine HCl	Demerol
Meperidine HCl	Meperidine
Meperidine HCl	Meperidine (bulk)
Meperidine HCl	Meperitab
Meperidine HCl in 0.9 % sodium chloride	Meperidine In 0.9 % Nacl
Meperidine HCl in 0.9 % sodium chloride/PF	Meperidine (PF) In 0.9 % Nacl
Meperidine HCl/PF	Demerol (PF)
Meperidine HCl/PF	Meperidine (PF)
Meperidine HCl/promethazine HCl	Mepergan
Meperidine HCl/promethazine HCl	Mepergan Fortis
Meperidine HCl/promethazine HCl	Meperidine-Promethazine
Meperidine HCl/promethazine HCl	Meprozone
Methadone HCl	Diskets
Methadone HCl	Dolophine
Methadone HCl	Methadone
Methadone HCl	Methadone (bulk)
Methadone HCl	Methadone Intensol
Methadone HCl	Methadose
Methadone hydrochloride in 0.9 % sodium chloride	Methadone In 0.9 % Sod. Chlor
Morphine sulfate	Arymo ER
Morphine sulfate	Avinza
Morphine sulfate	Kadian
Morphine sulfate	Morphabond ER
Morphine sulfate	Morphine
Morphine sulfate	Morphine (bulk)
Morphine sulfate	Morphine Concentrate
Morphine sulfate	Ms Contin
Morphine sulfate	Msir
Morphine sulfate	Msir Concentrate
Morphine sulfate	Oramorph SR
Morphine sulfate	Rms

Appendix H. Generic and Brand Names of Medical Products Used to Define Baseline Characteristics in this Request

Generic Name	Brand Name
Morphine sulfate	Roxanol Concentrate
Morphine sulfate	Roxanol-T Concentrate
Morphine sulfate in 0.9 % sodium chloride	Morphine In 0.9 % Sodium Chlor
Morphine sulfate in 0.9 % sodium chloride/PF	Morphine (PF) In 0.9 % Nacl
Morphine sulfate in sodium chloride, iso-osmotic/PF	Morphine(PF)In Iso Sod Chlorid
Morphine sulfate liposomal/PF	Depodur (PF)
Morphine sulfate/dextrose 5 % in water	Morphine In Dextrose 5 %
Morphine sulfate/dextrose 5%-water/PF	Morphine (PF) In Dextrose 5 %
Morphine sulfate/naltrexone HCl	Embeda
Morphine sulfate/PF	Astramorph-PF
Morphine sulfate/PF	Duramorph (PF)
Morphine sulfate/PF	Infumorph 200 P/F
Morphine sulfate/PF	Infumorph 500 P/F
Morphine sulfate/PF	Infumorph P/F
Morphine sulfate/PF	Mitigo (PF)
Morphine sulfate/PF	Morphine (PF)
Nalbuphine HCl	Nalbuphine
Nalbuphine HCl	Nalbuphine (bulk)
Nalbuphine HCl	Nubain
Oxycodone HCl	Dazidox
Oxycodone HCl	Endocodone
Oxycodone HCl	Eth-Oxydose
Oxycodone HCl	Oxaydo
Oxycodone HCl	Oxecta
Oxycodone HCl	Oxycodone
Oxycodone HCl	Oxycodone (bulk)
Oxycodone HCl	Oxycontin
Oxycodone HCl	Oxyfast
Oxycodone HCl	Oxyir
Oxycodone HCl	Percolone
Oxycodone HCl	Roxicodone
Oxycodone HCl	Roxicodone Intensol
Oxycodone HCl	Roxybond
Oxycodone HCl/acetaminophen	Alcet
Oxycodone HCl/acetaminophen	Endocet
Oxycodone HCl/acetaminophen	Lynox
Oxycodone HCl/acetaminophen	Magnacet
Oxycodone HCl/acetaminophen	Nalocet
Oxycodone HCl/acetaminophen	Narvox
Oxycodone HCl/acetaminophen	Oxycodone-Acetaminophen
Oxycodone HCl/acetaminophen	Percocet
Oxycodone HCl/acetaminophen	Perloxx
Oxycodone HCl/acetaminophen	Primalev
Oxycodone HCl/acetaminophen	Primlev
Oxycodone HCl/acetaminophen	Roxicet
Oxycodone HCl/acetaminophen	Tylox

Appendix H. Generic and Brand Names of Medical Products Used to Define Baseline Characteristics in this Request

Generic Name	Brand Name
Oxycodone HCl/acetaminophen	Xartemis XR
Oxycodone HCl/acetaminophen	Xolox
Oxycodone HCl/aspirin	Endodan
Oxycodone HCl/aspirin	Oxycodone-Aspirin
Oxycodone HCl/aspirin	Percodan
Oxycodone HCl/oxycodone terephthalate/aspirin	Endodan (Old Formula)
Oxycodone HCl/oxycodone terephthalate/aspirin	Oxycodone HCl-Oxycodone-ASA
Oxycodone myristate	Xtampza ER
Oxycodone/aspirin	Percodan Demi
Oxymorphone HCl	Numorphan
Oxymorphone HCl	Opana
Oxymorphone HCl	Opana ER
Oxymorphone HCl	Oxymorphone
Pentazocine HCl/acetaminophen	Pentazocine-Acetaminophen
Pentazocine HCl/acetaminophen	Talacen
Pentazocine HCl/aspirin	Talwin Compound
Pentazocine HCl/naloxone HCl	Pentazocine-Naloxone
Pentazocine HCl/naloxone HCl	Talwin NX
Pentazocine lactate	Talwin
Propoxyphene HCl	Darvon
Propoxyphene HCl	Pp-Cap
Propoxyphene HCl	Propoxyphene
Propoxyphene HCl/acetaminophen	Propoxyphene-Acetaminophen
Propoxyphene HCl/acetaminophen	Wygesic
Propoxyphene HCl/aspirin/caffeine	Darvon Compound 32
Propoxyphene HCl/aspirin/caffeine	Darvon Compound-65
Propoxyphene HCl/aspirin/caffeine	Pc-Cap
Propoxyphene HCl/aspirin/caffeine	Propoxyphene Compound-65
Propoxyphene napsylate	Darvon-N
Propoxyphene napsylate	Propoxyphene Napsylate
Propoxyphene napsylate	Propoxyphene Napsylate (bulk)
Propoxyphene napsylate/acetaminophen	Balacet 325
Propoxyphene napsylate/acetaminophen	Darvocet A500
Propoxyphene napsylate/acetaminophen	Darvocet-N 100
Propoxyphene napsylate/acetaminophen	Darvocet-N 50
Propoxyphene napsylate/acetaminophen	Propoxacet-N 100
Propoxyphene napsylate/acetaminophen	Propoxyphene N-Acetaminophen
Propoxyphene napsylate/acetaminophen	Trycet
Sufentanil citrate	Dsuvia
Sufentanil citrate/bupivacaine HCl/0.9 % sodium chloride/PF	Sufentanil-Bupivacain-NaCl(PF)
Tapentadol HCl	Nucynta
Tapentadol HCl	Nucynta ER
Tramadol HCl	Conzip
Tramadol HCl	Rybix ODT
Tramadol HCl	Ryzolt
Tramadol HCl	Tramadol

Appendix H. Generic and Brand Names of Medical Products Used to Define Baseline Characteristics in this Request

Generic Name	Brand Name
Tramadol HCl	Tramadol Hydrochloride (bulk)
Tramadol HCl	Ultram
Tramadol HCl	Ultram ER
Tramadol HCl/acetaminophen	Tramadol-Acetaminophen
Tramadol HCl/acetaminophen	Ultracet
Tramadol HCl/dietary supplement,misc. Cb.11	Theratrtramadol-60
Tramadol HCl/dietary supplement,misc. Cb.11	Theratrtramadol-90
Hypnotics	
Amobarbital sodium	Amytal
Amobarbital sodium/secobarbital sodium	Tuinal
Butobarbital sodium	Butisol
Butalbital	Butalbital (bulk)
Chloral hydrate	Aquachloral
Chloral hydrate	Chloral Hydrate
Chloral hydrate	Chloral Hydrate (bulk)
Chloral hydrate	Somnote
Dexmedetomidine HCl	Dexmedetomidine
Dexmedetomidine HCl	Precedex
Dexmedetomidine HCl in 0.9 % sodium chloride	Dexmedetomidine In 0.9 % NaCl
Dexmedetomidine HCl in 0.9 % sodium chloride	Precedex In 0.9 % Sodium Chlor
Dexmedetomidine in 5 % dextrose in water	Dexmedetomidine In Dextrose 5%
Dichloralphenazone	Dichloralphenazone (bulk)
Diphenhydramine HCl	Diphenhydramine HCl
Doxepin HCl	Silenor
Estazolam	Estazolam
Estazolam	Prosom
Eszopiclone	Eszopiclone
Eszopiclone	Lunesta
Ethchlorvynol	Placidyl
Flurazepam HCl	Dalmane
Flurazepam HCl	Flurazepam
Lorazepam	Ativan
Lorazepam	Lorazepam
Lorazepam in 0.9 % sodium chloride	Lorazepam In 0.9% Sod Chloride
Lorazepam in 5 % dextrose and water	Lorazepam In Dextrose 5 %
Melatonin	Melatonin (bulk)
Mephobarbital	Mebaral
Mephobarbital	Mephobarbital
Midazolam	Midazolam (bulk)
Midazolam HCl	Midazolam
Midazolam HCl	Versed
Paraldehyde	Paraldehyde (bulk)
Pentobarbital sodium	Nembutal
Pentobarbital sodium	Nembutal Sodium
Pentobarbital sodium	Pentobarbital Sodium
Pentobarbital sodium	Pentobarbital Sodium (bulk)

