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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: October 11, 2018

Request Description: The purpose of this report was to compare the frequency of diagnoses for type 1 diabetes mellitus 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). Forward-backward mapping (FBM) was 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 5.4.4

<u>Data Source:</u> This request was run against the IBM® MarketScan® Commercial Claims and Encounters Database and Medicare Supplemental Database, which included 127 million members. Data from October 1, 2010 to September 31, 2016 were included in this report. The report includes three separate time periods: 1) October 1, 2010 to September 31, 2016, 2) April 1, 2015 to September 30, 2015, and 3) April 1, 2016 to September 30, 2016. See Appendix A for the dates of available data used in this report.

<u>Study Design:</u> We examined the incidence and prevalence of type 1 diabetes mellitus across the ICD-9-CM era (October 2010 - September 2015) and ICD-10-CM era (October 2015 - September 2016) in the US. 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 type 1 diabetes mellitus.

<u>Cohort Eligibility Criteria:</u> Members included in the cohorts were required to be enrolled in health plans with medical and drug coverage. The following age groups were included in the cohorts: <12, 12-18, 19-24, 25-44, 45-64, and 65+ years.

<u>Incident Cohorts:</u> 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 type 1 diabetes mellitus during which gaps in coverage of up to 45 days were allowed. Incident type 1 diabetes mellitus was defined as no previous type 1 diabetes mellitus in the 183 days preceding the index date with respect to ICD-9-CM and ICD-10-CM codes.

<u>Prevalent Cohorts:</u> There was no enrollment time requirement for members in the prevalent cohort. All qualifying diagnosis codes that occurred between October 1, 2010 and September 31, 2016 were included.

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

<u>Limitations</u>: 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.

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.

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



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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). 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* Type 1 Diabetes Mellitus 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 (April 1, 2015 - September 30, 2015 and April 1, 2016 - September 30, 2016)

	Members with Diagnosis	Eligible Members	Members with Diagnosis per 10,000 Eligible Members
Type 1 Diabetes Mellitus			
ICD-9 CM: April 1, 2015 - September 30, 2015			
	61,433	22,293,845	27.56
ICD-10 CM: April 1, 2016 - September 30, 2016			
	49,835	22,121,002	22.53

^{*}Incidence defined by 183 day washout



Figure 1. Incidence of Type 1 Diabetes Mellitus Diagnoses per 10,000 Eligible Members from October 2010 - September 2016 by Code Type, 183-Day Washout

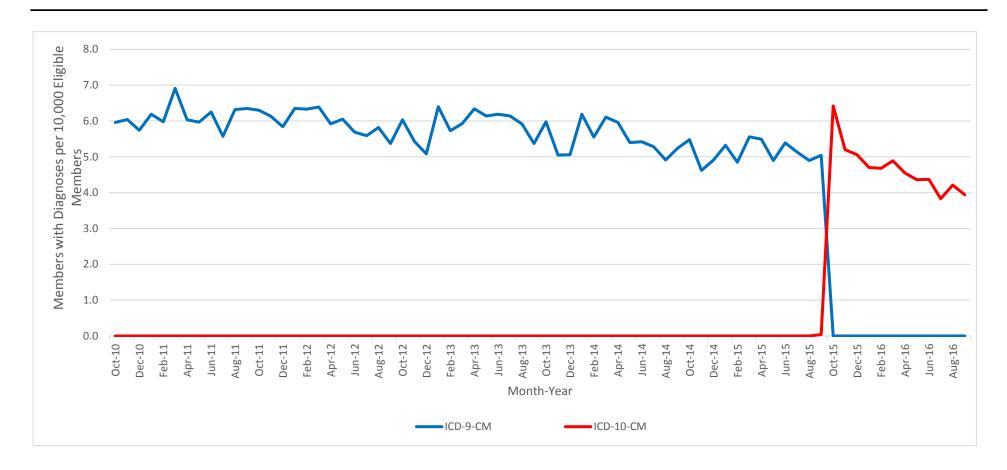
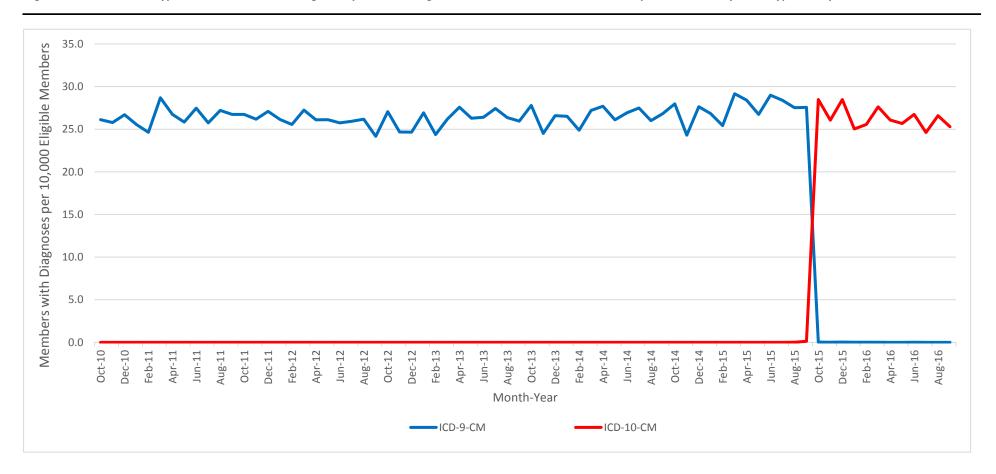




