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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).

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Overview

Date Run: October 25, 2017

Request Description: The purpose of this report was to compare the frequency of diagnoses and procedures for dialysis using International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) diagnosis codes, and Current Procedural Terminology, Fourth Edition (CPT-4) procedure codes. ICD-10-CM code definitions were determined by mapping from ICD-9-CM code definitions using the Centers for Medicare and Medicaid Services (CMS) General Equivalence Mappings (GEMs). Forward-backward mapping (FBM) was used to map ICD-9-CM to ICD-10-CM codes.¹ CPT-4 codes were used to supplement the ICD diagnoses and capture dialysis procedures.

Sentinel Modular Program Tool Used: Cohort Identification and Descriptive Analysis (CIDA) tool, version 5.0.5

Data Source: This request was run against data from 12 Data Partners contributing to the Sentinel Distributed Database (SDD). Data from October 1, 2010 to September 30, 2016 were included in this report. The report includes three separate time periods: 1) October 1, 2010 to September 30, 2016; 2) April 1, 2015 to September 30, 2015; and 3) April 1, 2016 to September 30, 2016. This request was distributed to Data Partners on October 25, 2017. See Appendix A for a list of dates of available data for each Data Partner.

Study Design: We examined the incidence and prevalence of dialysis across the ICD-9-CM era (October 2010 - September 2015) and ICD-10-CM era (October 2015 - September 2016) in the United States. Incidence was additionally evaluated from April 2015 to September 2015 and April 2016 to September 2016. See Appendix B for specific codes used to define dialysis in this request.

Cohort Eligibility Criteria: Members included in the cohort were required to be continuously enrolled in health plans with medical and drug coverage for at least six months (183 days) before their diagnosis or procedure date, during which gaps in coverage of up to 45 days were allowed. The following age groups were included in the cohort: 21-64, 65-74, 75-84, and 85-99 years.

Incident Cohorts: Members included in the incident cohorts were required to be continuously enrolled in health plans with medical and drug coverage for at least 183 days prior to dialysis diagnosis or procedure, during which gaps in coverage of up to 45 days were allowed. Incident dialysis was defined as no previous dialysis diagnosis or procedure in the 183 days preceding the index date with respect to the index-defining code type of interest.

Prevalent Cohorts: There was no enrollment time requirement for members in the prevalent cohorts. All qualifying diagnosis or procedure codes that occurred between October 1, 2010 and September 30, 2016 were included.

Please see Appendix C for detailed specifications of parameters used in the analyses for this request.

Limitations: Algorithms used to define outcomes are imperfect; thus, it is possible that there may be misclassification. 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.

¹Fung, K. W., et al. (2016). "Preparing for the ICD-10-CM Transition: Automated Methods for Translating ICD Codes in Clinical Phenotype Definitions." EGEMS (Wash DC) 4(1): 1211.

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**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, 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.

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 MP algorithm: 0: Counts all occurrences of an 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 days 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 1. Comparison of Incident* Dialysis Diagnoses or Procedures in the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) Eras (April 1, 2015 - September 30, 2015 and April 1, 2016 - September 30, 2016), by Code Type

	Members with Diagnosis/Procedure	Eligible Members	Members with Diagnosis/Procedure per 1,000 Eligible Members
Dialysis			
ICD-9-CM: April 1, 2015 - September 30, 2015	11,778	32,378,575	0.36
ICD-10-CM: April 1, 2016 - September 30, 2016	9,898	33,740,204	0.29
CPT-4: April 1, 2015 - September 30, 2015	6,596	32,365,664	0.20
CPT-4: April 1, 2016 - September 30, 2016	6,868	33,738,653	0.20
ICD-9-CM and CPT-4: April 1, 2015 - September 30, 2015	8,132	32,363,351	0.20
ICD-10-CM and CPT-4: April 1, 2016 - September 30, 2016	8,701	33,735,574	0.26

*Incidence defined by a 183 day washout

Figure 1. Incidence of Dialysis Diagnoses per 1,000 Eligible Members from October 2010 - September 2016 by Code Type, 183-Day Washout

