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 for Request: cder_mpl1p_wp098

Request ID: cder_mpl1p_wp098

Request Description: In this report we described characteristics of individuals with sodium-glucose cotransporter-2 (SGLT-2) inhibitors dispensings or sitagliptin dispensings, with or without type 1 diabetes or type 2 diabetes, as well as individuals with short/rapid-acting insulin and type 1 diabetes, in the Sentinel Distributed Database (SDD). Among these cohorts, we assessed occurrence of diabetic ketoacidosis (DKA) and calculated incidence rates.

Sentinel Routine Querying Module: Cohort Identification and Descriptive Analysis (CIDA) module, version 13.2.0, with custom programming.

Data Source: We distributed this query to six Data Partners (DPs) on October 23, 2024. These six DPs are a subset of the SDD. Data from Medicare patients having both fee-for-service medical coverage and Part D drug coverage are included. The study period included data from March 1, 2013 through February 29, 2024. Please see Appendix A for a list of dates of available data for each DP.

Study Design: We identified individuals with incident use of SGLT-2 inhibitors or sitagliptin, and prevalent users of short/rapid-acting insulin. We evaluated the occurrence of diabetic ketoacidosis within 365 days among the following: (1) incident users of SGLT-2 inhibitors or sitagliptin of any age who had evidence of type 1 diabetes (broad and narrow definitions), type 2 diabetes with evidence of insulin use, or type 2 diabetes without evidence of insulin use (2) prevalent users of short/rapid-acting insulin with type 1 diabetes (narrow definitions).

Exposures of Interest: We defined the exposures of interest, SGLT-2 inhibitors, sitagliptin, and short/rapid-acting insulin, using outpatient dispensing data and National Drug Codes (NDCs). Please see Appendix B for a list of generic and brand names of medical products used to define exposure in this request.

Outcomes of Interest: We defined the outcome of interest as diabetic ketoacidosis (DKA) in the inpatient or emergency department care settings. Please see Appendix C for a list of the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) and International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) codes used to define DKA in this report.

Cohort Eligibility Criteria: We required members to be enrolled in health plans with medical and drug coverage in the 365 days prior to their index date in order to be included in the cohort; a gap in coverage of up to 45 days was allowed and treated as continuous enrollment. The following age groups were included in the cohort: <12, 12-18, 19-24, 25-44, 45-64, ≥65 years. For the SGLT-2 inhibitors and sitagliptin cohorts, we excluded index exposure episodes if there was evidence of SGLT-2 inhibitors or sitagliptin in the 365 days prior to the index dispensing. For select cohorts, we required evidence of type 1 diabetes (broad or narrow definition) or type 2 diabetes prior to the index dispensing. The following diabetes definitions were applied:

Broad type 1 diabetes: In the 365 days to five days prior to the index dispensing, the proportion of type 1 diabetes codes to type 2 diabetes codes is greater than 50%.

Narrow type 1 diabetes: In the 365 days to five days prior to the index dispensing, the proportion of type 1 diabetes codes to type 2 diabetes codes is greater than 50% AND in the 365 days to one day prior to the index dispensing there is evidence of short/rapid-acting insulin AND NO evidence of non-insulin antidiabetic drugs (excluding metformin).

Type 2 diabetes without insulin: In the 365 days to five days prior to the index dispensing, there is at least one type 2 diabetes code AND NO evidence of type 1 diabetes codes AND in the 365 days to one day prior to the index dispensing there is no evidence of insulin use.

Type 2 diabetes with evidence of insulin use: In the 365 days to five days prior to the index dispensing, there is at least one type 2 diabetes code AND NO evidence of type 1 diabetes codes AND in the 365 days to one day prior to the index dispensing there is evidence of insulin use.

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Please see Appendix D for a list of Healthcare Common Procedure Coding System, Level II (HCPCS), ICD-9-CM, and ICD-10-CM codes and Appendix E for a list of generic and brand names of medical products used to define inclusion and exclusion criteria in this request.

Follow-up Time: We created exposure episodes based on the number of days of product supplied per dispensing in the outpatient pharmacy dispensing data. We bridged together episodes less than ten days apart and added ten days to the end of each episode. These "as treated" episodes are the time during which we assessed for outcomes. Follow-up began on the day of the index dispensing and continued until the first occurrence of any of the following: 1) end of exposure episode (up to 365 days), 2) death, 3) end of available DP data, 4) query end date, 5) occurrence of diabetic ketoacidosis, 6) switch to sitagliptin (SGLT-2 inhibitor cohorts), or 7) switch to SGLT-2 inhibitor (sitagliptin cohorts).

Baseline Characteristics: We assessed the following characteristics on the date of the index dispensing: age, sex, race, ethnicity, and year. We assessed the following characteristics in the 365 days prior to and including the index dispensing: adapted diabetes complications severity index (aDCSI)[1], combined comorbidity score[2], chronic kidney disease stages, ambulatory encounters, emergency room encounters, inpatient hospital encounters, non-acute institutional encounters, other ambulatory encounters, filled prescriptions, generics dispensed, and unique drug classes dispensed. We assessed the following characteristics in the 365 days prior to and excluding the index dispensing: history of diabetic ketoacidosis, metformin, sulfonylureas, thiazolidinediones, alpha-glucosidase inhibitors, meglitinides, dipeptidyl peptidase-4 (DPP-4) inhibitors, SGLT-2 inhibitors, glucagon-like peptide-1 receptor agonists (GLP-1 RAs), other oral antidiabetic drugs, short/rapid-acting insulin, long/intermediate-acting insulin, combination insulin, and insulin pump. We assessed the following characteristics on the day after the index dispensing and following 365 days: number of diabetic ketoacidosis events (1, 2, 3, 4, or 5+).

Please see Appendix F for a list of Current Procedural Terminology, Fourth Edition (CPT-4), Current Procedural Terminology, Second Edition (CPT-2), HCPCS, ICD-9-CM, ICD-10-CM, International Classification of Diseases, Tenth Revision, Procedural Coding System (ICD-10-PCS), and revenue (RE) codes, and Appendix G for a list of generic and brand names of medical products used to define baseline characteristics in this request.

Sensitivity Analyses: We performed sensitivity analyses in the SGLT-2 inhibitors and sitagliptin narrow type 1 diabetes cohorts to allow individuals with a diabetic ketoacidosis event on the date of the index dispensing to be included in the analysis. In the case of an event on the same day as the index exposure, the event would not be counted but the patient would not be dropped from the cohort.

Please see Appendices H through K for the specifications of parameters and design diagram used in this request.

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

Notes: Please contact the Sentinel Operations Center (info@sentinelsystem.org) for questions and to provide comments/suggestions for future enhancements to this document. For more information on the specific routine querying module utilized in this query, please refer to the documentation on Type 2 analyses within our documentation library accessible at https://dev.sentinelsystem.org/projects/SENTINEL/repos/sentinel-routine-querying-tool-documentation/browse

[1]Chang H-Y, Weiner JP, Richards TM, Bleich SN, Segal JB. Validating the adapted Diabetes Complications Severity Index in claims data. Am J Manag Care. 2012;18(11):721-726.

[2]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. Sun JW, Rogers JR, Her Q, Welch EC, Panozzo CA, Toh S, Gagne JJ. Adaptation and validation of the combined comorbidity score for ICD-10-CM. Med Care. 2017;55(12):1046-1051.

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

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).
Code Days - the minimum number of times the diagnosis must be found during the evaluation period in order to fulfill the algorithm to identify the corresponding patient characteristic.
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.
Computed Start Marketing Date - represents the first observed dispensing date among all valid users within a GROUP (scenario) within each Data Partner site.
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.

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

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
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.
Switch Evaluation Step Value - value used to differentiate evaluation step. Each switch pattern can support up to 2 evaluation steps (0 = switch pattern evaluation start; 1 = first evaluation; 2 = second evaluation).
Switch Gap Inclusion Indicator - indicator for whether gaps in treatment episodes that are included in a switch episode will be counted as part of the switch episode duration.
Switch Pattern Cohort Inclusion Date - indicates which date to use for inclusion into the switch pattern cohort of interest as well as optionally as the index date of the treatment episode initiating the switch pattern. Valid options are the product approval date, product marketing date, other requester defined date, or computed start marketing date.
Switch Pattern Cohort Inclusion Strategy - indicates how the switch pattern cohort inclusion date will be used: 01: used only as a switch cohort entry date. First treatment episode dispensing date is used as index for computing time to first switch; 02: used as switch cohort entry date and as initial switch step index date for computing time to first switch.
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. Aggregated Characteristics of Sodium-Glucose Cotransporter-2 (SGLT-2) Inhibitor Users in the Sentinel Distributed Database (SDD) from March 1, 2013 to February 29, 2024

Patient Characteristics	Number	
Unique patients	2,271,283	
Demographic Characteristics	**Mean**	**Standard Deviation**
Age (years)	64.0	10.8
Age	**Number**	**Percent**
0-11 years	80	0.0%
12-18 years	1,804	0.1%
19-24 years	7,434	0.3%
25-44 years	203,916	9.0%
45-64 years	865,512	38.1%
≥ 65 years	1,192,537	52.5%
Sex		
Female	1,049,592	46.2%
Male	1,221,691	53.8%
Race[1]		
American Indian or Alaska Native	15,973	0.7%
Asian	79,442	3.5%
Black or African American	257,274	11.3%
Multi-racial	9,358	0.4%
Native Hawaiian or Other Pacific Islander	7,068	0.3%
Unknown	572,601	25.2%
White	1,329,567	58.5%
Hispanic origin		
Yes	140,564	6.2%
No	1,586,535	69.9%
Unknown	544,184	24.0%
Year		
2013	13,710	0.6%
2014	69,222	3.0%
2015	110,759	4.9%
2016	110,577	4.9%
2017	144,429	6.4%
2018	146,960	6.5%
2019	203,016	8.9%
2020	248,808	11.0%
2021	401,238	17.7%
2022	388,358	17.1%
2023	418,541	18.4%
2024	15,665	0.7%

Table 1a. Aggregated Characteristics of Sodium-Glucose Cotransporter-2 (SGLT-2) Inhibitor Users in the Sentinel Distributed Database (SDD) from March 1, 2013 to February 29, 2024

Health Characteristics	Mean	Standard Deviation
Adapted Diabetes Complications Severity Index (aDCSI)[2]	2.2	2.1
Combined comorbidity score[3]	2.8	3.0
Chronic Kidney Disease [-365, 0]	**Number**	**Percent**
Chronic Kidney Disease Stage 1	1,662,930	73.2%
Chronic Kidney Disease Stage 2	143,545	6.3%
Chronic Kidney Disease Stage 3	381,199	16.8%
Chronic Kidney Disease Stage 4 or 5	83,609	3.7%
Diabetic Ketoacidosis (DKA)	**Number**	**Percent**
History of DKA [-365, -1]	15,426	0.7%
1 DKA Event Post-Exposure [1, 365]	6,507	0.3%
2 DKA Events Post-Exposure [1, 365]	2,310	0.1%
3 DKA Events Post-Exposure [1, 365]	1,552	0.1%
4 DKA Events Post-Exposure [1, 365]	1,192	0.1%
5+ DKA Events Post-Exposure [1, 365]	3,362	0.1%
Anti-Diabetic Treatments [-365, -1]	**Number**	**Percent**
Metformin	1,472,112	64.8%
Sulfonylureas	684,187	30.1%
Thiazolidinediones	157,569	6.9%
Alpha-Glucosidase Inhibitors	9,204	0.4%
Meglitinides	23,196	1.0%
Dipeptidyl Peptidase-4 (DPP-4) Inhibitors	169,531	7.5%
Sodium-Glucose Cotransporter-2 (SGLT-2) Inhibitors	0	0.0%
Glucagon-Like Peptide-1 Receptor Agonists (GLP-1 RAs)	429,658	18.9%
Other Oral Antidiabetic Drugs	12,331	0.5%
Insulin Products [-365, -1]	**Number**	**Percent**
Short/Rapid-Acting Insulin	325,248	14.3%
Long/Intermediate-Acting Insulin	581,936	25.6%
Combination Insulin	63,700	2.8%
Insulin Pump	7,838	0.3%

Table 1a. Aggregated Characteristics of Sodium-Glucose Cotransporter-2 (SGLT-2) Inhibitor Users in the Sentinel Distributed Database (SDD) from March 1, 2013 to February 29, 2024

Health Service Utilization Intensity Metrics	Mean	Standard Deviation
Mean number of ambulatory encounters	21.6	19.3
Mean number of emergency room encounters	0.8	1.9
Mean number of inpatient hospital encounters	0.3	0.9
Mean number of non-acute institutional encounters	0.1	0.4
Mean number of other ambulatory encounters	9.0	24.2
Mean number of filled prescriptions	50.3	39.1
Mean number of generics dispensed	13.7	6.7
Mean number of unique drug classes dispensed	11.5	5.8

[1]Race data may not be completely populated at all Data Partners; therefore, data about race may be incomplete.

[2]Chang H-Y, Weiner JP, Richards TM, Bleich SN, Segal JB. Validating the adapted Diabetes Complications Severity Index in claims data. Am J Manag Care. 2012;18(11):721-726.

[3]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. Sun JW, Rogers JR, Her Q, Welch EC, Panozzo CA, Toh S, Gagne JJ. Adaptation and validation of the combined comorbidity score for ICD-10-CM. Med Care. 2017;55(12):1046-1051.

Table 1b. Aggregated Characteristics of Sitagliptin Users in the Sentinel Distributed Database (SDD) from March 1, 2013 to February 29, 2024

Patient Characteristics	Number	
Unique patients	1,598,255	
Demographic Characteristics	**Mean**	**Standard Deviation**
Age (years)	66.1	11.5
Age	**Number**	**Percent**
0-11 years	56	0.0%
12-18 years	1,154	0.1%
19-24 years	4,600	0.3%
25-44 years	121,664	7.6%
45-64 years	529,542	33.1%
≥ 65 years	941,239	58.9%
Sex		
Female	852,011	53.3%
Male	746,244	46.7%
Race[1]		
American Indian or Alaska Native	9,607	0.6%
Asian	71,642	4.5%
Black or African American	220,667	13.8%
Multi-racial	4,807	0.3%
Native Hawaiian or Other Pacific Islander	4,691	0.3%
Unknown	331,886	20.8%
White	954,955	59.7%
Hispanic origin		
Yes	107,682	6.7%
No	1,210,682	75.8%
Unknown	279,891	17.5%
Year		
2013	126,655	7.9%
2014	172,673	10.8%
2015	173,798	10.9%
2016	179,240	11.2%
2017	203,007	12.7%
2018	186,980	11.7%
2019	166,323	10.4%
2020	138,323	8.7%
2021	130,475	8.2%
2022	69,068	4.3%
2023	49,421	3.1%
2024	2,292	0.1%

Table 1b. Aggregated Characteristics of Sitagliptin Users in the Sentinel Distributed Database (SDD) from March 1, 2013 to February 29, 2024

Health Characteristics	Mean	Standard Deviation
Adapted Diabetes Complications Severity Index (aDCSI)[2]	2.1	2.1
Combined comorbidity score[3]	2.6	3.1
Chronic Kidney Disease [-365, 0]	**Number**	**Percent**
Chronic Kidney Disease Stage 1	1,208,787	75.6%
Chronic Kidney Disease Stage 2	107,738	6.7%
Chronic Kidney Disease Stage 3	211,258	13.2%
Chronic Kidney Disease Stage 4 or 5	70,472	4.4%
Diabetic Ketoacidosis (DKA)	**Number**	**Percent**
History of DKA [-365, -1]	12,404	0.8%
1 DKA Event Post-Exposure [1, 365]	4,316	0.3%
2 DKA Events Post-Exposure [1, 365]	1,344	0.1%
3 DKA Events Post-Exposure [1, 365]	916	0.1%
4 DKA Events Post-Exposure [1, 365]	800	0.1%
5+ DKA Events Post-Exposure [1, 365]	2,450	0.2%
Anti-Diabetic Treatments [-365, -1]	**Number**	**Percent**
Metformin	1,110,843	69.5%
Sulfonylureas	637,709	39.9%
Thiazolidinediones	104,597	6.5%
Alpha-Glucosidase Inhibitors	7,901	0.5%
Meglitinides	22,043	1.4%
Dipeptidyl Peptidase-4 (DPP-4) Inhibitors	113,872	7.1%
Sodium-Glucose Cotransporter-2 (SGLT-2) Inhibitors	0	0.0%
Glucagon-Like Peptide-1 Receptor Agonists (GLP-1 RAs)	76,851	4.8%
Other Oral Antidiabetic Drugs	10,409	0.7%
Insulin Products [-365, -1]	**Number**	**Percent**
Short/Rapid-Acting Insulin	147,398	9.2%
Long/Intermediate-Acting Insulin	285,174	17.8%
Combination Insulin	38,783	2.4%
Insulin Pump	1,812	0.1%

Table 1b. Aggregated Characteristics of Sitagliptin Users in the Sentinel Distributed Database (SDD) from March 1, 2013 to February 29, 2024

Health Service Utilization Intensity Metrics	Mean	Standard Deviation
Mean number of ambulatory encounters	21.6	24.0
Mean number of emergency room encounters	0.8	2.0
Mean number of inpatient hospital encounters	0.4	1.0
Mean number of non-acute institutional encounters	0.1	0.6
Mean number of other ambulatory encounters	10.9	27.7
Mean number of filled prescriptions	53.1	43.0
Mean number of generics dispensed	13.5	6.9
Mean number of unique drug classes dispensed	11.3	5.9

[1]Race data may not be completely populated at all Data Partners; therefore, data about race may be incomplete.

[2]Chang H-Y, Weiner JP, Richards TM, Bleich SN, Segal JB. Validating the adapted Diabetes Complications Severity Index in claims data. Am J Manag Care. 2012;18(11):721-726.

[3]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. Sun JW, Rogers JR, Her Q, Welch EC, Panozzo CA, Toh S, Gagne JJ. Adaptation and validation of the combined comorbidity score for ICD-10-CM. Med Care. 2017;55(12):1046-1051.

Table 1c. Aggregated Characteristics of Sodium-Glucose Cotransporter-2 (SGLT-2) Inhibitor Users, with a History of Type 1 Diabetes - Broad Definition (Primary Analysis), in the Sentinel Distributed Database (SDD) from March 1, 2013 to February 29, 2024

Patient Characteristics	Number	
Unique patients	17,003	
Demographic Characteristics	**Mean**	**Standard Deviation**
Age (years)	55.3	13.2
Age	**Number**	**Percent**
0-11 years	*****	*****
12-18 years	*****	*****
19-24 years	465	2.7%
25-44 years	3,960	23.3%
45-64 years	6,988	41.1%
≥ 65 years	5,416	31.9%
Sex		
Female	8,384	49.3%
Male	8,619	50.7%
Race[1]		
American Indian or Alaska Native	65	0.4%
Asian	319	1.9%
Black or African American	1,621	9.5%
Multi-racial	116	0.7%
Native Hawaiian or Other Pacific Islander	23	0.1%
Unknown	5,499	32.3%
White	9,360	55.0%
Hispanic origin		
Yes	954	5.6%
No	10,492	61.7%
Unknown	5,557	32.7%
Year		
2013	331	1.9%
2014	1,503	8.8%
2015	1,979	11.6%
2016	1,256	7.4%
2017	1,299	7.6%
2018	1,234	7.3%
2019	1,543	9.1%
2020	1,564	9.2%
2021	2,375	14.0%
2022	1,884	11.1%
2023	1,966	11.6%
2024	69	0.4%

Table 1c. Aggregated Characteristics of Sodium-Glucose Cotransporter-2 (SGLT-2) Inhibitor Users, with a History of Type 1 Diabetes - Broad Definition (Primary Analysis), in the Sentinel Distributed Database (SDD) from March 1, 2013 to February 29, 2024

Health Characteristics	Mean	Standard Deviation
Adapted Diabetes Complications Severity Index (aDCSI)[2]	2.3	2.2
Combined comorbidity score[3]	2.4	2.7
Chronic Kidney Disease [-365, 0]	**Number**	**Percent**
Chronic Kidney Disease Stage 1	13,039	76.7%
Chronic Kidney Disease Stage 2	1,116	6.6%
Chronic Kidney Disease Stage 3	2,147	12.6%
Chronic Kidney Disease Stage 4 or 5	701	4.1%
Diabetic Ketoacidosis (DKA)	**Number**	**Percent**
History of DKA [-365, -1]	824	4.8%
1 DKA Event Post-Exposure [1, 365]	291	1.7%
2 DKA Events Post-Exposure [1, 365]	121	0.7%
3 DKA Events Post-Exposure [1, 365]	95	0.6%
4 DKA Events Post-Exposure [1, 365]	64	0.4%
5+ DKA Events Post-Exposure [1, 365]	198	1.2%
Anti-Diabetic Treatments [-365, -1]	**Number**	**Percent**
Metformin	6,602	38.8%
Sulfonylureas	1,909	11.2%
Thiazolidinediones	703	4.1%
Alpha-Glucosidase Inhibitors	55	0.3%
Meglitinides	116	0.7%
Dipeptidyl Peptidase-4 (DPP-4) Inhibitors	593	3.5%
Sodium-Glucose Cotransporter-2 (SGLT-2) Inhibitors	0	0.0%
Glucagon-Like Peptide-1 Receptor Agonists (GLP-1 RAs)	2,742	16.1%
Other Oral Antidiabetic Drugs	140	0.8%
Insulin Products [-365, -1]	**Number**	**Percent**
Short/Rapid-Acting Insulin	11,289	66.4%
Long/Intermediate-Acting Insulin	9,702	57.1%
Combination Insulin	925	5.4%
Insulin Pump	2,907	17.1%

Table 1c. Aggregated Characteristics of Sodium-Glucose Cotransporter-2 (SGLT-2) Inhibitor Users, with a History of Type 1 Diabetes - Broad Definition (Primary Analysis), in the Sentinel Distributed Database (SDD) from March 1, 2013 to February 29, 2024

Health Service Utilization Intensity Metrics	Mean	Standard Deviation
Mean number of ambulatory encounters	22.5	21.9
Mean number of emergency room encounters	0.7	1.8
Mean number of inpatient hospital encounters	0.3	0.9
Mean number of non-acute institutional encounters	0.0	0.3
Mean number of other ambulatory encounters	12.4	31.9
Mean number of filled prescriptions	53.3	43.7
Mean number of generics dispensed	13.8	7.0
Mean number of unique drug classes dispensed	11.7	6.0

[1]Race data may not be completely populated at all Data Partners; therefore, data about race may be incomplete.

[2]Chang H-Y, Weiner JP, Richards TM, Bleich SN, Segal JB. Validating the adapted Diabetes Complications Severity Index in claims data. Am J Manag Care. 2012;18(11):721-726.

[3]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. Sun JW, Rogers JR, Her Q, Welch EC, Panozzo CA, Toh S, Gagne JJ. Adaptation and validation of the combined comorbidity score for ICD-10-CM. Med Care. 2017;55(12):1046-1051.

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 1d. Aggregated Characteristics of Sitagliptin Users, with a History of Type 1 Diabetes - Broad Definition (Primary Analysis), in the Sentinel Distributed Database (SDD) from March 1, 2013 to February 29, 2024

Patient Characteristics	Number	
Unique patients	8,154	
Demographic Characteristics	**Mean**	**Standard Deviation**
Age (years)	62.6	14.2
Age	**Number**	**Percent**
0-11 years	*****	*****
12-18 years	*****	*****
19-24 years	139	1.7%
25-44 years	1,094	13.4%
45-64 years	2,727	33.4%
≥ 65 years	4,127	50.6%
Sex		
Female	4,294	52.7%
Male	3,860	47.3%
Race[1]		
American Indian or Alaska Native	44	0.5%
Asian	330	4.0%
Black or African American	1,404	17.2%
Multi-racial	*****	*****
Native Hawaiian or Other Pacific Islander	*****	*****
Unknown	1,887	23.1%
White	4,452	54.6%
Hispanic origin		
Yes	652	8.0%
No	6,047	74.2%
Unknown	1,455	17.8%
Year		
2013	1,062	13.0%
2014	1,247	15.3%
2015	1,162	14.3%
2016	864	10.6%
2017	945	11.6%
2018	851	10.4%
2019	641	7.9%
2020	534	6.5%
2021	457	5.6%
2022	218	2.7%
2023	162	2.0%
2024	11	0.1%

Table 1d. Aggregated Characteristics of Sitagliptin Users, with a History of Type 1 Diabetes - Broad Definition (Primary Analysis), in the Sentinel Distributed Database (SDD) from March 1, 2013 to February 29, 2024

Health Characteristics	Mean	Standard Deviation
Adapted Diabetes Complications Severity Index (aDCSI)[2]	2.5	2.3
Combined comorbidity score[3]	2.8	3.1
Chronic Kidney Disease [-365, 0]	**Number**	**Percent**
Chronic Kidney Disease Stage 1	6,101	74.8%
Chronic Kidney Disease Stage 2	631	7.7%
Chronic Kidney Disease Stage 3	821	10.1%
Chronic Kidney Disease Stage 4 or 5	601	7.4%
Diabetic Ketoacidosis (DKA)	**Number**	**Percent**
History of DKA [-365, -1]	398	4.9%
1 DKA Event Post-Exposure [1, 365]	77	0.9%
2 DKA Events Post-Exposure [1, 365]	38	0.5%
3 DKA Events Post-Exposure [1, 365]	24	0.3%
4 DKA Events Post-Exposure [1, 365]	21	0.3%
5+ DKA Events Post-Exposure [1, 365]	95	1.2%
Anti-Diabetic Treatments [-365, -1]	**Number**	**Percent**
Metformin	4,345	53.3%
Sulfonylureas	2,268	27.8%
Thiazolidinediones	432	5.3%
Alpha-Glucosidase Inhibitors	38	0.5%
Meglitinides	149	1.8%
Dipeptidyl Peptidase-4 (DPP-4) Inhibitors	559	6.9%
Sodium-Glucose Cotransporter-2 (SGLT-2) Inhibitors	0	0.0%
Glucagon-Like Peptide-1 Receptor Agonists (GLP-1 RAs)	363	4.5%
Other Oral Antidiabetic Drugs	58	0.7%
Insulin Products [-365, -1]	**Number**	**Percent**
Short/Rapid-Acting Insulin	2,891	35.5%
Long/Intermediate-Acting Insulin	4,039	49.5%
Combination Insulin	730	9.0%
Insulin Pump	158	1.9%

Table 1d. Aggregated Characteristics of Sitagliptin Users, with a History of Type 1 Diabetes - Broad Definition (Primary Analysis), in the Sentinel Distributed Database (SDD) from March 1, 2013 to February 29, 2024

Health Service Utilization Intensity Metrics	Mean	Standard Deviation
Mean number of ambulatory encounters	25.4	37.0
Mean number of emergency room encounters	0.7	1.8
Mean number of inpatient hospital encounters	0.4	1.2
Mean number of non-acute institutional encounters	0.2	0.7
Mean number of other ambulatory encounters	18.9	41.9
Mean number of filled prescriptions	63.5	53.8
Mean number of generics dispensed	14.5	7.4
Mean number of unique drug classes dispensed	12.1	6.2

[1]Race data may not be completely populated at all Data Partners; therefore, data about race may be incomplete.

[2]Chang H-Y, Weiner JP, Richards TM, Bleich SN, Segal JB. Validating the adapted Diabetes Complications Severity Index in claims data. Am J Manag Care. 2012;18(11):721-726.

[3]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. Sun JW, Rogers JR, Her Q, Welch EC, Panozzo CA, Toh S, Gagne JJ. Adaptation and validation of the combined comorbidity score for ICD-10-CM. Med Care. 2017;55(12):1046-1051.

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Table 1e. Aggregated Characteristics of Sodium-Glucose Cotransporter-2 (SGLT-2) Inhibitor Users, with a History of Type 1 Diabetes - Broad Definition (Sensitivity Analysis), in the Sentinel Distributed Database (SDD) from March 1, 2013 to February 29, 2024

Patient Characteristics	Number	
Unique patients	17,120	
Demographic Characteristics	**Mean**	**Standard Deviation**
Age (years)	55.3	13.2
Age	**Number**	**Percent**
0-11 years	*****	*****
12-18 years	*****	*****
19-24 years	468	2.7%
25-44 years	3,985	23.3%
45-64 years	7,042	41.1%
≥ 65 years	5,449	31.8%
Sex		
Female	8,447	49.3%
Male	8,673	50.7%
Race[1]		
American Indian or Alaska Native	68	0.4%
Asian	326	1.9%
Black or African American	1,644	9.6%
Multi-racial	117	0.7%
Native Hawaiian or Other Pacific Islander	23	0.1%
Unknown	5,534	32.3%
White	9,408	55.0%
Hispanic origin		
Yes	968	5.7%
No	10,568	61.7%
Unknown	5,584	32.6%
Year		
2013	332	1.9%
2014	1,505	8.8%
2015	1,988	11.6%
2016	1,267	7.4%
2017	1,310	7.7%
2018	1,251	7.3%
2019	1,555	9.1%
2020	1,580	9.2%
2021	2,395	14.0%
2022	1,891	11.0%
2023	1,974	11.5%
2024	72	0.4%

Table 1e. Aggregated Characteristics of Sodium-Glucose Cotransporter-2 (SGLT-2) Inhibitor Users, with a History of Type 1 Diabetes - Broad Definition (Sensitivity Analysis), in the Sentinel Distributed Database (SDD) from March 1, 2013 to February 29, 2024

Health Characteristics	Mean	Standard Deviation
Adapted Diabetes Complications Severity Index (aDCSI)[2]	2.3	2.2
Combined comorbidity score[3]	2.4	2.7
Chronic Kidney Disease [-365, 0]	**Number**	**Percent**
Chronic Kidney Disease Stage 1	13,114	76.6%
Chronic Kidney Disease Stage 2	1,136	6.6%
Chronic Kidney Disease Stage 3	2,164	12.6%
Chronic Kidney Disease Stage 4 or 5	706	4.1%
Diabetic Ketoacidosis (DKA)	**Number**	**Percent**
History of DKA [-365, -1]	857	5.0%
1 DKA Event Post-Exposure [1, 365]	293	1.7%
2 DKA Events Post-Exposure [1, 365]	123	0.7%
3 DKA Events Post-Exposure [1, 365]	98	0.6%
4 DKA Events Post-Exposure [1, 365]	65	0.4%
5+ DKA Events Post-Exposure [1, 365]	208	1.2%
Anti-Diabetic Treatments [-365, -1]	**Number**	**Percent**
Metformin	6,649	38.8%
Sulfonylureas	1,933	11.3%
Thiazolidinediones	708	4.1%
Alpha-Glucosidase Inhibitors	56	0.3%
Meglitinides	118	0.7%
Dipeptidyl Peptidase-4 (DPP-4) Inhibitors	595	3.5%
Sodium-Glucose Cotransporter-2 (SGLT-2) Inhibitors	0	0.0%
Glucagon-Like Peptide-1 Receptor Agonists (GLP-1 RAs)	2,753	16.1%
Other Oral Antidiabetic Drugs	140	0.8%
Insulin Products [-365, -1]	**Number**	**Percent**
Short/Rapid-Acting Insulin	11,347	66.3%
Long/Intermediate-Acting Insulin	9,774	57.1%
Combination Insulin	933	5.4%
Insulin Pump	2,910	17.0%

Table 1e. Aggregated Characteristics of Sodium-Glucose Cotransporter-2 (SGLT-2) Inhibitor Users, with a History of Type 1 Diabetes - Broad Definition (Sensitivity Analysis), in the Sentinel Distributed Database (SDD) from March 1, 2013 to February 29, 2024

Health Service Utilization Intensity Metrics	Mean	Standard Deviation
Mean number of ambulatory encounters	22.5	22.0
Mean number of emergency room encounters	0.7	1.8
Mean number of inpatient hospital encounters	0.3	1.0
Mean number of non-acute institutional encounters	0.0	0.3
Mean number of other ambulatory encounters	12.5	32.0
Mean number of filled prescriptions	53.3	43.7
Mean number of generics dispensed	13.8	7.0
Mean number of unique drug classes dispensed	11.7	6.0

[1]Race data may not be completely populated at all Data Partners; therefore, data about race may be incomplete.