Figure 2. Prevalence of Type 1 Diabetes Mellitus Diagnoses per 10,000 Eligible Members from October 2010 - September 2016 by Code Type, 0-Day Washout





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	3/31/2017

¹ The IBM MarketScan Databases includes a sample of 127.2 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. Appendix B. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) and International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) Diagnosis Codes Used to Define Type 1 Diabetes Mellitus

Code	Description	Code Type
	ICD-9-CM	
250.01	Diabetes mellitus without mention of complication, type I [juvenile type], not stated as uncontrolled	ICD-9-CM
250.03	Diabetes mellitus without mention of complication, type I [juvenile type], uncontrolled	ICD-9-CM
250.21	Diabetes with hyperosmolarity, type I [juvenile type], not stated as uncontrolled	ICD-9-CM
250.23	Diabetes with hyperosmolarity, type I [juvenile type], uncontrolled	ICD-9-CM
250.11	Diabetes with ketoacidosis, type I [juvenile type], not stated as uncontrolled	ICD-9-CM
250.13	Diabetes with ketoacidosis, type I [juvenile type], uncontrolled	ICD-9-CM
250.61	Diabetes with neurological manifestations, type I [juvenile type], not stated as uncontrolled	ICD-9-CM
250.63	Diabetes with neurological manifestations, type I [juvenile type], uncontrolled	ICD-9-CM
250.51	Diabetes with ophthalmic manifestations, type I [juvenile type], not stated as uncontrolled	ICD-9-CM
250.53	Diabetes with ophthalmic manifestations, type I [juvenile type], uncontrolled	ICD-9-CM
250.31	Diabetes with other coma, type I [juvenile type], not stated as uncontrolled	ICD-9-CM
250.33	Diabetes with other coma, type I [juvenile type], uncontrolled	ICD-9-CM
250.81	Diabetes with other specified manifestations, type I [juvenile type], not stated as uncontrolled	ICD-9-CM
250.83	Diabetes with other specified manifestations, type I [juvenile type], uncontrolled	ICD-9-CM
250.71	Diabetes with peripheral circulatory disorders, type I [juvenile type], not stated as uncontrolled	ICD-9-CM
250.73	Diabetes with peripheral circulatory disorders, type I [juvenile type], uncontrolled	ICD-9-CM
250.41	Diabetes with renal manifestations, type I [juvenile type], not stated as uncontrolled	ICD-9-CM
250.43	Diabetes with renal manifestations, type I [juvenile type], uncontrolled	ICD-9-CM
250.91	Diabetes with unspecified complication, type I [juvenile type], not stated as uncontrolled	ICD-9-CM
250.93	Diabetes with unspecified complication, type I [juvenile type], uncontrolled	ICD-9-CM
	ICD-10-CM	
E10.3299	Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, unspecified eye	ICD-10-CM
E10.3319	Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, unspecified eye	ICD-10-CM
E10.3499	Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema, unspecified eye	ICD-10-CM
E10.37	Type 1 diabetes mellitus with diabetic macular edema, resolved following treatment	ICD-10-CM
E10.37X9	Type 1 diabetes mellitus with diabetic macular edema, resolved following treatment, unspecified eye	ICD-10-CM
E10.3219	Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, unspecified eye	ICD-10-CM
E10.3213	Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, bilateral	ICD-10-CM
E10.3211	Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, right eye	ICD-10-CM
E10.3212	Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, left eye	ICD-10-CM
E10.3293	Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, bilateral	ICD-10-CM