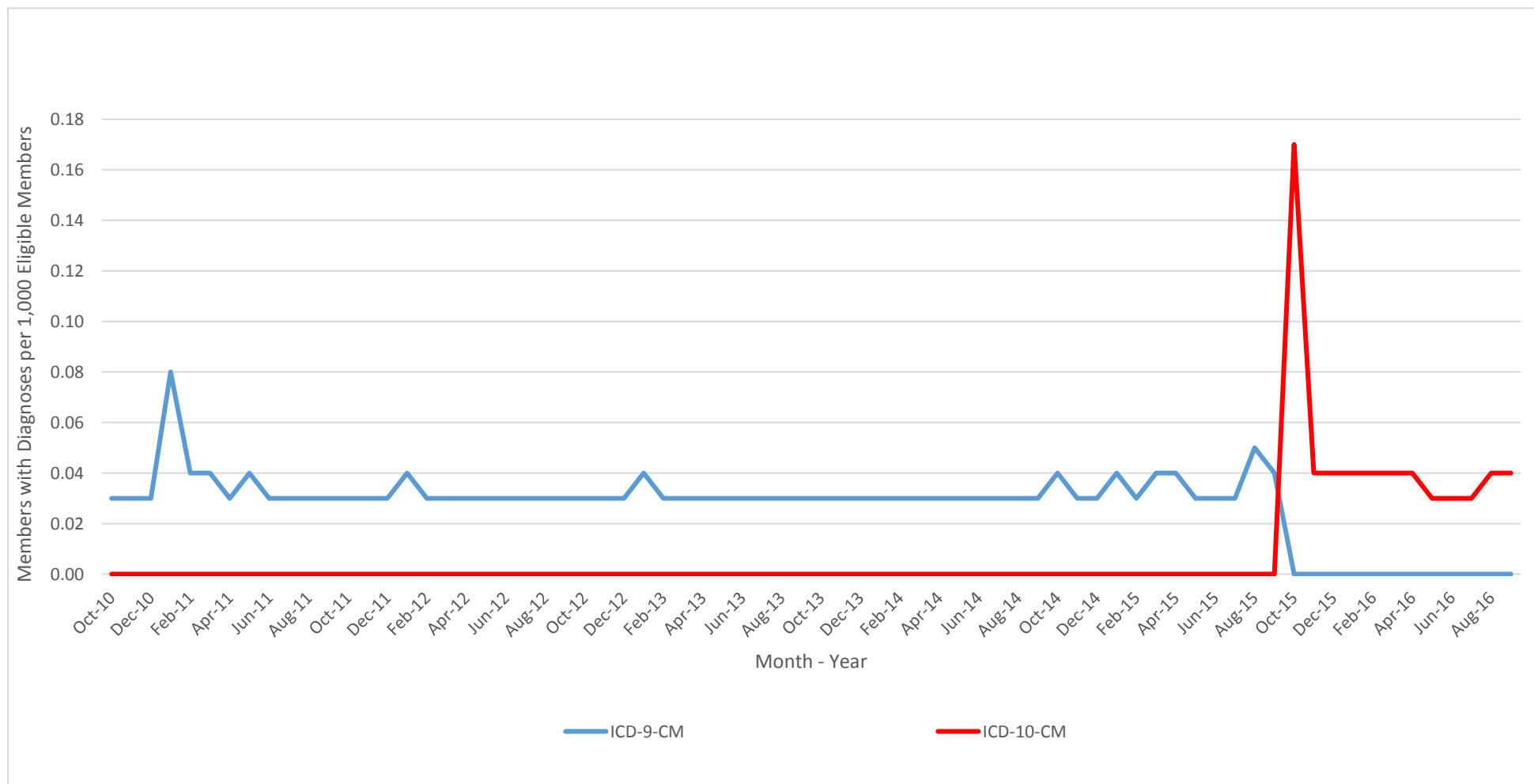
