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).

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Overview

Date Run: April 28, 2017

Request Description: The purpose of this report was to compare the frequency of diagnoses for diabetes mellitus with pregnancy using International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) and International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) 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). Simple forward mapping (SFM) and forward-backward mapping (FBM) were used to map ICD-9-CM to ICD-10-CM codes.[1]

Sentinel Modular Program Tool Used: Cohort Identification and Descriptive Analysis (CIDA) tool, version 3.3.6

Data Source: This request was run against the IBM® MarketScan® Commercial Claims and Encounters Database and Medicare Supplemental Database, which included 121 million members. Data from October 1, 2010 to March 31, 2016 were included in this report. The report includes three separate time periods: 1) October 1, 2010 to March 31, 2016, 2) January 1, 2015 to March 31, 2015, and 3) January 1, 2016 to March 31, 2016. See Appendix A for the dates of available data used in this report.

Study Design: We examined the incidence and prevalence of diabetes mellitus with pregnancy across the ICD-9-CM era (October 2010 to September 2015) and ICD-10-CM era (October 2015 to March 2016) in the US. Incidence was additionally evaluated from January 2015 to March 2015 and January 2016 to March 2016. See Appendices B - D for specific codes.

Cohort Eligibility Criteria: Members included in the cohorts were required to be enrolled in health plans with at least medical coverage. The following age groups were included in the cohorts: 2-17, 18-44, 45-64, and 65+ years.

Incident Cohorts: Members included in the incident cohorts were required to be continuously enrolled in health plans with at least medical coverage for at least 183 days prior to diabetes mellitus with pregnancy during which gaps in coverage of up to 45 days were allowed. Incident diabetes mellitus with pregnancy was defined as no previous diabetes mellitus with pregnancy in the 183 days preceding the index date with respect to ICD-9-CM and ICD-10-CM codes.

Prevalent Cohorts: There was no enrollment requirement for members in the prevalent cohorts. All qualifying diagnosis codes that occurred between October 1, 2010 and March 31, 2016 were included.

Please refer to Appendix E 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. The MarketScan claims databases are based on a large convenience sample. Because the sample is not random, it may contain biases or fail to generalize well to other populations. Data come mostly from large employers; medium and small firms may be underrepresented.[2]

Notes: Please contact the Sentinel Operations Center Query Fulfillment Team (qf@sentinelsystem.org) for questions and to provide comments/suggestions for future enhancements to this document.

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[1]Fung, 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.

[2]IBM Watson Health (2018). [online] ibm.com. Available at: https://www.ibm.com/downloads/cas/OWZWJ0QO [Accessed 01 Mar. 2019].

Table of Contents

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). 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: (1): Cohort includes only the first valid treatment episode during the query period; (2): Cohort includes all valid treatment episodes during the query period; (3): 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* Diabetes Mellitus with Pregnancy Diagnoses in the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) and International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) Eras (January 1, 2015 - March 31, 2015 and January 1, 2016 - March 31, 2016)

	Members with Diagnosis	Eligible Members	Members with Diagnosis per 1,000 Eligible Members
Diabetes Mellitus with Pregnancy			
ICD-9-CM: January 1, 2015 - March 31, 2015			
	2,521	22,222,672	0.11
ICD-10-CM: Simple Forward Mapping: January 1, 2016 - March 31, 2016			
	1,065	22,698,244	0.05
ICD-10-CM: Forward-Backward Mapping: January 1, 2016 - March 31, 2016			
	1,936	22,697,298	0.09