Appendix H. Generic and Brand Names of Medical Products Used to Define Baseline Characteristics in this Request

Generic Name	Brand Name
Phenobarbital	Phenobarbital
Phenobarbital	Phenobarbital (bulk)
Phenobarbital sodium	Luminal
Phenobarbital sodium	Phenobarbital Sodium
Phenobarbital sodium in 0.9 % sodium chloride	Phenobarbital In 0.9 % Sod Chl
Quazepam	Doral
Quazepam	Quazepam
Ramelteon	Ramelteon
Ramelteon	Rozerem
Secobarbital sodium	Seconal
Secobarbital sodium	Seconal Sodium
Suvorexant	Belsomra
Tasimelteon	Hetlioz
Temazepam	Restoril
Temazepam	Temazepam
Temazepam/dietary supplement no.8	Strazepam
Triazolam	Halcion
Triazolam	Triazolam
Tryptophan	Tryptophan
Zaleplon	Sonata
Zaleplon	Zaleplon
Zolpidem tartrate	Ambien
Zolpidem tartrate	Ambien CR
Zolpidem tartrate	Ambien Pak
Zolpidem tartrate	Edluar
Zolpidem tartrate	Intermezzo
Zolpidem tartrate	Zolpidem
Zolpidem tartrate	Zolpimist
Buprenorphine	
Buprenorphine	Buprenorphine
Buprenorphine	Butrans
Buprenorphine	Sublocade
Buprenorphine HCl	Belbuca
Buprenorphine HCl	Buprenex
Buprenorphine HCl	Buprenorphine HCl
Buprenorphine HCl	Buprenorphine HCl (bulk)
Buprenorphine HCl	Probuphine
Buprenorphine HCl	Subutex
Methadone	
Methadone HCl	Diskets
Methadone HCl	Dolophine
Methadone HCl	Methadone
Methadone HCl	Methadone (bulk)
Methadone HCl	Methadone Intensol
Methadone HCl	Methadose
Methadone hydrochloride in 0.9 % sodium chloride	Methadone In 0.9 % Sod. Chlor

Appendix H. Generic and Brand Names of Medical Products Used to Define Baseline Characteristics in this Request

Generic Name	Brand Name
Naloxone	
Naloxone HCl	Evzio
Naloxone HCl	Naloxone
Naloxone HCl	Naloxone (bulk)
Naloxone HCl	Narcan
Naltrexone	
Naltrexone	Naltrexone (bulk)
Naltrexone HCl	Depade
Naltrexone HCl	Naltrexone
Naltrexone HCl	Naltrexone HCl (bulk)
Naltrexone HCl	Revia
Naltrexone hydrochloride dihydrate	Naltrexone HCl Dihydrate(bulk)
Naltrexone microspheres	Vivitrol
Suspected teratogens	
Danazol	Danazol
Danazol	Danazol (bulk)
Danazol	Danocrine
Drospirenone/estradiol	Angeliq
Estradiol cypionate/medroxyprogesterone acetate	Lunelle
Estradiol cypionate/medroxyprogesterone acetate	Medroxyprogest-Estradiol Cyp
Estradiol/levonorgestrel	Climara Pro
Estradiol/norethindrone acetate	Activella
Estradiol/norethindrone acetate	Amabelz
Estradiol/norethindrone acetate	Combipatch
Estradiol/norethindrone acetate	Estradiol-Norethindrone Acet
Estradiol/norethindrone acetate	Lopreeza
Estradiol/norethindrone acetate	Mimvey
Estradiol/norethindrone acetate	Mimvey Lo
Estradiol/norgestimate	Ortho-Prefest
Estradiol/norgestimate	Prefest
Estrogens, conjugated/medroxyprogesterone acetate	Premphase
Estrogens, conjugated/medroxyprogesterone acetate	Prempro
Etonogestrel	Implanon
Etonogestrel	Nexplanon
Etonogestrel/ethinyl estradiol	Nuvaring
Hydroxyprogesterone caproate	Hydroxyprogesterone Cap(Ppres)
Hydroxyprogesterone caproate	Hydroxyprogesterone Capr(bulk)
Hydroxyprogesterone caproate	Hydroxyprogesterone Caproate
Hydroxyprogesterone caproate	Makena
Hydroxyprogesterone caproate/PF	Hydroxyprogest(PF)(Preg Presv)
Hydroxyprogesterone caproate/PF	Makena (PF)
Leuprolide acetate/norethindrone acetate	Lupaneta Pack (1 Month)
Leuprolide acetate/norethindrone acetate	Lupaneta Pack (3 Month)
Levonorgestrel	Aftera
Levonorgestrel	Econtra EZ
Levonorgestrel	Econtra One-Step

Appendix H. Generic and Brand Names of Medical Products Used to Define Baseline Characteristics in this Request

Generic Name	Brand Name
Levonorgestrel	Fallback Solo
Levonorgestrel	Levonorgestrel
Levonorgestrel	My Choice
Levonorgestrel	My Way
Levonorgestrel	New Day
Levonorgestrel	Next Choice
Levonorgestrel	Next Choice One Dose
Levonorgestrel	Norplant System
Levonorgestrel	Opcicon One-Step
Levonorgestrel	Option-2
Levonorgestrel	Plan B
Levonorgestrel	Plan B One-Step
Levonorgestrel	React
Levonorgestrel	Take Action
Medroxyprogesterone acetate	Amen
Medroxyprogesterone acetate	Cycrin
Medroxyprogesterone acetate	Depo-Provera
Medroxyprogesterone acetate	Depo-Subq Provera 104
Medroxyprogesterone acetate	Medroxyprogesterone
Medroxyprogesterone acetate	Provera
Medroxyprogesterone acetate, micronized	Medroxyprogest, Ac Micro(bulk)
Megestrol acetate	Megace
Megestrol acetate	Megace ES
Megestrol acetate	Megestrol
Megestrol acetate, micronized	Megestrol Acetate, Micro (bulk)
Methimazole	Methimazole
Methimazole	Methimazole (bulk)
Methimazole	Northyx
Methimazole	Tapazole
Norelgestromin/ethinyl estradiol	Ortho Evra
Norelgestromin/ethinyl estradiol	Xulane
Norethindrone	Camila
Norethindrone	Deblitane
Norethindrone	Errin
Norethindrone	Heather
Norethindrone	Incassia
Norethindrone	Jencycla
Norethindrone	Jolivette
Norethindrone	Lyza
Norethindrone	Micronor (28)
Norethindrone	Nora-BE
Norethindrone	Norethindrone (bulk)
Norethindrone	Norethindrone (Contraceptive)
Norethindrone	Norlyda
Norethindrone	Norlyroc
Norethindrone	Nor-Q-D

Appendix H. Generic and Brand Names of Medical Products Used to Define Baseline Characteristics in this Request

Generic Name	Brand Name
Norethindrone	Ortho Micronor
Norethindrone	Sharobel
Norethindrone	Tulana
Norethindrone acetate	Aygestin
Norethindrone acetate	Norethindrone Acetate
Norethindrone acetate	Norethindrone Acetate (bulk)
Norethindrone acetate-ethinyl estradiol	Femhrt 1/5
Norethindrone acetate-ethinyl estradiol	Femhrt Low Dose
Norethindrone acetate-ethinyl estradiol	Fyavolv
Norethindrone acetate-ethinyl estradiol	Jevantique
Norethindrone acetate-ethinyl estradiol	Jevantique Lo
Norethindrone acetate-ethinyl estradiol	Jinteli
Norethindrone acetate-ethinyl estradiol	Norethindrone Ac-Eth Estradiol
Norgestrel	Ovrette
Progesterone	Progesterone
Progesterone	Progesterone (bulk)
Progesterone	Progesterone In Oil
Progesterone, micronized	Crinone
Progesterone, micronized	Prochieve
Progesterone, micronized	Progesterone Micronized
Progesterone, micronized	Progesterone Micronized (bulk)
Progesterone, micronized	Prometrium
Progesterone, micronized	First-Progesterone Mc 10
Progesterone, micronized	First-Progesterone Mc 5
Propylthiouracil	Propylthiouracil
Propylthiouracil	Propylthiouracil (bulk)
Segesterone acetate/ethinyl estradiol	Annovera
Nonsteroidal anti-inflammatory drugs	
Bromfenac sodium	Bromfenac Sodium (bulk)
Bupivacaine/ketorolac/ketamine	Bupivacaine-Ketorolac-Ketamine
Celecoxib	Celebrex
Celecoxib	Celecoxib
Celecoxib	Celecoxib (bulk)
Celecoxib/capsaicin/menthol	Capxib
Celecoxib/capsaicin/methyl salicylate/menthol	Nudroxipak
Celecoxib/lidocaine/menthol	Lidoxib
Chlorpheniramine maleate/phenylephrine HCl/ibuprofen	Advil Allergy-Congestion Rlf
Chlorpheniramine maleate/pseudoephedrine HCl/ibuprofen	Advil Allergy Sinus
Chlorpheniramine maleate/pseudoephedrine HCl/ibuprofen	Advil Multi-Symptom Cold
Chlorpheniramine maleate/pseudoephedrine HCl/ibuprofen	Children's Advil Allergy Sinus
Diclofenac potassium	Cambia
Diclofenac potassium	Cataflam
Diclofenac potassium	Diclofenac Potassium
Diclofenac potassium	Zipsor
Diclofenac sodium	Diclofenac Sodium
Diclofenac sodium	Diclofenac Sodium (bulk)