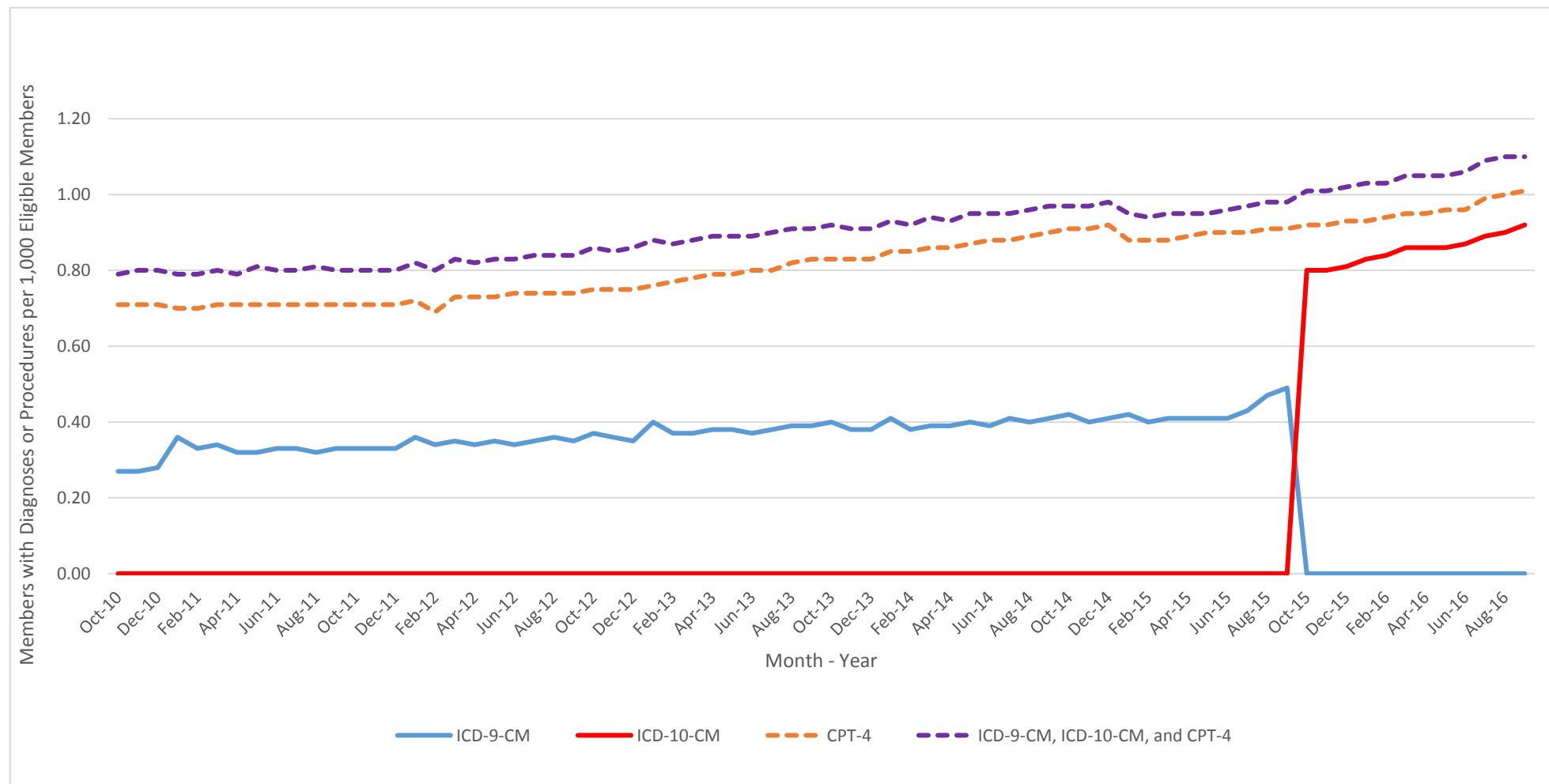