[2]Chang H-Y, Weiner JP, Richards TM, Bleich SN, Segal JB. Validating the adapted Diabetes Complications Severity Index in claims data. Am J Manag Care. 2012;18(11):721-726.

[3]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. Sun JW, Rogers JR, Her Q, Welch EC, Panozzo CA, Toh S, Gagne JJ. Adaptation and validation of the combined comorbidity score for ICD-10-CM. Med Care. 2017;55(12):1046-1051.

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Table 1f. Aggregated Characteristics of Sitagliptin Users, with a History of Type 1 Diabetes - Broad Definition (Sensitivity Analysis), in the Sentinel Distributed Database (SDD) from March 1, 2013 to February 29, 2024

Patient Characteristics	Number	
Unique patients	8,265	
Demographic Characteristics	**Mean**	**Standard Deviation**
Age (years)	62.5	14.2
Age	**Number**	**Percent**
0-11 years	*****	*****
12-18 years	*****	*****
19-24 years	142	1.7%
25-44 years	1,117	13.5%
45-64 years	2,779	33.6%
≥ 65 years	4,158	50.3%
Sex		
Female	4,350	52.6%
Male	3,915	47.4%
Race[1]		
American Indian or Alaska Native	47	0.6%
Asian	337	4.1%
Black or African American	1,431	17.3%
Multi-racial	*****	*****
Native Hawaiian or Other Pacific Islander	*****	*****
Unknown	1,919	23.2%
White	4,493	54.4%
Hispanic origin		
Yes	666	8.1%
No	6,117	74.0%
Unknown	1,482	17.9%
Year		
2013	1,064	12.9%
2014	1,252	15.1%
2015	1,175	14.2%
2016	878	10.6%
2017	955	11.6%
2018	867	10.5%
2019	658	8.0%
2020	546	6.6%
2021	473	5.7%
2022	220	2.7%
2023	165	2.0%
2024	12	0.1%

Table 1f. Aggregated Characteristics of Sitagliptin Users, with a History of Type 1 Diabetes - Broad Definition (Sensitivity Analysis), in the Sentinel Distributed Database (SDD) from March 1, 2013 to February 29, 2024

Health Characteristics	Mean	Standard Deviation
Adapted Diabetes Complications Severity Index (aDCSI)[2]	2.5	2.3
Combined comorbidity score[3]	2.8	3.1
Chronic Kidney Disease [-365, 0]	**Number**	**Percent**
Chronic Kidney Disease Stage 1	6,179	74.8%
Chronic Kidney Disease Stage 2	645	7.8%
Chronic Kidney Disease Stage 3	834	10.1%
Chronic Kidney Disease Stage 4 or 5	607	7.3%
Diabetic Ketoacidosis (DKA)	**Number**	**Percent**
History of DKA [-365, -1]	426	5.2%
1 DKA Event Post-Exposure [1, 365]	80	1.0%
2 DKA Events Post-Exposure [1, 365]	40	0.5%
3 DKA Events Post-Exposure [1, 365]	26	0.3%
4 DKA Events Post-Exposure [1, 365]	21	0.3%
5+ DKA Events Post-Exposure [1, 365]	106	1.3%
Anti-Diabetic Treatments [-365, -1]	**Number**	**Percent**
Metformin	4,395	53.2%
Sulfonylureas	2,297	27.8%
Thiazolidinediones	436	5.3%
Alpha-Glucosidase Inhibitors	39	0.5%
Meglitinides	152	1.8%
Dipeptidyl Peptidase-4 (DPP-4) Inhibitors	563	6.8%
Sodium-Glucose Cotransporter-2 (SGLT-2) Inhibitors	0	0.0%
Glucagon-Like Peptide-1 Receptor Agonists (GLP-1 RAs)	369	4.5%
Other Oral Antidiabetic Drugs	58	0.7%
Insulin Products [-365, -1]	**Number**	**Percent**
Short/Rapid-Acting Insulin	2,937	35.5%
Long/Intermediate-Acting Insulin	4,101	49.6%
Combination Insulin	741	9.0%
Insulin Pump	159	1.9%

Table 1f. Aggregated Characteristics of Sitagliptin Users, with a History of Type 1 Diabetes - Broad Definition (Sensitivity Analysis), in the Sentinel Distributed Database (SDD) from March 1, 2013 to February 29, 2024

Health Service Utilization Intensity Metrics	Mean	Standard Deviation
Mean number of ambulatory encounters	25.4	37.0
Mean number of emergency room encounters	0.7	1.8
Mean number of inpatient hospital encounters	0.5	1.2
Mean number of non-acute institutional encounters	0.2	0.7
Mean number of other ambulatory encounters	18.9	41.9
Mean number of filled prescriptions	63.3	53.7
Mean number of generics dispensed	14.5	7.4
Mean number of unique drug classes dispensed	12.1	6.3

[1]Race data may not be completely populated at all Data Partners; therefore, data about race may be incomplete.

[2]Chang H-Y, Weiner JP, Richards TM, Bleich SN, Segal JB. Validating the adapted Diabetes Complications Severity Index in claims data. Am J Manag Care. 2012;18(11):721-726.

[3]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. Sun JW, Rogers JR, Her Q, Welch EC, Panozzo CA, Toh S, Gagne JJ. Adaptation and validation of the combined comorbidity score for ICD-10-CM. Med Care. 2017;55(12):1046-1051.

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Table 1g. Aggregated Characteristics of Sodium-Glucose Cotransporter-2 (SGLT-2) Inhibitor Users, with a History of Type 1 Diabetes - Narrow Definition (Primary Analysis), in the Sentinel Distributed Database (SDD) from March 1, 2013 to February 29, 2024

Patient Characteristics	Number	
Unique patients	8,674	
Demographic Characteristics	**Mean**	**Standard Deviation**
Age (years)	52.0	13.5
Age	**Number**	**Percent**
0-11 years	*****	*****
12-18 years	*****	*****
19-24 years	325	3.7%
25-44 years	2,576	29.7%
45-64 years	3,509	40.5%
≥ 65 years	2,146	24.7%
Sex		
Female	4,410	50.8%
Male	4,264	49.2%
Race[1]		
American Indian or Alaska Native	37	0.4%
Asian	120	1.4%
Black or African American	716	8.3%
Multi-racial	78	0.9%
Native Hawaiian or Other Pacific Islander	11	0.1%
Unknown	2,936	33.8%
White	4,776	55.1%
Hispanic origin		
Yes	426	4.9%
No	5,118	59.0%
Unknown	3,130	36.1%
Year		
2013	134	1.5%
2014	757	8.7%
2015	1,060	12.2%
2016	649	7.5%
2017	640	7.4%
2018	599	6.9%
2019	802	9.2%
2020	784	9.0%
2021	1,195	13.8%
2022	1,022	11.8%
2023	996	11.5%
2024	36	0.4%

Table 1g. Aggregated Characteristics of Sodium-Glucose Cotransporter-2 (SGLT-2) Inhibitor Users, with a History of Type 1 Diabetes - Narrow Definition (Primary Analysis), in the Sentinel Distributed Database (SDD) from March 1, 2013 to February 29, 2024

Health Characteristics	Mean	Standard Deviation
Adapted Diabetes Complications Severity Index (aDCSI)[2]	2.4	2.3
Combined comorbidity score[3]	2.5	2.6
Chronic Kidney Disease [-365, 0]	**Number**	**Percent**
Chronic Kidney Disease Stage 1	6,509	75.0%
Chronic Kidney Disease Stage 2	590	6.8%
Chronic Kidney Disease Stage 3	1,166	13.4%
Chronic Kidney Disease Stage 4 or 5	409	4.7%
Diabetic Ketoacidosis (DKA)	**Number**	**Percent**
History of DKA [-365, -1]	567	6.5%
1 DKA Event Post-Exposure [1, 365]	207	2.4%
2 DKA Events Post-Exposure [1, 365]	99	1.1%
3 DKA Events Post-Exposure [1, 365]	64	0.7%
4 DKA Events Post-Exposure [1, 365]	46	0.5%
5+ DKA Events Post-Exposure [1, 365]	144	1.7%
Anti-Diabetic Treatments [-365, -1]	**Number**	**Percent**
Metformin	2,163	24.9%
Sulfonylureas	0	0.0%
Thiazolidinediones	0	0.0%
Alpha-Glucosidase Inhibitors	0	0.0%
Meglitinides	0	0.0%
Dipeptidyl Peptidase-4 (DPP-4) Inhibitors	0	0.0%
Sodium-Glucose Cotransporter-2 (SGLT-2) Inhibitors	0	0.0%
Glucagon-Like Peptide-1 Receptor Agonists (GLP-1 RAs)	0	0.0%
Other Oral Antidiabetic Drugs	0	0.0%
Insulin Products [-365, -1]	**Number**	**Percent**
Short/Rapid-Acting Insulin	8,674	100.0%
Long/Intermediate-Acting Insulin	5,526	63.7%
Combination Insulin	195	2.2%
Insulin Pump	2,296	26.5%

Table 1g. Aggregated Characteristics of Sodium-Glucose Cotransporter-2 (SGLT-2) Inhibitor Users, with a History of Type 1 Diabetes - Narrow Definition (Primary Analysis), in the Sentinel Distributed Database (SDD) from March 1, 2013 to February 29, 2024

Health Service Utilization Intensity Metrics	Mean	Standard Deviation
Mean number of ambulatory encounters	22.9	21.8
Mean number of emergency room encounters	0.8	2.1
Mean number of inpatient hospital encounters	0.4	1.1
Mean number of non-acute institutional encounters	0.0	0.4
Mean number of other ambulatory encounters	12.1	28.2
Mean number of filled prescriptions	51.7	43.0
Mean number of generics dispensed	13.7	7.0
Mean number of unique drug classes dispensed	11.8	6.1

[1]Race data may not be completely populated at all Data Partners; therefore, data about race may be incomplete.

[2]Chang H-Y, Weiner JP, Richards TM, Bleich SN, Segal JB. Validating the adapted Diabetes Complications Severity Index in claims data. Am J Manag Care. 2012;18(11):721-726.

[3]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. Sun JW, Rogers JR, Her Q, Welch EC, Panozzo CA, Toh S, Gagne JJ. Adaptation and validation of the combined comorbidity score for ICD-10-CM. Med Care. 2017;55(12):1046-1051.

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Table 1h. Aggregated Characteristics of Sitagliptin Users, with a History of Type 1 Diabetes - Narrow Definition (Primary Analysis), in the Sentinel Distributed Database (SDD) from March 1, 2013 to February 29, 2024

Patient Characteristics	Number	
Unique patients	2,045	
Demographic Characteristics	**Mean**	**Standard Deviation**
Age (years)	56.5	15.4
Age	**Number**	**Percent**
0-11 years	*****	*****
12-18 years	*****	*****
19-24 years	73	3.6%
25-44 years	491	24.0%
45-64 years	683	33.4%
≥ 65 years	760	37.2%
Sex		
Female	1,139	55.7%
Male	906	44.3%
Race[1]		
American Indian or Alaska Native	*****	*****
Asian	49	2.4%
Black or African American	391	19.1%
Multi-racial	*****	*****
Native Hawaiian or Other Pacific Islander	*****	*****
Unknown	464	22.7%
White	1,123	54.9%
Hispanic origin		
Yes	168	8.2%
No	1,533	75.0%
Unknown	344	16.8%
Year		
2013	191	9.3%
2014	251	12.3%
2015	252	12.3%
2016	206	10.1%
2017	256	12.5%
2018	243	11.9%
2019	204	10.0%
2020	171	8.4%
2021	154	7.5%
2022	70	3.4%
2023	*****	*****
2024	*****	*****

Table 1h. Aggregated Characteristics of Sitagliptin Users, with a History of Type 1 Diabetes - Narrow Definition (Primary Analysis), in the Sentinel Distributed Database (SDD) from March 1, 2013 to February 29, 2024

Health Characteristics	Mean	Standard Deviation
Adapted Diabetes Complications Severity Index (aDCSI)[2]	3.0	2.5
Combined comorbidity score[3]	3.4	3.2
Chronic Kidney Disease [-365, 0]	**Number**	**Percent**
Chronic Kidney Disease Stage 1	1,432	70.0%
Chronic Kidney Disease Stage 2	205	10.0%
Chronic Kidney Disease Stage 3	224	11.0%
Chronic Kidney Disease Stage 4 or 5	184	9.0%
Diabetic Ketoacidosis (DKA)	**Number**	**Percent**
History of DKA [-365, -1]	250	12.2%
1 DKA Event Post-Exposure [1, 365]	39	1.9%
2 DKA Events Post-Exposure [1, 365]	24	1.2%
3 DKA Events Post-Exposure [1, 365]	13	0.6%
4 DKA Events Post-Exposure [1, 365]	16	0.8%
5+ DKA Events Post-Exposure [1, 365]	59	2.9%
Anti-Diabetic Treatments [-365, -1]	**Number**	**Percent**
Metformin	821	40.1%
Sulfonylureas	0	0.0%
Thiazolidinediones	0	0.0%
Alpha-Glucosidase Inhibitors	0	0.0%
Meglitinides	0	0.0%
Dipeptidyl Peptidase-4 (DPP-4) Inhibitors	0	0.0%
Sodium-Glucose Cotransporter-2 (SGLT-2) Inhibitors	0	0.0%
Glucagon-Like Peptide-1 Receptor Agonists (GLP-1 RAs)	0	0.0%
Other Oral Antidiabetic Drugs	0	0.0%
Insulin Products [-365, -1]	**Number**	**Percent**
Short/Rapid-Acting Insulin	2,045	100.0%
Long/Intermediate-Acting Insulin	1,703	83.3%
Combination Insulin	139	6.8%
Insulin Pump	116	5.7%

Table 1h. Aggregated Characteristics of Sitagliptin Users, with a History of Type 1 Diabetes - Narrow Definition (Primary Analysis), in the Sentinel Distributed Database (SDD) from March 1, 2013 to February 29, 2024

Health Service Utilization Intensity Metrics	Mean	Standard Deviation
Mean number of ambulatory encounters	28.5	39.7
Mean number of emergency room encounters	1.2	2.5
Mean number of inpatient hospital encounters	0.8	1.8
Mean number of non-acute institutional encounters	0.2	0.7
Mean number of other ambulatory encounters	27.7	49.4
Mean number of filled prescriptions	71.7	57.0
Mean number of generics dispensed	16.2	7.9
Mean number of unique drug classes dispensed	13.5	6.7

[1]Race data may not be completely populated at all Data Partners; therefore, data about race may be incomplete.

[2]Chang H-Y, Weiner JP, Richards TM, Bleich SN, Segal JB. Validating the adapted Diabetes Complications Severity Index in claims data. Am J Manag Care. 2012;18(11):721-726.

[3]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. Sun JW, Rogers JR, Her Q, Welch EC, Panozzo CA, Toh S, Gagne JJ. Adaptation and validation of the combined comorbidity score for ICD-10-CM. Med Care. 2017;55(12):1046-1051.

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Table 1i. Aggregated Characteristics of Sodium-Glucose Cotransporter-2 (SGLT-2) Inhibitor Users, with a History of Type 1 Diabetes - Narrow Definition (Sensitivity Analysis), in the Sentinel Distributed Database (SDD) from March 1, 2013 to February 29, 2024

Patient Characteristics	Number	
Unique patients	8,715	
Demographic Characteristics	**Mean**	**Standard Deviation**
Age (years)	52.0	13.5
Age	**Number**	**Percent**
0-11 years	*****	*****
12-18 years	*****	*****
19-24 years	326	3.7%
25-44 years	2,586	29.7%
45-64 years	3,530	40.5%
≥ 65 years	2,154	24.7%
Sex		
Female	4,431	50.8%
Male	4,284	49.2%
Race[1]		
American Indian or Alaska Native	38	0.4%
Asian	122	1.4%
Black or African American	724	8.3%
Multi-racial	79	0.9%
Native Hawaiian or Other Pacific Islander	11	0.1%
Unknown	2,944	33.8%
White	4,797	55.0%
Hispanic origin		
Yes	430	4.9%
No	5,150	59.1%
Unknown	3,135	36.0%
Year		
2013	135	1.5%
2014	757	8.7%
2015	1,063	12.2%
2016	654	7.5%
2017	644	7.4%
2018	604	6.9%
2019	803	9.2%
2020	789	9.1%
2021	1,204	13.8%
2022	1,026	11.8%
2023	1,000	11.5%
2024	36	0.4%

Table 1i. Aggregated Characteristics of Sodium-Glucose Cotransporter-2 (SGLT-2) Inhibitor Users, with a History of Type 1 Diabetes - Narrow Definition (Sensitivity Analysis), in the Sentinel Distributed Database (SDD) from March 1, 2013 to February 29, 2024

Health Characteristics	Mean	Standard Deviation
Adapted Diabetes Complications Severity Index (aDCSI)[2]	2.4	2.3
Combined comorbidity score[3]	2.5	2.6
Chronic Kidney Disease [-365, 0]	**Number**	**Percent**
Chronic Kidney Disease Stage 1	6,525	74.9%
Chronic Kidney Disease Stage 2	604	6.9%
Chronic Kidney Disease Stage 3	1,174	13.5%
Chronic Kidney Disease Stage 4 or 5	412	4.7%
Diabetic Ketoacidosis (DKA)	**Number**	**Percent**
History of DKA [-365, -1]	590	6.8%
1 DKA Event Post-Exposure [1, 365]	208	2.4%
2 DKA Events Post-Exposure [1, 365]	100	1.1%
3 DKA Events Post-Exposure [1, 365]	67	0.8%
4 DKA Events Post-Exposure [1, 365]	47	0.5%
5+ DKA Events Post-Exposure [1, 365]	152	1.7%
Anti-Diabetic Treatments [-365, -1]	**Number**	**Percent**
Metformin	2,169	24.9%
Sulfonylureas	0	0.0%
Thiazolidinediones	0	0.0%
Alpha-Glucosidase Inhibitors	0	0.0%
Meglitinides	0	0.0%
Dipeptidyl Peptidase-4 (DPP-4) Inhibitors	0	0.0%
Sodium-Glucose Cotransporter-2 (SGLT-2) Inhibitors	0	0.0%
Glucagon-Like Peptide-1 Receptor Agonists (GLP-1 RAs)	0	0.0%
Other Oral Antidiabetic Drugs	0	0.0%
Insulin Products [-365, -1]	**Number**	**Percent**
Short/Rapid-Acting Insulin	8,715	100.0%
Long/Intermediate-Acting Insulin	5,561	63.8%
Combination Insulin	196	2.2%
Insulin Pump	2,297	26.4%

Table 1i. Aggregated Characteristics of Sodium-Glucose Cotransporter-2 (SGLT-2) Inhibitor Users, with a History of Type 1 Diabetes - Narrow Definition (Sensitivity Analysis), in the Sentinel Distributed Database (SDD) from March 1, 2013 to February 29, 2024

Health Service Utilization Intensity Metrics	Mean	Standard Deviation
Mean number of ambulatory encounters	22.9	22.0
Mean number of emergency room encounters	0.8	2.1
Mean number of inpatient hospital encounters	0.4	1.1
Mean number of non-acute institutional encounters	0.0	0.4
Mean number of other ambulatory encounters	12.2	28.2
Mean number of filled prescriptions	51.7	43.1
Mean number of generics dispensed	13.7	7.0
Mean number of unique drug classes dispensed	11.8	6.1

[1]Race data may not be completely populated at all Data Partners; therefore, data about race may be incomplete.

[2]Chang H-Y, Weiner JP, Richards TM, Bleich SN, Segal JB. Validating the adapted Diabetes Complications Severity Index in claims data. Am J Manag Care. 2012;18(11):721-726.

[3]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. Sun JW, Rogers JR, Her Q, Welch EC, Panozzo CA, Toh S, Gagne JJ. Adaptation and validation of the combined comorbidity score for ICD-10-CM. Med Care. 2017;55(12):1046-1051.

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Table 1j. Aggregated Characteristics of Sitagliptin Users, with a History of Type 1 Diabetes - Narrow Definition (Sensitivity Analysis), in the Sentinel Distributed Database (SDD) from March 1, 2013 to February 29, 2024

Patient Characteristics	Number	
Unique patients	2,079	
Demographic Characteristics	**Mean**	**Standard Deviation**
Age (years)	56.3	15.3
Age	**Number**	**Percent**
0-11 years	*****	*****
12-18 years	*****	*****
19-24 years	74	3.6%
25-44 years	501	24.1%
45-64 years	700	33.7%
≥ 65 years	765	36.8%
Sex		
Female	1,154	55.5%
Male	925	44.5%
Race[1]		
American Indian or Alaska Native	*****	*****
Asian	50	2.4%
Black or African American	399	19.2%
Multi-racial	*****	*****
Native Hawaiian or Other Pacific Islander	*****	*****
Unknown	474	22.8%
White	1,136	54.6%
Hispanic origin		
Yes	172	8.3%
No	1,556	74.8%
Unknown	351	16.9%
Year		
2013	192	9.2%
2014	252	12.1%
2015	256	12.3%
2016	211	10.1%
2017	259	12.5%
2018	248	11.9%
2019	208	10.0%
2020	176	8.5%
2021	158	7.6%
2022	71	3.4%
2023	*****	*****
2024	*****	*****

Table 1j. Aggregated Characteristics of Sitagliptin Users, with a History of Type 1 Diabetes - Narrow Definition (Sensitivity Analysis), in the Sentinel Distributed Database (SDD) from March 1, 2013 to February 29, 2024

Health Characteristics	Mean	Standard Deviation
Adapted Diabetes Complications Severity Index (aDCSI)[2]	3.0	2.5
Combined comorbidity score[3]	3.5	3.2
Chronic Kidney Disease [-365, 0]	**Number**	**Percent**
Chronic Kidney Disease Stage 1	1,451	69.8%
Chronic Kidney Disease Stage 2	213	10.2%
Chronic Kidney Disease Stage 3	228	11.0%
Chronic Kidney Disease Stage 4 or 5	187	9.0%
Diabetic Ketoacidosis (DKA)	**Number**	**Percent**
History of DKA [-365, -1]	266	12.8%
1 DKA Event Post-Exposure [1, 365]	41	2.0%
2 DKA Events Post-Exposure [1, 365]	25	1.2%
3 DKA Events Post-Exposure [1, 365]	15	0.7%
4 DKA Events Post-Exposure [1, 365]	16	0.8%
5+ DKA Events Post-Exposure [1, 365]	69	3.3%
Anti-Diabetic Treatments [-365, -1]	**Number**	**Percent**
Metformin	829	39.9%
Sulfonylureas	0	0.0%
Thiazolidinediones	0	0.0%
Alpha-Glucosidase Inhibitors	0	0.0%
Meglitinides	0	0.0%
Dipeptidyl Peptidase-4 (DPP-4) Inhibitors	0	0.0%
Sodium-Glucose Cotransporter-2 (SGLT-2) Inhibitors	0	0.0%
Glucagon-Like Peptide-1 Receptor Agonists (GLP-1 RAs)	0	0.0%
Other Oral Antidiabetic Drugs	0	0.0%
Insulin Products [-365, -1]	**Number**	**Percent**
Short/Rapid-Acting Insulin	2,079	100.0%
Long/Intermediate-Acting Insulin	1,732	83.3%
Combination Insulin	143	6.9%
Insulin Pump	117	5.6%

Table 1j. Aggregated Characteristics of Sitagliptin Users, with a History of Type 1 Diabetes - Narrow Definition (Sensitivity Analysis), in the Sentinel Distributed Database (SDD) from March 1, 2013 to February 29, 2024

Health Service Utilization Intensity Metrics	Mean	Standard Deviation
Mean number of ambulatory encounters	28.5	39.9
Mean number of emergency room encounters	1.2	2.5
Mean number of inpatient hospital encounters	0.8	1.8
Mean number of non-acute institutional encounters	0.2	0.7
Mean number of other ambulatory encounters	27.5	49.1
Mean number of filled prescriptions	71.5	57.0
Mean number of generics dispensed	16.2	7.9
Mean number of unique drug classes dispensed	13.5	6.7

[1]Race data may not be completely populated at all Data Partners; therefore, data about race may be incomplete.

[2]Chang H-Y, Weiner JP, Richards TM, Bleich SN, Segal JB. Validating the adapted Diabetes Complications Severity Index in claims data. Am J Manag Care. 2012;18(11):721-726.

[3]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. Sun JW, Rogers JR, Her Q, Welch EC, Panozzo CA, Toh S, Gagne JJ. Adaptation and validation of the combined comorbidity score for ICD-10-CM. Med Care. 2017;55(12):1046-1051.

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Table 1k. Aggregated Characteristics of Sodium-Glucose Cotransporter-2 (SGLT-2) Inhibitor Users, with a History of Type 2 Diabetes with Insulin Use, in the Sentinel Distributed Database (SDD) from March 1, 2013 to February 29, 2024

Patient Characteristics	Number	
Unique patients	574,796	
Demographic Characteristics	**Mean**	**Standard Deviation**
Age (years)	62.8	10.5
Age	**Number**	**Percent**
0-11 years	*****	*****
12-18 years	*****	*****
19-24 years	1,649	0.3%
25-44 years	51,717	9.0%
45-64 years	246,941	43.0%
≥ 65 years	274,078	47.7%
Sex		
Female	282,505	49.1%
Male	292,291	50.9%
Race[1]		
American Indian or Alaska Native	6,032	1.0%
Asian	16,077	2.8%
Black or African American	78,781	13.7%
Multi-racial	2,036	0.4%
Native Hawaiian or Other Pacific Islander	2,005	0.3%
Unknown	140,023	24.4%
White	329,842	57.4%
Hispanic origin		
Yes	47,305	8.2%
No	411,167	71.5%
Unknown	116,324	20.2%
Year		
2013	3,932	0.7%
2014	19,977	3.5%
2015	29,342	5.1%
2016	27,808	4.8%
2017	39,160	6.8%
2018	41,975	7.3%
2019	59,257	10.3%
2020	72,669	12.6%
2021	111,521	19.4%
2022	86,298	15.0%
2023	80,200	14.0%
2024	2,657	0.5%

Table 1k. Aggregated Characteristics of Sodium-Glucose Cotransporter-2 (SGLT-2) Inhibitor Users, with a History of Type 2 Diabetes with Insulin Use, in the Sentinel Distributed Database (SDD) from March 1, 2013 to February 29, 2024

Health Characteristics	Mean	Standard Deviation
Adapted Diabetes Complications Severity Index (aDCSI)[2]	2.7	2.3
Combined comorbidity score[3]	3.2	3.0
Chronic Kidney Disease [-365, 0]	**Number**	**Percent**
Chronic Kidney Disease Stage 1	390,567	67.9%
Chronic Kidney Disease Stage 2	42,069	7.3%
Chronic Kidney Disease Stage 3	111,493	19.4%
Chronic Kidney Disease Stage 4 or 5	30,667	5.3%
Diabetic Ketoacidosis (DKA)	**Number**	**Percent**
History of DKA [-365, -1]	7,544	1.3%
1 DKA Event Post-Exposure [1, 365]	2,700	0.5%
2 DKA Events Post-Exposure [1, 365]	1,027	0.2%
3 DKA Events Post-Exposure [1, 365]	672	0.1%
4 DKA Events Post-Exposure [1, 365]	528	0.1%
5+ DKA Events Post-Exposure [1, 365]	1,489	0.3%
Anti-Diabetic Treatments [-365, -1]	**Number**	**Percent**
Metformin	374,242	65.1%
Sulfonylureas	166,207	28.9%
Thiazolidinediones	41,809	7.3%
Alpha-Glucosidase Inhibitors	2,903	0.5%
Meglitinides	7,961	1.4%
Dipeptidyl Peptidase-4 (DPP-4) Inhibitors	43,229	7.5%
Sodium-Glucose Cotransporter-2 (SGLT-2) Inhibitors	0	0.0%
Glucagon-Like Peptide-1 Receptor Agonists (GLP-1 RAs)	194,470	33.8%
Other Oral Antidiabetic Drugs	3,486	0.6%
Insulin Products [-365, -1]	**Number**	**Percent**
Short/Rapid-Acting Insulin	266,010	46.3%
Long/Intermediate-Acting Insulin	509,452	88.6%
Combination Insulin	53,261	9.3%
Insulin Pump	3,058	0.5%

Table 1k. Aggregated Characteristics of Sodium-Glucose Cotransporter-2 (SGLT-2) Inhibitor Users, with a History of Type 2 Diabetes with Insulin Use, in the Sentinel Distributed Database (SDD) from March 1, 2013 to February 29, 2024

Health Service Utilization Intensity Metrics	Mean	Standard Deviation
Mean number of ambulatory encounters	24.1	20.7
Mean number of emergency room encounters	1.0	2.3
Mean number of inpatient hospital encounters	0.4	1.0
Mean number of non-acute institutional encounters	0.1	0.4
Mean number of other ambulatory encounters	12.2	31.1
Mean number of filled prescriptions	64.2	45.8
Mean number of generics dispensed	16.3	7.2
Mean number of unique drug classes dispensed	13.3	6.1

[1]Race data may not be completely populated at all Data Partners; therefore, data about race may be incomplete.

[2]Chang H-Y, Weiner JP, Richards TM, Bleich SN, Segal JB. Validating the adapted Diabetes Complications Severity Index in claims data. Am J Manag Care. 2012;18(11):721-726.

[3]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. Sun JW, Rogers JR, Her Q, Welch EC, Panozzo CA, Toh S, Gagne JJ. Adaptation and validation of the combined comorbidity score for ICD-10-CM. Med Care. 2017;55(12):1046-1051.