Appendix H. Generic and Brand Names of Medical Products Used to Define Baseline Characteristics in this Request

Generic Name	Brand Name
Diclofenac sodium	Dyloject
Diclofenac sodium	Voltaren
Diclofenac sodium	Voltaren-XR
Diclofenac sodium, micronized	Diclofenac Sod, Micro (bulk)
Diclofenac sodium/capsaicin	Flexipak
Diclofenac sodium/capsaicin	Nudiclo Tabpak
Diclofenac sodium/capsaicin/methyl salicylate/menthol	Nudroxipak DSDR-50
Diclofenac sodium/capsaicin/methyl salicylate/menthol	Nudroxipak DSDR-75
Diclofenac sodium/capsicum oleoresin	Dermasilkrx Diclopak
Diclofenac sodium/capsicum oleoresin	Inflammacin
Diclofenac sodium/capsicum oleoresin	Previdolrx Plus Analgesic Pak
Diclofenac sodium/capsicum oleoresin	Xenaflamm
Diclofenac sodium/misoprostol	Arthrotec 50
Diclofenac sodium/misoprostol	Arthrotec 75
Diclofenac sodium/misoprostol	Diclofenac-Misoprostol
Diclofenac sodium/trolamine salicylate	Inflatherm
Diclofenac submicronized	Zorvolex
Etodolac	Etodolac
Etodolac	Etodolac (bulk)
Etodolac	Lodine
Etodolac	Lodine XL
Etodolac/capsaicin/methyl salicylate/menthol	Nudroxipak E-400
Fenoprofen calcium	Fenoprofen
Fenoprofen calcium	Fenortho
Fenoprofen calcium	Nalfon
Fenoprofen calcium	Profeno
Fenoprofen calcium, dihydrate	Fenoprofen Calcium Dihyd(bulk)
Flurbiprofen	Ansaid
Flurbiprofen	Flurbiprofen
Hydrocodone/ibuprofen	Hydrocodone-Ibuprofen
Hydrocodone/ibuprofen	Ibudone
Hydrocodone/ibuprofen	Reprexain
Hydrocodone/ibuprofen	Vicoprofen
Hydrocodone/ibuprofen	Xylon 10
Ibuprofen	Addaprin
Ibuprofen	Advanced Pain Relief
Ibuprofen	Advil
Ibuprofen	Advil Liqui-Gel
Ibuprofen	Advil Migraine
Ibuprofen	A-G Profen
Ibuprofen	Bupranol FP
Ibuprofen	Caldolor
Ibuprofen	Cap-Profen
Ibuprofen	Child Ibuprofen
Ibuprofen	Children's Advil
Ibuprofen	Children's Ibu-Drops

Appendix H. Generic and Brand Names of Medical Products Used to Define Baseline Characteristics in this Request

Generic Name	Brand Name
Ibuprofen	Children's Ibuprofen
Ibuprofen	Children's Medi-Profen
Ibuprofen	Children's Motrin
Ibuprofen	Children's Motrin Jr Strength
Ibuprofen	Children's Profen Ib
Ibuprofen	Childs Ibuprofen
Ibuprofen	Elixsure IB Suspension
Ibuprofen	Genpril
Ibuprofen	Ibu
Ibuprofen	Ibu-200
Ibuprofen	Ibu-Drops
Ibuprofen	Ibupain-200
Ibuprofen	Ibuprin
Ibuprofen	Ibuprofen
Ibuprofen	Ibuprofen (bulk)
Ibuprofen	Ibuprofen IB
Ibuprofen	Ibuprofen Jr Strength
Ibuprofen	Ibuprofen M
Ibuprofen	Ibutab
Ibuprofen	Ibu-Tab
Ibuprofen	Infant's Advil
Ibuprofen	Infants Ibu-Drops
Ibuprofen	Infant's Ibuprofen
Ibuprofen	Infant's Medi-Profen
Ibuprofen	Infant's Motrin
Ibuprofen	Infants Profenib
Ibuprofen	I-Prin
Ibuprofen	Medi-Profen
Ibuprofen	Menadol
Ibuprofen	Midol Max St Cramp Formula
Ibuprofen	Motrin
Ibuprofen	Motrin IB
Ibuprofen	Motrin Junior Strength
Ibuprofen	Motrin Migraine
Ibuprofen	Nuprin
Ibuprofen	Nuprin Menstrual Relief
Ibuprofen	Pediacare Fever
Ibuprofen	Profen IB
Ibuprofen	Provil
Ibuprofen	Q-Profen
Ibuprofen	Tab-Profen
Ibuprofen	Uni-Pro
Ibuprofen	Wal-Profen
Ibuprofen	Yaprofen
Ibuprofen lysine/PF	Ibuprofen Lysine (PF)
Ibuprofen lysine/PF	Neoprofen (Ibuprofen Lysn)(PF)

Appendix H. Generic and Brand Names of Medical Products Used to Define Baseline Characteristics in this Request

Generic Name	Brand Name
Ibuprofen/caffeine/vitamins b1, b2, b6, & b12	Ic400
Ibuprofen/caffeine/vitamins b1, b2, b6, & b12	Ic800
Ibuprofen/capsaicin/methyl salicylate/menthol	Nudroxipak I-800
Ibuprofen/dietary supplement,misc. Cb.11	Theraprofen-60
Ibuprofen/dietary supplement,misc. Cb.11	Theraprofen-90
Ibuprofen/diphenhydramine citrate	Advil PM
Ibuprofen/diphenhydramine citrate	Ibuprofen PM
Ibuprofen/diphenhydramine citrate	Ibuprofen-Diphenhydramine Cit
Ibuprofen/diphenhydramine citrate	Motrin PM
Ibuprofen/diphenhydramine HCl	Advil Pm Liqui-Gels
Ibuprofen/diphenhydramine HCl	Ibuprofen-Diphenhydramine HCl
Ibuprofen/famotidine	Duexis
Ibuprofen/irritants counter-irritants combination no.2	Comfort Pac-Ibuprofen
Ibuprofen/oxycodone HCl	Combunox
Ibuprofen/oxycodone HCl	Ibuprofen-Oxycodone
Ibuprofen/phenylephrine HCl	Advil Congestion Relief
Ibuprofen/phenylephrine HCl	Congestion Relief (Ibuprof-PE)
Ibuprofen/pseudoephedrine HCl	Advil Cold And Sinus
Ibuprofen/pseudoephedrine HCl	Advil Flu And Body Ache
Ibuprofen/pseudoephedrine HCl	Children's Advil Cold
Ibuprofen/pseudoephedrine HCl	Children's Dimetapp Cold,Fever
Ibuprofen/pseudoephedrine HCl	Children's Ibuprofen Cold
Ibuprofen/pseudoephedrine HCl	Children's Motrin Cold
Ibuprofen/pseudoephedrine HCl	Cold And Sinus Pain Relief
Ibuprofen/pseudoephedrine HCl	Cold-Sinus Relief
Ibuprofen/pseudoephedrine HCl	Dayquil Sinus Pressure/Pain
Ibuprofen/pseudoephedrine HCl	Dristan Sinus
Ibuprofen/pseudoephedrine HCl	Ibup Sinus
Ibuprofen/pseudoephedrine HCl	Ibuprofen Cold
Ibuprofen/pseudoephedrine HCl	Ibuprofen Cold-Sinus(With PSE)
Ibuprofen/pseudoephedrine HCl	Iprin Cold And Sinus
Ibuprofen/pseudoephedrine HCl	Motrin Cold
Ibuprofen/pseudoephedrine HCl	Motrin Cold And Sinus
Ibuprofen/pseudoephedrine HCl	Motrin Ib Sinus
Ibuprofen/pseudoephedrine HCl	Nuprin Cold Relief
Ibuprofen/pseudoephedrine HCl	Nuprin Flu Relief
Ibuprofen/pseudoephedrine HCl	Profen Ib Cold And Sinus
Ibuprofen/pseudoephedrine HCl	Pseudoephedrine-Ibuprofen
Ibuprofen/pseudoephedrine HCl	Vicks Dayquil (Pseudoeph-Ibup)
Ibuprofen/pseudoephedrine HCl	Wal-Profen Cold-Sinus
Ibuprofen/pseudoephedrine HCl	Wal-Profen D Cold And Sinus
Indomethacin	Indocin
Indomethacin	Indocin SR
Indomethacin	Indomethacin
Indomethacin sodium	Indocin I.V.
Indomethacin sodium	Indomethacin Sodium