Appendix B. Appendix B. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) and International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) Diagnosis Codes Used to Define Type 1 Diabetes Mellitus

Code	Description	Code Type
E10.3291	Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, right eye	ICD-10-CM
E10.3292	Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, left eye	ICD-10-CM
E10.3313	Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, bilateral	ICD-10-CM
E10.3311	Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, right eye	ICD-10-CM
E10.3312	Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, left eye	ICD-10-CM
E10.3399	Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema, unspecified eye	ICD-10-CM
E10.3393	Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema, bilateral	ICD-10-CM
E10.3391	Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema, right eye	ICD-10-CM
E10.3392	Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema, left eye	ICD-10-CM
E10.354	Type 1 diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment	ICD-10-CM
E10.3549	Type 1 diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, unspecified eye	ICD-10-CM
E10.3519	Type 1 diabetes mellitus with proliferative diabetic retinopathy with macular edema, unspecified eye	ICD-10-CM
E10.353	Type 1 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula	ICD-10-CM
E10.352	Type 1 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula	ICD-10-CM
E10.3529	Type 1 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, unspecified eye	ICD-10-CM
E10.3533	Type 1 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, bilateral	ICD-10-CM
E10.3531	Type 1 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, right eye	ICD-10-CM
E10.3532	Type 1 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, left eye	ICD-10-CM
E10.3539	Type 1 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, unspecified eye	ICD-10-CM
E10.3599	Type 1 diabetes mellitus with proliferative diabetic retinopathy without macular edema, unspecified eye	ICD-10-CM
E10.355	Type 1 diabetes mellitus with stable proliferative diabetic retinopathy	ICD-10-CM
E10.3419	Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, unspecified eye	ICD-10-CM



Appendix B. Appendix B. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) and International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) Diagnosis Codes Used to Define Type 1 Diabetes Mellitus