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Table 1l. Aggregated Characteristics of Sitagliptin Users, with a History of Type 2 Diabetes with Insulin Use, in the Sentinel Distributed Database (SDD) from March 1, 2013 to February 29, 2024

Patient Characteristics	Number	
Unique patients	274,184	
Demographic Characteristics	**Mean**	**Standard Deviation**
Age (years)	65.6	11.6
Age	**Number**	**Percent**
0-11 years	*****	*****
12-18 years	*****	*****
19-24 years	760	0.3%
25-44 years	20,794	7.6%
45-64 years	99,475	36.3%
≥ 65 years	152,966	55.8%
Sex		
Female	155,786	56.8%
Male	118,398	43.2%
Race[1]		
American Indian or Alaska Native	2,488	0.9%
Asian	9,741	3.6%
Black or African American	49,341	18.0%
Multi-racial	634	0.2%
Native Hawaiian or Other Pacific Islander	836	0.3%
Unknown	53,009	19.3%
White	158,135	57.7%
Hispanic origin		
Yes	24,360	8.9%
No	214,341	78.2%
Unknown	35,483	12.9%
Year		
2013	16,839	6.1%
2014	24,781	9.0%
2015	27,168	9.9%
2016	29,268	10.7%
2017	36,947	13.5%
2018	35,049	12.8%
2019	31,713	11.6%
2020	26,872	9.8%
2021	24,545	9.0%
2022	12,008	4.4%
2023	8,653	3.2%
2024	341	0.1%

Table 1l. Aggregated Characteristics of Sitagliptin Users, with a History of Type 2 Diabetes with Insulin Use, in the Sentinel Distributed Database (SDD) from March 1, 2013 to February 29, 2024

Health Characteristics	Mean	Standard Deviation
Adapted Diabetes Complications Severity Index (aDCSI)[2]	2.9	2.4
Combined comorbidity score[3]	3.7	3.4
Chronic Kidney Disease [-365, 0]	**Number**	**Percent**
Chronic Kidney Disease Stage 1	180,659	65.9%
Chronic Kidney Disease Stage 2	25,209	9.2%
Chronic Kidney Disease Stage 3	47,626	17.4%
Chronic Kidney Disease Stage 4 or 5	20,690	7.5%
Diabetic Ketoacidosis (DKA)	**Number**	**Percent**
History of DKA [-365, -1]	4,351	1.6%
1 DKA Event Post-Exposure [1, 365]	1,407	0.5%
2 DKA Events Post-Exposure [1, 365]	452	0.2%
3 DKA Events Post-Exposure [1, 365]	300	0.1%
4 DKA Events Post-Exposure [1, 365]	283	0.1%
5+ DKA Events Post-Exposure [1, 365]	809	0.3%
Anti-Diabetic Treatments [-365, -1]	**Number**	**Percent**
Metformin	172,646	63.0%
Sulfonylureas	99,130	36.2%
Thiazolidinediones	17,337	6.3%
Alpha-Glucosidase Inhibitors	1,763	0.6%
Meglitinides	5,289	1.9%
Dipeptidyl Peptidase-4 (DPP-4) Inhibitors	25,915	9.5%
Sodium-Glucose Cotransporter-2 (SGLT-2) Inhibitors	0	0.0%
Glucagon-Like Peptide-1 Receptor Agonists (GLP-1 RAs)	26,681	9.7%
Other Oral Antidiabetic Drugs	1,716	0.6%
Insulin Products [-365, -1]	**Number**	**Percent**
Short/Rapid-Acting Insulin	113,022	41.2%
Long/Intermediate-Acting Insulin	235,183	85.8%
Combination Insulin	28,776	10.5%
Insulin Pump	1,210	0.4%

Table 1l. Aggregated Characteristics of Sitagliptin Users, with a History of Type 2 Diabetes with Insulin Use, in the Sentinel Distributed Database (SDD) from March 1, 2013 to February 29, 2024

Health Service Utilization Intensity Metrics	Mean	Standard Deviation
Mean number of ambulatory encounters	25.4	28.9
Mean number of emergency room encounters	1.2	2.5
Mean number of inpatient hospital encounters	0.6	1.3
Mean number of non-acute institutional encounters	0.2	0.8
Mean number of other ambulatory encounters	18.5	37.9
Mean number of filled prescriptions	70.0	52.5
Mean number of generics dispensed	16.6	7.5
Mean number of unique drug classes dispensed	13.8	6.3

[1]Race data may not be completely populated at all Data Partners; therefore, data about race may be incomplete.

[2]Chang H-Y, Weiner JP, Richards TM, Bleich SN, Segal JB. Validating the adapted Diabetes Complications Severity Index in claims data. Am J Manag Care. 2012;18(11):721-726.

[3]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. Sun JW, Rogers JR, Her Q, Welch EC, Panozzo CA, Toh S, Gagne JJ. Adaptation and validation of the combined comorbidity score for ICD-10-CM. Med Care. 2017;55(12):1046-1051.

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Table 1m. Aggregated Characteristics of Sodium-Glucose Cotransporter-2 (SGLT-2) Inhibitor Users, with a History of Type 2 Diabetes with No Insulin Use, in the Sentinel Distributed Database (SDD) from March 1, 2013 to February 29, 2024

Patient Characteristics	Number	
Unique patients	1,305,322	
Demographic Characteristics	**Mean**	**Standard Deviation**
Age (years)	64.2	10.4
Age	**Number**	**Percent**
0-11 years	15	0.0%
12-18 years	616	0.0%
19-24 years	3,313	0.3%
25-44 years	111,722	8.6%
45-64 years	493,374	37.8%
≥ 65 years	696,282	53.3%
Sex		
Female	590,835	45.3%
Male	714,487	54.7%
Race[1]		
American Indian or Alaska Native	8,019	0.6%
Asian	53,316	4.1%
Black or African American	132,376	10.1%
Multi-racial	5,654	0.4%
Native Hawaiian or Other Pacific Islander	4,266	0.3%
Unknown	347,648	26.6%
White	754,043	57.8%
Hispanic origin		
Yes	75,505	5.8%
No	890,221	68.2%
Unknown	339,596	26.0%
Year		
2013	6,996	0.5%
2014	36,793	2.8%
2015	63,123	4.8%
2016	66,748	5.1%
2017	88,605	6.8%
2018	89,175	6.8%
2019	123,552	9.5%
2020	150,388	11.5%
2021	228,869	17.5%
2022	215,481	16.5%
2023	226,863	17.4%
2024	8,729	0.7%

Table 1m. Aggregated Characteristics of Sodium-Glucose Cotransporter-2 (SGLT-2) Inhibitor Users, with a History of Type 2 Diabetes with No Insulin Use, in the Sentinel Distributed Database (SDD) from March 1, 2013 to February 29, 2024

Health Characteristics	Mean	Standard Deviation
Adapted Diabetes Complications Severity Index (aDCSI)[2]	1.8	1.9
Combined comorbidity score[3]	2.4	2.8
Chronic Kidney Disease [-365, 0]	**Number**	**Percent**
Chronic Kidney Disease Stage 1	1,014,065	77.7%
Chronic Kidney Disease Stage 2	68,250	5.2%
Chronic Kidney Disease Stage 3	189,877	14.5%
Chronic Kidney Disease Stage 4 or 5	33,130	2.5%
Diabetic Ketoacidosis (DKA)	**Number**	**Percent**
History of DKA [-365, -1]	2,117	0.2%
1 DKA Event Post-Exposure [1, 365]	2,424	0.2%
2 DKA Events Post-Exposure [1, 365]	741	0.1%
3 DKA Events Post-Exposure [1, 365]	474	0.0%
4 DKA Events Post-Exposure [1, 365]	348	0.0%
5+ DKA Events Post-Exposure [1, 365]	895	0.1%
Anti-Diabetic Treatments [-365, -1]	**Number**	**Percent**
Metformin	988,398	75.7%
Sulfonylureas	481,647	36.9%
Thiazolidinediones	106,482	8.2%
Alpha-Glucosidase Inhibitors	5,519	0.4%
Meglitinides	13,413	1.0%
Dipeptidyl Peptidase-4 (DPP-4) Inhibitors	115,143	8.8%
Sodium-Glucose Cotransporter-2 (SGLT-2) Inhibitors	0	0.0%
Glucagon-Like Peptide-1 Receptor Agonists (GLP-1 RAs)	203,477	15.6%
Other Oral Antidiabetic Drugs	7,004	0.5%
Insulin Products [-365, -1]	**Number**	**Percent**
Short/Rapid-Acting Insulin	0	0.0%
Long/Intermediate-Acting Insulin	0	0.0%
Combination Insulin	0	0.0%
Insulin Pump	0	0.0%

Table 1m. Aggregated Characteristics of Sodium-Glucose Cotransporter-2 (SGLT-2) Inhibitor Users, with a History of Type 2 Diabetes with No Insulin Use, in the Sentinel Distributed Database (SDD) from March 1, 2013 to February 29, 2024

Health Service Utilization Intensity Metrics	Mean	Standard Deviation
Mean number of ambulatory encounters	19.7	17.8
Mean number of emergency room encounters	0.6	1.6
Mean number of inpatient hospital encounters	0.2	0.7
Mean number of non-acute institutional encounters	0.0	0.3
Mean number of other ambulatory encounters	7.2	20.5
Mean number of filled prescriptions	45.0	34.2
Mean number of generics dispensed	12.6	6.1
Mean number of unique drug classes dispensed	10.5	5.4

[1]Race data may not be completely populated at all Data Partners; therefore, data about race may be incomplete.

[2]Chang H-Y, Weiner JP, Richards TM, Bleich SN, Segal JB. Validating the adapted Diabetes Complications Severity Index in claims data. Am J Manag Care. 2012;18(11):721-726.

[3]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. Sun JW, Rogers JR, Her Q, Welch EC, Panozzo CA, Toh S, Gagne JJ. Adaptation and validation of the combined comorbidity score for ICD-10-CM. Med Care. 2017;55(12):1046-1051.

Table 1n. Aggregated Characteristics of Sitagliptin Users, with a History of Type 2 Diabetes with No Insulin Use, in the Sentinel Distributed Database (SDD) from March 1, 2013 to February 29, 2024

Patient Characteristics	Number	
Unique patients	1,134,448	
Demographic Characteristics	**Mean**	**Standard Deviation**
Age (years)	66.6	11.2
Age	**Number**	**Percent**
0-11 years	*****	*****
12-18 years	*****	*****
19-24 years	2,523	0.2%
25-44 years	78,710	6.9%
45-64 years	361,271	31.8%
≥ 65 years	691,467	61.0%
Sex		
Female	596,577	52.6%
Male	537,871	47.4%
Race[1]		
American Indian or Alaska Native	6,044	0.5%
Asian	53,850	4.7%
Black or African American	139,758	12.3%
Multi-racial	3,460	0.3%
Native Hawaiian or Other Pacific Islander	3,466	0.3%
Unknown	234,055	20.6%
White	693,815	61.2%
Hispanic origin		
Yes	68,928	6.1%
No	858,155	75.6%
Unknown	207,365	18.3%
Year		
2013	88,799	7.8%
2014	121,343	10.7%
2015	121,693	10.7%
2016	126,762	11.2%
2017	143,724	12.7%
2018	131,967	11.6%
2019	117,455	10.4%
2020	98,838	8.7%
2021	93,168	8.2%
2022	51,964	4.6%
2023	37,007	3.3%
2024	1,728	0.2%

Table 1n. Aggregated Characteristics of Sitagliptin Users, with a History of Type 2 Diabetes with No Insulin Use, in the Sentinel Distributed Database (SDD) from March 1, 2013 to February 29, 2024

Health Characteristics	Mean	Standard Deviation
Adapted Diabetes Complications Severity Index (aDCSI)[2]	1.9	1.9
Combined comorbidity score[3]	2.3	2.9
Chronic Kidney Disease [-365, 0]	**Number**	**Percent**
Chronic Kidney Disease Stage 1	888,308	78.3%
Chronic Kidney Disease Stage 2	67,506	6.0%
Chronic Kidney Disease Stage 3	140,584	12.4%
Chronic Kidney Disease Stage 4 or 5	38,050	3.4%
Diabetic Ketoacidosis (DKA)	**Number**	**Percent**
History of DKA [-365, -1]	2,775	0.2%
1 DKA Event Post-Exposure [1, 365]	2,011	0.2%
2 DKA Events Post-Exposure [1, 365]	545	0.0%
3 DKA Events Post-Exposure [1, 365]	369	0.0%
4 DKA Events Post-Exposure [1, 365]	308	0.0%
5+ DKA Events Post-Exposure [1, 365]	775	0.1%
Anti-Diabetic Treatments [-365, -1]	**Number**	**Percent**
Metformin	842,720	74.3%
Sulfonylureas	491,474	43.3%
Thiazolidinediones	79,066	7.0%
Alpha-Glucosidase Inhibitors	5,355	0.5%
Meglitinides	14,212	1.3%
Dipeptidyl Peptidase-4 (DPP-4) Inhibitors	77,787	6.9%
Sodium-Glucose Cotransporter-2 (SGLT-2) Inhibitors	0	0.0%
Glucagon-Like Peptide-1 Receptor Agonists (GLP-1 RAs)	44,004	3.9%
Other Oral Antidiabetic Drugs	7,378	0.7%
Insulin Products [-365, -1]	**Number**	**Percent**
Short/Rapid-Acting Insulin	0	0.0%
Long/Intermediate-Acting Insulin	0	0.0%
Combination Insulin	0	0.0%
Insulin Pump	0	0.0%

Table 1n. Aggregated Characteristics of Sitagliptin Users, with a History of Type 2 Diabetes with No Insulin Use, in the Sentinel Distributed Database (SDD) from March 1, 2013 to February 29, 2024

Health Service Utilization Intensity Metrics	Mean	Standard Deviation
Mean number of ambulatory encounters	20.4	21.3
Mean number of emergency room encounters	0.7	1.7
Mean number of inpatient hospital encounters	0.3	0.8
Mean number of non-acute institutional encounters	0.1	0.4
Mean number of other ambulatory encounters	8.3	22.8
Mean number of filled prescriptions	48.6	37.8
Mean number of generics dispensed	12.7	6.3
Mean number of unique drug classes dispensed	10.6	5.5

[1]Race data may not be completely populated at all Data Partners; therefore, data about race may be incomplete.

[2]Chang H-Y, Weiner JP, Richards TM, Bleich SN, Segal JB. Validating the adapted Diabetes Complications Severity Index in claims data. Am J Manag Care. 2012;18(11):721-726.

[3]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. Sun JW, Rogers JR, Her Q, Welch EC, Panozzo CA, Toh S, Gagne JJ. Adaptation and validation of the combined comorbidity score for ICD-10-CM. Med Care. 2017;55(12):1046-1051.

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 1o. Aggregated Characteristics of Short/Rapid-Acting Insulin Users, with Type 1 Diabetes - Narrow Definition, in the Sentinel Distributed Database (SDD) from March 1, 2013 to February 29, 2024

Patient Characteristics	Number	
Unique patients	683,436	
Demographic Characteristics	**Mean**	**Standard Deviation**
Age (years)	41.2	16.3
Age	**Number**	**Percent**
0-11 years	51,907	7.6%
12-18 years	81,107	11.9%
19-24 years	61,355	9.0%
25-44 years	198,842	29.1%
45-64 years	159,129	23.3%
≥ 65 years	131,096	19.2%
Sex		
Female	340,683	49.8%
Male	342,753	50.2%
Race[1]		
American Indian or Alaska Native	4,066	0.6%
Asian	7,035	1.0%
Black or African American	66,772	9.8%
Multi-racial	4,755	0.7%
Native Hawaiian or Other Pacific Islander	1,053	0.2%
Unknown	238,252	34.9%
White	361,503	52.9%
Hispanic origin		
Yes	45,121	6.6%
No	416,878	61.0%
Unknown	221,437	32.4%
Year		
2013	94,580	13.8%
2014	56,072	8.2%
2015	62,255	9.1%
2016	69,892	10.2%
2017	93,364	13.7%
2018	70,014	10.2%
2019	58,224	8.5%
2020	58,843	8.6%
2021	67,211	9.8%
2022	26,711	3.9%
2023	24,261	3.5%
2024	2,009	0.3%

Table 1o. Aggregated Characteristics of Short/Rapid-Acting Insulin Users, with Type 1 Diabetes - Narrow Definition, in the Sentinel Distributed Database (SDD) from March 1, 2013 to February 29, 2024

Health Characteristics	Mean	Standard Deviation
Adapted Diabetes Complications Severity Index (aDCSI)[2]	1.8	2.1
Combined comorbidity score[3]	2.0	2.3
Chronic Kidney Disease [-365, 0]	**Number**	**Percent**
Chronic Kidney Disease Stage 1	562,905	82.4%
Chronic Kidney Disease Stage 2	45,557	6.7%
Chronic Kidney Disease Stage 3	38,583	5.6%
Chronic Kidney Disease Stage 4 or 5	36,391	5.3%
Diabetic Ketoacidosis (DKA)	**Number**	**Percent**
History of DKA [-365, -1]	94,131	13.8%
1 DKA Event Post-Exposure [1, 365]	17,727	2.6%
2 DKA Events Post-Exposure [1, 365]	9,646	1.4%
3 DKA Events Post-Exposure [1, 365]	7,441	1.1%
4 DKA Events Post-Exposure [1, 365]	4,952	0.7%
5+ DKA Events Post-Exposure [1, 365]	18,954	2.8%
Anti-Diabetic Treatments [-365, -1]	**Number**	**Percent**
Metformin	56,052	8.2%
Sulfonylureas	0	0.0%
Thiazolidinediones	0	0.0%
Alpha-Glucosidase Inhibitors	0	0.0%
Meglitinides	0	0.0%
Dipeptidyl Peptidase-4 (DPP-4) Inhibitors	0	0.0%
Sodium-Glucose Cotransporter-2 (SGLT-2) Inhibitors	0	0.0%
Glucagon-Like Peptide-1 Receptor Agonists (GLP-1 RAs)	0	0.0%
Other Oral Antidiabetic Drugs	0	0.0%
Insulin Products [-365, -1]	**Number**	**Percent**
Short/Rapid-Acting Insulin	593,412	86.8%
Long/Intermediate-Acting Insulin	478,515	70.0%
Combination Insulin	20,412	3.0%
Insulin Pump	140,214	20.5%

Table 1o. Aggregated Characteristics of Short/Rapid-Acting Insulin Users, with Type 1 Diabetes - Narrow Definition, in the Sentinel Distributed Database (SDD) from March 1, 2013 to February 29, 2024

Health Service Utilization Intensity Metrics	Mean	Standard Deviation
Mean number of ambulatory encounters	20.7	32.0
Mean number of emergency room encounters	0.9	2.3
Mean number of inpatient hospital encounters	0.5	1.4
Mean number of non-acute institutional encounters	0.1	0.4
Mean number of other ambulatory encounters	11.9	28.6
Mean number of filled prescriptions	37.4	35.4
Mean number of generics dispensed	9.6	6.3
Mean number of unique drug classes dispensed	8.1	5.5

[1]Race data may not be completely populated at all Data Partners; therefore, data about race may be incomplete.

[2]Chang H-Y, Weiner JP, Richards TM, Bleich SN, Segal JB. Validating the adapted Diabetes Complications Severity Index in claims data. Am J Manag Care. 2012;18(11):721-726.

[3]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. Sun JW, Rogers JR, Her Q, Welch EC, Panozzo CA, Toh S, Gagne JJ. Adaptation and validation of the combined comorbidity score for ICD-10-CM. Med Care. 2017;55(12):1046-1051.

Table 2. Occurrence of Diabetic Ketoacidosis (DKA) in New Users of Sodium-Glucose Cotransporter-2 (SGLT-2) Inhibitor and Sitagliptin by History of Diabetes, as well as Short/Rapid-Acting Insulin Users with Type 1 Diabetes in the Sentinel Distributed Database (SDD) from March 1, 2013 to February 29, 2024

	Number of Patients	Number of Exposure Episodes with an Event	Total Years at Risk	Event Rate per 10,000 Patient-Years at Risk (95% Confidence Interval)
Overall				
SGLT-2 Inhibitor Users	2,271,283	8,178	980,439.4	83.41 (81.62, 85.24)
Sitagliptin Users	1,598,255	4,168	696,650.0	59.83 (58.04, 61.67)
History of Type 1 Diabetes - Broad Definition (Primary Analysis)				
SGLT-2 Inhibitor Users	17,003	438	7,111.7	615.88 (560.82, 676.35)
Sitagliptin Users	8,154	105	3,306.3	317.57 (262.29, 384.52)
History of Type 1 Diabetes - Broad Definition (Sensitivity Analysis)				
SGLT-2 Inhibitor Users	17,120	445	7,116.6	625.30 (569.82, 686.18)
Sitagliptin Users	8,265	108	3,309.3	326.35 (270.26, 394.09)
History of Type 1 Diabetes - Narrow Definition (Primary Analysis)				
SGLT-2 Inhibitor Users	8,674	326	3,548.1	918.80 (824.28, 1,024.16)
Sitagliptin Users	2,045	70	758.0	923.48 (730.61, 1,167.26)
History of Type 1 Diabetes - Narrow Definition (Sensitivity Analysis)				
SGLT-2 Inhibitor Users	8,715	331	3,551.1	932.10 (836.90, 1,038.12)
Sitagliptin Users	2,079	73	759.0	961.85 (764.68, 1,209.86)
History of Type 2 Diabetes with Insulin Use				
SGLT-2 Inhibitor Users	574,796	3,290	247,801.8	132.77 (128.31, 137.38)
Sitagliptin Users	274,184	1,270	111,547.1	113.85 (107.76, 120.29)
History of Type 2 Diabetes with No Insulin Use				
SGLT-2 Inhibitor Users	1,305,322	2,849	573,025.7	49.72 (47.93, 51.58)
Sitagliptin Users	1,134,448	1,782	507,172.0	35.14 (33.54, 36.81)
Type 1 Diabetes Population				
Short/Rapid-Acting Insulin Users	683,436	21,492	187,352.0	1,147.15 (1,131.91, 1,162.59)

Table 3. Occurrence of Diabetic Ketoacidosis (DKA) in New Users of Sodium-Glucose Cotransporter-2 (SGLT-2) Inhibitor and Sitagliptin by History of Diabetes, as well as Short/Rapid-Acting Insulin Users with Type 1 Diabetes in the Sentinel Distributed Database (SDD) from March 1, 2013 to February 29, 2024, by Sex

	Number of Patients	Number of Exposure Episodes with an Event	Total Years at Risk	Event Rate per 10,000 Patient-Years at Risk (95% Confidence Interval)
Overall				
SGLT-2 Inhibitor Users				
Female	1,049,592	4,195	432,805.6	96.93 (94.04, 99.90)
Male	1,221,691	3,983	547,633.8	72.73 (70.51, 75.03)
Sitagliptin Users				
Female	852,011	2,438	367,500.0	66.34 (63.76, 69.03)
Male	746,244	1,730	329,150.0	52.56 (50.14, 55.10)
History of Type 1 Diabetes - Broad Definition (Primary Analysis)				
SGLT-2 Inhibitor Users				
Female	8,384	256	3,339.1	766.68 (678.28, 866.59)
Male	8,619	182	3,772.7	482.42 (417.18, 557.85)
Sitagliptin Users				
Female	4,294	55	1,730.0	317.92 (244.08, 414.09)
Male	3,860	50	1,576.3	317.19 (240.40, 418.51)
History of Type 1 Diabetes - Broad Definition (Sensitivity Analysis)				
SGLT-2 Inhibitor Users				
Female	8,447	259	3,340.8	775.27 (686.37, 875.68)
Male	8,673	186	3,775.8	492.61 (426.66, 568.74)
Sitagliptin Users				
Female	4,350	56	1,731.3	323.45 (248.92, 420.30)
Male	3,915	52	1,578.0	329.54 (251.11, 432.46)
History of Type 1 Diabetes - Narrow Definition (Primary Analysis)				
SGLT-2 Inhibitor Users				
Female	4,410	191	1,710.0	1,116.99 (969.30, 1,287.19)
Male	4,264	135	1,838.2	734.43 (620.43, 869.39)
Sitagliptin Users				
Female	1,139	39	418.0	933.02 (681.69, 1,277.02)
Male	906	31	340.0	911.75 (641.20, 1,296.46)

Table 3. Occurrence of Diabetic Ketoacidosis (DKA) in New Users of Sodium-Glucose Cotransporter-2 (SGLT-2) Inhibitor and Sitagliptin by History of Diabetes, as well as Short/Rapid-Acting Insulin Users with Type 1 Diabetes in the Sentinel Distributed Database (SDD) from March 1, 2013 to February 29, 2024, by Sex

	Number of Patients	Number of Exposure Episodes with an Event	Total Years at Risk	Event Rate per 10,000 Patient-Years at Risk (95% Confidence Interval)
History of Type 1 Diabetes - Narrow Definition (Sensitivity Analysis)				
SGLT-2 Inhibitor Users				
Female	4,431	194	1,711.5	1,133.49 (984.70, 1,304.77)
Male	4,284	137	1,839.6	744.73 (629.90, 880.48)
Sitagliptin Users				
Female	1,154	40	418.2	956.45 (701.57, 1,303.92)
Male	925	33	340.7	968.48 (688.52, 1,362.29)
History of Type 2 Diabetes with Insulin Use				
SGLT-2 Inhibitor Users				
Female	282,505	1,765	116,624.1	151.34 (144.44, 158.57)
Male	292,291	1,525	131,177.7	116.25 (110.56, 122.24)
Sitagliptin Users				
Female	155,786	775	62,947.1	123.12 (114.75, 132.10)
Male	118,398	495	48,600.0	101.85 (93.26, 111.23)
History of Type 2 Diabetes with No Insulin Use				
SGLT-2 Inhibitor Users				
Female	590,835	1,367	247,479.7	55.24 (52.38, 58.24)
Male	714,487	1,482	325,545.9	45.52 (43.26, 47.90)
Sitagliptin Users				
Female	596,577	998	263,766.3	37.84 (35.56, 40.26)
Male	537,871	784	243,405.8	32.21 (30.03, 34.55)
Type 1 Diabetes Population				
Short/Rapid-Acting Insulin Users				
Female	340,683	11,707	92,383.1	1,267.22 (1,244.47, 1,290.39)
Male	342,753	9,785	94,968.9	1,030.34 (1,010.12, 1,050.96)

Table 4. Occurrence of Diabetic Ketoacidosis (DKA) in New Users of Sodium-Glucose Cotransporter-2 (SGLT-2) Inhibitor and Sitagliptin by History of Diabetes, as well as Short/Rapid-Acting Insulin Users with Type 1 Diabetes in the Sentinel Distributed Database (SDD) from March 1, 2013 to February 29, 2024, by Age Group

	Number of Patients	Number of Exposure Episodes with an Event	Total Years at Risk	Event Rate per 10,000 Patient-Years at Risk (95% Confidence Interval)
Overall				
SGLT-2 Inhibitor Users				
0-11 years	80	*****	*****	463.93 (65.35, 3,293.57)
12-18 years	1,804	*****	*****	390.61 (254.68, 599.10)
19-24 years	7,434	89	2,461.6	361.55 (293.72, 445.04)
25-44 years	203,916	1,362	77,758.2	175.16 (166.10, 184.71)
45-64 years	865,512	3,489	377,070.0	92.53 (89.51, 95.65)
≥ 65 years	1,192,537	3,216	522,590.4	61.54 (59.45, 63.70)
Sitagliptin Users				
0-11 years	56	0	15.8	0.00 (0.00, 0.00)
12-18 years	1,154	*****	*****	276.57 (143.90, 531.56)
19-24 years	4,600	*****	*****	222.97 (157.68, 315.30)
25-44 years	121,664	432	43,779.9	98.68 (89.80, 108.43)
45-64 years	529,542	1,540	221,594.7	69.50 (66.11, 73.06)
≥ 65 years	941,239	2,155	429,499.0	50.17 (48.10, 52.34)
History of Type 1 Diabetes - Broad Definition (Primary Analysis)				
SGLT-2 Inhibitor Users				
0-11 years	*****	*****	*****	7,319.64 (1,031.03, 51,964.51)
12-18 years	*****	*****	*****	1,545.30 (772.79, 3,090.03)
19-24 years	465	*****	*****	1,806.02 (1,238.52, 2,633.53)
25-44 years	3,960	150	1,574.2	952.89 (811.97, 1,118.26)
45-64 years	6,988	162	3,055.2	530.24 (454.56, 618.52)
≥ 65 years	5,416	90	2,279.7	394.78 (321.10, 485.39)
Sitagliptin Users				
0-11 years	*****	0	0.6	0.00 (0.00, 0.00)
12-18 years	*****	*****	*****	598.18 (84.26, 4,246.69)
19-24 years	139	*****	*****	1,101.81 (458.60, 2,647.17)
25-44 years	1,094	*****	*****	896.86 (634.24, 1,268.24)
45-64 years	2,727	35	1,098.8	318.52 (228.69, 443.62)
≥ 65 years	4,127	32	1,788.0	178.97 (126.56, 253.08)

Table 4. Occurrence of Diabetic Ketoacidosis (DKA) in New Users of Sodium-Glucose Cotransporter-2 (SGLT-2) Inhibitor and Sitagliptin by History of Diabetes, as well as Short/Rapid-Acting Insulin Users with Type 1 Diabetes in the Sentinel Distributed Database (SDD) from March 1, 2013 to February 29, 2024, by Age Group

	Number of Patients	Number of Exposure Episodes with an Event	Total Years at Risk	Event Rate per 10,000 Patient-Years at Risk (95% Confidence Interval)
History of Type 1 Diabetes - Broad Definition (Sensitivity Analysis)				
SGLT-2 Inhibitor Users				
0-11 years	*****	*****	*****	7,319.64 (1,031.03, 51,964.51)
12-18 years	*****	*****	*****	1,545.30 (772.79, 3,090.03)
19-24 years	468	*****	*****	1,806.02 (1,238.52, 2,633.53)
25-44 years	3,985	152	1,575.7	964.64 (822.85, 1,130.86)
45-64 years	7,042	166	3,058.0	542.84 (466.23, 632.03)
≥ 65 years	5,449	91	2,280.3	399.08 (324.96, 490.11)
Sitagliptin Users				
0-11 years	*****	0	0.6	0.00 (0.00, 0.00)
12-18 years	*****	*****	*****	598.18 (84.26, 4,246.69)
19-24 years	142	*****	*****	1,101.81 (458.60, 2,647.17)
25-44 years	1,117	*****	*****	895.26 (633.10, 1,265.98)
45-64 years	2,779	37	1,099.8	336.41 (243.75, 464.32)
≥ 65 years	4,158	33	1,789.3	184.43 (131.11, 259.42)
History of Type 1 Diabetes - Narrow Definition (Primary Analysis)				
SGLT-2 Inhibitor Users				
0-11 years	*****	*****	*****	8,908.54 (1,254.84, 63,244.61)
12-18 years	*****	*****	*****	1,904.61 (907.98, 3,995.18)
19-24 years	325	*****	*****	1,901.20 (1,212.68, 2,980.64)
25-44 years	2,576	115	998.7	1,151.47 (959.12, 1,382.38)
45-64 years	3,509	126	1,527.4	824.91 (692.75, 982.29)
≥ 65 years	2,146	58	884.1	656.01 (507.15, 848.56)
Sitagliptin Users				
0-11 years	*****	0	0.4	0.00 (0.00, 0.00)
12-18 years	*****	*****	*****	1,017.41 (143.31, 7,222.92)
19-24 years	73	*****	*****	1,172.43 (378.12, 3,635.27)
25-44 years	491	*****	*****	1,538.66 (1,022.47, 2,315.43)
45-64 years	683	22	256.1	859.00 (565.60, 1,304.59)
≥ 65 years	760	21	316.6	663.27 (432.45, 1,017.28)