Appendix H. Generic and Brand Names of Medical Products Used to Define Baseline Characteristics in this Request

Generic Name	Brand Name
Indomethacin, submicronized	Tivorbex
Ketoprofen	Actron
Ketoprofen	Ketoprofen
Ketoprofen	Orudis
Ketoprofen	Orudis KT
Ketoprofen	Oruvail
Ketoprofen, micronized	Ketoprofen, Micronized (bulk)
Ketorolac tromethamine	Ketorolac
Ketorolac tromethamine	Ketorolac (bulk)
Ketorolac tromethamine	Readysharp Ketorolac
Ketorolac tromethamine	Sprix
Ketorolac tromethamine	Toradol
Ketorolac/norflurane and pentafluoropropane (HFC 245fa)	Toronova II SUIK
Ketorolac/norflurane and pentafluoropropane (HFC 245fa)	Toronova SUIK
Lansoprazole/naproxen	PREVACID Naprapac
Meclofenamate sodium	Meclofenamate
Mefenamic acid	Mefenamic Acid
Mefenamic acid	Mefenamic Acid (bulk)
Mefenamic acid	Ponstel
Meloxicam	Meloxicam
Meloxicam	Meloxicam (bulk)
Meloxicam	Mobic
Meloxicam	Qmiiz ODT
Meloxicam, submicronized	Vivlodex
Meloxicam/irritants counter-irritants combination no.2	Comfort Pac-Meloxicam
Nabumetone	Nabumetone
Nabumetone	Nabumetone (bulk)
Nabumetone	Relafen
Nabumetone, micronized	Nabumetone, Micronized (bulk)
Nabumetone/capsaicin/methyl salicylate/menthol	Nudroxipak N-500
Naproxen	Ec-Naprosyn
Naproxen	Ec-Naproxen
Naproxen	Naprosyn
Naproxen	Naproxen
Naproxen	Romixen 500
Naproxen sodium	Aleve
Naproxen sodium	All Day Pain Relief
Naproxen sodium	All Day Relief
Naproxen sodium	Anaprox
Naproxen sodium	Anaprox DS
Naproxen sodium	Flanax (Naproxen)
Naproxen sodium	Mediprofen
Naproxen sodium	Midol (Naproxen)
Naproxen sodium	Naprelan
Naproxen sodium	Naprelan CR
Naproxen sodium	Naprelan Cr Dose Card

Appendix H. Generic and Brand Names of Medical Products Used to Define Baseline Characteristics in this Request

Generic Name	Brand Name
Naproxen sodium	Naproxen Sodium
Naproxen sodium	Wal-Proxen
Naproxen sodium/diphenhydramine HCl	Aleve PM
Naproxen sodium/menthol	Napropak Cool
Naproxen sodium/pseudoephedrine HCl	Aleve Cold And Sinus
Naproxen sodium/pseudoephedrine HCl	Aleve Sinus And Headache
Naproxen sodium/pseudoephedrine HCl	Aleve-D Sinus And Cold
Naproxen sodium/pseudoephedrine HCl	Aleve-D Sinus And Headache
Naproxen sodium/pseudoephedrine HCl	All Day Cold And Sinus
Naproxen sodium/pseudoephedrine HCl	All Day Pain Relief Sinus,Cold
Naproxen sodium/pseudoephedrine HCl	Cold And Sinus
Naproxen sodium/pseudoephedrine HCl	Sinus And Cold-D
Naproxen sodium/pseudoephedrine HCl	Sudafed 12 Hr Pressure-Pain
Naproxen sodium/pseudoephedrine HCl	Sudafed 12 Hr Sinus-Pain
Naproxen/capsaicin/menthol	Napropax
Naproxen/capsaicin/menthol	Naproxenpax
Naproxen/capsaicin/menthol/methyl salicylate	Pain Relief Collection
Naproxen/dietary supplement,misc. Cb.11	Theraproxen
Naproxen/dietary supplement,misc. Cb.11	Theraproxen-90
Naproxen/esomeprazole magnesium	Vimovo
Naproxen/irritant counter-irritant combination no.2	Comfort Pac-Naproxen
Oxaprozin	Daypro
Oxaprozin	Oxaprozin
Phenylbutazone	Phenylbutazone (bulk)
Piroxicam	Feldene
Piroxicam	Piroxicam
Piroxicam	Piroxicam (bulk)
Piroxicam/dietary supplement,misc. Cb.11	Therafeldamine
Rofecoxib	Vioxx
Ropivacaine HCl/clonidine HCl/ketorolac tromethamine	Ropivacaine-Clonidin-Ketorolac
Ropivacaine HCl/epinephrine/clonidine HCl/ketorolac trometh	Ropivacaine-Epi-Clonid-Ketorol
Ropivacaine/ketorolac/ketamine	Ropivacaine-Ketorolac-Ketamine
Sulindac	Clinoril
Sulindac	Sulindac
Sumatriptan succinate/naproxen sodium	Sumatriptan-Naproxen
Sumatriptan succinate/naproxen sodium	Treximet
Tolmetin sodium	Tolectin
Tolmetin sodium	Tolectin DS
Tolmetin sodium	Tolmetin
Valdecoxib	Bextra
Benzodiazepines	
Alprazolam	Alprazolam
Alprazolam	Alprazolam (bulk)
Alprazolam	Alprazolam Intenso
Alprazolam	Niravam

Appendix H. Generic and Brand Names of Medical Products Used to Define Baseline Characteristics in this Request

Generic Name	Brand Name
Alprazolam	Xanax
Alprazolam	Xanax XR
Alprazolam/dietary supplement, misc combo no.17	Gabazolamine
Amitriptyline HCl/chlordiazepoxide	Amitriptyline-Chlordiazepoxide
Amitriptyline HCl/chlordiazepoxide	Limbitrol
Amitriptyline HCl/chlordiazepoxide	Limbitrol DS
Chlordiazepoxide HCl	Chlordiazepoxide HCl
Chlordiazepoxide HCl	Librium
Chlordiazepoxide HCl	Poxi
Chlordiazepoxide/clidinium bromide	Chlordiazepoxide-Clidinium
Chlordiazepoxide/clidinium bromide	Librax (With Clidinium)
Clorazepate dipotassium	Clorazepate Dipotassium
Clorazepate dipotassium	Gen-XENE
Clorazepate dipotassium	Tranxene T-Tab
Clorazepate dipotassium	Tranxene-SD
Diazepam	Diastat
Diazepam	Diastat Acudial
Diazepam	Diastat Pediatric
Diazepam	Diastat Universal
Diazepam	Diazepam
Diazepam	Diazepam (bulk)
Diazepam	Diazepam Intensol
Diazepam	Valium
Diazepam (in soybean oil)	Dizac
Estazolam	Estazolam
Estazolam	Prosom
Flurazepam HCl	Dalmane
Flurazepam HCl	Flurazepam
Halazepam	Paxipam
Lorazepam	Ativan
Lorazepam	Lorazepam
Lorazepam	Lorazepam (bulk)
Lorazepam	Lorazepam Intensol
Lorazepam in 0.9 % sodium chloride	Lorazepam In 0.9% Sod Chloride
Lorazepam in 5 % dextrose and water	Lorazepam In Dextrose 5 %
Midazolam	Midazolam (bulk)
Midazolam HCl	Midazolam
Midazolam HCl	Versed
Midazolam HCl in 0.9 % sodium chloride	Midazolam In 0.9 % Sod Chlorid
Midazolam HCl in 0.9 % sodium chloride/PF	Midazolam (PF) In 0.9 % Nacl
Midazolam HCl in 5 % dextrose and water/PF	Midazolam In Dextrose 5 % (PF)
Midazolam HCl in dextrose 5% in water	Midazolam In Dextrose 5 %
Midazolam HCl/PF	Midazolam (PF)
Oxazepam	Oxazepam
Oxazepam	Serax
Quazepam	Doral

Appendix H. Generic and Brand Names of Medical Products Used to Define Baseline Characteristics in this Request