* Incidence defined by 90 day washout

Figure 1. Incidence of Diabetes Mellitus with Pregnancy Diagnoses per 1,000 Eligible Members from October 2010 - March 2016 by Code Type, 183-Day Washout
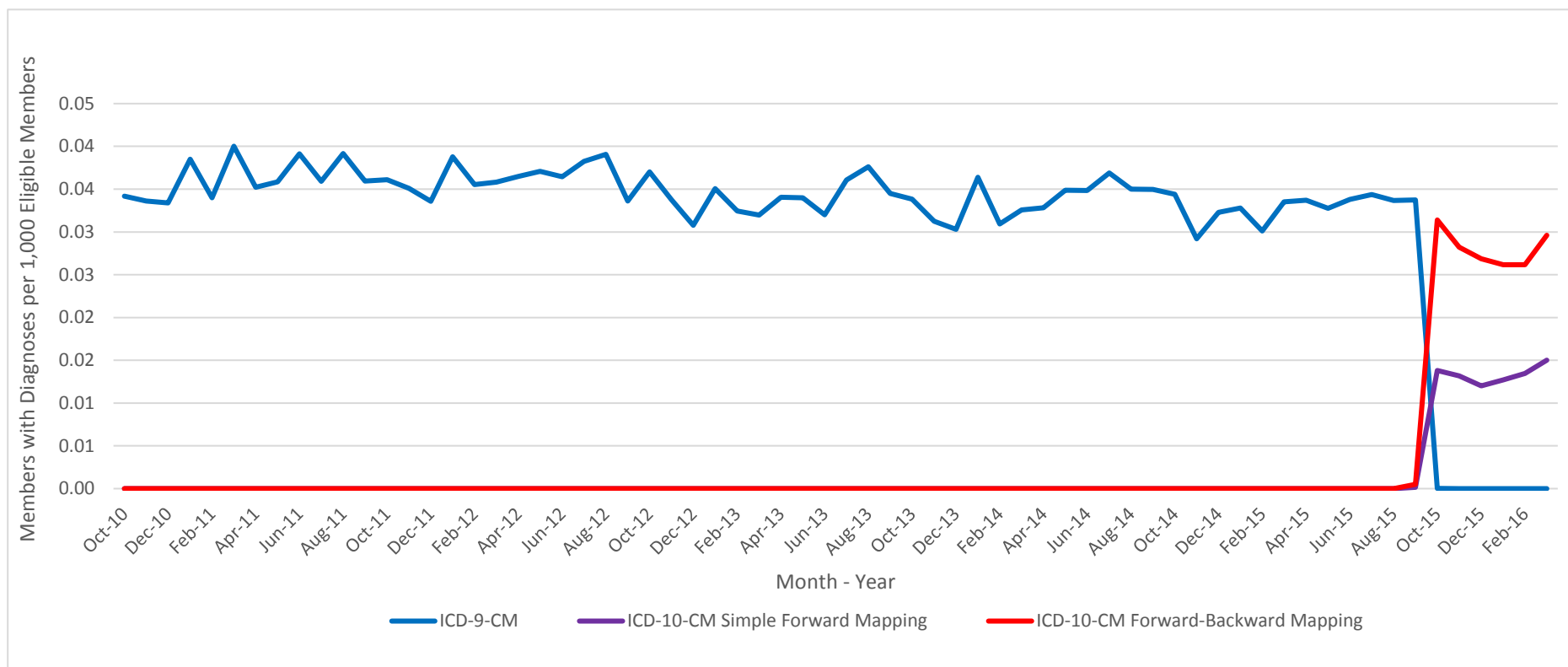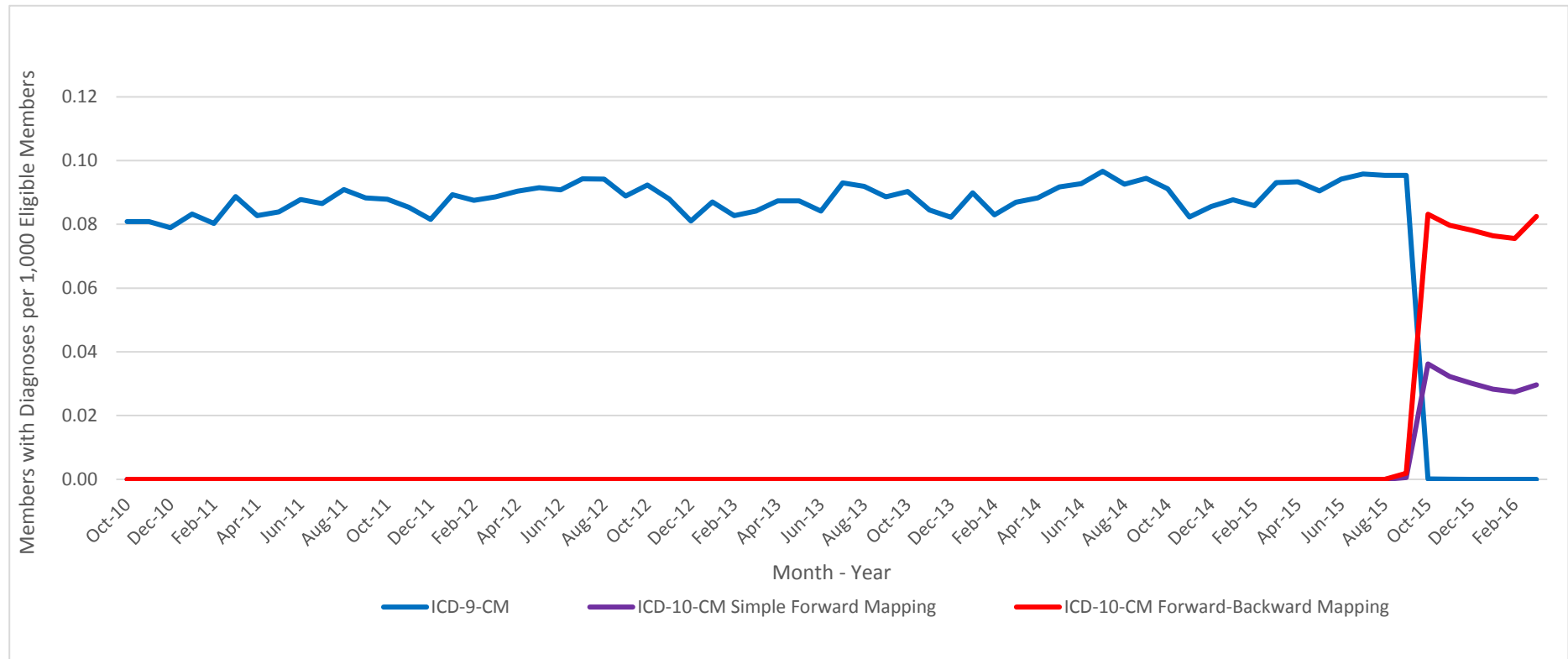
Figure 2. Prevalence of Diabetes Mellitus with Pregnancy Diagnoses per 1,000 Eligible Members from October 2010 - March 2016 by Code Type, 0-Day Washout