Table 4. Occurrence of Diabetic Ketoacidosis (DKA) in New Users of Sodium-Glucose Cotransporter-2 (SGLT-2) Inhibitor and Sitagliptin by History of Diabetes, as well as Short/Rapid-Acting Insulin Users with Type 1 Diabetes in the Sentinel Distributed Database (SDD) from March 1, 2013 to February 29, 2024, by Age Group

	Number of Patients	Number of Exposure Episodes with an Event	Total Years at Risk	Event Rate per 10,000 Patient-Years at Risk (95% Confidence Interval)
History of Type 1 Diabetes - Narrow Definition (Sensitivity Analysis)				
SGLT-2 Inhibitor Users				
0-11 years	*****	*****	*****	8,908.54 (1,254.84, 63,244.61)
12-18 years	*****	*****	*****	1,904.61 (907.98, 3,995.18)
19-24 years	326	*****	*****	1,901.20 (1,212.68, 2,980.64)
25-44 years	2,586	116	999.5	1,160.62 (967.51, 1,392.27)
45-64 years	3,530	129	1,529.5	843.44 (709.76, 1,002.30)
≥ 65 years	2,154	59	884.4	667.13 (516.88, 861.05)
Sitagliptin Users				
0-11 years	*****	0	0.4	0.00 (0.00, 0.00)
12-18 years	*****	*****	*****	1,017.41 (143.31, 7,222.92)
19-24 years	74	*****	*****	1,172.43 (378.12, 3,635.27)
25-44 years	501	*****	*****	1,534.27 (1,019.56, 2,308.84)
45-64 years	700	24	256.6	935.19 (626.82, 1,395.26)
≥ 65 years	765	22	316.6	694.85 (457.52, 1,055.29)
History of Type 2 Diabetes with Insulin Use				
SGLT-2 Inhibitor Users				
0-11 years	*****	0	0.2	0.00 (0.00, 0.00)
12-18 years	*****	*****	*****	332.57 (124.82, 886.13)
19-24 years	1,649	*****	*****	338.66 (216.01, 530.94)
25-44 years	51,717	472	19,795.9	238.43 (217.86, 260.94)
45-64 years	246,941	1,548	107,343.0	144.21 (137.20, 151.58)
≥ 65 years	274,078	1,247	119,981.3	103.93 (98.32, 109.86)
Sitagliptin Users				
0-11 years	*****	0	0.4	0.00 (0.00, 0.00)
12-18 years	*****	0	46.6	0.00 (0.00, 0.00)
19-24 years	760	*****	*****	259.08 (116.39, 576.68)
25-44 years	20,794	*****	*****	170.59 (142.64, 204.01)
45-64 years	99,475	525	39,708.0	132.22 (121.38, 144.02)
≥ 65 years	152,966	619	64,525.9	95.93 (88.66, 103.79)

Table 4. Occurrence of Diabetic Ketoacidosis (DKA) in New Users of Sodium-Glucose Cotransporter-2 (SGLT-2) Inhibitor and Sitagliptin by History of Diabetes, as well as Short/Rapid-Acting Insulin Users with Type 1 Diabetes in the Sentinel Distributed Database (SDD) from March 1, 2013 to February 29, 2024, by Age Group

	Number of Patients	Number of Exposure Episodes with an Event	Total Years at Risk	Event Rate per 10,000 Patient-Years at Risk (95% Confidence Interval)
History of Type 2 Diabetes with No Insulin Use				
SGLT-2 Inhibitor Users				
0-11 years	15	0	5.0	0.00 (0.00, 0.00)
12-18 years	616	*****	*****	163.02 (52.58, 505.46)
19-24 years	3,313	*****	*****	184.40 (118.97, 285.83)
25-44 years	111,722	358	43,184.3	82.90 (74.74, 91.95)
45-64 years	493,374	1,054	217,508.6	48.46 (45.62, 51.47)
≥ 65 years	696,282	1,414	311,059.1	45.46 (43.15, 47.89)
Sitagliptin Users				
0-11 years	*****	0	2.7	0.00 (0.00, 0.00)
12-18 years	*****	*****	*****	215.95 (69.65, 669.57)
19-24 years	2,523	*****	*****	164.45 (95.49, 283.21)
25-44 years	78,710	137	29,238.9	46.86 (39.63, 55.40)
45-64 years	361,271	554	154,519.7	35.85 (32.99, 38.97)
≥ 65 years	691,467	1,075	322,481.2	33.34 (31.40, 35.39)
Type 1 Diabetes Population				
Short/Rapid-Acting Insulin Users				
0-11 years	51,907	1,214	15,286.4	794.17 (750.73, 840.12)
12-18 years	81,107	2,948	23,149.8	1,273.45 (1,228.30, 1,320.26)
19-24 years	61,355	3,199	15,757.9	2,030.09 (1,960.94, 2,101.67)
25-44 years	198,842	8,625	51,730.4	1,667.30 (1,632.48, 1,702.86)
45-64 years	159,129	3,893	45,356.4	858.31 (831.77, 885.70)
≥ 65 years	131,096	1,613	36,071.1	447.17 (425.87, 469.54)

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 5. Occurrence of Diabetic Ketoacidosis (DKA) in New Users of Sodium-Glucose Cotransporter-2 (SGLT-2) Inhibitor and Sitagliptin by History of Diabetes, as well as Short/Rapid-Acting Insulin Users with Type 1 Diabetes in the Sentinel Distributed Database (SDD) from March 1, 2013 to February 29, 2024, by Year

	Number of Patients	Number of Exposure Episodes with an Event	Total Years at Risk	Event Rate per 10,000 Patient-Years at Risk (95% Confidence Interval)
Overall				
SGLT-2 Inhibitor Users				
2013	13,710	45	5,984.9	75.19 (56.14, 100.70)
2014	69,222	241	29,866.1	80.69 (71.12, 91.55)
2015	110,759	362	46,705.9	77.51 (69.92, 85.92)
2016	110,577	340	45,697.0	74.40 (66.90, 82.75)
2017	144,429	453	61,933.2	73.14 (66.71, 80.20)
2018	146,960	537	65,041.8	82.56 (75.87, 89.85)
2019	203,016	819	95,038.1	86.18 (80.47, 92.28)
2020	248,808	1,218	123,909.6	98.30 (92.93, 103.98)
2021	401,238	1,742	177,679.8	98.04 (93.54, 102.76)
2022	388,358	1,380	199,811.3	69.07 (65.52, 72.81)
2023	418,541	1,023	127,704.2	80.11 (75.35, 85.17)
2024	15,665	18	1,067.6	168.60 (106.22, 267.60)
Sitagliptin Users				
2013	126,655	288	53,112.7	54.22 (48.31, 60.86)
2014	172,673	382	73,299.6	52.11 (47.14, 57.61)
2015	173,798	364	74,991.6	48.54 (43.80, 53.79)
2016	179,240	384	78,684.7	48.80 (44.16, 53.94)
2017	203,007	518	90,545.8	57.21 (52.49, 62.35)
2018	186,980	523	83,982.4	62.27 (57.16, 67.85)
2019	166,323	462	75,476.7	61.21 (55.88, 67.05)
2020	138,323	464	65,137.0	71.23 (65.04, 78.02)
2021	130,475	462	54,874.0	84.19 (76.86, 92.23)
2022	69,068	205	32,007.3	64.05 (55.85, 73.44)
2023	49,421	116	14,387.9	80.62 (67.21, 96.72)
2024	2,292	0	150.3	0.00 (0.00, 0.00)

Table 5. Occurrence of Diabetic Ketoacidosis (DKA) in New Users of Sodium-Glucose Cotransporter-2 (SGLT-2) Inhibitor and Sitagliptin by History of Diabetes, as well as Short/Rapid-Acting Insulin Users with Type 1 Diabetes in the Sentinel Distributed Database (SDD) from March 1, 2013 to February 29, 2024, by Year

	Number of Patients	Number of Exposure Episodes with an Event	Total Years at Risk	Event Rate per 10,000 Patient-Years at Risk (95% Confidence Interval)
History of Type 1 Diabetes - Broad Definition (Primary Analysis)				
SGLT-2 Inhibitor Users				
2013	331	*****	*****	639.38 (332.68, 1,228.85)
2014	1,503	*****	*****	530.43 (380.85, 738.78)
2015	1,979	44	817.0	538.54 (400.76, 723.67)
2016	1,256	21	515.3	407.53 (265.71, 625.04)
2017	1,299	32	549.5	582.36 (411.83, 823.50)
2018	1,234	32	545.5	586.57 (414.81, 829.46)
2019	1,543	49	681.5	719.03 (543.43, 951.37)
2020	1,564	45	740.3	607.88 (453.86, 814.16)
2021	2,375	60	967.8	619.98 (481.38, 798.49)
2022	1,884	60	902.0	665.17 (516.46, 856.69)
2023	1,966	50	587.8	850.68 (644.74, 1,122.40)
2024	69	*****	*****	2,239.42 (315.44, 15,898.40)
Sitagliptin Users				
2013	1,062	*****	*****	92.42 (34.69, 246.25)
2014	1,247	*****	*****	191.89 (103.25, 356.65)
2015	1,162	11	467.5	235.28 (130.30, 424.86)
2016	864	12	338.7	354.30 (201.21, 623.87)
2017	945	18	412.1	436.81 (275.21, 693.31)
2018	851	15	334.9	447.90 (270.02, 742.96)
2019	641	12	269.5	445.32 (252.90, 784.14)
2020	534	*****	*****	347.18 (173.62, 694.22)
2021	457	*****	*****	540.47 (281.21, 1,038.75)
2022	218	*****	*****	323.60 (104.37, 1,003.37)
2023	162	*****	*****	764.17 (246.46, 2,369.43)
2024	11	0	0.8	0.00 (0.00, 0.00)

Table 5. Occurrence of Diabetic Ketoacidosis (DKA) in New Users of Sodium-Glucose Cotransporter-2 (SGLT-2) Inhibitor and Sitagliptin by History of Diabetes, as well as Short/Rapid-Acting Insulin Users with Type 1 Diabetes in the Sentinel Distributed Database (SDD) from March 1, 2013 to February 29, 2024, by Year

	Number of Patients	Number of Exposure Episodes with an Event	Total Years at Risk	Event Rate per 10,000 Patient-Years at Risk (95% Confidence Interval)
History of Type 1 Diabetes - Broad Definition (Sensitivity Analysis)				
SGLT-2 Inhibitor Users				
2013	332	*****	*****	639.38 (332.68, 1,228.85)
2014	1,505	*****	*****	530.43 (380.85, 738.78)
2015	1,988	44	817.0	538.54 (400.76, 723.67)
2016	1,267	21	515.3	407.53 (265.71, 625.04)
2017	1,310	32	549.5	582.36 (411.83, 823.50)
2018	1,251	33	545.6	604.83 (429.99, 850.77)
2019	1,555	49	680.9	719.68 (543.93, 952.24)
2020	1,580	48	742.1	646.79 (487.42, 858.28)
2021	2,395	60	969.3	619.02 (480.64, 797.26)
2022	1,891	61	903.4	675.19 (525.34, 867.79)
2023	1,974	52	588.4	883.70 (673.38, 1,159.70)
2024	72	*****	*****	2,239.42 (315.44, 15,898.40)
Sitagliptin Users				
2013	1,064	*****	*****	92.40 (34.68, 246.19)
2014	1,252	*****	*****	191.81 (103.21, 356.50)
2015	1,175	12	468.1	256.36 (145.59, 451.41)
2016	878	12	339.0	353.97 (201.02, 623.29)
2017	955	18	412.1	436.81 (275.21, 693.31)
2018	867	16	335.7	476.56 (291.95, 777.89)
2019	658	12	270.1	444.34 (252.34, 782.43)
2020	546	*****	*****	346.85 (173.46, 693.58)
2021	473	*****	*****	540.18 (281.06, 1,038.19)
2022	220	*****	*****	431.46 (161.93, 1,149.60)
2023	165	*****	*****	764.17 (246.46, 2,369.43)
2024	12	0	0.8	0.00 (0.00, 0.00)

Table 5. Occurrence of Diabetic Ketoacidosis (DKA) in New Users of Sodium-Glucose Cotransporter-2 (SGLT-2) Inhibitor and Sitagliptin by History of Diabetes, as well as Short/Rapid-Acting Insulin Users with Type 1 Diabetes in the Sentinel Distributed Database (SDD) from March 1, 2013 to February 29, 2024, by Year

	Number of Patients	Number of Exposure Episodes with an Event	Total Years at Risk	Event Rate per 10,000 Patient-Years at Risk (95% Confidence Interval)
History of Type 1 Diabetes - Narrow Definition (Primary Analysis)				
SGLT-2 Inhibitor Users				
2013	134	*****	*****	970.89 (404.11, 2,332.64)
2014	757	*****	*****	815.91 (555.53, 1,198.34)
2015	1,060	39	439.7	886.89 (647.98, 1,213.87)
2016	649	15	264.5	567.13 (341.90, 940.73)
2017	640	22	265.4	829.04 (545.88, 1,259.09)
2018	599	22	254.0	866.20 (570.35, 1,315.53)
2019	802	41	339.1	1,209.11 (890.28, 1,642.11)
2020	784	34	357.9	949.96 (678.77, 1,329.49)
2021	1,195	39	466.5	835.99 (610.80, 1,144.21)
2022	1,022	46	484.9	948.60 (710.52, 1,266.45)
2023	996	36	303.7	1,185.27 (854.96, 1,643.18)
2024	36	*****	*****	4,559.93 (642.30, 32,372.40)
Sitagliptin Users				
2013	191	*****	*****	146.37 (20.62, 1,039.12)
2014	251	*****	*****	485.95 (202.26, 1,167.53)
2015	252	*****	*****	907.05 (471.95, 1,743.30)
2016	206	*****	*****	685.07 (285.14, 1,645.92)
2017	256	12	106.0	1,132.06 (642.90, 1,993.40)
2018	243	13	81.6	1,593.00 (924.98, 2,743.47)
2019	204	*****	*****	1,043.31 (521.75, 2,086.24)
2020	171	*****	*****	982.03 (441.18, 2,185.91)
2021	154	*****	*****	1,025.52 (426.84, 2,463.89)
2022	70	*****	*****	1,011.40 (326.19, 3,135.98)
2023	*****	*****	*****	2,806.74 (905.21, 8,702.66)
2024	*****	0	0.1	0.00 (0.00, 0.00)

Table 5. Occurrence of Diabetic Ketoacidosis (DKA) in New Users of Sodium-Glucose Cotransporter-2 (SGLT-2) Inhibitor and Sitagliptin by History of Diabetes, as well as Short/Rapid-Acting Insulin Users with Type 1 Diabetes in the Sentinel Distributed Database (SDD) from March 1, 2013 to February 29, 2024, by Year

	Number of Patients	Number of Exposure Episodes with an Event	Total Years at Risk	Event Rate per 10,000 Patient-Years at Risk (95% Confidence Interval)
History of Type 1 Diabetes - Narrow Definition (Sensitivity Analysis)				
SGLT-2 Inhibitor Users				
2013	135	*****	*****	970.89 (404.11, 2,332.64)
2014	757	*****	*****	815.91 (555.53, 1,198.34)
2015	1,063	39	439.7	886.89 (647.98, 1,213.87)
2016	654	15	264.5	567.13 (341.90, 940.73)
2017	644	22	265.4	829.04 (545.88, 1,259.09)
2018	604	23	254.0	905.35 (601.62, 1,362.41)
2019	803	41	339.1	1,209.11 (890.28, 1,642.11)
2020	789	35	358.0	977.58 (701.89, 1,361.56)
2021	1,204	39	468.0	833.31 (608.84, 1,140.54)
2022	1,026	47	486.1	966.94 (726.50, 1,286.95)
2023	1,000	38	303.9	1,250.32 (909.77, 1,718.32)
2024	36	*****	*****	4,559.93 (642.30, 32,372.40)
Sitagliptin Users				
2013	192	*****	*****	146.37 (20.62, 1,039.12)
2014	252	*****	*****	485.45 (202.05, 1,166.32)
2015	256	*****	*****	1,004.76 (540.61, 1,867.41)
2016	211	*****	*****	685.07 (285.14, 1,645.92)
2017	259	12	106.0	1,132.06 (642.90, 1,993.40)
2018	248	14	81.6	1,715.48 (1,015.99, 2,896.56)
2019	208	*****	*****	1,038.97 (519.58, 2,077.56)
2020	176	*****	*****	978.61 (439.64, 2,178.30)
2021	158	*****	*****	1,025.52 (426.84, 2,463.89)
2022	71	*****	*****	1,348.41 (506.07, 3,592.77)
2023	*****	*****	*****	2,806.74 (905.21, 8,702.66)
2024	*****	0	0.1	0.00 (0.00, 0.00)

Table 5. Occurrence of Diabetic Ketoacidosis (DKA) in New Users of Sodium-Glucose Cotransporter-2 (SGLT-2) Inhibitor and Sitagliptin by History of Diabetes, as well as Short/Rapid-Acting Insulin Users with Type 1 Diabetes in the Sentinel Distributed Database (SDD) from March 1, 2013 to February 29, 2024, by Year

	Number of Patients	Number of Exposure Episodes with an Event	Total Years at Risk	Event Rate per 10,000 Patient-Years at Risk (95% Confidence Interval)
History of Type 2 Diabetes with Insulin Use				
SGLT-2 Inhibitor Users				
2013	3,932	*****	*****	69.72 (39.59, 122.77)
2014	19,977	61	8,642.6	70.58 (54.92, 90.71)
2015	29,342	121	12,367.6	97.84 (81.87, 116.92)
2016	27,808	115	11,310.2	101.68 (84.69, 122.07)
2017	39,160	188	16,637.7	113.00 (97.95, 130.36)
2018	41,975	212	18,526.0	114.43 (100.02, 130.92)
2019	59,257	352	27,608.2	127.50 (114.85, 141.54)
2020	72,669	511	35,573.3	143.65 (131.72, 156.66)
2021	111,521	744	47,749.1	155.81 (145.01, 167.42)
2022	86,298	575	43,272.1	132.88 (122.45, 144.20)
2023	80,200	394	24,216.4	162.70 (147.40, 179.58)
2024	2,657	*****	*****	282.11 (117.42, 677.79)
Sitagliptin Users				
2013	16,839	66	6,858.1	96.24 (75.61, 122.50)
2014	24,781	83	9,971.1	83.24 (67.13, 103.22)
2015	27,168	104	11,020.1	94.37 (77.87, 114.37)
2016	29,268	106	11,949.4	88.71 (73.33, 107.31)
2017	36,947	184	15,422.9	119.30 (103.25, 137.85)
2018	35,049	164	14,670.3	111.79 (95.93, 130.28)
2019	31,713	148	13,330.0	111.03 (94.51, 130.44)
2020	26,872	138	11,675.4	118.20 (100.03, 139.66)
2021	24,545	161	9,298.0	173.16 (148.37, 202.08)
2022	12,008	79	5,025.5	157.20 (126.09, 195.98)
2023	8,653	37	2,305.2	160.51 (116.29, 221.53)
2024	341	0	21.1	0.00 (0.00, 0.00)

Table 5. Occurrence of Diabetic Ketoacidosis (DKA) in New Users of Sodium-Glucose Cotransporter-2 (SGLT-2) Inhibitor and Sitagliptin by History of Diabetes, as well as Short/Rapid-Acting Insulin Users with Type 1 Diabetes in the Sentinel Distributed Database (SDD) from March 1, 2013 to February 29, 2024, by Year

	Number of Patients	Number of Exposure Episodes with an Event	Total Years at Risk	Event Rate per 10,000 Patient-Years at Risk (95% Confidence Interval)
History of Type 2 Diabetes with No Insulin Use				
SGLT-2 Inhibitor Users				
2013	6,996	*****	*****	25.98 (12.99, 51.94)
2014	36,793	66	16,013.8	41.21 (32.38, 52.46)
2015	63,123	79	26,884.9	29.38 (23.57, 36.63)
2016	66,748	97	28,066.6	34.56 (28.32, 42.17)
2017	88,605	128	38,491.7	33.25 (27.96, 39.54)
2018	89,175	156	39,819.9	39.18 (33.49, 45.83)
2019	123,552	269	58,354.8	46.10 (40.90, 51.95)
2020	150,388	445	75,873.4	58.65 (53.45, 64.36)
2021	228,869	659	103,618.7	63.60 (58.92, 68.64)
2022	215,481	544	111,840.3	48.64 (44.72, 52.90)
2023	226,863	390	70,387.6	55.41 (50.17, 61.19)
2024	8,729	*****	*****	134.63 (67.33, 269.21)
Sitagliptin Users				
2013	88,799	103	37,801.9	27.25 (22.46, 33.05)
2014	121,343	171	52,580.6	32.52 (27.99, 37.78)
2015	121,693	128	53,790.1	23.80 (20.01, 28.30)
2016	126,762	168	57,014.3	29.47 (25.33, 34.28)
2017	143,724	204	65,831.2	30.99 (27.01, 35.55)
2018	131,967	215	60,936.1	35.28 (30.87, 40.33)
2019	117,455	204	54,844.2	37.20 (32.43, 42.67)
2020	98,838	231	47,830.8	48.30 (42.45, 54.94)
2021	93,168	211	40,776.3	51.75 (45.21, 59.22)
2022	51,964	99	24,663.1	40.14 (32.96, 48.88)
2023	37,007	48	10,989.3	43.68 (32.92, 57.96)
2024	1,728	0	114.1	0.00 (0.00, 0.00)

Table 5. Occurrence of Diabetic Ketoacidosis (DKA) in New Users of Sodium-Glucose Cotransporter-2 (SGLT-2) Inhibitor and Sitagliptin by History of Diabetes, as well as Short/Rapid-Acting Insulin Users with Type 1 Diabetes in the Sentinel Distributed Database (SDD) from March 1, 2013 to February 29, 2024, by Year

	Number of Patients	Number of Exposure Episodes with an Event	Total Years at Risk	Event Rate per 10,000 Patient-Years at Risk (95% Confidence Interval)
Type 1 Diabetes Population				
Short/Rapid-Acting Insulin Users				
2013	94,580	1,636	22,077.6	741.02 (705.97, 777.82)
2014	56,072	1,069	15,100.4	707.93 (666.74, 751.67)
2015	62,255	1,672	15,899.3	1,051.62 (1,002.40, 1,103.25)
2016	69,892	2,637	18,070.2	1,459.31 (1,404.66, 1,516.08)
2017	93,364	4,049	25,434.7	1,591.92 (1,543.63, 1,641.72)
2018	70,014	2,784	19,903.2	1,398.77 (1,347.76, 1,451.71)
2019	58,224	2,086	17,491.9	1,192.56 (1,142.46, 1,244.85)
2020	58,843	2,145	18,766.4	1,143.00 (1,095.64, 1,192.41)
2021	67,211	2,226	18,581.4	1,197.97 (1,149.23, 1,248.79)
2022	26,711	697	9,387.8	742.46 (689.33, 799.67)
2023	24,261	*****	*****	741.47 (678.14, 810.71)
2024	2,009	*****	*****	649.17 (337.77, 1,247.66)

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

Table 6. Occurrence of Diabetic Ketoacidosis (DKA) in New Users of Sodium-Glucose Cotransporter-2 (SGLT-2) Inhibitor and Sitagliptin by History of Diabetes, as well as Short/Rapid-Acting Insulin Users with Type 1 Diabetes in the Sentinel Distributed Database (SDD) from March 1, 2013 to February 29, 2024, by Chronic Kidney Disease Stage

	Number of Patients	Number of Exposure Episodes with an Event	Total Years at Risk	Event Rate per 10,000 Patient-Years at Risk (95% Confidence Interval)
Overall				
SGLT-2 Inhibitor Users				
Evidence of Chronic Kidney Disease Stage 1	1,662,930	5,400	723,913.1	74.59 (72.63, 76.61)
Evidence of Chronic Kidney Disease Stage 2	143,545	997	58,745.1	169.72 (159.50, 180.59)
Evidence of Chronic Kidney Disease Stage 3	381,199	1,334	163,760.1	81.46 (77.20, 85.95)
Evidence of Chronic Kidney Disease Stage 4 or 5	83,609	447	34,021.2	131.39 (119.76, 144.15)
Sitagliptin Users				
Evidence of Chronic Kidney Disease Stage 1	1,208,787	2,288	526,250.6	43.48 (41.73, 45.30)
Evidence of Chronic Kidney Disease Stage 2	107,738	647	45,851.5	141.11 (130.64, 152.41)
Evidence of Chronic Kidney Disease Stage 3	211,258	769	95,333.1	80.66 (75.16, 86.57)
Evidence of Chronic Kidney Disease Stage 4 or 5	70,472	464	29,214.8	158.82 (145.01, 173.95)
History of Type 1 Diabetes - Broad Definition (Primary Analysis)				
SGLT-2 Inhibitor Users				
Evidence of Chronic Kidney Disease Stage 1	13,039	283	5,544.5	510.42 (454.28, 573.49)
Evidence of Chronic Kidney Disease Stage 2	1,116	65	429.9	1,511.86 (1,185.58, 1,927.94)
Evidence of Chronic Kidney Disease Stage 3	2,147	65	862.3	753.81 (591.13, 961.27)
Evidence of Chronic Kidney Disease Stage 4 or 5	701	25	275.0	908.95 (614.18, 1,345.19)
Sitagliptin Users				
Evidence of Chronic Kidney Disease Stage 1	6,101	48	2,493.6	192.49 (145.06, 255.43)
Evidence of Chronic Kidney Disease Stage 2	631	24	251.3	955.09 (640.16, 1,424.94)
Evidence of Chronic Kidney Disease Stage 3	821	18	327.0	550.51 (346.84, 873.78)
Evidence of Chronic Kidney Disease Stage 4 or 5	601	15	234.4	639.84 (385.73, 1,061.34)

Table 6. Occurrence of Diabetic Ketoacidosis (DKA) in New Users of Sodium-Glucose Cotransporter-2 (SGLT-2) Inhibitor and Sitagliptin by History of Diabetes, as well as Short/Rapid-Acting Insulin Users with Type 1 Diabetes in the Sentinel Distributed Database (SDD) from March 1, 2013 to February 29, 2024, by Chronic Kidney Disease Stage

	Number of Patients	Number of Exposure Episodes with an Event	Total Years at Risk	Event Rate per 10,000 Patient-Years at Risk (95% Confidence Interval)
History of Type 1 Diabetes - Broad Definition (Sensitivity Analysis)				
SGLT-2 Inhibitor Users				
Evidence of Chronic Kidney Disease Stage 1	13,114	284	5,544.4	512.23 (455.99, 575.41)
Evidence of Chronic Kidney Disease Stage 2	1,136	69	433.0	1,593.67 (1,258.70, 2,017.77)
Evidence of Chronic Kidney Disease Stage 3	2,164	66	863.7	764.16 (600.35, 972.66)
Evidence of Chronic Kidney Disease Stage 4 or 5	706	26	275.6	943.43 (642.35, 1,385.63)
Sitagliptin Users				
Evidence of Chronic Kidney Disease Stage 1	6,179	49	2,494.7	196.41 (148.45, 259.88)
Evidence of Chronic Kidney Disease Stage 2	645	24	251.7	953.47 (639.08, 1,422.53)
Evidence of Chronic Kidney Disease Stage 3	834	20	327.9	609.92 (393.49, 945.40)
Evidence of Chronic Kidney Disease Stage 4 or 5	607	15	234.9	638.52 (384.94, 1,059.15)
History of Type 1 Diabetes - Narrow Definition (Primary Analysis)				
SGLT-2 Inhibitor Users				
Evidence of Chronic Kidney Disease Stage 1	6,509	205	2,704.8	757.90 (660.94, 869.09)
Evidence of Chronic Kidney Disease Stage 2	590	50	209.2	2,390.38 (1,811.70, 3,153.89)
Evidence of Chronic Kidney Disease Stage 3	1,166	55	471.4	1,166.77 (895.79, 1,519.72)
Evidence of Chronic Kidney Disease Stage 4 or 5	409	16	162.7	983.31 (602.40, 1,605.07)
Sitagliptin Users				
Evidence of Chronic Kidney Disease Stage 1	1,432	30	542.2	553.30 (386.86, 791.35)
Evidence of Chronic Kidney Disease Stage 2	205	17	75.7	2,245.42 (1,395.87, 3,612.00)
Evidence of Chronic Kidney Disease Stage 3	224	12	81.4	1,474.52 (837.38, 2,596.42)
Evidence of Chronic Kidney Disease Stage 4 or 5	184	11	58.7	1,873.69 (1,037.64, 3,383.37)

Table 6. Occurrence of Diabetic Ketoacidosis (DKA) in New Users of Sodium-Glucose Cotransporter-2 (SGLT-2) Inhibitor and Sitagliptin by History of Diabetes, as well as Short/Rapid-Acting Insulin Users with Type 1 Diabetes in the Sentinel Distributed Database (SDD) from March 1, 2013 to February 29, 2024, by Chronic Kidney Disease Stage

	Number of Patients	Number of Exposure Episodes with an Event	Total Years at Risk	Event Rate per 10,000 Patient-Years at Risk (95% Confidence Interval)
History of Type 1 Diabetes - Narrow Definition (Sensitivity Analysis)				
SGLT-2 Inhibitor Users				
Evidence of Chronic Kidney Disease Stage 1	6,525	205	2,704.9	757.87 (660.91, 869.06)
Evidence of Chronic Kidney Disease Stage 2	604	53	210.9	2,513.41 (1,920.17, 3,289.93)
Evidence of Chronic Kidney Disease Stage 3	1,174	56	472.5	1,185.11 (912.03, 1,539.95)
Evidence of Chronic Kidney Disease Stage 4 or 5	412	17	162.8	1,044.33 (649.21, 1,679.91)
Sitagliptin Users				
Evidence of Chronic Kidney Disease Stage 1	1,451	31	542.8	571.09 (401.62, 812.05)
Evidence of Chronic Kidney Disease Stage 2	213	17	75.9	2,239.10 (1,391.95, 3,601.84)
Evidence of Chronic Kidney Disease Stage 3	228	14	81.4	1,720.15 (1,018.76, 2,904.45)
Evidence of Chronic Kidney Disease Stage 4 or 5	187	11	58.8	1,870.29 (1,035.75, 3,377.22)
History of Type 2 Diabetes with Insulin Use				
SGLT-2 Inhibitor Users				
Evidence of Chronic Kidney Disease Stage 1	390,567	2,068	168,898.8	122.44 (117.28, 127.83)
Evidence of Chronic Kidney Disease Stage 2	42,069	408	17,315.8	235.62 (213.83, 259.63)
Evidence of Chronic Kidney Disease Stage 3	111,493	599	48,754.0	122.86 (113.41, 133.11)
Evidence of Chronic Kidney Disease Stage 4 or 5	30,667	215	12,833.1	167.53 (146.57, 191.50)
Sitagliptin Users				
Evidence of Chronic Kidney Disease Stage 1	180,659	657	73,186.3	89.77 (83.16, 96.90)
Evidence of Chronic Kidney Disease Stage 2	25,209	205	10,128.0	202.41 (176.51, 232.10)
Evidence of Chronic Kidney Disease Stage 3	47,626	260	20,004.1	129.97 (115.10, 146.77)
Evidence of Chronic Kidney Disease Stage 4 or 5	20,690	148	8,228.7	179.86 (153.10, 211.30)