Generic Name	Brand Name
Quazepam	Quazepam
Temazepam	Restoril
Temazepam	Temazepam
Temazepam/dietary supplement no.8	Strazepam
Triazolam	Halcion
Triazolam	Triazolam
Barbituates (non-anticonvulsants)	
Amobarbital sodium	Amytal
Amobarbital sodium/secobarbital sodium	Tuinal
Butobarbital sodium	Butisol
Mephobarbital	Mebaral
Mephobarbital	Mephobarbital
Methohexital sodium	Brevital
Methohexital sodium in sterile water for injection/PF	Methohexital In Water (PF)
Pentobarbital sodium	Nembutal
Pentobarbital sodium	Nembutal Sodium
Pentobarbital sodium	Pentobarbital Sodium
Pentobarbital sodium	Pentobarbital Sodium (bulk)
Secobarbital sodium	Seconal
Secobarbital sodium	Seconal Sodium
Theophylline/ephedrine HCl/phenobarbital	Asthma
Theophylline/ephedrine HCl/phenobarbital	Theophylline-Ephed-Phenobarb
Thiopental sodium	Pentothal
Thiopental sodium	Thiopental Sodium
Other anticonvulsants	
Carbamazepine	Carbamazepine
Carbamazepine	Tegretol XR
Clobazam	Sympazan
Clonazepam	Klonopin
Clonazepam	Klonopin
Diazepam	Diazepam
Divalproex sodium	Depakote
Divalproex sodium	Depakote ER
Divalproex sodium	Depakote Sprinkles
Felbamate	Felbatol
Gabapentin/lidocaine HCl/menthol	Active-Pac
Gabapentin/lidocaine HCl/menthol	Smatrix Gabakit
Lacosamide	Vimpat
Levetiracetam	Levetiracetam
Levetiracetam	Spritam
Levetiracetam in sodium chloride, iso-osmotic	Levetiracetam In NaCl (Iso-Os)
Phenobarbital	Phenobarbital
Phenobarbital	Phenobarbital (bulk)
Phenobarbital sodium	Phenobarbital Sodium
Phenytoin	Dilantin Infatabs
Potassium bromide	Potassium Bromide (bulk)

Appendix H. Generic and Brand Names of Medical Products Used to Define Baseline Characteristics in this Request

Generic Name	Brand Name
Valproic acid	Stavzor
Valproic acid	Valproic Acid (bulk)
Vigabatrin	Vigadrone
Zonisamide	Zonisamide

Appendix I.1. Specifications for Parameters Used to Define This Request; Analysis 1 and Analysis 2

This request used the Cohort Identification and Descriptive Analysis (CIDA) module, version 8.1.1, with Pregnancy tool, to replicate the Hernandez-Diaz, et al. study assessing risk of oral clefts with topiramate use during the first trimester of pregnancy in the Sentinel Distributed Database (SDD).

Query Period: January 1, 2000 - September 30, 2015 (last delivery: July 1, 2015)
Coverage Requirement: Medical and Drug Coverage
Enrollment Gap: 45 days
Enrollment Requirement prior to Delivery Date: 391 days (301 day delivery length + 90 day pre-pregnancy exposure assessment period)
Enrollment Requirement following Delivery Date: 0 days
Age Restriction: 12-20, 21-30, 31-40, 41-54 years
Sex: Female

	Primary Analysis		Secondary Analysis	
	Analysis 1		Analysis 2 - Non epilepsy indication	
Pregnancy Episode Creation				
Delivery Washout¹ (days)	180	180	180	180
Pre/Post Term Evaluation Window (days)	7	7	7	7
Pregnancy Duration in Absence of Specific Duration (days)	273	273	273	273
Mother-infant Linkage Requirement¹	BC, RE, SI, LA, OT	BC, RE, SI, LA, OT	BC, RE, SI, LA, OT	BC, RE, SI, LA, OT
Allowed # of Days b-n Infant BD and Delivery date	3 days	3 days	3 days	3 days
Allowed Gap between Infant Delivery and Enrollment	Any	Any	Any	Any
Pre-pregnancy Period	Not specified	Not specified	Not specified	Not specified
Drug/Exposure				
Prevalent Exposure/Comparator	Topiramate	Unexposed (No topiramate or other anticonvulsant use)	Topiramate	Unexposed (No topiramate or other anticonvulsant use)
Incident with Respect to:	NA	NA	NA	NA
Washout (days)	None	None	None	None
Exposure Episode Length (ITT)	NA	NA	NA	NA
Cohort Definition	Cohort includes all valid medical product exposure episodes during a pregnancy episode	Cohort includes all valid medical product exposure episodes during a pregnancy episode	Cohort includes all valid medical product exposure episodes during a pregnancy episode	Cohort includes all valid medical product exposure episodes during a pregnancy episode
Exposure Unit	Trimester	Trimester	Trimester	Trimester
Evaluation Window	(1,1)	(-1,1)	(1,1)	(-1,1)
Episode Gap (days)	0	0	0	0
Episode Extension Period (days)	0	0	0	0

Appendix I.1. Specifications for Parameters Used to Define This Request; Analysis 1 and Analysis 2

	Primary Analysis		Secondary Analysis	
	Analysis 1		Analysis 2 - Non epilepsy indication	
Stockpiling Option Forced Days Supply Notes	OFF 1	OFF 1	OFF 1	OFF 1
		The comparator requires no use of topiramate from -90,90 days around exposure, which is achieved using exclusions		The comparator requires no use of topiramate from -90,90 days around exposure, which is achieved using exclusions
Inclusion/Exclusion Pre-Existing Condition Include/Exclude Evaluation Period Code Days Population to which Inclusion/Exclusion applies Index Date to Define Inclusion/Exclusion Criteria		Other anticonvulsants (including lamotrigine) Exclusion (-90, 90) 1 Mom claims Pregnancy start date		Other anticonvulsants (including lamotrigine) Exclusion (-90, 90) 1 Mom claims Pregnancy start date
Pre-Existing Condition Include/Exclude Evaluation Period Code Days Population to which Inclusion/Exclusion applies Index Date to Define Inclusion/Exclusion Criteria		Topiramate Exclusion (-90, -1) 1 Mom claims Pregnancy start date		Topiramate Exclusion (-90, -1) 1 Mom claims Pregnancy start date
Pre-Existing Condition Include/Exclude Evaluation Period Code Days Population to which Inclusion/Exclusion applies Index Date to Define Inclusion/Exclusion Criteria	Chromosomal abnormality Exclusion (0, 273) 1 Mom claims (default) Pregnancy start date (default)	Chromosomal abnormality Exclusion (0, 273) 1 Mom claims (default) Pregnancy start date (default)	Chromosomal abnormality Exclusion (0, 273) 1 Mom claims (default) Pregnancy start date (default)	Chromosomal abnormality Exclusion (0, 273) 1 Mom claims (default) Pregnancy start date (default)

Appendix I.1. Specifications for Parameters Used to Define This Request; Analysis 1 and Analysis 2

	Primary Analysis		Secondary Analysis	
	Analysis 1		Analysis 2 - Non epilepsy indication	
Pre-Existing Condition	Teratogens (lithium, antineoplastic agents, isotretinoin, misoprostol, thalidomide, warfarin)	Teratogens (lithium, antineoplastic agents, isotretinoin, misoprostol, thalidomide, warfarin)	Teratogens (lithium, antineoplastic agents, isotretinoin, misoprostol, thalidomide, warfarin)	Teratogens (lithium, antineoplastic agents, isotretinoin, misoprostol, thalidomide, warfarin)
Include/Exclude	Exclusion	Exclusion	Exclusion	Exclusion
Evaluation Period	(0, 90) or 1st trimester	(0, 90) or 1st trimester	(0, 90) or 1st trimester	(0, 90) or 1st trimester
Code Days	1	1	1	1
Population to which Inclusion/Exclusion applies	Mom claims (default)	Mom claims (default)	Mom claims (default)	Mom claims (default)
Index Date to Define Inclusion/Exclusion Criteria	Pregnancy start date (default)	Pregnancy start date (default)	Pregnancy start date (default)	Pregnancy start date (default)
Pre-Existing Condition	Live birth delivery	Live birth delivery	Live birth delivery	Live birth delivery
Include/Exclude	Exclusion	Exclusion	Exclusion	Exclusion
Evaluation Period	(0, 121)	(0, 121)	(0, 121)	(0, 121)
Code Days	1	1	1	1
Population to which Inclusion/Exclusion applies	Mom claims (default)	Mom claims (default)	Mom claims (default)	Mom claims (default)
Index Date to Define Inclusion/Exclusion Criteria	Pregnancy start date (default)	Pregnancy start date (default)	Pregnancy start date (default)	Pregnancy start date (default)
Pre-Existing Condition			Epilepsy or seizures	Epilepsy or seizures
Include/Exclude			Exclusion	Exclusion
Evaluation Period			(-90,90)	(-90,90)
Code Days			1	1
Population to which Inclusion/Exclusion applies			Mom claims	Mom claims
Index Date to Define Inclusion/Exclusion Criteria			Pregnancy start date	Pregnancy start date
Event/Outcome	Oral clefts		Oral clefts	
Event/Outcome	Oral clefts		Oral clefts	
Index Date to Anchor for Outcome Assessment	Pregnancy Delivery Date		Pregnancy Delivery Date	
Evaluation window	(0, 90) (minimum date of combo required in this window)		(0, 90) (minimum date of combo required in this window)	
Care Setting/Principal Diagnosis	Any		Any	
Claims to Evaluate Outcome	Mother and infant claims		Mother and infant claims	
Incident with Respect to:	Oral clefts		Oral clefts	