Code	Description	Codo Torre
Code	Description The description of the second state of the second sta	Code Type
E10.3413	Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, bilateral	ICD-10-CM
E10.3411	Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, right eye	ICD-10-CM
E10.3412	Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, left eye	ICD-10-CM
E10.3493	Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema, bilateral	ICD-10-CM
E10.3491	Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema, right eye	ICD-10-CM
E10.3492	Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema, lef eye	t ICD-10-CM
E10.39	Type 1 diabetes mellitus with other diabetic ophthalmic complication	ICD-10-CM
E10.35	Type 1 diabetes mellitus with proliferative diabetic retinopathy	ICD-10-CM
E10	Type 1 diabetes mellitus	ICD-10-CM
E10.37X3	Type 1 diabetes mellitus with diabetic macular edema, resolved following treatment, bilateral	ICD-10-CM
E10.37X1	Type 1 diabetes mellitus with diabetic macular edema, resolved following treatment, right eye	ICD-10-CM
E10.37X2	Type 1 diabetes mellitus with diabetic macular edema, resolved following treatment, left eye	ICD-10-CM
E10.3543	Type 1 diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, bilateral	ICD-10-CM
E10.3541	Type 1 diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, right eye	ICD-10-CM
E10.3542	Type 1 diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, left eye	ICD-10-CM
E10.3513	Type 1 diabetes mellitus with proliferative diabetic retinopathy with macular edema, bilateral	ICD-10-CM
E10.3511	Type 1 diabetes mellitus with proliferative diabetic retinopathy with macular edema, right eye	ICD-10-CM
E10.3512	Type 1 diabetes mellitus with proliferative diabetic retinopathy with macular edema, left eye	ICD-10-CM
E10.3523	Type 1 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, bilateral	ICD-10-CM
E10.3521	Type 1 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, right eye	ICD-10-CM
E10.3522	Type 1 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, left eye	ICD-10-CM
E10.3593	Type 1 diabetes mellitus with proliferative diabetic retinopathy without macular edema, bilateral	ICD-10-CM
E10.3591	Type 1 diabetes mellitus with proliferative diabetic retinopathy without macular edema, right eye	ICD-10-CM
E10.3592	Type 1 diabetes mellitus with proliferative diabetic retinopathy without macular edema, left eye	ICD-10-CM
E10.3553	Type 1 diabetes mellitus with stable proliferative diabetic retinopathy, bilateral	ICD-10-CM
E10.3552	Type 1 diabetes mellitus with stable proliferative diabetic retinopathy, left eye	ICD-10-CM
E10.3551	Type 1 diabetes mellitus with stable proliferative diabetic retinopathy, right eye	ICD-10-CM
E10.3559	Type 1 diabetes mellitus with stable proliferative diabetic retinopathy, unspecified eye	ICD-10-CM
E10.5	Type 1 diabetes mellitus with circulatory complications	ICD-10-CM
E10.22	Type 1 diabetes mellitus with diabetic chronic kidney disease	ICD-10-CM



Appendix B. Appendix B. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) and International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) Diagnosis Codes Used to Define Type 1 Diabetes Mellitus