Table 6. Occurrence of Diabetic Ketoacidosis (DKA) in New Users of Sodium-Glucose Cotransporter-2 (SGLT-2) Inhibitor and Sitagliptin by History of Diabetes, as well as Short/Rapid-Acting Insulin Users with Type 1 Diabetes in the Sentinel Distributed Database (SDD) from March 1, 2013 to February 29, 2024, by Chronic Kidney Disease Stage

	Number of Patients	Number of Exposure Episodes with an Event	Total Years at Risk	Event Rate per 10,000 Patient-Years at Risk (95% Confidence Interval)
History of Type 2 Diabetes with No Insulin Use				
SGLT-2 Inhibitor Users				
Evidence of Chronic Kidney Disease Stage 1	1,014,065	2,093	448,462.6	46.67 (44.71, 48.71)
Evidence of Chronic Kidney Disease Stage 2	68,250	228	28,590.8	79.75 (70.04, 90.80)
Evidence of Chronic Kidney Disease Stage 3	189,877	415	82,516.7	50.29 (45.68, 55.37)
Evidence of Chronic Kidney Disease Stage 4 or 5	33,130	113	13,455.6	83.98 (69.84, 100.98)
Sitagliptin Users				
Evidence of Chronic Kidney Disease Stage 1	888,308	1,138	395,800.4	28.75 (27.13, 30.47)
Evidence of Chronic Kidney Disease Stage 2	67,506	207	29,653.9	69.81 (60.92, 79.99)
Evidence of Chronic Kidney Disease Stage 3	140,584	293	65,323.1	44.85 (40.00, 50.30)
Evidence of Chronic Kidney Disease Stage 4 or 5	38,050	144	16,394.7	87.83 (74.60, 103.42)
Type 1 Diabetes Population				
Short/Rapid-Acting Insulin Users				
Evidence of Chronic Kidney Disease Stage 1	562,905	12,676	158,334.9	800.58 (786.76, 814.64)
Evidence of Chronic Kidney Disease Stage 2	45,557	4,984	10,155.4	4,907.72 (4,773.34, 5,045.88)
Evidence of Chronic Kidney Disease Stage 3	38,583	1,448	10,174.3	1,423.20 (1,351.75, 1,498.43)
Evidence of Chronic Kidney Disease Stage 4 or 5	36,391	2,384	8,687.4	2,744.21 (2,636.23, 2,856.61)

Table 7. Summary of Patient-Level Cohort Attrition in the Sentinel Distributed Database (SDD) from March 1, 2013 to February 29, 2024

	Overall			
	Sodium-Glucose Cotransporter-2 (SGLT-2) Inhibitor Users		Sitagliptin Users	
	Remaining	Excluded	Remaining	Excluded
Members meeting enrollment and demographic requirements				
Enrolled at any point during the query period	426,727,379	N/A	426,727,379	N/A
Had required coverage type (medical and/or drug coverage)	318,162,769	108,564,610	318,162,769	108,564,610
Enrolled during specified age range	318,156,030	6,739	318,156,030	6,739
Had requestable medical charts	318,156,030	0	318,156,030	0
Met demographic requirements (sex, race, and Hispanic origin)	318,043,485	112,545	318,043,485	112,545
Members with a valid index event				
Had any cohort-defining claim during the query period	*****	*****	*****	*****
Claim recorded during specified age range	*****	*****	*****	*****
Episode defining index claim recorded during the query period	4,341,461	0	3,636,120	154,143
Members with required pre-index history				
Had sufficient pre-index continuous enrollment	3,125,798	1,215,663	2,581,724	1,054,396
Met inclusion and exclusion criteria[1]	2,288,997	836,801	1,614,969	966,755
Evidence of anti-diabetic treatment	N/A	N/A	N/A	N/A
Evidence of any insulin	N/A	N/A	N/A	N/A
Evidence of type 1 diabetes	N/A	N/A	N/A	N/A
Evidence of study exposure washout	N/A	836,801	N/A	966,755
No evidence of Klompas definition type 1 diabetes inclusion	N/A	N/A	N/A	N/A
No evidence of type 2 diabetes	N/A	N/A	N/A	N/A
Met event incidence criteria	2,288,997	0	1,614,969	0
Had sufficient post-index continuous enrollment	2,288,997	0	1,614,969	0
Had minimum days' supply on index date	2,288,997	0	1,614,969	0
Had index episode of at least required length	2,288,997	0	1,614,969	0
Had index episode longer than blackout period	2,271,588	17,409	1,599,074	15,895
Did not have an event during blackout period	2,271,283	305	1,598,255	819
Final cohort				
Number of members	2,271,283	N/A	1,598,255	N/A
Number of episodes	2,271,283	N/A	1,598,255	N/A

Table 7. Summary of Patient-Level Cohort Attrition in the Sentinel Distributed Database (SDD) from March 1, 2013 to February 29, 2024

	History of Type 1 Diabetes - Broad Definition (Primary Analysis)			
	SGLT-2 Inhibitor Users		Sitagliptin Users	
	Remaining	Excluded	Remaining	Excluded
Members meeting enrollment and demographic requirements				
Enrolled at any point during the query period	426,727,379	N/A	426,727,379	N/A
Had required coverage type (medical and/or drug coverage)	318,162,769	108,564,610	318,162,769	108,564,610
Enrolled during specified age range	318,156,030	6,739	318,156,030	6,739
Had requestable medical charts	318,156,030	0	318,156,030	0
Met demographic requirements (sex, race, and Hispanic origin)	318,043,485	112,545	318,043,485	112,545
Members with a valid index event				
Had any cohort-defining claim during the query period	*****	*****	*****	*****
Claim recorded during specified age range	*****	*****	*****	*****
Episode defining index claim recorded during the query period	4,341,461	0	3,636,120	154,143
Members with required pre-index history				
Had sufficient pre-index continuous enrollment	3,125,798	1,215,663	2,581,724	1,054,396
Met inclusion and exclusion criteria[1]	17,120	3,108,678	8,265	2,573,459
Evidence of anti-diabetic treatment	N/A	N/A	N/A	N/A
Evidence of any insulin	N/A	N/A	N/A	N/A
Evidence of type 1 diabetes	N/A	N/A	N/A	N/A
Evidence of study exposure washout	N/A	1,795,110	N/A	1,782,805
No evidence of Klompas definition type 1 diabetes inclusion	N/A	3,105,297	N/A	2,570,882
No evidence of type 2 diabetes	N/A	N/A	N/A	N/A
Met event incidence criteria	17,120	0	8,265	0
Had sufficient post-index continuous enrollment	17,120	0	8,265	0
Had minimum days' supply on index date	17,120	0	8,265	0
Had index episode of at least required length	17,120	0	8,265	0
Had index episode longer than blackout period	17,021	99	8,171	94
Did not have an event during blackout period	17,003	18	8,154	17
Final cohort				
Number of members	17,003	N/A	8,154	N/A
Number of episodes	17,003	N/A	8,154	N/A

Table 7. Summary of Patient-Level Cohort Attrition in the Sentinel Distributed Database (SDD) from March 1, 2013 to February 29, 2024

	History of Type 1 Diabetes - Broad Definition (Sensitivity Analysis)			
	SGLT-2 Inhibitor Users		Sitagliptin Users	
	Remaining	Excluded	Remaining	Excluded
Members meeting enrollment and demographic requirements				
Enrolled at any point during the query period	426,727,379	N/A	426,727,379	N/A
Had required coverage type (medical and/or drug coverage)	318,162,769	108,564,610	318,162,769	108,564,610
Enrolled during specified age range	318,156,030	6,739	318,156,030	6,739
Had requestable medical charts	318,156,030	0	318,156,030	0
Met demographic requirements (sex, race, and Hispanic origin)	318,043,485	112,545	318,043,485	112,545
Members with a valid index event				
Had any cohort-defining claim during the query period	*****	*****	*****	*****
Claim recorded during specified age range	*****	*****	*****	*****
Episode defining index claim recorded during the query period	4,341,461	0	3,636,120	154,143
Members with required pre-index history				
Had sufficient pre-index continuous enrollment	3,125,798	1,215,663	2,581,724	1,054,396
Met inclusion and exclusion criteria[1]	17,120	3,108,678	8,265	2,573,459
Evidence of anti-diabetic treatment	N/A	N/A	N/A	N/A
Evidence of any insulin	N/A	N/A	N/A	N/A
Evidence of type 1 diabetes	N/A	N/A	N/A	N/A
Evidence of study exposure washout	N/A	1,795,110	N/A	1,782,805
No evidence of Klompas definition type 1 diabetes inclusion	N/A	3,105,297	N/A	2,570,882
No evidence of type 2 diabetes	N/A	N/A	N/A	N/A
Met event incidence criteria	17,120	0	8,265	0
Had sufficient post-index continuous enrollment	17,120	0	8,265	0
Had minimum days' supply on index date	17,120	0	8,265	0
Had index episode of at least required length	17,120	0	8,265	0
Had index episode longer than blackout period	17,120	0	8,265	0
Did not have an event during blackout period	17,120	0	8,265	0
Final cohort				
Number of members	17,120	N/A	8,265	N/A
Number of episodes	17,120	N/A	8,265	N/A

Table 7. Summary of Patient-Level Cohort Attrition in the Sentinel Distributed Database (SDD) from March 1, 2013 to February 29, 2024

	History of Type 1 Diabetes - Narrow Definition (Primary Analysis)			
	SGLT-2 Inhibitor Users		Sitagliptin Users	
	Remaining	Excluded	Remaining	Excluded
Members meeting enrollment and demographic requirements				
Enrolled at any point during the query period	426,727,379	N/A	426,727,379	N/A
Had required coverage type (medical and/or drug coverage)	318,162,769	108,564,610	318,162,769	108,564,610
Enrolled during specified age range	318,156,030	6,739	318,156,030	6,739
Had requestable medical charts	318,156,030	0	318,156,030	0
Met demographic requirements (sex, race, and Hispanic origin)	318,043,485	112,545	318,043,485	112,545
Members with a valid index event				
Had any cohort-defining claim during the query period	*****	*****	*****	*****
Claim recorded during specified age range	*****	*****	*****	*****
Episode defining index claim recorded during the query period	4,341,461	0	3,636,120	154,143
Members with required pre-index history				
Had sufficient pre-index continuous enrollment	3,125,798	1,215,663	2,581,724	1,054,396
Met inclusion and exclusion criteria[1]	8,715	3,117,083	2,079	2,579,645
Evidence of anti-diabetic treatment	N/A	2,333,145	N/A	1,614,017
Evidence of any insulin	N/A	N/A	N/A	N/A
Evidence of type 1 diabetes	N/A	N/A	N/A	N/A
Evidence of study exposure washout	N/A	1,799,264	N/A	1,786,039
No evidence of Klompas definition type 1 diabetes inclusion	N/A	3,113,083	N/A	2,578,259
No evidence of type 2 diabetes	N/A	N/A	N/A	N/A
Met event incidence criteria	8,715	0	2,079	0
Had sufficient post-index continuous enrollment	8,715	0	2,079	0
Had minimum days' supply on index date	8,715	0	2,079	0
Had index episode of at least required length	8,715	0	2,079	0
Had index episode longer than blackout period	8,687	28	*****	*****
Did not have an event during blackout period	8,674	13	2,045	*****
Final cohort				
Number of members	8,674	N/A	2,045	N/A
Number of episodes	8,674	N/A	2,045	N/A

Table 7. Summary of Patient-Level Cohort Attrition in the Sentinel Distributed Database (SDD) from March 1, 2013 to February 29, 2024

	History of Type 1 Diabetes - Narrow Definition (Sensitivity Analysis)			
	SGLT-2 Inhibitor Users		Sitagliptin Users	
	Remaining	Excluded	Remaining	Excluded
Members meeting enrollment and demographic requirements				
Enrolled at any point during the query period	426,727,379	N/A	426,727,379	N/A
Had required coverage type (medical and/or drug coverage)	318,162,769	108,564,610	318,162,769	108,564,610
Enrolled during specified age range	318,156,030	6,739	318,156,030	6,739
Had requestable medical charts	318,156,030	0	318,156,030	0
Met demographic requirements (sex, race, and Hispanic origin)	318,043,485	112,545	318,043,485	112,545
Members with a valid index event				
Had any cohort-defining claim during the query period	*****	*****	*****	*****
Claim recorded during specified age range	*****	*****	*****	*****
Episode defining index claim recorded during the query period	4,341,461	0	3,636,120	154,143
Members with required pre-index history				
Had sufficient pre-index continuous enrollment	3,125,798	1,215,663	2,581,724	1,054,396
Met inclusion and exclusion criteria[1]	8,715	3,117,083	2,079	2,579,645
Evidence of anti-diabetic treatment	N/A	2,333,145	N/A	1,614,017
Evidence of any insulin	N/A	N/A	N/A	N/A
Evidence of type 1 diabetes	N/A	N/A	N/A	N/A
Evidence of study exposure washout	N/A	1,799,264	N/A	1,786,039
No evidence of Klompas definition type 1 diabetes inclusion	N/A	3,113,083	N/A	2,578,259
No evidence of type 2 diabetes	N/A	N/A	N/A	N/A
Met event incidence criteria	8,715	0	2,079	0
Had sufficient post-index continuous enrollment	8,715	0	2,079	0
Had minimum days' supply on index date	8,715	0	2,079	0
Had index episode of at least required length	8,715	0	2,079	0
Had index episode longer than blackout period	8,715	0	2,079	0
Did not have an event during blackout period	8,715	0	2,079	0
Final cohort				
Number of members	8,715	N/A	2,079	N/A
Number of episodes	8,715	N/A	2,079	N/A

Table 7. Summary of Patient-Level Cohort Attrition in the Sentinel Distributed Database (SDD) from March 1, 2013 to February 29, 2024

	History of Type 2 Diabetes with Insulin Use			
	SGLT-2 Inhibitor Users		Sitagliptin Users	
	Remaining	Excluded	Remaining	Excluded
Members meeting enrollment and demographic requirements				
Enrolled at any point during the query period	426,727,379	N/A	426,727,379	N/A
Had required coverage type (medical and/or drug coverage)	318,162,769	108,564,610	318,162,769	108,564,610
Enrolled during specified age range	318,156,030	6,739	318,156,030	6,739
Had requestable medical charts	318,156,030	0	318,156,030	0
Met demographic requirements (sex, race, and Hispanic origin)	318,043,485	112,545	318,043,485	112,545
Members with a valid index event				
Had any cohort-defining claim during the query period	*****	*****	*****	*****
Claim recorded during specified age range	*****	*****	*****	*****
Episode defining index claim recorded during the query period	4,341,461	0	3,636,120	154,143
Members with required pre-index history				
Had sufficient pre-index continuous enrollment	3,125,798	1,215,663	2,581,724	1,054,396
Met inclusion and exclusion criteria[1]	578,583	2,547,215	277,725	2,303,999
Evidence of anti-diabetic treatment	N/A	N/A	N/A	N/A
Evidence of any insulin	N/A	N/A	N/A	N/A
Evidence of type 1 diabetes	N/A	204,690	N/A	260,222
Evidence of study exposure washout	N/A	1,533,252	N/A	1,645,195
No evidence of Klompas definition type 1 diabetes inclusion	N/A	2,228,279	N/A	2,016,398
No evidence of type 2 diabetes	N/A	N/A	N/A	N/A
Met event incidence criteria	578,583	0	277,725	0
Had sufficient post-index continuous enrollment	578,583	0	277,725	0
Had minimum days' supply on index date	578,583	0	277,725	0
Had index episode of at least required length	578,583	0	277,725	0
Had index episode longer than blackout period	574,881	3,702	274,312	3,413
Did not have an event during blackout period	574,796	85	274,184	128
Final cohort				
Number of members	574,796	N/A	274,184	N/A
Number of episodes	574,796	N/A	274,184	N/A

Table 7. Summary of Patient-Level Cohort Attrition in the Sentinel Distributed Database (SDD) from March 1, 2013 to February 29, 2024

	History of Type 2 Diabetes with No Insulin Use			
	SGLT-2 Inhibitor Users		Sitagliptin Users	
	Remaining	Excluded	Remaining	Excluded
Members meeting enrollment and demographic requirements				
Enrolled at any point during the query period	426,727,379	N/A	426,727,379	N/A
Had required coverage type (medical and/or drug coverage)	318,162,769	108,564,610	318,162,769	108,564,610
Enrolled during specified age range	318,156,030	6,739	318,156,030	6,739
Had requestable medical charts	318,156,030	0	318,156,030	0
Met demographic requirements (sex, race, and Hispanic origin)	318,043,485	112,545	318,043,485	112,545
Members with a valid index event				
Had any cohort-defining claim during the query period	*****	*****	*****	*****
Claim recorded during specified age range	*****	*****	*****	*****
Episode defining index claim recorded during the query period	4,341,461	0	3,636,120	154,143
Members with required pre-index history				
Had sufficient pre-index continuous enrollment	3,125,798	1,215,663	2,581,724	1,054,396
Met inclusion and exclusion criteria[1]	1,316,574	1,809,224	1,145,189	1,436,535
Evidence of anti-diabetic treatment	N/A	N/A	N/A	N/A
Evidence of any insulin	N/A	951,191	N/A	646,244
Evidence of type 1 diabetes	N/A	214,595	N/A	246,935
Evidence of study exposure washout	N/A	1,239,836	N/A	1,198,601
No evidence of Klompas definition type 1 diabetes inclusion	N/A	N/A	N/A	N/A
No evidence of type 2 diabetes	N/A	331,863	N/A	148,162
Met event incidence criteria	1,316,574	0	1,145,189	0
Had sufficient post-index continuous enrollment	1,316,574	0	1,145,189	0
Had minimum days' supply on index date	1,316,574	0	1,145,189	0
Had index episode of at least required length	1,316,574	0	1,145,189	0
Had index episode longer than blackout period	1,305,433	11,141	1,134,833	10,356
Did not have an event during blackout period	1,305,322	111	1,134,448	385
Final cohort				
Number of members	1,305,322	N/A	1,134,448	N/A
Number of episodes	1,305,322	N/A	1,134,448	N/A

Table 7. Summary of Patient-Level Cohort Attrition in the Sentinel Distributed Database (SDD) from March 1, 2013 to February 29, 2024

	Type 1 Diabetes Population	
	Short/Rapid-Acting Insulin Users	
	Remaining	Excluded
Members meeting enrollment and demographic requirements		
Enrolled at any point during the query period	426,727,379	N/A
Had required coverage type (medical and/or drug coverage)	318,162,769	108,564,610
Enrolled during specified age range	318,156,030	6,739
Had requestable medical charts	318,156,030	0
Met demographic requirements (sex, race, and Hispanic origin)	318,043,485	112,545
Members with a valid index event		
Had any cohort-defining claim during the query period	6,209,488	311,833,997
Claim recorded during specified age range	6,209,457	31
Episode defining index claim recorded during the query period	6,164,342	45,115
Members with required pre-index history		
Had sufficient pre-index continuous enrollment	4,585,106	1,579,236
Met inclusion and exclusion criteria[1]	685,422	3,899,684
Evidence of anti-diabetic treatment	N/A	1,969,962
Evidence of any insulin	N/A	N/A
Evidence of type 1 diabetes	N/A	N/A
Evidence of study exposure washout	N/A	N/A
No evidence of Klompas definition type 1 diabetes inclusion	N/A	3,886,630
No evidence of type 2 diabetes	N/A	N/A
Met event incidence criteria	685,422	0
Had sufficient post-index continuous enrollment	685,422	0
Had minimum days' supply on index date	685,422	0
Had index episode of at least required length	685,422	0
Had index episode longer than blackout period	684,849	573
Did not have an event during blackout period	683,436	1,413
Final cohort		
Number of members	683,436	N/A
Number of episodes	683,436	N/A

[1]Patients can meet multiple inclusion and/or exclusion criteria; therefore, the total number of patients excluded overall may not equal the sum of all patients in each criterion.

*****Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.

N/A: Not applicable

Appendix A. Dates of Available Data for Each Data Partner (DP) as of Request Distribution Date (October 23, 2024)

Masked DP ID	DP Start Date	DP End Date[1]
DP01	01/01/2006	02/29/2024
DP02	01/01/2007	10/31/2023
DP03	01/01/2008	12/31/2023
DP04	01/01/2014	12/31/2021
DP05	01/01/2008	01/31/2024
DP06	01/01/2010	09/30/2023

[1]End Date represents the earliest of: (1) query end date, or (2) last day of the most recent month for which all of a Data Partner's data tables (enrollment, dispensing, etc.) have at least 80% of the record count relative to the prior month.

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

Generic Name	Brand Name
Sodium-Glucose Cotransporter-2 (SGLT-2) Inhibitors	
bexagliflozin	Brenzavvy
bexagliflozin	bexagliflozin
canagliflozin	INVOKANA
canagliflozin	Invokana
canagliflozin/metformin HCl	Invokamet
canagliflozin/metformin HCl	Invokamet XR
dapagliflozin propanediol	Farxiga
dapagliflozin propanediol/metformin HCl	Xigduo XR
empagliflozin	Jardiance
empagliflozin/metformin HCl	Synjardy
empagliflozin/metformin HCl	Synjardy XR
ertugliflozin pidolate	Steglatro
ertugliflozin pidolate/metformin HCl	Segluromet
sotagliflozin	Inpefa
Sitagliptin	
sitagliptin phosphate	Januvia
sitagliptin phosphate/metformin HCl	Janumet
sitagliptin phosphate/metformin HCl	Janumet XR
sitagliptin phosphate/simvastatin	Juvisync
Short/Rapid-Acting Insulin	
insulin aspart	Novolog FlexPen U-100 Insulin
insulin aspart	Novolog PenFill U-100 Insulin
insulin aspart	Novolog U-100 Insulin aspart
insulin aspart	insulin aspart U-100
insulin aspart (niacinamide)	Fiasp FlexTouch U-100 Insulin
insulin aspart (niacinamide)	Fiasp Penfill U-100 Insulin
insulin aspart (niacinamide)	Fiasp U-100 Insulin
insulin aspart (niacinamide)/pump cartridge	Fiasp Pumpcart
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 Tempo Pen(U-100)Insuln
insulin lispro	Humalog U-100 Insulin
insulin lispro	insulin lispro
insulin lispro-aabc	Lyumjev KwikPen U-100 Insulin
insulin lispro-aabc	Lyumjev KwikPen U-200 Insulin
insulin lispro-aabc	Lyumjev Tempo Pen(U-100)Insuln
insulin lispro-aabc	Lyumjev U-100 Insulin
insulin regular, human	Afrezza
insulin regular, human	Humulin R Regular U-100 Insuln

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

Generic Name	Brand Name
insulin regular, human	Humulin R U-500 (Conc) Insulin
insulin regular, human	Humulin R U-500 (Conc) Kwikpen
insulin regular, human	Novolin R FlexPen
insulin regular, human	Novolin R Regular U100 Insulin
insulin regular, human in 0.9 % sodium chloride	Myxredlin

Appendix C. 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) Codes Used to Define Outcomes in this Request

Code	Description	Code Category	Code Type
	Diabetic Ketoacidosis		
250.10	Diabetes with ketoacidosis, type II or unspecified type, not stated as uncontrolled	Diagnosis	ICD-9-CM
250.11	Diabetes with ketoacidosis, type I [juvenile type], not stated as uncontrolled	Diagnosis	ICD-9-CM
250.12	Diabetes with ketoacidosis, type II or unspecified type, uncontrolled	Diagnosis	ICD-9-CM
250.13	Diabetes with ketoacidosis, type I [juvenile type], uncontrolled	Diagnosis	ICD-9-CM
E10.10	Type 1 diabetes mellitus with ketoacidosis without coma	Diagnosis	ICD-10-CM
E10.11	Type 1 diabetes mellitus with ketoacidosis with coma	Diagnosis	ICD-10-CM
E11.10	Type 2 diabetes mellitus with ketoacidosis without coma	Diagnosis	ICD-10-CM
E11.11	Type 2 diabetes mellitus with ketoacidosis with coma	Diagnosis	ICD-10-CM
E13.10	Other specified diabetes mellitus with ketoacidosis without coma	Diagnosis	ICD-10-CM
E13.11	Other specified diabetes mellitus with ketoacidosis with coma	Diagnosis	ICD-10-CM

Appendix D. List of Healthcare Common Procedure Coding System, Level II (HCPCS), International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), and International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) Codes Used to Define Inclusion/Exclusion Criteria in this Request

Code	Description	Code Category	Code Type
	Type 1 Diabetes		
250.01	Diabetes mellitus without mention of complication, type I [juvenile type], not stated as uncontrolled	Diagnosis	ICD-9-CM
250.03	Diabetes mellitus without mention of complication, type I [juvenile type],	Diagnosis	ICD-9-CM
250.11	Diabetes with ketoacidosis, type I [juvenile type], not stated as uncontrolled	Diagnosis	ICD-9-CM
250.13	Diabetes with ketoacidosis, type I [juvenile type], uncontrolled	Diagnosis	ICD-9-CM
250.21	Diabetes with hyperosmolarity, type I [juvenile type], not stated as uncontrolled	Diagnosis	ICD-9-CM
250.31	Diabetes with other coma, type I [juvenile type], not stated as uncontrolled	Diagnosis	ICD-9-CM
250.33	Diabetes with other coma, type I [juvenile type], uncontrolled	Diagnosis	ICD-9-CM
250.41	Diabetes with renal manifestations, type I [juvenile type], not stated as uncontrolled	Diagnosis	ICD-9-CM
250.43	Diabetes with renal manifestations, type I [juvenile type], uncontrolled	Diagnosis	ICD-9-CM
250.51	Diabetes with ophthalmic manifestations, type I [juvenile type], not stated as uncontrolled	Diagnosis	ICD-9-CM
250.53	Diabetes with ophthalmic manifestations, type I [juvenile type], uncontrolled	Diagnosis	ICD-9-CM
250.61	Diabetes with neurological manifestations, type I [juvenile type], not stated as uncontrolled	Diagnosis	ICD-9-CM
250.63	Diabetes with neurological manifestations, type I [juvenile type], uncontrolled	Diagnosis	ICD-9-CM
250.71	Diabetes with peripheral circulatory disorders, type I [juvenile type], not stated as uncontrolled	Diagnosis	ICD-9-CM
250.73	Diabetes with peripheral circulatory disorders, type I [juvenile type], uncontrolled	Diagnosis	ICD-9-CM
250.81	Diabetes with other specified manifestations, type I [juvenile type], not stated as uncontrolled	Diagnosis	ICD-9-CM
250.83	Diabetes with other specified manifestations, type I [juvenile type], uncontrolled	Diagnosis	ICD-9-CM
250.91	Diabetes with unspecified complication, type I [juvenile type], not stated as uncontrolled	Diagnosis	ICD-9-CM
250.93	Diabetes with unspecified complication, type I [juvenile type], uncontrolled	Diagnosis	ICD-9-CM
E10.10	Type 1 diabetes mellitus with ketoacidosis without coma	Diagnosis	ICD-10-CM
E10.11	Type 1 diabetes mellitus with ketoacidosis with coma	Diagnosis	ICD-10-CM
E10.21	Type 1 diabetes mellitus with diabetic nephropathy	Diagnosis	ICD-10-CM
E10.22	Type 1 diabetes mellitus with diabetic chronic kidney disease	Diagnosis	ICD-10-CM
E10.29	Type 1 diabetes mellitus with other diabetic kidney complication	Diagnosis	ICD-10-CM
E10.311	Type 1 diabetes mellitus with unspecified diabetic retinopathy with macular edema	Diagnosis	ICD-10-CM
E10.319	Type 1 diabetes mellitus with unspecified diabetic retinopathy without macular	Diagnosis	ICD-10-CM
E10.321	Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema	Diagnosis	ICD-10-CM
E10.3211	Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, right eye	Diagnosis	ICD-10-CM
E10.3212	Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, left eye	Diagnosis	ICD-10-CM
E10.3213	Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, bilateral	Diagnosis	ICD-10-CM
E10.3219	Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, unspecified eye	Diagnosis	ICD-10-CM
E10.329	Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema	Diagnosis	ICD-10-CM

Appendix D. List of Healthcare Common Procedure Coding System, Level II (HCPCS), International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), and International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) Codes Used to Define Inclusion/Exclusion Criteria in this Request

Code	Description	Code Category	Code Type
E10.3291	Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, right eye	Diagnosis	ICD-10-CM
E10.3292	Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, left eye	Diagnosis	ICD-10-CM
E10.3293	Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, bilateral	Diagnosis	ICD-10-CM
E10.3299	Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, unspecified eye	Diagnosis	ICD-10-CM
E10.331	Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema	Diagnosis	ICD-10-CM
E10.3311	Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, right eye	Diagnosis	ICD-10-CM
E10.3312	Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, left eye	Diagnosis	ICD-10-CM
E10.3313	Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, bilateral	Diagnosis	ICD-10-CM
E10.3319	Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, unspecified eye	Diagnosis	ICD-10-CM
E10.339	Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema	Diagnosis	ICD-10-CM
E10.3391	Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema, right eye	Diagnosis	ICD-10-CM
E10.3392	Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema, left eye	Diagnosis	ICD-10-CM
E10.3393	Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema, bilateral	Diagnosis	ICD-10-CM
E10.3399	Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema, unspecified eye	Diagnosis	ICD-10-CM
E10.341	Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema	Diagnosis	ICD-10-CM
E10.3411	Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, right eye	Diagnosis	ICD-10-CM
E10.3412	Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, left eye	Diagnosis	ICD-10-CM
E10.3413	Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, bilateral	Diagnosis	ICD-10-CM
E10.3419	Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, unspecified eye	Diagnosis	ICD-10-CM
E10.349	Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema	Diagnosis	ICD-10-CM
E10.3491	Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema, right eye	Diagnosis	ICD-10-CM
E10.3492	Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema, left eye	Diagnosis	ICD-10-CM
E10.3493	Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema, bilateral	Diagnosis	ICD-10-CM

Appendix D. List of Healthcare Common Procedure Coding System, Level II (HCPCS), International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), and International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) Codes Used to Define Inclusion/Exclusion Criteria in this Request