Appendix I.1. Specifications for Parameters Used to Define This Request; Analysis 1 and Analysis 2

	Primary Analysis	Secondary Analysis
	Analysis 1	Analysis 2 - Non epilepsy indication
Incident Care Setting	Any	Any
Washout (days)	N/A	N/A
Blackout Period (days)	N/A	N/A
Propensity Score Matching		
Covariates	See Appendix J	See Appendix J
Covariate Evaluation Window	See Appendix J	See Appendix J
Index Date for Covariates and PS Risk Set	Pregnancy start date	Pregnancy start date
Matching Ratio	1:1	1:1
Matching Caliper Settings	0.05	0.05
Analysis Type	Logistic regression	Logistic regression
Propensity Score Stratification	10	10
Subgroup Analysis		
Stratifying Variable	Epilepsy or seizures	
Re-Matching	Whole Population	
Subgroup Analysis		
Stratifying Variable	Migraine/headache or bipolar	
Re-Matching	Whole Population	

International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM), Healthcare Common Procedure Coding System (HCPCS), and Current Procedural Terminology, Fourth Edition (CPT-4) codes are provided by Optum360. ICD-10-CM codes were mapped from ICD-9-CM codes using the Centers for Medicare and Medicaid Services General Equivalence Mappings.

NDC codes are checked against First Data Bank's "National Drug Data File (NDDF®) Plus."

¹The 180-day delivery washout plus the exclusion of live birth deliveries in the 121 days after pregnancy start ensures no evidence of live birth delivery for the duration of the pregnancy period.

²Mother-infant linkage requirements: Birth certificate (BC), Data Partner maintained birth registry (RE), Health plan subscriber or family number (SI), Exact or probabilistic last name and address match based upon health plan administrative data (LA), Other (OT)

Appendix I.2. Specifications for Parameters Used to Define This Request; Analysis 3 and Analysis 4

This request used the Cohort Identification and Descriptive Analysis (CIDA) module, version 8.1.1, with Pregnancy tool, to replicate the Hernandez-Diaz, et al. study assessing risk of oral clefts with topiramate use during the first trimester of pregnancy in the Sentinel Distributed Database (SDD).

Query Period: January 1, 2000 - September 30, 2015 (last delivery: July 1, 2015)

Coverage Requirement: Medical and Drug Coverage

Enrollment Gap: 45 days

Enrollment Requirement prior to Delivery Date: 391 days (301 day delivery length + 90 day pre-pregnancy exposure assessment period)

Enrollment Requirement following Delivery Date: 0 days

Age Restriction: 12-20, 21-30, 31-40, 41-54 years

Sex: Female

	Secondary Analysis		Secondary Analysis	
	Analysis 3 - Monotherapy		Analysis 4 - Active comparator	
Pregnancy Episode Creation				
Delivery Washout¹ (days)	180	180	180	180
Pre/Post Term Evaluation Window (days)	7	7	7	7
Pregnancy Duration in Absence of Specific Duration (days)	273	273	273	273
Mother-infant Linkage Requirement¹	BC, RE, SI, LA, OT	BC, RE, SI, LA, OT	BC, RE, SI, LA, OT	BC, RE, SI, LA, OT
Allowed # of Days b-n Infant BD and Delivery date	3 days	3 days	3 days	3 days
Allowed Gap between Infant Delivery and Enrollment	Any	Any	Any	Any
Pre-pregnancy Period	Not specified	Not specified	Not specified	Not specified
Drug/Exposure				
Prevalent Exposure/Comparator	Topiramate	Unexposed (No topiramate or other anticonvulsant use)	Topiramate	Lamotrigine
Incident with Respect to:	NA	NA	NA	NA
Washout (days)	None	None	None	None
Exposure Episode Length (ITT)	NA	NA	NA	NA
Cohort Definition	Cohort includes all valid medical product exposure episodes during a pregnancy episode	Cohort includes all valid medical product exposure episodes during a pregnancy episode	Cohort includes all valid medical product exposure episodes during a pregnancy episode	Cohort includes all valid medical product exposure episodes during a pregnancy episode
Exposure Unit	Trimester	Trimester	Trimester	Trimester
Evaluation Window	(1,1)	(-1,1)	(1,1)	(1,1)
Episode Gap (days)	0	0	0	0
Episode Extension Period (days)	0	0	0	0

Appendix I.2. Specifications for Parameters Used to Define This Request; Analysis 3 and Analysis 4

	Primary Analysis		Secondary Analysis	
	Analysis 1		Analysis 2 - Non epilepsy indication	
Stockpiling Option Forced Days Supply Notes	OFF 1	OFF 1	OFF 1	OFF 1
		The comparator requires no use of topiramate from -90,90 days around exposure, which is achieved using exclusions		
Inclusion/Exclusion Pre-Existing Condition Include/Exclude Evaluation Period Code Days Population to which Inclusion/Exclusion applies Index Date to Define Inclusion/Exclusion Criteria	Other anticonvulsant (including lamotrigine) Exclusion (-90, 90) 1	Other anticonvulsants (including lamotrigine) Exclusion (-90, 90) 1 Mom claims Pregnancy start date	Lamotrigine Exclusion (-90, 90) 1 Mom claims Pregnancy start date	Topiramate Exclusion (-90, 90) 1 Mom claims Pregnancy start date
Pre-Existing Condition Include/Exclude Evaluation Period Code Days Population to which Inclusion/Exclusion applies Index Date to Define Inclusion/Exclusion Criteria		Topiramate Exclusion (-90, -1) 1 Mom claims Pregnancy start date		
Pre-Existing Condition Include/Exclude Evaluation Period Code Days Population to which Inclusion/Exclusion applies Index Date to Define Inclusion/Exclusion Criteria	Chromosomal abnormality Exclusion (0, 273) 1 Mom claims (default) Pregnancy start date (default)	Chromosomal abnormality Exclusion (0, 273) 1 Mom claims (default) Pregnancy start date (default)	Chromosomal abnormality Exclusion (0, 273) 1 Mom claims (default) Pregnancy start date (default)	Chromosomal abnormality Exclusion (0, 273) 1 Mom claims (default) Pregnancy start date (default)

Appendix I.2. Specifications for Parameters Used to Define This Request; Analysis 3 and Analysis 4

	Primary Analysis		Secondary Analysis	
	Analysis 1		Analysis 2 - Non epilepsy indication	
Pre-Existing Condition Include/Exclude Evaluation Period Code Days Population to which Inclusion/Exclusion applies Index Date to Define Inclusion/Exclusion Criteria	Teratogens (lithium, antineoplastic agents, isotretinoin, misoprostol, thalidomide, warfarin) Exclusion (0, 90) or 1st trimester 1 Mom claims (default) Pregnancy start date (default)	Teratogens (lithium, antineoplastic agents, isotretinoin, misoprostol, thalidomide, warfarin) Exclusion (0, 90) or 1st trimester 1 Mom claims (default) Pregnancy start date (default)	Teratogens (lithium, antineoplastic agents, isotretinoin, misoprostol, thalidomide, warfarin) Exclusion (0, 90) or 1st trimester 1 Mom claims (default) Pregnancy start date (default)	Teratogens (lithium, antineoplastic agents, isotretinoin, misoprostol, thalidomide, warfarin) Exclusion (0, 90) or 1st trimester 1 Mom claims (default) Pregnancy start date (default)
Pre-Existing Condition Include/Exclude Evaluation Period Code Days Population to which Inclusion/Exclusion applies Index Date to Define Inclusion/Exclusion Criteria	Live birth delivery Exclusion (0, 121) 1 Mom claims (default) Pregnancy start date (default)	Live birth delivery Exclusion (0, 121) 1 Mom claims (default) Pregnancy start date (default)	Live birth delivery Exclusion (0, 121) 1 Mom claims (default) Pregnancy start date (default)	Live birth delivery Exclusion (0, 121) 1 Mom claims (default) Pregnancy start date (default)
Pre-Existing Condition Include/Exclude Evaluation Period Code Days Population to which Inclusion/Exclusion applies Index Date to Define Inclusion/Exclusion Criteria				
Event/Outcome Event/Outcome Index Date to Anchor for Outcome Assessment Evaluation window Care Setting/Principal Diagnosis Claims to Evaluate Outcome Incident with Respect to:	Oral clefts Pregnancy Delivery Date (0, 90) (minimum date of combo required in this window) Any Mother and infant claims Oral clefts		Oral clefts Pregnancy Delivery Date (0, 90) (minimum date of combo required in this window) Any Mother and infant claims Oral clefts	

Appendix I.2. Specifications for Parameters Used to Define This Request; Analysis 3 and Analysis 4

	Primary Analysis	Secondary Analysis
	Analysis 1	Analysis 2 - Non epilepsy indication
Incident Care Setting	Any	Any
Washout (days)	N/A	N/A
Blackout Period (days)	N/A	N/A
Propensity Score Matching		
Covariates	See Appendix J	See Appendix J
Covariate Evaluation Window	See Appendix J	See Appendix J
Index Date for Covariates and PS Risk Set	Pregnancy start date	Pregnancy start date
Matching Ratio	1:1	1:1
Matching Caliper Settings	0.05	0.05
Analysis Type	Logistic regression	Logistic regression
Propensity Score Stratification	10	10
Subgroup Analysis		
Stratifying Variable		
Re-Matching		
Subgroup Analysis		
Stratifying Variable		
Re-Matching		

International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM), Healthcare Common Procedure Coding System (HCPCS), and Current Procedural Terminology, Fourth Edition (CPT-4) codes are provided by Optum360. ICD-10-CM codes were mapped from ICD-9-CM codes using the Centers for Medicare and Medicaid Services General Equivalence Mappings.