Figure 2. Prevalence of Dialysis Diagnoses or Procedures per 1,000 Eligible Members from October 2010 - September 2016 by Code Type, 0-Day Washout



Appendix A. Dates of Available Data for Each Data Partner as of Request Distribution Date (October 25, 2017)

DP ID	Start Date¹	End Date¹
DP0001	10/1/2010	6/30/2016
DP0002	10/1/2010	6/30/2016
DP0003	10/1/2010	9/30/2016
DP0004	10/1/2010	9/30/2016
DP0005	10/1/2010	9/30/2016
DP0006	10/1/2010	9/30/2016
DP0007	10/1/2010	9/30/2016
DP0008	10/1/2010	9/30/2016
DP0009	10/1/2010	9/30/2016
DP0010	10/1/2010	9/30/2016
DP0011	10/1/2010	9/30/2016
DP0012	10/1/2010	9/30/2016

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. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM), and Current Procedural Terminology, Fourth Edition (CPT-4) Codes Used to Define Dialysis

Code	Description	Code Type	Code Category
ICD-9-CM			
792.5	Cloudy (hemodialysis) (peritoneal) dialysis affluent	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
V56.3	Encounter for adequacy testing for dialysis	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
ICD-10-CM			
R88.0	Cloudy (hemodialysis) (peritoneal) dialysis effluent	ICD-10-CM	Diagnosis
Z49.01	Encounter for fitting and adjustment of extracorporeal dialysis catheter	ICD-10-CM	Diagnosis
Z49.02	Encounter for fitting and adjustment of peritoneal dialysis catheter	ICD-10-CM	Diagnosis
Z49.31	Encounter for adequacy testing for hemodialysis	ICD-10-CM	Diagnosis
Z49.32	Encounter for adequacy testing for peritoneal dialysis	ICD-10-CM	Diagnosis
Z91.15	Patient's noncompliance with renal dialysis	ICD-10-CM	Diagnosis
Z99.2	Dependence on renal dialysis	ICD-10-CM	Diagnosis
CPT-4			
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
90951	End-stage renal disease (ESRD) related services monthly, 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; with 4 or more face-to-face visits by a physician or other qualified health care professional per month	CPT-4	Procedure

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Code	Description	Code Type	Code Category
90952	End-stage renal disease (ESRD) related services monthly, 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; with 2-3 face-to-face visits by a physician or other qualified health care professional per month	CPT-4	Procedure
90953	End-stage renal disease (ESRD) related services monthly, 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; with 1 face-to-face visit by a physician or other qualified health care professional per month	CPT-4	Procedure
90954	End-stage renal disease (ESRD) related services monthly, for patients 2-11 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
90955	End-stage renal disease (ESRD) related services monthly, for patients 2-11 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
90956	End-stage renal disease (ESRD) related services monthly, for patients 2-11 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
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
90964	End-stage renal disease (ESRD) related services for home dialysis per full month, for patients 2-11 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents	CPT-4	Procedure

Appendix B. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM), and Current Procedural Terminology, Fourth Edition (CPT-4) Codes Used to Define Dialysis

Code	Description	Code Type	Code Category
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
90967	End-stage renal disease (ESRD) related services for dialysis less than a full month of service, per day; for patients younger than 2 years of age	CPT-4	Procedure
90968	End-stage renal disease (ESRD) related services for dialysis less than a full month of service, per day; for patients 2-11 years of age	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
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

Appendix C. Specifications for Parameters for this Request

Sentinel's Cohort Identification and Descriptive Analysis (CIDA) tool, version 5.0.5 was used to compare the frequency of diagnoses and procedures for dialysis using International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM), and Current Procedural Terminology, Fourth Edition (CPT-4).

Enrollment Gap: 45 days
Age Groups: 21-64, 65-74, 75-84, 85-99 years
Enrollment Requirement: 183 days for incidence scenarios; 0 days for prevalence scenarios
Coverage Requirement: Medical and drug coverage

Scenario	Query Start Date	Query End Date	Event					Cohort Definition	Care Setting
			Event	Event Code Type	Incident with Respect To:	Washout (days)			
1	4/1/2015	9/30/2015	Dialysis	ICD-9-CM	ICD-9-CM	183	First valid event only	Ambulatory Visit or Other Ambulatory Visit	
2	4/1/2015	9/30/2015	Dialysis	CPT-4	CPT-4	183	First valid event only	AV or OA	
3	4/1/2015	9/30/2015	Dialysis	ICD-9-CM, CPT-4	ICD-9-CM, CPT-4	183	First valid event only	AV or OA	
4	4/1/2016	9/30/2016	Dialysis	ICD-10-CM	ICD-10-CM	183	First valid event only	AV or OA	
5	4/1/2016	9/30/2016	Dialysis	CPT-4	CPT-4	183	First valid event only	AV or OA	
6	4/1/2016	9/30/2016	Dialysis	ICD-10-CM, CPT-4	ICD-10-CM, CPT-4	183	First valid event only	AV or OA	
7	10/1/2010	9/30/2016	Dialysis	ICD-9-CM	ICD-9-CM or ICD-10-CM	183	First valid event only	AV or OA	
8	10/1/2010	9/30/2016	Dialysis	ICD-10-CM	ICD-9-CM or ICD-10-CM	183	First valid event only	AV or OA	
9	10/1/2010	9/30/2016	Dialysis	ICD-9-CM	N/A	0	Any valid events	AV or OA	
10	10/1/2010	9/30/2016	Dialysis	ICD-10-CM	N/A	0	Any valid events	AV or OA	
11	10/1/2010	9/30/2016	Dialysis	CPT-4	N/A	0	Any valid events	AV or OA	
12	10/1/2010	9/30/2016	Dialysis	ICD-9-CM, ICD-10-CM, CPT-4	N/A	0	Any valid events	AV or OA	

ICD-9-CM and ICD-10-CM 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.