Code	Description	Code Category	Code Type
E10.3499	Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema, unspecified eye	Diagnosis	ICD-10-CM
E10.351	Type 1 diabetes mellitus with proliferative diabetic retinopathy with macular edema	Diagnosis	ICD-10-CM
E10.3511	Type 1 diabetes mellitus with proliferative diabetic retinopathy with macular edema, right eye	Diagnosis	ICD-10-CM
E10.3512	Type 1 diabetes mellitus with proliferative diabetic retinopathy with macular edema, left eye	Diagnosis	ICD-10-CM
E10.3513	Type 1 diabetes mellitus with proliferative diabetic retinopathy with macular edema, bilateral	Diagnosis	ICD-10-CM
E10.3519	Type 1 diabetes mellitus with proliferative diabetic retinopathy with macular edema, unspecified eye	Diagnosis	ICD-10-CM
E10.3521	Type 1 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, right eye	Diagnosis	ICD-10-CM
E10.3522	Type 1 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, left eye	Diagnosis	ICD-10-CM
E10.3523	Type 1 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, bilateral	Diagnosis	ICD-10-CM
E10.3529	Type 1 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, unspecified eye	Diagnosis	ICD-10-CM
E10.3531	Type 1 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, right eye	Diagnosis	ICD-10-CM
E10.3532	Type 1 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, left eye	Diagnosis	ICD-10-CM
E10.3533	Type 1 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, bilateral	Diagnosis	ICD-10-CM
E10.3539	Type 1 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, unspecified eye	Diagnosis	ICD-10-CM
E10.3541	Type 1 diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, right eye	Diagnosis	ICD-10-CM
E10.3542	Type 1 diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, left eye	Diagnosis	ICD-10-CM
E10.3543	Type 1 diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, bilateral	Diagnosis	ICD-10-CM
E10.3549	Type 1 diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, unspecified	Diagnosis	ICD-10-CM
E10.3551	Type 1 diabetes mellitus with stable proliferative diabetic retinopathy, right eye	Diagnosis	ICD-10-CM
E10.3552	Type 1 diabetes mellitus with stable proliferative diabetic retinopathy, left eye	Diagnosis	ICD-10-CM
E10.3553	Type 1 diabetes mellitus with stable proliferative diabetic retinopathy, bilateral	Diagnosis	ICD-10-CM
E10.3559	Type 1 diabetes mellitus with stable proliferative diabetic retinopathy, unspecified	Diagnosis	ICD-10-CM
E10.359	Type 1 diabetes mellitus with proliferative diabetic retinopathy without macular edema	Diagnosis	ICD-10-CM
E10.3591	Type 1 diabetes mellitus with proliferative diabetic retinopathy without macular edema, right eye	Diagnosis	ICD-10-CM
E10.3592	Type 1 diabetes mellitus with proliferative diabetic retinopathy without macular edema, left eye	Diagnosis	ICD-10-CM

Appendix D. List of Healthcare Common Procedure Coding System, Level II (HCPCS), International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), and International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) Codes Used to Define Inclusion/Exclusion Criteria in this Request

Code	Description	Code Category	Code Type
E10.3593	Type 1 diabetes mellitus with proliferative diabetic retinopathy without macular edema, bilateral	Diagnosis	ICD-10-CM
E10.3599	Type 1 diabetes mellitus with proliferative diabetic retinopathy without macular edema, unspecified eye	Diagnosis	ICD-10-CM
E10.36	Type 1 diabetes mellitus with diabetic cataract	Diagnosis	ICD-10-CM
E10.37X1	Type 1 diabetes mellitus with diabetic macular edema, resolved following treatment, right eye	Diagnosis	ICD-10-CM
E10.37X2	Type 1 diabetes mellitus with diabetic macular edema, resolved following treatment, left eye	Diagnosis	ICD-10-CM
E10.37X3	Type 1 diabetes mellitus with diabetic macular edema, resolved following treatment, bilateral	Diagnosis	ICD-10-CM
E10.37X9	Type 1 diabetes mellitus with diabetic macular edema, resolved following treatment, unspecified eye	Diagnosis	ICD-10-CM
E10.39	Type 1 diabetes mellitus with other diabetic ophthalmic complication	Diagnosis	ICD-10-CM
E10.40	Type 1 diabetes mellitus with diabetic neuropathy, unspecified	Diagnosis	ICD-10-CM
E10.41	Type 1 diabetes mellitus with diabetic mononeuropathy	Diagnosis	ICD-10-CM
E10.42	Type 1 diabetes mellitus with diabetic polyneuropathy	Diagnosis	ICD-10-CM
E10.43	Type 1 diabetes mellitus with diabetic autonomic (poly)neuropathy	Diagnosis	ICD-10-CM
E10.44	Type 1 diabetes mellitus with diabetic amyotrophy	Diagnosis	ICD-10-CM
E10.49	Type 1 diabetes mellitus with other diabetic neurological complication	Diagnosis	ICD-10-CM
E10.51	Type 1 diabetes mellitus with diabetic peripheral angiopathy without gangrene	Diagnosis	ICD-10-CM
E10.52	Type 1 diabetes mellitus with diabetic peripheral angiopathy with gangrene	Diagnosis	ICD-10-CM
E10.59	Type 1 diabetes mellitus with other circulatory complications	Diagnosis	ICD-10-CM
E10.610	Type 1 diabetes mellitus with diabetic neuropathic arthropathy	Diagnosis	ICD-10-CM
E10.618	Type 1 diabetes mellitus with other diabetic arthropathy	Diagnosis	ICD-10-CM
E10.620	Type 1 diabetes mellitus with diabetic dermatitis	Diagnosis	ICD-10-CM
E10.621	Type 1 diabetes mellitus with foot ulcer	Diagnosis	ICD-10-CM
E10.622	Type 1 diabetes mellitus with other skin ulcer	Diagnosis	ICD-10-CM
E10.628	Type 1 diabetes mellitus with other skin complications	Diagnosis	ICD-10-CM
E10.630	Type 1 diabetes mellitus with periodontal disease	Diagnosis	ICD-10-CM
E10.638	Type 1 diabetes mellitus with other oral complications	Diagnosis	ICD-10-CM
E10.641	Type 1 diabetes mellitus with hypoglycemia with coma	Diagnosis	ICD-10-CM
E10.649	Type 1 diabetes mellitus with hypoglycemia without coma	Diagnosis	ICD-10-CM
E10.65	Type 1 diabetes mellitus with hyperglycemia	Diagnosis	ICD-10-CM
E10.69	Type 1 diabetes mellitus with other specified complication	Diagnosis	ICD-10-CM
E10.8	Type 1 diabetes mellitus with unspecified complications	Diagnosis	ICD-10-CM
E10.9	Type 1 diabetes mellitus without complications	Diagnosis	ICD-10-CM
250.00	Diabetes mellitus without mention of complication, type II or unspecified type, not stated as uncontrolled	Diagnosis	ICD-9-CM
250.02	Diabetes mellitus without mention of complication, type II or unspecified type, uncontrolled	Diagnosis	ICD-9-CM
	Type 2 Diabetes		
250.10	Diabetes with ketoacidosis, type II or unspecified type, not stated as uncontrolled	Diagnosis	ICD-9-CM
250.12	Diabetes with ketoacidosis, type II or unspecified type, uncontrolled	Diagnosis	ICD-9-CM
250.20	Diabetes with hyperosmolarity, type II or unspecified type, not stated as uncontrolled	Diagnosis	ICD-9-CM
250.22	Diabetes with hyperosmolarity, type II or unspecified type, uncontrolled	Diagnosis	ICD-9-CM

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Code	Description	Code Category	Code Type
250.30	Diabetes with other coma, type II or unspecified type, not stated as uncontrolled	Diagnosis	ICD-9-CM
250.32	Diabetes with other coma, type II or unspecified type, uncontrolled	Diagnosis	ICD-9-CM
250.40	Diabetes with renal manifestations, type II or unspecified type, not stated as uncontrolled	Diagnosis	ICD-9-CM
250.42	Diabetes with renal manifestations, type II or unspecified type, uncontrolled	Diagnosis	ICD-9-CM
250.50	Diabetes with ophthalmic manifestations, type II or unspecified type, not stated as uncontrolled	Diagnosis	ICD-9-CM
250.52	Diabetes with ophthalmic manifestations, type II or unspecified type, uncontrolled	Diagnosis	ICD-9-CM
250.60	Diabetes with neurological manifestations, type II or unspecified type, not stated as uncontrolled	Diagnosis	ICD-9-CM
250.62	Diabetes with neurological manifestations, type II or unspecified type, uncontrolled	Diagnosis	ICD-9-CM
250.70	Diabetes with peripheral circulatory disorders, type II or unspecified type, not stated as uncontrolled	Diagnosis	ICD-9-CM
250.72	Diabetes with peripheral circulatory disorders, type II or unspecified type,	Diagnosis	ICD-9-CM
250.80	Diabetes with other specified manifestations, type II or unspecified type, not stated as uncontrolled	Diagnosis	ICD-9-CM
250.82	Diabetes with other specified manifestations, type II or unspecified type,	Diagnosis	ICD-9-CM
250.90	Diabetes with unspecified complication, type II or unspecified type, not stated as uncontrolled	Diagnosis	ICD-9-CM
250.92	Diabetes with unspecified complication, type II or unspecified type, uncontrolled	Diagnosis	ICD-9-CM
E11.00	Type 2 diabetes mellitus with hyperosmolarity without nonketotic hyperglycemic-hyperosmolar coma (NKHHC)	Diagnosis	ICD-10-CM
E11.01	Type 2 diabetes mellitus with hyperosmolarity with coma	Diagnosis	ICD-10-CM
E11.10	Type 2 diabetes mellitus with ketoacidosis without coma	Diagnosis	ICD-10-CM
E11.11	Type 2 diabetes mellitus with ketoacidosis with coma	Diagnosis	ICD-10-CM
E11.21	Type 2 diabetes mellitus with diabetic nephropathy	Diagnosis	ICD-10-CM
E11.22	Type 2 diabetes mellitus with diabetic chronic kidney disease	Diagnosis	ICD-10-CM
E11.29	Type 2 diabetes mellitus with other diabetic kidney complication	Diagnosis	ICD-10-CM
E11.311	Type 2 diabetes mellitus with unspecified diabetic retinopathy with macular edema	Diagnosis	ICD-10-CM
E11.319	Type 2 diabetes mellitus with unspecified diabetic retinopathy without macular	Diagnosis	ICD-10-CM
E11.321	Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema	Diagnosis	ICD-10-CM
E11.3211	Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, right eye	Diagnosis	ICD-10-CM
E11.3212	Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, left eye	Diagnosis	ICD-10-CM
E11.3213	Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, bilateral	Diagnosis	ICD-10-CM
E11.3219	Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, unspecified eye	Diagnosis	ICD-10-CM
E11.329	Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema	Diagnosis	ICD-10-CM
E11.3291	Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, right eye	Diagnosis	ICD-10-CM
E11.3292	Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, left eye	Diagnosis	ICD-10-CM

Appendix D. List of Healthcare Common Procedure Coding System, Level II (HCPCS), International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), and International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) Codes Used to Define Inclusion/Exclusion Criteria in this Request

Code	Description	Code Category	Code Type
E11.3293	Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, bilateral	Diagnosis	ICD-10-CM
E11.3299	Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, unspecified eye	Diagnosis	ICD-10-CM
E11.331	Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema	Diagnosis	ICD-10-CM
E11.3311	Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, right eye	Diagnosis	ICD-10-CM
E11.3312	Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, left eye	Diagnosis	ICD-10-CM
E11.3313	Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, bilateral	Diagnosis	ICD-10-CM
E11.3319	Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, unspecified eye	Diagnosis	ICD-10-CM
E11.339	Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema	Diagnosis	ICD-10-CM
E11.3391	Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema, right eye	Diagnosis	ICD-10-CM
E11.3392	Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema, left eye	Diagnosis	ICD-10-CM
E11.3393	Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema, bilateral	Diagnosis	ICD-10-CM
E11.3399	Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema, unspecified eye	Diagnosis	ICD-10-CM
E11.341	Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema	Diagnosis	ICD-10-CM
E11.3411	Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, right eye	Diagnosis	ICD-10-CM
E11.3412	Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, left eye	Diagnosis	ICD-10-CM
E11.3413	Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, bilateral	Diagnosis	ICD-10-CM
E11.3419	Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, unspecified eye	Diagnosis	ICD-10-CM
E11.349	Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema	Diagnosis	ICD-10-CM
E11.3491	Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema, right eye	Diagnosis	ICD-10-CM
E11.3492	Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema, left eye	Diagnosis	ICD-10-CM
E11.3493	Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema, bilateral	Diagnosis	ICD-10-CM
E11.3499	Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema, unspecified eye	Diagnosis	ICD-10-CM
E11.351	Type 2 diabetes mellitus with proliferative diabetic retinopathy with macular edema	Diagnosis	ICD-10-CM

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Code	Description	Code Category	Code Type
E11.3511	Type 2 diabetes mellitus with proliferative diabetic retinopathy with macular edema, right eye	Diagnosis	ICD-10-CM
E11.3512	Type 2 diabetes mellitus with proliferative diabetic retinopathy with macular edema, left eye	Diagnosis	ICD-10-CM
E11.3513	Type 2 diabetes mellitus with proliferative diabetic retinopathy with macular edema, bilateral	Diagnosis	ICD-10-CM
E11.3519	Type 2 diabetes mellitus with proliferative diabetic retinopathy with macular edema, unspecified eye	Diagnosis	ICD-10-CM
E11.3521	Type 2 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, right eye	Diagnosis	ICD-10-CM
E11.3522	Type 2 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, left eye	Diagnosis	ICD-10-CM
E11.3523	Type 2 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, bilateral	Diagnosis	ICD-10-CM
E11.3529	Type 2 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, unspecified eye	Diagnosis	ICD-10-CM
E11.3531	Type 2 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, right eye	Diagnosis	ICD-10-CM
E11.3532	Type 2 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, left eye	Diagnosis	ICD-10-CM
E11.3533	Type 2 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, bilateral	Diagnosis	ICD-10-CM
E11.3539	Type 2 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, unspecified eye	Diagnosis	ICD-10-CM
E11.3541	Type 2 diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, right eye	Diagnosis	ICD-10-CM
E11.3542	Type 2 diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, left eye	Diagnosis	ICD-10-CM
E11.3543	Type 2 diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, bilateral	Diagnosis	ICD-10-CM
E11.3549	Type 2 diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, unspecified	Diagnosis	ICD-10-CM
E11.3551	Type 2 diabetes mellitus with stable proliferative diabetic retinopathy, right eye	Diagnosis	ICD-10-CM
E11.3552	Type 2 diabetes mellitus with stable proliferative diabetic retinopathy, left eye	Diagnosis	ICD-10-CM
E11.3553	Type 2 diabetes mellitus with stable proliferative diabetic retinopathy, bilateral	Diagnosis	ICD-10-CM
E11.3559	Type 2 diabetes mellitus with stable proliferative diabetic retinopathy, unspecified	Diagnosis	ICD-10-CM
E11.359	Type 2 diabetes mellitus with proliferative diabetic retinopathy without macular edema	Diagnosis	ICD-10-CM
E11.3591	Type 2 diabetes mellitus with proliferative diabetic retinopathy without macular edema, right eye	Diagnosis	ICD-10-CM
E11.3592	Type 2 diabetes mellitus with proliferative diabetic retinopathy without macular edema, left eye	Diagnosis	ICD-10-CM
E11.3593	Type 2 diabetes mellitus with proliferative diabetic retinopathy without macular edema, bilateral	Diagnosis	ICD-10-CM
E11.3599	Type 2 diabetes mellitus with proliferative diabetic retinopathy without macular edema, unspecified eye	Diagnosis	ICD-10-CM

Appendix D. List of Healthcare Common Procedure Coding System, Level II (HCPCS), International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), and International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) Codes Used to Define Inclusion/Exclusion Criteria in this Request

Code	Description	Code Category	Code Type
E11.36	Type 2 diabetes mellitus with diabetic cataract	Diagnosis	ICD-10-CM
E11.37X1	Type 2 diabetes mellitus with diabetic macular edema, resolved following treatment, right eye	Diagnosis	ICD-10-CM
E11.37X2	Type 2 diabetes mellitus with diabetic macular edema, resolved following treatment, left eye	Diagnosis	ICD-10-CM
E11.37X3	Type 2 diabetes mellitus with diabetic macular edema, resolved following treatment, bilateral	Diagnosis	ICD-10-CM
E11.37X9	Type 2 diabetes mellitus with diabetic macular edema, resolved following treatment, unspecified eye	Diagnosis	ICD-10-CM
E11.39	Type 2 diabetes mellitus with other diabetic ophthalmic complication	Diagnosis	ICD-10-CM
E11.40	Type 2 diabetes mellitus with diabetic neuropathy, unspecified	Diagnosis	ICD-10-CM
E11.41	Type 2 diabetes mellitus with diabetic mononeuropathy	Diagnosis	ICD-10-CM
E11.42	Type 2 diabetes mellitus with diabetic polyneuropathy	Diagnosis	ICD-10-CM
E11.43	Type 2 diabetes mellitus with diabetic autonomic (poly)neuropathy	Diagnosis	ICD-10-CM
E11.44	Type 2 diabetes mellitus with diabetic amyotrophy	Diagnosis	ICD-10-CM
E11.49	Type 2 diabetes mellitus with other diabetic neurological complication	Diagnosis	ICD-10-CM
E11.51	Type 2 diabetes mellitus with diabetic peripheral angiopathy without gangrene	Diagnosis	ICD-10-CM
E11.52	Type 2 diabetes mellitus with diabetic peripheral angiopathy with gangrene	Diagnosis	ICD-10-CM
E11.59	Type 2 diabetes mellitus with other circulatory complications	Diagnosis	ICD-10-CM
E11.610	Type 2 diabetes mellitus with diabetic neuropathic arthropathy	Diagnosis	ICD-10-CM
E11.618	Type 2 diabetes mellitus with other diabetic arthropathy	Diagnosis	ICD-10-CM
E11.620	Type 2 diabetes mellitus with diabetic dermatitis	Diagnosis	ICD-10-CM
E11.621	Type 2 diabetes mellitus with foot ulcer	Diagnosis	ICD-10-CM
E11.622	Type 2 diabetes mellitus with other skin ulcer	Diagnosis	ICD-10-CM
E11.628	Type 2 diabetes mellitus with other skin complications	Diagnosis	ICD-10-CM
E11.630	Type 2 diabetes mellitus with periodontal disease	Diagnosis	ICD-10-CM
E11.638	Type 2 diabetes mellitus with other oral complications	Diagnosis	ICD-10-CM
E11.641	Type 2 diabetes mellitus with hypoglycemia with coma	Diagnosis	ICD-10-CM
E11.649	Type 2 diabetes mellitus with hypoglycemia without coma	Diagnosis	ICD-10-CM
E11.65	Type 2 diabetes mellitus with hyperglycemia	Diagnosis	ICD-10-CM
E11.69	Type 2 diabetes mellitus with other specified complication	Diagnosis	ICD-10-CM
E11.8	Type 2 diabetes mellitus with unspecified complications	Diagnosis	ICD-10-CM
E11.9	Type 2 diabetes mellitus without complications	Diagnosis	ICD-10-CM
	Short/Rapid-Acting Insulin		
S5550	Insulin, rapid onset, 5 units	Procedure	HCPCS
S5551	Insulin, most rapid onset (Lispro or Aspart); 5 units	Procedure	HCPCS
	Any Insulin		
A4225	Supplies for external insulin infusion pump, syringe type cartridge, sterile, each	Procedure	HCPCS
A4230	Infusion set for external insulin pump, nonneedle cannula type	Procedure	HCPCS
A4231	Infusion set for external insulin pump, needle type	Procedure	HCPCS
A4232	Syringe with needle for external insulin pump, sterile, 3 cc	Procedure	HCPCS
E0784	External ambulatory infusion pump, insulin	Procedure	HCPCS
J1811	Insulin (Fiasp) for administration through DME (i.e., insulin pump) per 50 units	Procedure	HCPCS
J1813	Insulin (Lyumjev) for administration through DME (i.e., insulin pump) per 50 units	Procedure	HCPCS
J1817	Insulin for administration through DME (i.e., insulin pump) per 50 units	Procedure	HCPCS

Appendix D. List of Healthcare Common Procedure Coding System, Level II (HCPCS), International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), and International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) Codes Used to Define Inclusion/Exclusion Criteria in this Request

Code	Description	Code Category	Code Type
S1034	Artificial pancreas device system (e.g., low glucose suspend [LGS] feature) including continuous glucose monitor, blood glucose device, insulin pump and computer algorithm that communicates with all of the devices	Procedure	HCPCS
S5550	Insulin, rapid onset, 5 units	Procedure	HCPCS
S5551	Insulin, most rapid onset (Lispro or Aspart); 5 units	Procedure	HCPCS
S5552	Insulin, intermediate acting (NPH or LENTE); 5 units	Procedure	HCPCS
S5553	Insulin, long acting; 5 units	Procedure	HCPCS
S5565	Insulin cartridge for use in insulin delivery device other than pump; 150 units	Procedure	HCPCS
S5566	Insulin cartridge for use in insulin delivery device other than pump; 300 units	Procedure	HCPCS
S9145	Insulin pump initiation, instruction in initial use of pump (pump not included)	Procedure	HCPCS

Appendix E. List of Generic and Brand Names of Medical Products Used to Define Inclusion/Exclusion Criteria in this Request

Generic Name	Brand Name
Short/Rapid-Acting Insulin	
insulin aspart	Novolog FlexPen U-100 Insulin
insulin aspart	Novolog PenFill U-100 Insulin
insulin aspart	Novolog U-100 Insulin aspart
insulin aspart	insulin aspart U-100
insulin aspart (niacinamide)	Fiasp FlexTouch U-100 Insulin
insulin aspart (niacinamide)	Fiasp Penfill U-100 Insulin
insulin aspart (niacinamide)	Fiasp U-100 Insulin
insulin aspart (niacinamide)/pump cartridge	Fiasp Pumpcart
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 Tempo Pen(U-100)Insuln
insulin lispro	Humalog U-100 Insulin
insulin lispro	insulin lispro
insulin lispro-aabc	Lyumjev KwikPen U-100 Insulin
insulin lispro-aabc	Lyumjev KwikPen U-200 Insulin
insulin lispro-aabc	Lyumjev Tempo Pen(U-100)Insuln
insulin lispro-aabc	Lyumjev U-100 Insulin
insulin regular, human	Afrezza
insulin regular, human	Humulin R Regular U-100 Insuln
insulin regular, human	Humulin R U-500 (Conc) Insulin
insulin regular, human	Humulin R U-500 (Conc) Kwikpen
insulin regular, human	Novolin R FlexPen
insulin regular, human	Novolin R Regular U100 Insulin
insulin regular, human in 0.9 % sodium chloride	Myxredlin
Any 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 FlexPen
insulin NPH human isophane	Novolin N NPH U-100 Insulin
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 FlexPen U-100
insulin NPH human isophane/insulin regular, human	Novolin 70/30 U-100 Insulin
insulin aspart	Novolog FlexPen U-100 Insulin
insulin aspart	Novolog PenFill U-100 Insulin
insulin aspart	Novolog U-100 Insulin aspart
insulin aspart	insulin aspart U-100
insulin aspart (niacinamide)	Fiasp FlexTouch U-100 Insulin
insulin aspart (niacinamide)	Fiasp Penfill U-100 Insulin
insulin aspart (niacinamide)	Fiasp U-100 Insulin

Appendix E. List of Generic and Brand Names of Medical Products Used to Define Inclusion/Exclusion Criteria in this Request

Generic Name	Brand Name
insulin aspart (niacinamide)/pump cartridge	Fiasp Pumpcart
insulin aspart protamine human/insulin aspart	Novolog Mix 70-30 U-100 Insuln
insulin aspart protamine human/insulin aspart	Novolog Mix 70-30FlexPen U-100
insulin aspart protamine human/insulin aspart	insulin asp prt-insulin aspart
insulin degludec	Tresiba FlexTouch U-100
insulin degludec	Tresiba FlexTouch U-200
insulin degludec	Tresiba U-100 Insulin
insulin degludec	insulin degludec
insulin degludec/liraglutide	Xultophy 100/3.6
insulin detemir	Levemir FlexPen
insulin detemir	Levemir FlexTouch U100 Insulin
insulin detemir	Levemir U-100 Insulin
insulin glargine,human recombinant analog	Basaglar KwikPen U-100 Insulin
insulin glargine,human recombinant analog	Basaglar Tempo Pen(U-100)Insln
insulin glargine,human recombinant analog	Lantus Solostar U-100 Insulin
insulin glargine,human recombinant analog	Lantus U-100 Insulin
insulin glargine,human recombinant analog	Semglee Pen U-100 Insulin
insulin glargine,human recombinant analog	Semglee 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	insulin glargine
insulin glargine,human recombinant analog	insulin glargine U-300 conc
insulin glargine,human recombinant analog/lixisenatide	Soliqua 100/33
insulin glargine-aglr	Rezvoglar KwikPen
insulin glargine-yfgn	Semglee(insulin glarg-yfgn)Pen
insulin glargine-yfgn	Semglee(insulin glargine-yfgn)
insulin glargine-yfgn	insulin glargine-yfgn
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 Tempo Pen(U-100)Insuln
insulin lispro	Humalog U-100 Insulin
insulin lispro	insulin lispro
insulin lispro protamine and insulin lispro	Humalog Mix 50-50 Insuln 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)Insuln
insulin lispro protamine and insulin lispro	insulin lispro protamin-lispro
insulin lispro-aabc	Lyumjev KwikPen U-100 Insulin
insulin lispro-aabc	Lyumjev KwikPen U-200 Insulin
insulin lispro-aabc	Lyumjev Tempo Pen(U-100)Insuln
insulin lispro-aabc	Lyumjev U-100 Insulin
insulin regular, human	Afrezza
insulin regular, human	Humulin R Regular U-100 Insuln

Appendix E. List of Generic and Brand Names of Medical Products Used to Define Inclusion/Exclusion Criteria in this Request

Generic Name	Brand Name
insulin regular, human	Humulin R U-500 (Conc) Insulin
insulin regular, human	Humulin R U-500 (Conc) Kwikpen
insulin regular, human	Novolin R FlexPen
insulin regular, human	Novolin R Regular U100 Insulin
insulin regular, human in 0.9 % sodium chloride	Myxredlin
Non-Insulin Antidiabetic	
acarbose	Precose
acarbose	acarbose
acarbose	acarbose (bulk)
albiglutide	Tanzeum
alogliptin benzoate	Nesina
alogliptin benzoate	alogliptin
alogliptin benzoate/metformin HCl	Kazano
alogliptin benzoate/metformin HCl	alogliptin-metformin
alogliptin benzoate/pioglitazone HCl	Oseni
alogliptin benzoate/pioglitazone HCl	alogliptin-pioglitazone
bexagliflozin	Brenzavvy
bexagliflozin	bexagliflozin
bromocriptine mesylate	Cycloset
bromocriptine mesylate	Parlodel
bromocriptine mesylate	bromocriptine
canagliflozin	INVOKANA
canagliflozin	Invokana
canagliflozin/metformin HCl	Invokamet
canagliflozin/metformin HCl	Invokamet XR
chlorpropamide	chlorpropamide
colesevelam HCl	WelChol
colesevelam HCl	colesevelam
dapagliflozin propanediol	Farxiga
dapagliflozin propanediol/metformin HCl	Xigduo XR
dulaglutide	Trulicity
empagliflozin	Jardiance
empagliflozin/metformin HCl	Synjardy
empagliflozin/metformin HCl	Synjardy XR
ertugliflozin pidolate	Steglatro
ertugliflozin pidolate/metformin HCl	Segluromet
exenatide	Byetta
exenatide microspheres	Bydureon
exenatide microspheres	Bydureon BCise
glimepiride	Amaryl
glimepiride	glimepiride
glipizide	Glucotrol
glipizide	Glucotrol XL
glipizide	glipizide
glipizide	glipizide (bulk)
glipizide/metformin HCl	glipizide-metformin
glyburide	Diabeta

Appendix E. List of Generic and Brand Names of Medical Products Used to Define Inclusion/Exclusion Criteria in this Request

Generic Name	Brand Name
glyburide	glyburide
glyburide	glyburide (bulk)
glyburide,micronized	Glynase
glyburide,micronized	glyburide micronized
glyburide/metformin HCl	Glucovance
glyburide/metformin HCl	glyburide-metformin
insulin degludec/liraglutide	Xultophy 100/3.6
insulin glargine and lixisenatide	Soliqua 100/33
insulin glargine,human recombinant analog/lixisenatide	Soliqua 100/33
linagliptin	Tradjenta
linagliptin/metformin HCl	Jentadueto
linagliptin/metformin HCl	Jentadueto XR
liraglutide	Saxenda
liraglutide	Victoza 2-Pak
liraglutide	Victoza 3-Pak
lixisenatide	Adlyxin
miglitol	Glyset
miglitol	miglitol
nateglinide	Starlix
nateglinide	nateglinide
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
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	saxagliptin
saxagliptin HCl/metformin HCl	Kombiglyze XR
saxagliptin HCl/metformin HCl	saxagliptin-metformin
semaglutide	Ozempic
semaglutide	Rybelsus
semaglutide	Wegovy
sotagliflozin	Inpefa
tirzepatide	Mounjaro
tirzepatide	Zepbound
tolazamide	tolazamide
tolbutamide	tolbutamide

Appendix F. List of Current Procedural Terminology, Fourth Edition (CPT-4), Current Procedural Terminology, Second Edition (CPT-2), Healthcare Common Procedure Coding System, Level II (HCPCS), International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM), International Classification of Diseases, Tenth Revision, Procedural Coding System (ICD-10-PCS), and Revenue (RE) Codes Used to Define Baseline Characteristics in this Request

Code	Description	Code Category	Code Type
	Any Chronic Kidney Disease		
585.1	Chronic kidney disease, Stage I	Diagnosis	ICD-9-CM
585.2	Chronic kidney disease, Stage II (mild)	Diagnosis	ICD-9-CM
585.3	Chronic kidney disease, Stage III (moderate)	Diagnosis	ICD-9-CM
585.4	Chronic kidney disease, Stage IV (severe)	Diagnosis	ICD-9-CM
585.5	Chronic kidney disease, Stage V	Diagnosis	ICD-9-CM
585.6	End stage renal disease	Diagnosis	ICD-9-CM
585.9	Chronic kidney disease, unspecified	Diagnosis	ICD-9-CM
N18.1	Chronic kidney disease, stage 1	Diagnosis	ICD-10-CM
N18.2	Chronic kidney disease, stage 2 (mild)	Diagnosis	ICD-10-CM
N18.3	Chronic kidney disease, stage 3 (moderate)	Diagnosis	ICD-10-CM
N18.30	Chronic kidney disease, stage 3 unspecified	Diagnosis	ICD-10-CM
N18.31	Chronic kidney disease, stage 3a	Diagnosis	ICD-10-CM
N18.32	Chronic kidney disease, stage 3b	Diagnosis	ICD-10-CM
N18.4	Chronic kidney disease, stage 4 (severe)	Diagnosis	ICD-10-CM
N18.5	Chronic kidney disease, stage 5	Diagnosis	ICD-10-CM
N18.6	End stage renal disease	Diagnosis	ICD-10-CM
N18.9	Chronic kidney disease, unspecified	Diagnosis	ICD-10-CM
	Chronic Kidney Disease Stage 4/5		
585.4	Chronic kidney disease, Stage IV (severe)	Diagnosis	ICD-9-CM
585.5	Chronic kidney disease, Stage V	Diagnosis	ICD-9-CM
N18.4	Chronic kidney disease, stage 4 (severe)	Diagnosis	ICD-10-CM
N18.5	Chronic kidney disease, stage 5	Diagnosis	ICD-10-CM
	Chronic Kidney Disease Stage 3		
585.3	Chronic kidney disease, Stage III (moderate)	Diagnosis	ICD-9-CM
N18.3	Chronic kidney disease, stage 3 (moderate)	Diagnosis	ICD-10-CM
N18.30	Chronic kidney disease, stage 3 unspecified	Diagnosis	ICD-10-CM
N18.31	Chronic kidney disease, stage 3a	Diagnosis	ICD-10-CM
N18.32	Chronic kidney disease, stage 3b	Diagnosis	ICD-10-CM
	Chronic Kidney Disease or Renal Failure		
583.6	Nephritis and nephropathy, not specified as acute or chronic, with lesion of renal cortical necrosis	Diagnosis	ICD-9-CM
583.7	Nephritis and nephropathy, not specified as acute or chronic, with lesion of renal medullary necrosis	Diagnosis	ICD-9-CM
584.5	Acute kidney failure with lesion of tubular necrosis	Diagnosis	ICD-9-CM
584.6	Acute kidney failure with lesion of renal cortical necrosis	Diagnosis	ICD-9-CM
584.7	Acute kidney failure with lesion of medullary [papillary] necrosis	Diagnosis	ICD-9-CM
584.8	Acute kidney failure with other specified pathological lesion in kidney	Diagnosis	ICD-9-CM
584.9	Acute kidney failure, unspecified	Diagnosis	ICD-9-CM
585.1	Chronic kidney disease, Stage I	Diagnosis	ICD-9-CM
585.2	Chronic kidney disease, Stage II (mild)	Diagnosis	ICD-9-CM
585.3	Chronic kidney disease, Stage III (moderate)	Diagnosis	ICD-9-CM
585.4	Chronic kidney disease, Stage IV (severe)	Diagnosis	ICD-9-CM
585.5	Chronic kidney disease, Stage V	Diagnosis	ICD-9-CM