NDC codes are checked against First Data Bank's "National Drug Data File (NDDF®) Plus."

¹The 180-day delivery washout plus the exclusion of live birth deliveries in the 121 days after pregnancy start ensures no evidence of live birth delivery for the duration of the pregnancy period.

²Mother-infant linkage requirements: Birth certificate (BC), Data Partner maintained birth registry (RE), Health plan subscriber or family number (SI), Exact or probabilistic last name and address match based upon health plan administrative data (LA), Other (OT)

Appendix I.3. Specifications for Parameters Used to Define This Request; Analysis 5 and Analysis 6

This request used the Cohort Identification and Descriptive Analysis (CIDA) module, version 8.1.1, with Pregnancy tool, to replicate the Hernandez-Diaz, et al. study assessing risk of oral clefts with topiramate use during the first trimester of pregnancy in the Sentinel Distributed Database (SDD).

Query Period: January 1, 2000 - September 30, 2015 (last delivery: July 1, 2015)
Coverage Requirement: Medical and Drug Coverage
Enrollment Gap: 45 days
Enrollment Requirement prior to Delivery Date: 391 days (301 day delivery length + 90 day pre-pregnancy exposure assessment period)
Enrollment Requirement following Delivery Date: 0 days
Age Restriction: 12-20, 21-30, 31-40, 41-54 years
Sex: Female

	Secondary Analysis		Sensitivity Analysis	
	Analysis 5 - Require 2 fills		Analysis 6 - Allowing overlapping days supply	
Pregnancy Episode Creation				
Delivery Washout¹ (days)	180	180	180	180
Pre/Post Term Evaluation Window (days)	7	7	7	7
Pregnancy Duration in Absence of Specific Duration (days)	273	273	273	273
Mother-infant Linkage Requirement¹	BC, RE, SI, LA, OT	BC, RE, SI, LA, OT	BC, RE, SI, LA, OT	BC, RE, SI, LA, OT
Allowed # of Days b-n Infant BD and Delivery date	3 days	3 days	3 days	3 days
Allowed Gap between Infant Delivery and Enrollment	Any	Any	Any	Any
Pre-pregnancy Period	Not specified	Not specified	Not specified	Not specified
Drug/Exposure				
Prevalent Exposure/Comparator	Topiramate	Unexposed (No topiramate or other anticonvulsant use)	Topiramate	Unexposed (No topiramate or other anticonvulsant use)
Incident with Respect to:	NA	NA	NA	NA
Washout (days)	None	None	None	None
Exposure Episode Length (ITT)	NA	NA	NA	NA
Cohort Definition	Cohort includes all valid medical product exposure episodes during a pregnancy episode	Cohort includes all valid medical product exposure episodes during a pregnancy episode	Cohort includes all valid medical product exposure episodes during a pregnancy episode	Cohort includes all valid medical product exposure episodes during a pregnancy episode
Exposure Unit	Trimester	Trimester	Trimester	Trimester
Evaluation Window	(1,1)	(-1,1)	(1,1)	(-1,1)
Episode Gap (days)	0	0	0	0
Episode Extension Period (days)	0	0	0	0

Appendix I.3. Specifications for Parameters Used to Define This Request; Analysis 5 and Analysis 6

	Primary Analysis		Secondary Analysis	
	Analysis 1		Analysis 2 - Non epilepsy indication	
Stockpiling Option Forced Days Supply Notes	OFF 1	OFF 1	ON -	ON -
		The comparator requires no use of topiramate from -90,90 days around exposure, which is achieved using exclusions		The comparator requires no use of topiramate from -90,90 days around exposure, which is achieved using exclusions
Inclusion/Exclusion Pre-Existing Condition Include/Exclude Evaluation Period Code Days Population to which Inclusion/Exclusion applies Index Date to Define Inclusion/Exclusion Criteria	Topiramate Inclusion (0, 90) 2 Mom claims Pregnancy start date	Other anticonvulsants (including lamotrigine) Exclusion (-90, 90) 1 Mom claims Pregnancy start date		Other anticonvulsants (including lamotrigine) Exclusion (-90, 90) 1 Mom claims Pregnancy start date
Pre-Existing Condition Include/Exclude Evaluation Period Code Days Population to which Inclusion/Exclusion applies Index Date to Define Inclusion/Exclusion Criteria		Topiramate Exclusion (-90, -1) 1 Mom claims Pregnancy start date		Topiramate Exclusion (-90, -1) 1 Mom claims Pregnancy start date
Pre-Existing Condition Include/Exclude Evaluation Period Code Days Population to which Inclusion/Exclusion applies Index Date to Define Inclusion/Exclusion Criteria	Chromosomal abnormality Exclusion (0, 273) 1 Mom claims (default) Pregnancy start date (default)	Chromosomal abnormality Exclusion (0, 273) 1 Mom claims (default) Pregnancy start date (default)	Chromosomal abnormality Exclusion (0, 273) 1 Mom claims (default) Pregnancy start date (default)	Chromosomal abnormality Exclusion (0, 273) 1 Mom claims (default) Pregnancy start date (default)

Appendix I.3. Specifications for Parameters Used to Define This Request; Analysis 5 and Analysis 6

	Primary Analysis		Secondary Analysis	
	Analysis 1		Analysis 2 - Non epilepsy indication	
Pre-Existing Condition	Teratogens (lithium, antineoplastic agents, isotretinoin, misoprostol, thalidomide, warfarin)	Teratogens (lithium, antineoplastic agents, isotretinoin, misoprostol, thalidomide, warfarin)	Teratogens (lithium, antineoplastic agents, isotretinoin, misoprostol, thalidomide, warfarin)	Teratogens (lithium, antineoplastic agents, isotretinoin, misoprostol, thalidomide, warfarin)
Include/Exclude	Exclusion	Exclusion	Exclusion	Exclusion
Evaluation Period	(0, 90) or 1st trimester	(0, 90) or 1st trimester	(0, 90) or 1st trimester	(0, 90) or 1st trimester
Code Days	1	1	1	1
Population to which Inclusion/Exclusion applies	Mom claims (default)	Mom claims (default)	Mom claims (default)	Mom claims (default)
Index Date to Define Inclusion/Exclusion Criteria	Pregnancy start date (default)	Pregnancy start date (default)	Pregnancy start date (default)	Pregnancy start date (default)
Pre-Existing Condition	Live birth delivery	Live birth delivery	Live birth delivery	Live birth delivery
Include/Exclude	Exclusion	Exclusion	Exclusion	Exclusion
Evaluation Period	(0, 121)	(0, 121)	(0, 121)	(0, 121)
Code Days	1	1	1	1
Population to which Inclusion/Exclusion applies	Mom claims (default)	Mom claims (default)	Mom claims (default)	Mom claims (default)
Index Date to Define Inclusion/Exclusion Criteria	Pregnancy start date (default)	Pregnancy start date (default)	Pregnancy start date (default)	Pregnancy start date (default)
Pre-Existing Condition				
Include/Exclude				
Evaluation Period				
Code Days				
Population to which Inclusion/Exclusion applies				
Index Date to Define Inclusion/Exclusion Criteria				
Event/Outcome	Oral clefts		Oral clefts	
Event/Outcome	Oral clefts		Oral clefts	
Index Date to Anchor for Outcome Assessment	Pregnancy Delivery Date		Pregnancy Delivery Date	
Evaluation window	(0, 90) (minimum date of combo required in this window)		(0, 90) (minimum date of combo required in this window)	
Care Setting/Principal Diagnosis	Any		Any	
Claims to Evaluate Outcome	Mother and infant claims		Mother and infant claims	
Incident with Respect to:	Oral clefts		Oral clefts	

Appendix I.3. Specifications for Parameters Used to Define This Request; Analysis 5 and Analysis 6

	Primary Analysis	Secondary Analysis
	Analysis 1	Analysis 2 - Non epilepsy indication
Incident Care Setting	Any	Any
Washout (days)	N/A	N/A
Blackout Period (days)	N/A	N/A
Propensity Score Matching		
Covariates	See Appendix J	See Appendix J
Covariate Evaluation Window	See Appendix J	See Appendix J
Index Date for Covariates and PS Risk Set	Pregnancy start date	Pregnancy start date
Matching Ratio	1:1	1:1
Matching Caliper Settings	0.05	0.05
Analysis Type	Logistic regression	Logistic regression
Propensity Score Stratification	10	10
Subgroup Analysis		
Stratifying Variable		Epilepsy or seizures
Re-Matching		Whole Population
Subgroup Analysis		
Stratifying Variable		Migraine/headache or bipolar
Re-Matching		Whole Population

International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM), Healthcare Common Procedure Coding System (HCPCS), and Current Procedural Terminology, Fourth Edition (CPT-4) codes are provided by Optum360. ICD-10-CM codes were mapped from ICD-9-CM codes using the Centers for Medicare and Medicaid Services General Equivalence Mappings.