Appendix A. Dates Available for IBM® MarketScan® Commercial and Medicare Supplemental Databases

Databases	Start Date	End Date
IBM MarketScan Commercial and Medicare Supplemental Databases[1]	1/1/2010	3/31/2016

[1] The IBM MarketScan Databases includes a sample of 121 million employees, dependents, and retirees in the United States with primary or Medicare supplemental coverage through privately insured fee-for-service, point-of-service, or capitated health plans. The IBM MarketScan claims databases are based on a large convenience sample. Because the sample is not random, it may contain biases or fail to generalize well to other populations. Data come mostly from large employers; medium and small firms may be underrepresented. For more information on the IBM MarketScan Databases, please review the White Paper here: https://www.ibm.com/downloads/cas/OWZWJ0QO

Appendix B. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) Codes Used to Define Diabetes Mellitus with Pregnancy

Code	Description	Code Type
648.0	Maternal diabetes mellitus complicating pregnancy, childbirth, or the puerperium	ICD-9-CM
648.00	Maternal diabetes mellitus, complicating pregnancy, childbirth, or the puerperium, unspecified as to episode of care	ICD-9-CM
648.01	Maternal diabetes mellitus with delivery	ICD-9-CM
648.02	Maternal diabetes mellitus with delivery, with current postpartum complication	ICD-9-CM
648.03	Maternal diabetes mellitus, antepartum	ICD-9-CM
648.04	Maternal diabetes mellitus, complicating pregnancy, childbirth, or the puerperium, postpartum condition or complication	ICD-9-CM

Appendix C. List of International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) Codes Used to Define Diabetes Mellitus with Pregnancy, Simple Forward Mapping (SFM)

Code	Description	Code Type
O24.319	Unspecified pre-existing diabetes mellitus in pregnancy, unspecified trimester	ICD-10-CM
O24.32	Unspecified pre-existing diabetes mellitus in childbirth	ICD-10-CM
O24.92	Unspecified diabetes mellitus in childbirth	ICD-10-CM
O24.913	Unspecified diabetes mellitus in pregnancy, third trimester	ICD-10-CM
O24.912	Unspecified diabetes mellitus in pregnancy, second trimester	ICD-10-CM
O24.911	Unspecified diabetes mellitus in pregnancy, first trimester	ICD-10-CM
O24.93	Unspecified diabetes mellitus in the puerperium	ICD-10-CM

Appendix D. List of International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) Codes Used to Define Diabetes Mellitus with Pregnancy, Forward-Backward Mapping (FBM)