CodeDescriptionCode TypeE10.41Type 1 diabetes mellitus with diabetic mononeuropathyICD-10-CME10.40Type 1 diabetes mellitus with diabetic neuropathy, unspecifiedICD-10-CME10.42Type 1 diabetes mellitus with diabetic polyneuropathyICD-10-CME10.44Type 1 diabetes mellitus with diabetic amyotrophyICD-10-CME10.61Type 1 diabetes mellitus with diabetic arthropathyICD-10-CME10.36Type 1 diabetes mellitus with diabetic cataractICD-10-CME10.620Type 1 diabetes mellitus with diabetic dermatitisICD-10-CME10.21Type 1 diabetes mellitus with diabetic nephropathyICD-10-CME10.641Type 1 diabetes mellitus with hypoglycemia with comaICD-10-CME10.649Type 1 diabetes mellitus with hypoglycemia without comaICD-10-CME10.11Type 1 diabetes mellitus with ketoacidosis with comaICD-10-CME10.10Type 1 diabetes mellitus with ketoacidosis without comaICD-10-CME10.2Type 1 diabetes mellitus with ketoacidosis without comaICD-10-CME10.3Type 1 diabetes mellitus with neurological complicationsICD-10-CME10.3Type 1 diabetes mellitus with other circulatory complicationsICD-10-CME10.59Type 1 diabetes mellitus with other circulatory complicationsICD-10-CME10.618Type 1 diabetes mellitus with other diabetic arthropathyICD-10-CME10.628Type 1 diabetes mellitus with other diabetic kidney complicationsICD-10-CM
E10.40Type 1 diabetes mellitus with diabetic neuropathy, unspecifiedICD-10-CME10.42Type 1 diabetes mellitus with diabetic polyneuropathyICD-10-CME10.44Type 1 diabetes mellitus with diabetic amyotrophyICD-10-CME10.61Type 1 diabetes mellitus with diabetic arthropathyICD-10-CME10.36Type 1 diabetes mellitus with diabetic cataractICD-10-CME10.620Type 1 diabetes mellitus with diabetic dermatitisICD-10-CME10.21Type 1 diabetes mellitus with diabetic nephropathyICD-10-CME10.641Type 1 diabetes mellitus with hypoglycemia with comaICD-10-CME10.649Type 1 diabetes mellitus with hypoglycemia without comaICD-10-CME10.11Type 1 diabetes mellitus with ketoacidosis with comaICD-10-CME10.10Type 1 diabetes mellitus with ketoacidosis without comaICD-10-CME10.2Type 1 diabetes mellitus with kidney complicationsICD-10-CME10.3Type 1 diabetes mellitus with neurological complicationsICD-10-CME10.3Type 1 diabetes mellitus with ophthalmic complicationsICD-10-CME10.59Type 1 diabetes mellitus with other circulatory complicationsICD-10-CME10.618Type 1 diabetes mellitus with other diabetic arthropathyICD-10-CME10.629Type 1 diabetes mellitus with other diabetic arthropathyICD-10-CCM
E10.42 Type 1 diabetes mellitus with diabetic polyneuropathy E10.44 Type 1 diabetes mellitus with diabetic amyotrophy E10.61 Type 1 diabetes mellitus with diabetic arthropathy E10.36 Type 1 diabetes mellitus with diabetic cataract E10.40 Type 1 diabetes mellitus with diabetic cataract E10.620 Type 1 diabetes mellitus with diabetic dermatitis E10.21 Type 1 diabetes mellitus with diabetic nephropathy E10.641 Type 1 diabetes mellitus with hypoglycemia with coma E10.649 Type 1 diabetes mellitus with hypoglycemia without coma E10.11 Type 1 diabetes mellitus with ketoacidosis with coma E10.10 Type 1 diabetes mellitus with ketoacidosis with coma E10.11 Type 1 diabetes mellitus with ketoacidosis without coma E10.10 Type 1 diabetes mellitus with ketoacidosis without coma E10.10 Type 1 diabetes mellitus with kidney complications E10.4 Type 1 diabetes mellitus with neurological complications E10.3 Type 1 diabetes mellitus with ophthalmic complications E10.59 Type 1 diabetes mellitus with other circulatory complications E10.618 Type 1 diabetes mellitus with other diabetic arthropathy E10.29 Type 1 diabetes mellitus with other diabetic kidney complication E10.60 Type 1 diabetes mellitus with other diabetic kidney complication E10.618 Type 1 diabetes mellitus with other diabetic arthropathy E10.619 Type 1 diabetes mellitus with other diabetic kidney complication
E10.44Type 1 diabetes mellitus with diabetic amyotrophyICD-10-CME10.61Type 1 diabetes mellitus with diabetic arthropathyICD-10-CME10.36Type 1 diabetes mellitus with diabetic cataractICD-10-CME10.620Type 1 diabetes mellitus with diabetic dermatitisICD-10-CME10.21Type 1 diabetes mellitus with diabetic nephropathyICD-10-CME10.641Type 1 diabetes mellitus with hypoglycemia with comaICD-10-CME10.649Type 1 diabetes mellitus with hypoglycemia without comaICD-10-CME10.11Type 1 diabetes mellitus with ketoacidosis with comaICD-10-CME10.10Type 1 diabetes mellitus with ketoacidosis without comaICD-10-CME10.2Type 1 diabetes mellitus with kidney complicationsICD-10-CME10.3Type 1 diabetes mellitus with neurological complicationsICD-10-CME10.59Type 1 diabetes mellitus with other circulatory complicationsICD-10-CME10.618Type 1 diabetes mellitus with other diabetic arthropathyICD-10-CME10.29Type 1 diabetes mellitus with other diabetic kidney complicationICD-10-CM
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E10.29 Type 1 diabetes mellitus with other diabetic kidney complication ICD-10-CM
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E10.638 Type 1 diabetes mellitus with other oral complications ICD-10-CM
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E10.628 Type 1 diabetes mellitus with other skin complications ICD-10-CM
E10.69 Type 1 diabetes mellitus with other specified complication ICD-10-CM
E10.6 Type 1 diabetes mellitus with other specified complications ICD-10-CM
E10.630 Type 1 diabetes mellitus with periodontal disease ICD-10-CM
E10.31 Type 1 diabetes mellitus with unspecified diabetic retinopathy ICD-10-CM
E10.8 Type 1 diabetes mellitus with unspecified complications ICD-10-CM
E10.621 Type 1 diabetes mellitus with foot ulcer ICD-10-CM
E10.65 Type 1 diabetes mellitus with hyperglycemia ICD-10-CM
E10.64 Type 1 diabetes mellitus with hypoglycemia ICD-10-CM
E10.1 Type 1 diabetes mellitus with ketoacidosis ICD-10-CM
E10.63 Type 1 diabetes mellitus with oral complications ICD-10-CM
E10.622 Type 1 diabetes mellitus with other skin ulcer ICD-10-CM
E10.62 Type 1 diabetes mellitus with skin complications ICD-10-CM
E10.9 Type 1 diabetes mellitus without complications ICD-10-CM
E10.329 Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema ICD-10-CM
E10.52 Type 1 diabetes mellitus with diabetic peripheral angiopathy with gangrene ICD-10-CM
E10.51 Type 1 diabetes mellitus with diabetic peripheral angiopathy without gangrene ICD-10-CM
E10.43 Type 1 diabetes mellitus with diabetic autonomic (poly)neuropathy ICD-10-CM
E10.610 Type 1 diabetes mellitus with diabetic neuropathic arthropathy ICD-10-CM
E10.321 Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema ICD-10-CM
E10.32 Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy ICD-10-CM