NDC codes are checked against First Data Bank's "National Drug Data File (NDDF®) Plus."

¹The 180-day delivery washout plus the exclusion of live birth deliveries in the 121 days after pregnancy start ensures no evidence of live birth delivery for the duration of the pregnancy period.

²Mother-infant linkage requirements: Birth certificate (BC), Data Partner maintained birth registry (RE), Health plan subscriber or family number (SI), Exact or probabilistic last name and address match based upon health plan administrative data (LA), Other (OT)

Appendix J. Baseline Covariate Groups Evaluated in this Request										
Covariate number	Group	Covariate evaluation window (in relation to pregnancy start)	Care setting	Number of instances the covariate should be found in evaluation period	Analysis 1 PS model	Analysis 2 PS model	Analysis 3 PS model	Analysis 4 PS model	Analysis 5 PS model	Analysis 6 PS model
	Age (continuous: 12+ years)	On delivery date	Any	1	Yes	Yes	Yes	Yes	Yes	Yes
	Race (White, Black, Hispanic, Other or unknown)	On delivery date	Any	1	No ¹	No ¹	No ¹	No ¹	No ¹	No ¹
	Year of delivery	On delivery date	Any	1	No ¹	No ¹	No ¹	No ¹	No ¹	No ¹
Topiramate indications										
1	Epilepsy or seizures	(-90, 90)	Any	1	Yes	No ²	Yes	Yes	Yes	Yes
2	Migraine or headache	(-90, 90)	Any	1	No ²	No ²	No ²	No ²	No ²	No ²
3	Bipolar disorder	(-90, 90)	Any	1	No ²	No ²	No ²	No ²	No ²	No ²
44	Migraine/headache or bipolar (covariate 2 or covariate 3)	(-90, 90)	Any	1	Yes	Yes	Yes	Yes	Yes	Yes
4	Neuropathic pain	(-90, 90)	Any	1	Yes	Yes	Yes	Yes	Yes	Yes
5	Nonneuropathic pain	(-90, 90)	Any	1	Yes	Yes	Yes	Yes	Yes	Yes
6	Obesity	(-90, 90)	Any	1	Yes	Yes	Yes	Yes	Yes	Yes
7	Smoking	(-90, 90)	Any	1	Yes	Yes	Yes	Yes	Yes	Yes
Other health conditions										
8	Depression	(-90, 90)	Any	1	Yes	Yes	Yes	Yes	Yes	Yes
9	Anxiety	(-90, 90)	Any	1	Yes	Yes	Yes	Yes	Yes	Yes
10	Psychosis	(-90, 90)	Any	1	No ¹	No ¹	No ¹	No ¹	No ¹	No ¹
11	Other psychiatric disorders	(-90, 90)	Any	1	Yes	Yes	Yes	Yes	Yes	Yes
12	Sleep disorder	(-90, 90)	Any	1	Yes	Yes	Yes	Yes	No ¹	Yes
13	Fibromyalgia	(-90, 90)	Any	1	Yes	Yes	Yes	Yes	Yes	Yes
14	Diabetes Mellitus	(-90, 90)	Any	1	No ¹	No ¹	No ¹	No ¹	No ¹	No ¹
15	Hypertension	(-90, 90)	Any	1	Yes	Yes	Yes	Yes	Yes	Yes

Appendix J. Baseline Covariate Groups Evaluated in this Request										
Covariate number	Group	Covariate evaluation window (in relation to pregnancy start)	Care setting	Number of instances the covariate should be found in evaluation period	Analysis 1 PS model	Analysis 2 PS model	Analysis 3 PS model	Analysis 4 PS model	Analysis 5 PS model	Analysis 6 PS model
Other medications										
16	Valproate	(0, 90)	Any	1	No ²	No ²	No ²	No ²	No ²	No ²
17	Carbamazepine	(0, 90)	Any	1	No ²	No ²	No ²	No ²	No ²	No ²
18	Phenytoin	(0, 90)	Any	1	No ²	No ²	No ²	No ²	No ²	No ²
43	Other anticonvulsants (excluding topiramate and lamotrigine)	(0, 90)	Any	1	No ²	No ²	No ²	Yes	No ²	No ²
19	Benzodiazepine	(0, 90)	Any	1	Yes	Yes	Yes	Yes	Yes	Yes
20	Triptans	(0, 90)	Any	1	Yes	Yes	Yes	Yes	Yes	Yes
21	Antipsychotics	(0, 90)	Any	1	Yes	Yes	Yes	Yes	Yes	Yes
22	Antidepressants	(0, 90)	Any	1	Yes	Yes	Yes	Yes	Yes	Yes
23	Antihypertensive	(0, 90)	Any	1	Yes	Yes	Yes	Yes	Yes	Yes
24	Anxiolytics	(0, 90)	Any	1	Yes	Yes	Yes	Yes	Yes	Yes
25	Stimulants	(0, 90)	Any	1	Yes	Yes	Yes	Yes	Yes	Yes
26	Barbiturates	(0, 90)	Any	1	No ¹	No ¹	No ¹	No ¹	No ¹	No ¹
42	Barbiturates (non-anticonvulsants)	(0, 90)	Any	1	No ¹	No ¹	No ¹	No ¹	No ¹	No ¹
27	Insulin	(0, 90)	Any	1	No ¹	No ¹	No ¹	No ¹	No ¹	No ¹
28	Noninsulin antidiabetic medications	(0, 90)	Any	1	Yes	Yes	Yes	Yes	Yes	Yes
29	Opioids	(0, 90)	Any	1	Yes	Yes	Yes	Yes	Yes	Yes
Proxies for health and health care use										
	Charlson Comorbidity Index	(-90, 0)	Any	1	Yes	Yes	Yes	Yes	Yes	Yes
	Number of inpatient hospital stays	(-90, 0)	Any	1	Yes	Yes	Yes	Yes	Yes	Yes

Appendix J. Baseline Covariate Groups Evaluated in this Request										
Covariate number	Group	Covariate evaluation window (in relation to pregnancy start)	Care setting	Number of instances the covariate should be found in evaluation period	Analysis 1 PS model	Analysis 2 PS model	Analysis 3 PS model	Analysis 4 PS model	Analysis 5 PS model	Analysis 6 PS model
	Number of ambulatory visits	(-90, 0)	Any	1	Yes	Yes	Yes	Yes	Yes	Yes
	Number of filled prescriptions	(-90, 0)	Any	1	Yes	Yes	Yes	Yes	Yes	Yes
Additional covariates										
30	Other pain conditions	(-90, 90)	Any	1	Yes	Yes	Yes	Yes	Yes	Yes
31	Attention deficit/hyperactivity disorder	(-90, 90)	Any	1	Yes	Yes	Yes	Yes	No ¹	Yes
32	Alcohol or drug abuse/dependence	(-90, 90)	Any	1	No ¹	No ¹	No ¹	No ¹	No ¹	No ¹
33	Chronic fatigue syndrome	(-90, 90)	Any	1	No ¹	No ¹	No ¹	No ¹	No ¹	No ¹
34	Kidney disease	(-90, 90)	Any	1	No ¹	No ¹	No ¹	No ¹	No ¹	No ¹
35	Hypnotics	(0, 90)	Any	1	Yes	Yes	Yes	Yes	Yes	Yes
36	Buprenorphine	(0, 90)	Any	1	No ¹	No ¹	No ¹	No ¹	No ¹	No ¹
37	Methadone	(0, 90)	Any	1	No ¹	No ¹	No ¹	No ¹	No ¹	No ¹
38	Naloxone	(0, 90)	Any	1	No ¹	No ¹	No ¹	No ¹	No ¹	No ¹
39	Naltrexone	(0, 90)	Any	1	No ¹	No ¹	No ¹	No ¹	No ¹	No ¹
40	Teratogens (methimazole, danazol, propylthiouracil, synthetic progestins)	(0, 90)	Any	1	Yes	Yes	Yes	Yes	Yes	Yes
41	NSAIDS	(0, 90)	Any	1	Yes	Yes	Yes	Yes	Yes	Yes

¹Covariate not included in PS model due to low prevalence (count <5) in topiramate group in preliminary analyses

²Covariate not included in PS model because not appropriate for inclusion in specific analysis (e.g. subgroup analysis, different version of this covariate included instead)