Code	Description	Code Type
O24.319	Unspecified pre-existing diabetes mellitus in pregnancy, unspecified trimester	ICD-10-CM
O24.32	Unspecified pre-existing diabetes mellitus in childbirth	ICD-10-CM
O24.92	Unspecified diabetes mellitus in childbirth	ICD-10-CM
O24.913	Unspecified diabetes mellitus in pregnancy, third trimester	ICD-10-CM
O24.912	Unspecified diabetes mellitus in pregnancy, second trimester	ICD-10-CM
O24.911	Unspecified diabetes mellitus in pregnancy, first trimester	ICD-10-CM
O24.93	Unspecified diabetes mellitus in the puerperium	ICD-10-CM
O24.019	Pre-existing type 1 diabetes mellitus, in pregnancy, unspecified trimester	ICD-10-CM
O24.919	Unspecified diabetes mellitus in pregnancy, unspecified trimester	ICD-10-CM
O24.819	Other pre-existing diabetes mellitus in pregnancy, unspecified trimester	ICD-10-CM
O24.119	Pre-existing type 2 diabetes mellitus, in pregnancy, unspecified trimester	ICD-10-CM
O24.011	Pre-existing type 1 diabetes mellitus, in pregnancy, first trimester	ICD-10-CM
O24.82	Other pre-existing diabetes mellitus in childbirth	ICD-10-CM
O24.813	Other pre-existing diabetes mellitus in pregnancy, third trimester	ICD-10-CM
O24.812	Other pre-existing diabetes mellitus in pregnancy, second trimester	ICD-10-CM
O24.811	Other pre-existing diabetes mellitus in pregnancy, first trimester	ICD-10-CM
O24.313	Unspecified pre-existing diabetes mellitus in pregnancy, third trimester	ICD-10-CM
O24.312	Unspecified pre-existing diabetes mellitus in pregnancy, second trimester	ICD-10-CM
O24.311	Unspecified pre-existing diabetes mellitus in pregnancy, first trimester	ICD-10-CM
O24.12	Pre-existing type 2 diabetes mellitus, in childbirth	ICD-10-CM
O24.113	Pre-existing type 2 diabetes mellitus, in pregnancy, third trimester	ICD-10-CM
O24.112	Pre-existing type 2 diabetes mellitus, in pregnancy, second trimester	ICD-10-CM
O24.111	Pre-existing type 2 diabetes mellitus, in pregnancy, first trimester	ICD-10-CM
O24.02	Pre-existing type 1 diabetes mellitus, in childbirth	ICD-10-CM
O24.013	Pre-existing type 1 diabetes mellitus, in pregnancy, third trimester	ICD-10-CM
O24.012	Pre-existing type 1 diabetes mellitus, in pregnancy, second trimester	ICD-10-CM
O24.03	Pre-existing type 1 diabetes mellitus, in the puerperium	ICD-10-CM
O24.83	Other pre-existing diabetes mellitus in the puerperium	ICD-10-CM
O24.33	Unspecified pre-existing diabetes mellitus in the puerperium	ICD-10-CM
O24.13	Pre-existing type 2 diabetes mellitus, in the puerperium	ICD-10-CM

Appendix E. Specifications for Parameters for this Request

Sentinel's Cohort Identification and Descriptive Analysis (CIDA) tool, version 3.3.6, was used to compare the frequency of diagnoses for diabetes mellitus with pregnancy using International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-9-CM) versus ICD-10-CM codes.

Enrollment Gap: 45 days
Age Groups: 2-17, 18-44, 45-64, 65+ years
Enrollment Requirement: 183 days
Coverage Requirement: At least medical coverage

Scenario	Code Source	Query Start Date	Query End Date	Event	Incident with respect to:	Washout (days)	Cohort Definition	Caresetting
1	ICD-9-CM Code Search	1/1/2015	3/31/2015	Diabetes mellitus with pregnancy	ICD-9-CM	90	First valid event only	Any
2	SFM	1/1/2016	3/31/2016	Diabetes mellitus with pregnancy	ICD-10-CM SFM	90	First valid event only	Any
3	FBM	1/1/2016	3/31/2016	Diabetes mellitus with pregnancy	ICD-10-CM FBM	90	First valid event only	Any
4	ICD-9-CM Code Search	10/1/2010	3/31/2016	Diabetes mellitus with pregnancy	ICD-9-CM or ICD-10-CM SFM	183	First valid event only	Any
6	SFM	10/1/2010	3/31/2016	Diabetes mellitus with pregnancy	ICD-9-CM or ICD-10-CM SFM	183	First valid event only	Any
7	FBM	10/1/2010	3/31/2016	Diabetes mellitus with pregnancy	ICD-9-CM or ICD-10-CM FBM	183	First valid event only	Any
8	ICD-9-CM Code Search	10/1/2010	3/31/2016	Diabetes mellitus with pregnancy	NA	0	All valid events	Any
9	SFM	10/1/2010	3/31/2016	Diabetes mellitus with pregnancy	NA	0	All valid events	Any
10	FBM	10/1/2010	3/31/2016	Diabetes mellitus with pregnancy	NA	0	All valid events	Any

The "Event" column group header spans the Event, Incident with respect to, Washout (days), Cohort Definition columns.

ICD-9-CM and ICD-10-CM are provided by Optum360. ICD-10-CM codes were mapped from ICD-9-CM codes with the Centers for Medicare and Medicaid Services General Equivalence Mappings, using simple forward mapping (SFM) and forward-backward mapping (FBM).