Appendix B. Appendix B. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) and International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) Diagnosis Codes Used to Define Type 1 Diabetes Mellitus

Code	Description	Code Type
E10.339	Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema	ICD-10-CM
E10.331	Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema	ICD-10-CM
E10.33	Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy	ICD-10-CM
E10.49	Type 1 diabetes mellitus with other diabetic neurological complication	ICD-10-CM
E10.351	Type 1 diabetes mellitus with proliferative diabetic retinopathy with macular edema	ICD-10-CM
E10.349	Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema	ICD-10-CM
E10.341	Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema	ICD-10-CM
E10.34	Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy	ICD-10-CM
E10.319	Type 1 diabetes mellitus with unspecified diabetic retinopathy without macular edema	ICD-10-CM
E10.311	Type 1 diabetes mellitus with unspecified diabetic retinopathy with macular edema	ICD-10-CM
E10.359	Type 1 diabetes mellitus with proliferative diabetic retinopathy without macular edema	ICD-10-CM



Appendix C. Specifications for Parameters for this Request

Sentinel's Cohort Identification and Descriptive Analysis (CIDA) tool, version 5.4.4, was used to compare the frequency of diagnoses for type 1 diabetes mellitus using International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) versus International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) diagnosis codes.

Enrollment Gap: 45 days

Age Groups: <12, 12-18, 19-24, 25-44, 45-64, 65+ years

Enrollment Requirement: 183 days for incidence scenarios; 0 days for prevalence scenarios

Coverage Requirement: Medical and drug coverage

Event

	Query Start Date	Query End Date	Event	Event Code Type	Incident with Respect to:	Washout (days)	Cohort Definition
1	4/1/2015	9/30/2015	Type 1 diabetes mellitus	ICD-9-CM	ICD-9-CM	183	All valid events
2	4/1/2016	9/30/2016	Type 1 diabetes mellitus	ICD-10-CM	ICD-10-CM	183	All valid events
3	10/1/2010	9/30/2016	Type 1 diabetes mellitus	ICD-9-CM	ICD-9-CM or ICD-10-CM	183	All valid events
4	10/1/2010	9/30/2016	Type 1 diabetes mellitus	ICD-10-CM	ICD-9-CM or ICD-10-CM	183	All valid events
5	10/1/2010	9/30/2016	Type 1 diabetes mellitus	ICD-9-CM	N/A	0	All valid events
6	10/1/2010	9/30/2016	Type 1 diabetes mellitus	ICD-10-CM	N/A	0	All valid events

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.