Appendix F. List of Current Procedural Terminology, Fourth Edition (CPT-4), Current Procedural Terminology, Second Edition (CPT-2), Healthcare Common Procedure Coding System, Level II (HCPCS), International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM), International Classification of Diseases, Tenth Revision, Procedural Coding System (ICD-10-PCS), and Revenue (RE) Codes Used to Define Baseline Characteristics in this Request

Code	Description	Code Category	Code Type
585.6	End stage renal disease	Diagnosis	ICD-9-CM
585.9	Chronic kidney disease, unspecified	Diagnosis	ICD-9-CM
586	Unspecified renal failure	Diagnosis	ICD-9-CM
N17.0	Acute kidney failure with tubular necrosis	Diagnosis	ICD-10-CM
N17.1	Acute kidney failure with acute cortical necrosis	Diagnosis	ICD-10-CM
N17.2	Acute kidney failure with medullary necrosis	Diagnosis	ICD-10-CM
N17.8	Other acute kidney failure	Diagnosis	ICD-10-CM
N17.9	Acute kidney failure, unspecified	Diagnosis	ICD-10-CM
N18.1	Chronic kidney disease, stage 1	Diagnosis	ICD-10-CM
N18.2	Chronic kidney disease, stage 2 (mild)	Diagnosis	ICD-10-CM
N18.3	Chronic kidney disease, stage 3 (moderate)	Diagnosis	ICD-10-CM
N18.30	Chronic kidney disease, stage 3 unspecified	Diagnosis	ICD-10-CM
N18.31	Chronic kidney disease, stage 3a	Diagnosis	ICD-10-CM
N18.32	Chronic kidney disease, stage 3b	Diagnosis	ICD-10-CM
N18.4	Chronic kidney disease, stage 4 (severe)	Diagnosis	ICD-10-CM
N18.5	Chronic kidney disease, stage 5	Diagnosis	ICD-10-CM
N18.6	End stage renal disease	Diagnosis	ICD-10-CM
N18.9	Chronic kidney disease, unspecified	Diagnosis	ICD-10-CM
N19	Unspecified kidney failure	Diagnosis	ICD-10-CM
	Dialysis		
0505F	Hemodialysis plan of care documented (ESRD, P-ESRD)	Procedure	CPT-2
0507F	Peritoneal dialysis plan of care documented (ESRD)	Procedure	CPT-2
0800	Inpatient renal dialysis-general classification	Procedure	RE
0801	Inpatient renal dialysis-inpatient hemodialysis	Procedure	RE
0802	Inpatient renal dialysis-inpatient peritoneal (non-CAPD)	Procedure	RE
0803	Inpatient renal dialysis-inpatient CAPD	Procedure	RE
0804	Inpatient renal dialysis-inpatient CCPD	Procedure	RE
0809	Inpatient renal dialysis-other inpatient dialysis	Procedure	RE
0820	Hemodialysis OP or home dialysis-general classification	Procedure	RE
0821	Hemodialysis OP or home dialysis-hemodialysis-composite or other rate	Procedure	RE
0822	Hemodialysis OP or home dialysis-home supplies	Procedure	RE
0823	Hemodialysis OP or home dialysis-home equipment	Procedure	RE
0824	Hemodialysis OP or home dialysis-maintenance/100%	Procedure	RE
0825	Hemodialysis OP or home dialysis-support services	Procedure	RE
0829	Hemodialysis OP or home dialysis-other	Procedure	RE
0830	Peritoneal dialysis OP or home-general classification	Procedure	RE
0831	Peritoneal dialysis OP or home-peritoneal-composite or other rate	Procedure	RE
0832	Peritoneal dialysis OP or home-home supplies	Procedure	RE
0833	Peritoneal dialysis OP or home-home equipment	Procedure	RE
0834	Peritoneal dialysis OP or home-maintenance/100%	Procedure	RE
0835	Peritoneal dialysis OP or home-support services	Procedure	RE
0839	Peritoneal dialysis OP or home-other	Procedure	RE
0840	CAPD outpatient-general classification	Procedure	RE
0841	CAPD outpatient-CAPD/composite or other rate	Procedure	RE

Appendix F. List of Current Procedural Terminology, Fourth Edition (CPT-4), Current Procedural Terminology, Second Edition (CPT-2), Healthcare Common Procedure Coding System, Level II (HCPCS), International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM), International Classification of Diseases, Tenth Revision, Procedural Coding System (ICD-10-PCS), and Revenue (RE) Codes Used to Define Baseline Characteristics in this Request

Code	Description	Code Category	Code Type
0842	CAPD outpatient-home supplies	Procedure	RE
0843	CAPD outpatient-home equipment	Procedure	RE
0844	CAPD outpatient-maintenance/100%	Procedure	RE
0845	CAPD outpatient-support services	Procedure	RE
0849	CAPD outpatient-other	Procedure	RE
0850	CCPD outpatient-general classification	Procedure	RE
0851	CCPD outpatient-CCPD/composite or other rate	Procedure	RE
0852	CCPD outpatient-home supplies	Procedure	RE
0853	CCPD outpatient-home equipment	Procedure	RE
0854	CCPD outpatient-maintenance/100%	Procedure	RE
0855	CCPD outpatient-support services	Procedure	RE
0859	CCPD outpatient-other	Procedure	RE
0880	Miscellaneous dialysis-general classification	Procedure	RE
0881	Miscellaneous dialysis-ultrafiltration	Procedure	RE
0882	Miscellaneous dialysis-home dialysis aide visit (eff 9/93)	Procedure	RE
0889	Miscellaneous dialysis-other	Procedure	RE
39.95	Hemodialysis	Procedure	ICD-9-CM
3E1M39Z	Irrigation of Peritoneal Cavity using Dialysate, Percutaneous Approach	Procedure	ICD-10-PCS
4052F	Hemodialysis via functioning arteriovenous (AV) fistula (ESRD)	Procedure	CPT-2
4053F	Hemodialysis via functioning arteriovenous (AV) graft (ESRD)	Procedure	CPT-2
4054F	Hemodialysis via catheter (ESRD)	Procedure	CPT-2
4055F	Patient receiving peritoneal dialysis (ESRD)	Procedure	CPT-2
458.21	Hypotension of hemodialysis	Diagnosis	ICD-9-CM
54.98	Peritoneal dialysis	Procedure	ICD-9-CM
75791	Angiography, arteriovenous shunt (eg, dialysis patient fistula/graft), complete evaluation of dialysis access, including fluoroscopy, image documentation and report (includes injections of contrast and all necessary imaging from the arterial anastomosis and adjacent artery through entire venous outflow including the inferior or superior vena cava), radiological supervision and interpretation	Procedure	CPT-4
792.5	Cloudy (hemodialysis) (peritoneal) dialysis affluent	Diagnosis	ICD-9-CM
90935	Hemodialysis procedure with single evaluation by a physician or other qualified health care professional	Procedure	CPT-4
90937	Hemodialysis procedure requiring repeated evaluation(s) with or without substantial revision of dialysis prescription	Procedure	CPT-4
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	Procedure	CPT-4
90940	Hemodialysis access flow study to determine blood flow in grafts and arteriovenous fistulae by an indicator method	Procedure	CPT-4
90941	Hemodialysis, For Acute Renal Failure And Or Intoxication,	Procedure	CPT-4
90942	Hemodialysis, For Acute Renal Failure And Or Intoxication,	Procedure	CPT-4
90943	Hemodialysis, For Acute Renal Failure And Or Intoxication,	Procedure	CPT-4
90944	Hemodialysis, For Acute Renal Failure And Or Intoxication,	Procedure	CPT-4

Appendix F. List of Current Procedural Terminology, Fourth Edition (CPT-4), Current Procedural Terminology, Second Edition (CPT-2), Healthcare Common Procedure Coding System, Level II (HCPCS), International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM), International Classification of Diseases, Tenth Revision, Procedural Coding System (ICD-10-PCS), and Revenue (RE) Codes Used to Define Baseline Characteristics in this Request

Code	Description	Code Category	Code Type
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	Procedure	CPT-4
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	Procedure	CPT-4
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	Procedure	CPT-4
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	Procedure	CPT-4
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	Procedure	CPT-4
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	Procedure	CPT-4
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	Procedure	CPT-4
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	Procedure	CPT-4
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	Procedure	CPT-4
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	Procedure	CPT-4
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	Procedure	CPT-4

Appendix F. List of Current Procedural Terminology, Fourth Edition (CPT-4), Current Procedural Terminology, Second Edition (CPT-2), Healthcare Common Procedure Coding System, Level II (HCPCS), International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM), International Classification of Diseases, Tenth Revision, Procedural Coding System (ICD-10-PCS), and Revenue (RE) Codes Used to Define Baseline Characteristics in this Request

Code	Description	Code Category	Code Type
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	Procedure	CPT-4
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	Procedure	CPT-4
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	Procedure	CPT-4
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	Procedure	CPT-4
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	Procedure	CPT-4
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	Procedure	CPT-4
90966	End-stage renal disease (ESRD) related services for home dialysis per full month, for patients 20 years of age and older	Procedure	CPT-4
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	Procedure	CPT-4
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	Procedure	CPT-4
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	Procedure	CPT-4
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	Procedure	CPT-4
90976	Peritoneal Dialysis For End-stage Renal Disease (esrd),	Procedure	CPT-4
90977	Peritoneal Dialysis For End-stage Renal Disease (esrd),	Procedure	CPT-4
90978	Peritoneal Dialysis For End-stage Renal Disease (esrd),	Procedure	CPT-4
90979	Peritoneal Dialysis For End-stage Renal Disease (esrd),	Procedure	CPT-4
90982	Peritoneal Dialysis For End-stage Renal Disease (esrd),	Procedure	CPT-4
90983	Peritoneal Dialysis For End-stage Renal Disease (esrd),	Procedure	CPT-4
90984	Peritoneal Dialysis For End-stage Renal Disease (esrd),	Procedure	CPT-4
90985	Peritoneal Dialysis For End-stage Renal Disease (esrd),	Procedure	CPT-4
90988	Supervision Of Hemodialysis In Hospital Or Other Facility (excluding Home Dialysis), On Monthly Basis	Procedure	CPT-4
90989	Dialysis training, patient, including helper where applicable, any mode, completed course	Procedure	CPT-4
90990	Hemodialysis Training And/or Counseling	Procedure	CPT-4
90991	Home Hemodialysis Care, Outpatient, For Those Services Either Provided By The Physician Primarily Responsible	Procedure	CPT-4
90992	Peritoneal Dialysis Training And/or Counseling	Procedure	CPT-4

Appendix F. List of Current Procedural Terminology, Fourth Edition (CPT-4), Current Procedural Terminology, Second Edition (CPT-2), Healthcare Common Procedure Coding System, Level II (HCPCS), International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM), International Classification of Diseases, Tenth Revision, Procedural Coding System (ICD-10-PCS), and Revenue (RE) Codes Used to Define Baseline Characteristics in this Request

Code	Description	Code Category	Code Type
90993	Dialysis training, patient, including helper where applicable, any mode, course not completed, per training session	Procedure	CPT-4
90994	Supervision Of Chronic Ambulatory Peritoneal Dialysis (capd), Home Or Out-patient (monthly)	Procedure	CPT-4
90995	End Stage Renal Disease (esrd) Related Services, Per Full Month	Procedure	CPT-4
90996	Continuous Arteriovenous Hemofiltration (cavh) (per Day)	Procedure	CPT-4
90998	End Stage Renal Disease (esrd) Related Services (less Than Full Month), Per Day	Procedure	CPT-4
90999	Unlisted dialysis procedure, inpatient or outpatient	Procedure	CPT-4
99512	Home visit for hemodialysis	Procedure	CPT-4
99559	Home infusion of peritoneal dialysis, per visit	Procedure	CPT-4
996.56	Mechanical complications due to peritoneal dialysis catheter	Diagnosis	ICD-9-CM
996.68	Infection and inflammatory reaction due to peritoneal dialysis catheter	Diagnosis	ICD-9-CM
996.73	Other complications due to renal dialysis device, implant, and graft	Diagnosis	ICD-9-CM
A4655	Needles and syringes for dialysis	Procedure	HCPCS
A4663	Blood pressure cuff only	Procedure	HCPCS
A4672	Drainage extension line, sterile, for dialysis, each	Procedure	HCPCS
A4690	Dialyzer (artificial kidneys), all types, all sizes, for hemodialysis, each	Procedure	HCPCS
A4700	Standard dialysate solution, each	Procedure	HCPCS
A4705	Bicarbonate dialysate solution, each	Procedure	HCPCS
A4720	Dialysate solution, any concentration of dextrose, fluid volume greater than 249 cc, but less than or equal to 999 cc, for peritoneal dialysis	Procedure	HCPCS
A4721	Dialysate solution, any concentration of dextrose, fluid volume greater than 999 cc but less than or equal to 1999 cc, for peritoneal dialysis	Procedure	HCPCS
A4722	Dialysate solution, any concentration of dextrose, fluid volume greater than 1999 cc but less than or equal to 2999 cc, for peritoneal dialysis	Procedure	HCPCS
A4723	Dialysate solution, any concentration of dextrose, fluid volume greater than 2999 cc but less than or equal to 3999 cc, for peritoneal dialysis	Procedure	HCPCS
A4724	Dialysate solution, any concentration of dextrose, fluid volume greater than 3999 cc but less than or equal to 4999 cc, for peritoneal dialysis	Procedure	HCPCS
A4725	Dialysate solution, any concentration of dextrose, fluid volume greater than 4999 cc but less than or equal to 5999 cc, for peritoneal dialysis	Procedure	HCPCS
A4726	Dialysate solution, any concentration of dextrose, fluid volume greater than 5999 cc, for peritoneal dialysis	Procedure	HCPCS
A4728	Dialysate solution, nondextrose containing, 500 ml	Procedure	HCPCS
A4760	Dialysate solution test kit, for peritoneal dialysis, any type, each	Procedure	HCPCS
A4765	Dialysate concentrate, powder, additive for peritoneal dialysis, per packet	Procedure	HCPCS
A4766	Dialysate concentrate, solution, additive for peritoneal dialysis, per 10 ml	Procedure	HCPCS
A4780	Sterilizing agent for dialysis equipment, per gallon	Procedure	HCPCS
A4790	Cleansing agents for equipment for dialysis only	Procedure	HCPCS
A4800	Heparin for dialysis and antidote, any strength, porcine or beef, up to 1000 units, 10-30 ml (for parenteral use see b4216)	Procedure	HCPCS
A4820	Hemodialysis kit supplies	Procedure	HCPCS
A4910	Non-medical supplies for dialysis, (i.e., scale, scissors, stopwatch, etc.)	Procedure	HCPCS
A4913	Miscellaneous dialysis supplies, not otherwise specified	Procedure	HCPCS

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Code	Description	Code Category	Code Type
A4919	Dialyzer holder, each	Procedure	HCPCS
A4929	Tourniquet for dialysis, each	Procedure	HCPCS
B50W0ZZ	Plain Radiography of Dialysis Shunt/Fistula using High Osmolar Contrast	Procedure	ICD-10-PCS
B50W1ZZ	Plain Radiography of Dialysis Shunt/Fistula using Low Osmolar Contrast	Procedure	ICD-10-PCS
B50WYZZ	Plain Radiography of Dialysis Shunt/Fistula using Other Contrast	Procedure	ICD-10-PCS
B51W0ZA	Fluoroscopy of Dialysis Shunt/Fistula using High Osmolar Contrast, Guidance	Procedure	ICD-10-PCS
B51W0ZZ	Fluoroscopy of Dialysis Shunt/Fistula using High Osmolar Contrast	Procedure	ICD-10-PCS
B51W1ZA	Fluoroscopy of Dialysis Shunt/Fistula using Low Osmolar Contrast, Guidance	Procedure	ICD-10-PCS
B51W1ZZ	Fluoroscopy of Dialysis Shunt/Fistula using Low Osmolar Contrast	Procedure	ICD-10-PCS
B51WYZA	Fluoroscopy of Dialysis Shunt/Fistula using Other Contrast, Guidance	Procedure	ICD-10-PCS
B51WYZZ	Fluoroscopy of Dialysis Shunt/Fistula using Other Contrast	Procedure	ICD-10-PCS
B51WZZA	Fluoroscopy of Dialysis Shunt/Fistula, Guidance	Procedure	ICD-10-PCS
B51WZZZ	Fluoroscopy of Dialysis Shunt/Fistula	Procedure	ICD-10-PCS
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	Procedure	HCPCS
C1750	Catheter, hemodialysis/peritoneal, long-term	Procedure	HCPCS
C1752	Catheter, hemodialysis/peritoneal, short-term	Procedure	HCPCS
C1881	Dialysis access system (implantable)	Procedure	HCPCS
E1510	Kidney, dialysate delivery system kidney machine, pump recirculating, air removal system, flowrate meter, power off, heater and temperature control with alarm, IV poles, pressure gauge, concentrate container	Procedure	HCPCS
E1570	Adjustable chair, for ESRD patients	Procedure	HCPCS
E1590	Hemodialysis machine	Procedure	HCPCS
E1592	Automatic intermittent peritoneal dialysis system	Procedure	HCPCS
E1594	Cycler dialysis machine for peritoneal dialysis	Procedure	HCPCS
E1632	Wearable artificial kidney, each	Procedure	HCPCS
E1634	Peritoneal dialysis clamps, each	Procedure	HCPCS
E1635	Compact (portable) travel hemodialyzer system	Procedure	HCPCS
E1637	Hemostats, each	Procedure	HCPCS
E1638	Heating pad, for peritoneal dialysis, any size, each	Procedure	HCPCS
E1639	Scale, each	Procedure	HCPCS
E1699	Dialysis equipment, not otherwise specified	Procedure	HCPCS
E872.2	Failure of sterile precautions during kidney dialysis and other perfusion	Diagnosis	ICD-9-CM
E879.1	Kidney dialysis as the cause of abnormal reaction of patient, or of later complication, without mention of misadventure at time of procedure	Diagnosis	ICD-9-CM
G0257	Unscheduled or emergency dialysis treatment for an ESRD patient in a hospital outpatient department that is not certified as an ESRD facility	Procedure	HCPCS
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	Procedure	HCPCS

Appendix F. List of Current Procedural Terminology, Fourth Edition (CPT-4), Current Procedural Terminology, Second Edition (CPT-2), Healthcare Common Procedure Coding System, Level II (HCPCS), International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM), International Classification of Diseases, Tenth Revision, Procedural Coding System (ICD-10-PCS), and Revenue (RE) Codes Used to Define Baseline Characteristics in this Request

Code	Description	Code Category	Code Type
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	Procedure	HCPCS
G0323	End Stage Renal disease (ESRD) related services for home dialysis patients per full month; for patients 20 years of age and older	Procedure	HCPCS
G0324	ESRD related services for home dialysis (less than full month), per day; for patients under 2 years of age	Procedure	HCPCS
G0325	ESRD related services for home dialysis (less than full month), per day; for patients between 2 and 11 years of age	Procedure	HCPCS
G0326	ESRD related services for home dialysis (less than full month), per day; for patients between twelve and nineteen years of age	Procedure	HCPCS
G0327	ESRD related services for home dialysis (less than full month), per day; for patients twenty years of age and over	Procedure	HCPCS
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)	Procedure	HCPCS
G8076	ESRD patient with documented dialysis dose of URR less than 65% (or Kt/V less than 1.2)	Procedure	HCPCS
G8081	ESRD patient requiring hemodialysis vascular access documented to have received autogenous AV fistula	Procedure	HCPCS
G8082	ESRD patient requiring hemodialysis documented to have received vascular access other than autogenous AV fistula	Procedure	HCPCS
G8085	ESRD patient requiring hemodialysis vascular access was not an eligible candidate for autogenous AV fistula	Procedure	HCPCS
G8714	Hemodialysis treatment performed exactly 3 times per week > 90 days	Procedure	HCPCS
G8715	Hemodialysis treatment performed less than 3 times per week or greater than 3 times per week	Procedure	HCPCS
G8727	Patient receiving hemodialysis, peritoneal dialysis or kidney transplantation	Procedure	HCPCS
G9231	Documentation of end stage renal disease (ESRD), dialysis, renal transplant before or during the measurement period or pregnancy during the measurement period	Procedure	HCPCS
I95.3	Hypotension of hemodialysis	Diagnosis	ICD-10-CM
J0882	Injection, darbepoetin alfa, 1 mcg (for ESRD on dialysis)	Procedure	HCPCS
J0886	Injection, epoetin alfa, 1000 units (for ESRD on dialysis)	Procedure	HCPCS
J0887	Injection, epoetin beta, 1 mcg, (for ESRD on dialysis)	Procedure	HCPCS
K0610	Peritoneal dialysis clamp, each	Procedure	HCPCS
K0612	Drainage extension line, sterile, for dialysis, each	Procedure	HCPCS
Q0139	Injection, ferumoxytol, for treatment of iron deficiency anemia, 1 mg (for ESRD on dialysis)	Procedure	HCPCS
Q4054	Injection, darbepoetin alfa, 1 mcg (for ESRD on dialysis)	Procedure	HCPCS
Q4055	Injection, epoetin alfa, 1000 units (for ESRD on dialysis)	Procedure	HCPCS
Q4081	Injection, epoetin alfa, 100 units (for ESRD on dialysis)	Procedure	HCPCS
Q9972	Injection, epoetin beta, 1 microgram, (for ESRD on dialysis)	Procedure	HCPCS
R88.0	Cloudy (hemodialysis) (peritoneal) dialysis effluent	Diagnosis	ICD-10-CM

Appendix F. List of Current Procedural Terminology, Fourth Edition (CPT-4), Current Procedural Terminology, Second Edition (CPT-2), Healthcare Common Procedure Coding System, Level II (HCPCS), International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM), International Classification of Diseases, Tenth Revision, Procedural Coding System (ICD-10-PCS), and Revenue (RE) Codes Used to Define Baseline Characteristics in this Request

Code	Description	Code Category	Code Type
S9335	Home therapy, hemodialysis; administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing services coded separately), per diem	Procedure	HCPCS
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	Procedure	HCPCS
T81.502	Unspecified complication of foreign body accidentally left in body following kidney dialysis	Diagnosis	ICD-10-CM
T81.502A	Unspecified complication of foreign body accidentally left in body following kidney dialysis, initial encounter	Diagnosis	ICD-10-CM
T81.502D	Unspecified complication of foreign body accidentally left in body following kidney dialysis, subsequent encounter	Diagnosis	ICD-10-CM
T81.502S	Unspecified complication of foreign body accidentally left in body following kidney dialysis, sequela	Diagnosis	ICD-10-CM
T81.512	Adhesions due to foreign body accidentally left in body following kidney dialysis	Diagnosis	ICD-10-CM
T81.512A	Adhesions due to foreign body accidentally left in body following kidney dialysis, initial encounter	Diagnosis	ICD-10-CM
T81.512D	Adhesions due to foreign body accidentally left in body following kidney dialysis, subsequent encounter	Diagnosis	ICD-10-CM
T81.512S	Adhesions due to foreign body accidentally left in body following kidney dialysis, sequela	Diagnosis	ICD-10-CM
T81.522	Obstruction due to foreign body accidentally left in body following kidney dialysis	Diagnosis	ICD-10-CM
T81.522A	Obstruction due to foreign body accidentally left in body following kidney dialysis, initial encounter	Diagnosis	ICD-10-CM
T81.522D	Obstruction due to foreign body accidentally left in body following kidney dialysis, subsequent encounter	Diagnosis	ICD-10-CM
T81.522S	Obstruction due to foreign body accidentally left in body following kidney dialysis, sequela	Diagnosis	ICD-10-CM
T81.532	Perforation due to foreign body accidentally left in body following kidney dialysis	Diagnosis	ICD-10-CM
T81.532A	Perforation due to foreign body accidentally left in body following kidney dialysis, initial encounter	Diagnosis	ICD-10-CM
T81.532D	Perforation due to foreign body accidentally left in body following kidney dialysis, subsequent encounter	Diagnosis	ICD-10-CM
T81.532S	Perforation due to foreign body accidentally left in body following kidney dialysis, sequela	Diagnosis	ICD-10-CM
T81.592	Other complications of foreign body accidentally left in body following kidney dialysis	Diagnosis	ICD-10-CM
T81.592A	Other complications of foreign body accidentally left in body following kidney dialysis, initial encounter	Diagnosis	ICD-10-CM
T81.592D	Other complications of foreign body accidentally left in body following kidney dialysis, subsequent encounter	Diagnosis	ICD-10-CM
T81.592S	Other complications of foreign body accidentally left in body following kidney dialysis, sequela	Diagnosis	ICD-10-CM
T82.41XA	Breakdown (mechanical) of vascular dialysis catheter, initial encounter	Diagnosis	ICD-10-CM

Appendix F. List of Current Procedural Terminology, Fourth Edition (CPT-4), Current Procedural Terminology, Second Edition (CPT-2), Healthcare Common Procedure Coding System, Level II (HCPCS), International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM), International Classification of Diseases, Tenth Revision, Procedural Coding System (ICD-10-PCS), and Revenue (RE) Codes Used to Define Baseline Characteristics in this Request

Code	Description	Code Category	Code Type
T82.41XD	Breakdown (mechanical) of vascular dialysis catheter, subsequent encounter	Diagnosis	ICD-10-CM
T82.41XS	Breakdown (mechanical) of vascular dialysis catheter, sequela	Diagnosis	ICD-10-CM
T82.42XA	Displacement of vascular dialysis catheter, initial encounter	Diagnosis	ICD-10-CM
T82.42XD	Displacement of vascular dialysis catheter, subsequent encounter	Diagnosis	ICD-10-CM
T82.42XS	Displacement of vascular dialysis catheter, sequela	Diagnosis	ICD-10-CM
T82.43XA	Leakage of vascular dialysis catheter, initial encounter	Diagnosis	ICD-10-CM
T82.43XD	Leakage of vascular dialysis catheter, subsequent encounter	Diagnosis	ICD-10-CM
T82.43XS	Leakage of vascular dialysis catheter, sequela	Diagnosis	ICD-10-CM
T82.49XA	Other complication of vascular dialysis catheter, initial encounter	Diagnosis	ICD-10-CM
T82.49XD	Other complication of vascular dialysis catheter, subsequent encounter	Diagnosis	ICD-10-CM
T82.49XS	Other complication of vascular dialysis catheter, sequela	Diagnosis	ICD-10-CM
T85.611	Breakdown (mechanical) of intraperitoneal dialysis catheter	Diagnosis	ICD-10-CM
T85.611A	Breakdown (mechanical) of intraperitoneal dialysis catheter, initial encounter	Diagnosis	ICD-10-CM
T85.611D	Breakdown (mechanical) of intraperitoneal dialysis catheter, subsequent	Diagnosis	ICD-10-CM
T85.611S	Breakdown (mechanical) of intraperitoneal dialysis catheter, sequela	Diagnosis	ICD-10-CM
T85.621	Displacement of intraperitoneal dialysis catheter	Diagnosis	ICD-10-CM
T85.621A	Displacement of intraperitoneal dialysis catheter, initial encounter	Diagnosis	ICD-10-CM
T85.621D	Displacement of intraperitoneal dialysis catheter, subsequent encounter	Diagnosis	ICD-10-CM
T85.621S	Displacement of intraperitoneal dialysis catheter, sequela	Diagnosis	ICD-10-CM
T85.631	Leakage of intraperitoneal dialysis catheter	Diagnosis	ICD-10-CM
T85.631A	Leakage of intraperitoneal dialysis catheter, initial encounter	Diagnosis	ICD-10-CM
T85.631D	Leakage of intraperitoneal dialysis catheter, subsequent encounter	Diagnosis	ICD-10-CM
T85.631S	Leakage of intraperitoneal dialysis catheter, sequela	Diagnosis	ICD-10-CM
T85.691	Other mechanical complication of intraperitoneal dialysis catheter	Diagnosis	ICD-10-CM
T85.691A	Other mechanical complication of intraperitoneal dialysis catheter, initial encounter	Diagnosis	ICD-10-CM
T85.691D	Other mechanical complication of intraperitoneal dialysis catheter, subsequent encounter	Diagnosis	ICD-10-CM
T85.691S	Other mechanical complication of intraperitoneal dialysis catheter, sequela	Diagnosis	ICD-10-CM
T85.71XA	Infection and inflammatory reaction due to peritoneal dialysis catheter, initial encounter	Diagnosis	ICD-10-CM
T85.71XD	Infection and inflammatory reaction due to peritoneal dialysis catheter, subsequent encounter	Diagnosis	ICD-10-CM
T85.71XS	Infection and inflammatory reaction due to peritoneal dialysis catheter, sequela	Diagnosis	ICD-10-CM
V45.1	Renal dialysis status	Diagnosis	ICD-9-CM
V45.11	Renal dialysis status	Diagnosis	ICD-9-CM
V45.12	Noncompliance with renal dialysis	Diagnosis	ICD-9-CM
V56.0	Encounter for extracorporeal dialysis	Diagnosis	ICD-9-CM
V56.1	Fitting and adjustment of extracorporeal dialysis catheter	Diagnosis	ICD-9-CM
V56.2	Fitting and adjustment of peritoneal dialysis catheter	Diagnosis	ICD-9-CM
V56.3	Encounter for adequacy testing for dialysis	Diagnosis	ICD-9-CM
V56.31	Encounter for adequacy testing for hemodialysis	Diagnosis	ICD-9-CM
V56.32	Encounter for adequacy testing for peritoneal dialysis	Diagnosis	ICD-9-CM
V56.8	Encounter other dialysis	Diagnosis	ICD-9-CM

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Code	Description	Code Category	Code Type
Y62.2	Failure of sterile precautions during kidney dialysis and other perfusion	Diagnosis	ICD-10-CM
Y84.1	Kidney dialysis as the cause of abnormal reaction of the patient, or of later complication, without mention of misadventure at the time of the procedure	Diagnosis	ICD-10-CM
Z49.01	Encounter for fitting and adjustment of extracorporeal dialysis catheter	Diagnosis	ICD-10-CM
Z49.02	Encounter for fitting and adjustment of peritoneal dialysis catheter	Diagnosis	ICD-10-CM
Z49.31	Encounter for adequacy testing for hemodialysis	Diagnosis	ICD-10-CM
Z49.32	Encounter for adequacy testing for peritoneal dialysis	Diagnosis	ICD-10-CM
Z91.15	Patient's noncompliance with renal dialysis	Diagnosis	ICD-10-CM
Z94.0	Kidney transplant status	Diagnosis	ICD-10-CM
Z99.2	Dependence on renal dialysis	Diagnosis	ICD-10-CM
	Chronic Kidney Disease Treatment		
C1774	Injection, darbepoetin alfa (for non esrd use), per 1 mcg	Procedure	HCPCS
J0635	Injection, calcitriol, 1 mcg amp.	Procedure	HCPCS
J0636	Injection, calcitriol, 0.1 mcg	Procedure	HCPCS
J0880	Injection, darbepoetin alfa, 5 mcg	Procedure	HCPCS
J0881	Injection, darbepoetin alfa, 1 mcg (non-ESRD use)	Procedure	HCPCS
J0882	Injection, darbepoetin alfa, 1 mcg (for ESRD on dialysis)	Procedure	HCPCS
J0885	Injection, epoetin alfa, (for non-ESRD use), 1000 units	Procedure	HCPCS
J0886	Injection, epoetin alfa, 1000 units (for ESRD on dialysis)	Procedure	HCPCS
Q0137	Injection, darbepoetin alfa, 1 mcg (non-ESRD use)	Procedure	HCPCS
Q4054	Injection, darbepoetin alfa, 1 mcg (for ESRD on dialysis)	Procedure	HCPCS
Q4055	Injection, epoetin alfa, 1000 units (for ESRD on dialysis)	Procedure	HCPCS
Q4081	Injection, epoetin alfa, 100 units (for ESRD on dialysis)	Procedure	HCPCS
Q5105	Injection, epoetin alfa-epbx, biosimilar, (Retacrit) (for ESRD on dialysis), 100 units	Procedure	HCPCS
Q5106	Injection, epoetin alfa-epbx, biosimilar, (Retacrit) (for non-ESRD use), 1000 units	Procedure	HCPCS
S0112	INJECTION, DARBEPOETIN ALFA, 1 MCG	Procedure	HCPCS
S0169	Calcitriol, 0.25 mcg	Procedure	HCPCS
	Diabetic Ketoacidosis		
250.10	Diabetes with ketoacidosis, type II or unspecified type, not stated as uncontrolled	Diagnosis	ICD-9-CM
250.11	Diabetes with ketoacidosis, type I [juvenile type], not stated as uncontrolled	Diagnosis	ICD-9-CM
250.12	Diabetes with ketoacidosis, type II or unspecified type, uncontrolled	Diagnosis	ICD-9-CM
250.13	Diabetes with ketoacidosis, type I [juvenile type], uncontrolled	Diagnosis	ICD-9-CM
E10.10	Type 1 diabetes mellitus with ketoacidosis without coma	Diagnosis	ICD-10-CM
E10.11	Type 1 diabetes mellitus with ketoacidosis with coma	Diagnosis	ICD-10-CM
E11.10	Type 2 diabetes mellitus with ketoacidosis without coma	Diagnosis	ICD-10-CM
E11.11	Type 2 diabetes mellitus with ketoacidosis with coma	Diagnosis	ICD-10-CM
E13.10	Other specified diabetes mellitus with ketoacidosis without coma	Diagnosis	ICD-10-CM
E13.11	Other specified diabetes mellitus with ketoacidosis with coma	Diagnosis	ICD-10-CM
	Long/Intermediate-Acting Insulin		
S5552	Insulin, intermediate acting (NPH or LENTE); 5 units	Procedure	HCPCS
S5553	Insulin, long acting; 5 units	Procedure	HCPCS
	Short/Rapid-Acting Insulin		
S5550	Insulin, rapid onset, 5 units	Procedure	HCPCS
S5551	Insulin, most rapid onset (Lispro or Aspart); 5 units	Procedure	HCPCS

Appendix F. List of Current Procedural Terminology, Fourth Edition (CPT-4), Current Procedural Terminology, Second Edition (CPT-2), Healthcare Common Procedure Coding System, Level II (HCPCS), International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM), International Classification of Diseases, Tenth Revision, Procedural Coding System (ICD-10-PCS), and Revenue (RE) Codes Used to Define Baseline Characteristics in this Request

Code	Description	Code Category	Code Type
	Insulin Pump		
A4225	Supplies for external insulin infusion pump, syringe type cartridge, sterile, each	Procedure	HCPCS
A4230	Infusion set for external insulin pump, nonneedle cannula type	Procedure	HCPCS
A4231	Infusion set for external insulin pump, needle type	Procedure	HCPCS
A4232	Syringe with needle for external insulin pump, sterile, 3 cc	Procedure	HCPCS
E0784	External ambulatory infusion pump, insulin	Procedure	HCPCS
J1811	Insulin (Fiasp) for administration through DME (i.e., insulin pump) per 50 units	Procedure	HCPCS
J1813	Insulin (Lyumjev) for administration through DME (i.e., insulin pump) per 50 units	Procedure	HCPCS
J1817	Insulin for administration through DME (i.e., insulin pump) per 50 units	Procedure	HCPCS
S1034	Artificial pancreas device system (e.g., low glucose suspend [LGS] feature) including continuous glucose monitor, blood glucose device, insulin pump and computer algorithm that communicates with all of the devices	Procedure	HCPCS
S5565	Insulin cartridge for use in insulin delivery device other than pump; 150 units	Procedure	HCPCS
S5566	Insulin cartridge for use in insulin delivery device other than pump; 300 units	Procedure	HCPCS
S9145	Insulin pump initiation, instruction in initial use of pump (pump not included)	Procedure	HCPCS

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

Generic Name	Brand Name
Chronic Kidney Disease Treatment	
calcium acetate	Eliphos
calcium acetate	PhosLo
calcium acetate	Phoslyra
calcium acetate	calcium acetate(phosphat bind)
calcium carbonate/magnesium carbonate	Antacid Extra-Strength
calcium carbonate/magnesium carbonate	Cidatrine-TM
calcium carbonate/magnesium carbonate	MagneBind 300
calcium carbonate/magnesium carbonate	Magnebind 400
calcium carbonate/magnesium carbonate	Sintra-ES
darbepoetin alfa in polysorbate 80	Aranesp (in polysorbate)
epoetin alfa	Epogen
epoetin alfa	Procrit
epoetin alfa-epbx	Retacrit
lanthanum carbonate	Fosrenol
lanthanum carbonate	lanthanum
methoxy polyethylene glycol-epoetin beta	Mircera
potassium bicarbonate/sodium bicarbonate/citric acid	Alka-Seltzer Gold
sevelamer HCl	Renagel
sevelamer HCl	sevelamer HCl
sevelamer carbonate	Renvela
sevelamer carbonate	sevelamer carbonate
simethicone/sodium bicarbonate/citric acid	E-Z-Gas II
sodium bicarbonate	sodium bicarbonate
sodium bicarbonate/citric acid	Alka-Seltzer Heartburn
sodium bicarbonate/citric acid	Citrocarbonate Antacid
sucroferric oxyhydroxide	Velphoro
Metformin	
alogliptin benzoate/metformin HCl	Kazano
alogliptin benzoate/metformin HCl	alogliptin-metformin
canagliflozin/metformin HCl	Invokamet
canagliflozin/metformin HCl	Invokamet XR
dapagliflozin propanediol/metformin HCl	Xigduo XR
dapagliflozin propanediol/metformin HCl	dapaglifloz propaned-metformin
empagliflozin/linagliptin/metformin HCl	Trijardy XR
empagliflozin/metformin HCl	Synjardy
empagliflozin/metformin HCl	Synjardy XR
ertugliflozin pidolate/metformin HCl	Segluromet
glipizide/metformin HCl	glipizide-metformin
glyburide/metformin HCl	Glucovance
glyburide/metformin HCl	glyburide-metformin
linagliptin/metformin HCl	Jentadueto
linagliptin/metformin HCl	Jentadueto XR
metformin HCl	Fortamet
metformin HCl	Glucophage
metformin HCl	Glucophage XR
metformin HCl	Glumetza
metformin HCl	Riomet

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

Generic Name	Brand Name
metformin HCl	Riomet ER
metformin HCl	metformin
metformin HCl/blood sugar diagnostic	DM2
pioglitazone HCl/metformin HCl	Actoplus MET
pioglitazone HCl/metformin HCl	Actoplus Met XR
pioglitazone HCl/metformin HCl	pioglitazone-metformin
repaglinide/metformin HCl	Prandimet
repaglinide/metformin HCl	repaglinide-metformin
rosiglitazone maleate/metformin HCl	Avandamet
saxagliptin HCl/metformin HCl	Kombiglyze XR
saxagliptin HCl/metformin HCl	saxagliptin-metformin
sitagliptin phosphate/metformin HCl	Janumet
sitagliptin phosphate/metformin HCl	Janumet XR
Sulfonylureas	
chlorpropamide	chlorpropamide
glimepiride	Amaryl
glimepiride	glimepiride
glipizide	Glucotrol
glipizide	Glucotrol XL
glipizide	glipizide
glipizide	glipizide (bulk)
glipizide/metformin HCl	glipizide-metformin
glyburide	Diabeta
glyburide	glyburide
glyburide	glyburide (bulk)
glyburide,micronized	Glynase
glyburide,micronized	glyburide micronized
glyburide/metformin HCl	Glucovance
glyburide/metformin HCl	glyburide-metformin
pioglitazone HCl/glimepiride	DUETACT
pioglitazone HCl/glimepiride	pioglitazone-glimepiride
rosiglitazone maleate/glimepiride	Avandaryl
tolazamide	tolazamide
tolbutamide	tolbutamide
Thiazolidinediones	
alogliptin benzoate/pioglitazone HCl	Oseni
alogliptin benzoate/pioglitazone HCl	alogliptin-pioglitazone
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
rosiglitazone maleate	Avandia
rosiglitazone maleate/glimepiride	Avandaryl
rosiglitazone maleate/metformin HCl	Avandamet

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

Generic Name	Brand Name
Alpha-Glucosidase Inhibitors	
acarbose	Precose
acarbose	acarbose
acarbose	acarbose (bulk)
miglitol	Glyset
miglitol	miglitol
Meglitinides	
nateglinide	Starlix
nateglinide	nateglinide
repaglinide	Prandin
repaglinide	repaglinide
repaglinide/metformin HCl	Prandimet
repaglinide/metformin HCl	repaglinide-metformin
Dipeptidyl Peptidase-4 (DPP-4) Inhibitors	
alogliptin benzoate	Nesina
alogliptin benzoate	alogliptin
alogliptin benzoate/metformin HCl	Kazano
alogliptin benzoate/metformin HCl	alogliptin-metformin
alogliptin benzoate/pioglitazone HCl	Oseni
alogliptin benzoate/pioglitazone HCl	alogliptin-pioglitazone
linagliptin	Tradjenta
linagliptin/metformin HCl	Jentadueto
linagliptin/metformin HCl	Jentadueto XR
saxagliptin HCl	Onglyza
saxagliptin HCl	saxagliptin
saxagliptin HCl/metformin HCl	Kombiglyze XR
saxagliptin HCl/metformin HCl	saxagliptin-metformin
Sodium-Glucose Cotransporter-2 (SGLT-2) Inhibitors	
bexagliflozin	Brenzavvy
bexagliflozin	bexagliflozin
canagliflozin	INVOKANA
canagliflozin	Invokana
canagliflozin/metformin HCl	Invokamet
canagliflozin/metformin HCl	Invokamet XR
dapagliflozin propanediol	Farxiga
dapagliflozin propanediol/metformin HCl	Xigduo XR
empagliflozin	Jardiance
empagliflozin/metformin HCl	Synjardy
empagliflozin/metformin HCl	Synjardy XR
ertugliflozin pidolate	Steglatro
ertugliflozin pidolate/metformin HCl	Segluromet
sotagliflozin	Inpefa
Glucagon-Like Peptide-1 Receptor Agonists (GLP-1 RAs)	
albiglutide	Tanzeum
dulaglutide	Trulicity
exenatide	Byetta
exenatide microspheres	Bydureon
exenatide microspheres	Bydureon BCise

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

Generic Name	Brand Name
insulin degludec/liraglutide	Xultophy 100/3.6
insulin glargine and lixisenatide	Soliqua 100/33
insulin glargine,human recombinant analog/lixisenatide	Soliqua 100/33
liraglutide	Saxenda
liraglutide	Victoza 2-Pak
liraglutide	Victoza 3-Pak
lixisenatide	Adlyxin
semaglutide	Ozempic
semaglutide	Rybelsus
semaglutide	Wegovy
tirzepatide	Mounjaro
tirzepatide	Zepbound
Other Antidiabetics	
bromocriptine mesylate	Cycloset
bromocriptine mesylate	Parlodel
bromocriptine mesylate	bromocriptine
colesevelam HCl	WelChol
colesevelam HCl	colesevelam
Long/Intermediate-Acting 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 FlexPen
insulin NPH human isophane	Novolin N NPH U-100 Insulin
insulin degludec	Tresiba FlexTouch U-100
insulin degludec	Tresiba FlexTouch U-200
insulin degludec	Tresiba U-100 Insulin
insulin degludec	insulin degludec
insulin degludec/liraglutide	Xultophy 100/3.6
insulin detemir	Levemir FlexPen
insulin detemir	Levemir FlexTouch U100 Insulin
insulin detemir	Levemir U-100 Insulin
insulin glargine,human recombinant analog	Basaglar KwikPen U-100 Insulin
insulin glargine,human recombinant analog	Basaglar Tempo Pen(U-100)Insln
insulin glargine,human recombinant analog	Lantus Solostar U-100 Insulin
insulin glargine,human recombinant analog	Lantus U-100 Insulin
insulin glargine,human recombinant analog	Semglee Pen U-100 Insulin
insulin glargine,human recombinant analog	Semglee 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	insulin glargine
insulin glargine,human recombinant analog	insulin glargine U-300 conc
insulin glargine,human recombinant analog/lixisenatide	Soliqua 100/33
insulin glargine-aglr	Rezvoglar KwikPen
insulin glargine-yfgn	Semglee(insulin glarg-yfgn)Pen
insulin glargine-yfgn	Semglee(insulin glargine-yfgn)
insulin glargine-yfgn	insulin glargine-yfgn

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

Generic Name	Brand Name
Short/Rapid-Acting Insulin	
insulin aspart	Novolog FlexPen U-100 Insulin
insulin aspart	Novolog PenFill U-100 Insulin
insulin aspart	Novolog U-100 Insulin aspart
insulin aspart	insulin aspart U-100
insulin aspart (niacinamide)	Fiasp FlexTouch U-100 Insulin
insulin aspart (niacinamide)	Fiasp Penfill U-100 Insulin
insulin aspart (niacinamide)	Fiasp U-100 Insulin
insulin aspart (niacinamide)/pump cartridge	Fiasp Pumpcart
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 Tempo Pen(U-100)Insuln
insulin lispro	Humalog U-100 Insulin
insulin lispro	insulin lispro
insulin lispro-aabc	Lyumjev KwikPen U-100 Insulin
insulin lispro-aabc	Lyumjev KwikPen U-200 Insulin
insulin lispro-aabc	Lyumjev Tempo Pen(U-100)Insuln
insulin lispro-aabc	Lyumjev U-100 Insulin
insulin regular, human	Afrezza
insulin regular, human	Humulin R Regular U-100 Insuln
insulin regular, human	Humulin R U-500 (Conc) Insulin
insulin regular, human	Humulin R U-500 (Conc) Kwikpen
insulin regular, human	Novolin R FlexPen
insulin regular, human	Novolin R Regular U100 Insulin
insulin regular, human in 0.9 % sodium chloride	Myxredlin
Combination Insulin	
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 FlexPen U-100
insulin NPH human isophane/insulin regular, human	Novolin 70/30 U-100 Insulin
insulin aspart protamine human/insulin aspart	Novolog Mix 70-30 U-100 Insuln
insulin aspart protamine human/insulin aspart	Novolog Mix 70-30FlexPen U-100
insulin aspart protamine human/insulin aspart	insulin asp prt-insulin aspart
insulin lispro protamine and insulin lispro	Humalog Mix 50-50 Insuln 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)Insuln
insulin lispro protamine and insulin lispro	insulin lispro protamin-lispro

Appendix H. Specifications Defining Parameters Used in this Request

This request executed the Cohort Identification and Descriptive Analysis (CIDA) tool [version 13.2.0] to estimate rates of diabetic ketoacidosis (DKA) among patients with sodium-glucose cotransporter-2 (SGLT-2) inhibitors or sitagliptin exposure and a history of diabetes in the Sentinel Distributed Database (SDD).

Query Period: March 1, 2013 - Most recently available data (February 29, 2024)
Coverage requirement: Medical & Drug Coverage
Pre-index enrollment requirement: 365 days
Post-index requirement: 0 days
Enrollment gap: 45 days
Age groups: <12, 12-18, 19-24, 25-44, 45-64, ≥65 years
Strata: Age, sex, year, chronic kidney disease (CKD) definition (covar 26, 27, 28, 29)
Restrictions: Male/Female sex
Envelope macro: Reclassify encounters during inpatient stay as inpatient
Freeze data: No

	Exposure									
Scenario	Index Exposure	Cohort Definition	Incident Exposure Washout Period	Incident with Respect to:	Exclude Evidence of Days Supply if Event Washout Includes Dispensings	Treatment Episode Gap Type	Treatment Episode Gap	Exposure Episode Extension Period	Maximum Exposure Episode Duration	Care Setting
1	SGLT-2 Inhibitors	**01:** Cohort includes only the first valid exposure episode during the query period	365	All study exposures of interest, SGLT-2 and sitagliptin (see exclusion)	No	**F:** Fixed episode gap.	10	10	365	n/a[1]
2	Sitagliptin	**01:** Cohort includes only the first valid exposure episode during the query period	365	All study exposures of interest, SGLT-2 and sitagliptin (see exclusion)	No	**F:** Fixed episode gap.	10	10	365	n/a

Appendix H. Specifications Defining Parameters Used in this Request										
	Exposure									
Scenario	Index Exposure	Cohort Definition	Incident Exposure Washout Period	Incident with Respect to:	Exclude Evidence of Days Supply if Event Washout Includes	Treatment Episode Gap Type	Treatment Episode Gap	Exposure Episode Extension Period	Maximum Exposure Episode Duration	Care Setting
3	SGLT-2 Inhibitors	**01:** Cohort includes only the first valid exposure episode during the query period	365	All study exposures of interest, SGLT-2 and sitagliptin (see exclusion)	No	**F:** Fixed episode gap.	10	10	365	n/a
4	Sitagliptin	**01:** Cohort includes only the first valid exposure episode during the query period	365	All study exposures of interest, SGLT-2 and sitagliptin (see exclusion)	No	**F:** Fixed episode gap.	10	10	365	n/a
5	SGLT-2 Inhibitors	**01:** Cohort includes only the first valid exposure episode during the query period	365	All study exposures of interest, SGLT-2 and sitagliptin (see exclusion)	No	**F:** Fixed episode gap.	10	10	365	n/a

Appendix H. Specifications Defining Parameters Used in this Request										
	Exposure									
Scenario	Index Exposure	Cohort Definition	Incident Exposure Washout Period	Incident with Respect to:	Exclude Evidence of Days Supply if Event Washout Includes	Treatment Episode Gap Type	Treatment Episode Gap	Exposure Episode Extension Period	Maximum Exposure Episode Duration	Care Setting
6	Sitagliptin	**01:** Cohort includes only the first valid exposure episode during the query period	365	All study exposures of interest, SGLT-2 and sitagliptin (see exclusion)	No	**F:** Fixed episode gap.	10	10	365	n/a
7	SGLT-2 Inhibitors	**01:** Cohort includes only the first valid exposure episode during the query period	365	All study exposures of interest, SGLT-2 and sitagliptin (see exclusion)	No	**F:** Fixed episode gap.	10	10	365	n/a
8	Sitagliptin	**01:** Cohort includes only the first valid exposure episode during the query period	365	All study exposures of interest, SGLT-2 and sitagliptin (see exclusion)	No	**F:** Fixed episode gap.	10	10	365	n/a

Appendix H. Specifications Defining Parameters Used in this Request										
	Exposure									
Scenario	Index Exposure	Cohort Definition	Incident Exposure Washout Period	Incident with Respect to:	Exclude Evidence of Days Supply if Event Washout Includes	Treatment Episode Gap Type	Treatment Episode Gap	Exposure Episode Extension Period	Maximum Exposure Episode Duration	Care Setting
9	SGLT-2 Inhibitors	**01:** Cohort includes only the first valid exposure episode during the query period	365	All study exposures of interest, SGLT-2 and sitagliptin (see exclusion)	No	**F:** Fixed episode gap.	10	10	365	n/a
10	Sitagliptin	**01:** Cohort includes only the first valid exposure episode during the query period	365	All study exposures of interest, SGLT-2 and sitagliptin (see exclusion)	No	**F:** Fixed episode gap.	10	10	365	n/a

Appendix H. Specifications Defining Parameters Used in this Request										
	Exposure									
Scenario	Index Exposure	Cohort Definition	Incident Exposure Washout Period	Incident with Respect to:	Exclude Evidence of Days Supply if Event Washout Includes	Treatment Episode Gap Type	Treatment Episode Gap	Exposure Episode Extension Period	Maximum Exposure Episode Duration	Care Setting
11	SGLT-2 Inhibitors	**01:** Cohort includes only the first valid exposure episode during the query period	365	All study exposures of interest, SGLT-2 and sitagliptin (see exclusion)	No	**F:** Fixed episode gap.	10	10	365	n/a
12	Sitagliptin	**01:** Cohort includes only the first valid exposure episode during the query period	365	All study exposures of interest, SGLT-2 and sitagliptin (see exclusion)	No	**F:** Fixed episode gap.	10	10	365	n/a
13	SGLT-2 Inhibitors	**01:** Cohort includes only the first valid exposure episode during the query period	365	All study exposures of interest, SGLT-2 and sitagliptin (see exclusion)	No	**F:** Fixed episode gap.	10	10	365	n/a

Appendix H. Specifications Defining Parameters Used in this Request										
	Exposure									
Scenario	Index Exposure	Cohort Definition	Incident Exposure Washout Period	Incident with Respect to:	Exclude Evidence of Days Supply if Event Washout Includes	Treatment Episode Gap Type	Treatment Episode Gap	Exposure Episode Extension Period	Maximum Exposure Episode Duration	Care Setting
14	Sitagliptin	**01:** Cohort includes only the first valid exposure episode during the query period	365	All study exposures of interest, SGLT-2 and sitagliptin (see exclusion)	No	**F:** Fixed episode gap.	10	10	365	n/a
15	Short/Rapid-Acting Insulin	**01:** Cohort includes only the first valid exposure episode during the query period	0	n/a	No	**F:** Fixed episode gap.	10	10	365	n/a

Appendix H. Specifications Defining Parameters Used in this Request (Continued)											
	Exposure			Inclusion/Exclusion Criteria							
Scenario	Principal Diagnosis Position	Create Baseline Table (Y/N)	End At-Risk Period at Evidence of	Inclusion/ Exclusion Group	Criteria	Care Setting	Principal Diagnosis Position	Evaluation Period Start	Evaluation Period End	Exclude Evidence of Days Supply if Event Washout Includes Dispensings	Number of Instances for the Condition
1	n/a	Yes	*End of exposure episode (up to 365 days) *Death *Data Partner (DP) end date *Query end date *Occurrence of a Diabetic Ketoacidosis (DKA) event *Switch to sitagliptin	Washout (SGLT-2 + sitagliptin)	Exclusion	Any	n/a	-365	-1	No	1
2	n/a	Yes	*End of exposure episode (up to 365 days) *Death *DP end date *Query end date *Occurrence of a DKA event *Switch to SGLT-2 inhibitor	Washout (SGLT-2 + sitagliptin)	Exclusion	Any	n/a	-365	-1	No	1

Appendix H. Specifications Defining Parameters Used in this Request (Continued)											
	Exposure			Inclusion/Exclusion Criteria							
Scenario	Principal Diagnosis Position	Create Baseline Table (Y/N)	End At-Risk Period at Evidence of	Inclusion/ Exclusion Group	Criteria	Care Setting	Principal Diagnosis Position	Evaluation Period Start	Evaluation Period End	Exclude Evidence of Days Supply if Event Washout Includes Dispensings	Number of Instances for the Condition
3	n/a	Yes	*End of exposure episode (up to 365 days) *Death *DP end date *Query end date *Occurrence of a DKA event *Switch to sitagliptin	Type 1 Diabetes (>50% of all diabetes codes are T1DM) [PLUS]	Inclusion	Any	n/a	-365	-5	No	1
				AND NOT							
				Washout (SGLT-2 + sitagliptin)	Exclusion	Any	n/a	-365	-1	No	1
4	n/a	Yes	*End of exposure episode (up to 365 days) *Death *DP end date *Query end date *Occurrence of a DKA event *Switch to SGLT-2 inhibitor	Type 1 Diabetes (>50% of all diabetes codes are T1DM) [PLUS]	Inclusion	Any	n/a	-365	-5	No	1
				AND NOT							
				Washout (SGLT-2 + sitagliptin)	Exclusion	Any	n/a	-365	-1	No	1

Appendix H. Specifications Defining Parameters Used in this Request (Continued)

	Exposure			Inclusion/Exclusion Criteria							
Scenario	Principal Diagnosis Position	Create Baseline Table (Y/N)	End At-Risk Period at Evidence of	Inclusion/ Exclusion Group	Criteria	Care Setting	Principal Diagnosis Position	Evaluation Period Start	Evaluation Period End	Exclude Evidence of Days Supply if Event Washout Includes Dispensings	Number of Instances for the Condition
5	n/a	Yes	*End of exposure episode (up to 365 days) *Death *DP end date *Query end date *Occurrence of a DKA event *Switch to sitagliptin	Type 1 Diabetes (>50% of all diabetes codes are T1DM) [PLUS]	Inclusion	Any	n/a	-365	-5	No	1
				AND NOT							
				Washout (SGLT-2 + sitagliptin)	Exclusion	Any	n/a	-365	-1	No	1
6	n/a	Yes	*End of exposure episode (up to 365 days) *Death *DP end date *Query end date *Occurrence of a DKA event *Switch to SGLT-2 inhibitor	Type 1 Diabetes (>50% of all diabetes codes are T1DM) [PLUS]	Inclusion	Any	n/a	-365	-5	No	1
				AND NOT							
				Washout (SGLT-2 + sitagliptin)	Exclusion	Any	n/a	-365	-1	No	1

Appendix H. Specifications Defining Parameters Used in this Request (Continued)											
	Exposure			Inclusion/Exclusion Criteria							
Scenario	Principal Diagnosis Position	Create Baseline Table (Y/N)	End At-Risk Period at Evidence of	Inclusion/ Exclusion Group	Criteria	Care Setting	Principal Diagnosis Position	Evaluation Period Start	Evaluation Period End	Exclude Evidence of Days Supply if Event Washout Includes Dispensings	Number of Instances for the Condition
7	n/a	Yes	*End of exposure episode (up to 365 days) *Death *DP end date *Query end date *Occurrence of a DKA event *Switch to sitagliptin	Type 1 Diabetes (>50% of all diabetes codes are T1DM) [PLUS]	Inclusion	Any	n/a	-365	-5	No	1
				AND							
				Short- or rapid-acting insulin	Inclusion	Any	n/a	-365	-1	No	1
				AND NOT							
				Non-insulin antidiabetic (excluding Metformin)	Exclusion	Any	n/a	-365	-1	No	1
				OR							
				Washout (SGLT-2 + sitagliptin)	Exclusion	Any	n/a	-365	-1	No	1

Appendix H. Specifications Defining Parameters Used in this Request (Continued)

	Exposure			Inclusion/Exclusion Criteria							
Scenario	Principal Diagnosis Position	Create Baseline Table (Y/N)	End At-Risk Period at Evidence of	Inclusion/ Exclusion Group	Criteria	Care Setting	Principal Diagnosis Position	Evaluation Period Start	Evaluation Period End	Exclude Evidence of Days Supply if Event Washout Includes Dispensings	Number of Instances for the Condition
8	n/a	Yes	*End of exposure episode (up to 365 days) *Death *DP end date *Query end date *Occurrence of a DKA event *Switch to SGLT-2 inhibitor	Type 1 Diabetes (>50% of all diabetes codes are T1DM) [PLUS]	Inclusion	Any	n/a	-365	-5	No	1
				AND							
				Short- or rapid-acting insulin	Inclusion	Any	n/a	-365	-1	No	1
				AND NOT							
				Non-insulin antidiabetic (excluding Metformin)	Exclusion	Any	n/a	-365	-1	No	1
				OR							
				Washout (SGLT-2 + sitagliptin)	Exclusion	Any	n/a	-365	-1	No	1

Appendix H. Specifications Defining Parameters Used in this Request (Continued)											
	Exposure			Inclusion/Exclusion Criteria							
Scenario	Principal Diagnosis Position	Create Baseline Table (Y/N)	End At-Risk Period at Evidence of	Inclusion/ Exclusion Group	Criteria	Care Setting	Principal Diagnosis Position	Evaluation Period Start	Evaluation Period End	Exclude Evidence of Days Supply if Event Washout Includes Dispensings	Number of Instances for the Condition
9	n/a	Yes	*End of exposure episode (up to 365 days) *Death *DP end date *Query end date *Occurrence of a DKA event *Switch to sitagliptin	Type 1 Diabetes (>50% of all diabetes codes are T1DM) [PLUS]	Inclusion	Any	n/a	-365	-5	No	1
				AND							
				Short- or rapid-acting insulin	Inclusion	Any	n/a	-365	-1	No	1
				AND NOT							
				Non-insulin antidiabetic (excluding Metformin)	Exclusion	Any	n/a	-365	-1	No	1
				OR							
				Washout (SGLT-2 + sitagliptin)	Exclusion	Any	n/a	-365	-1	No	1

Appendix H. Specifications Defining Parameters Used in this Request (Continued)

	Exposure			Inclusion/Exclusion Criteria							
Scenario	Principal Diagnosis Position	Create Baseline Table (Y/N)	End At-Risk Period at Evidence of	Inclusion/ Exclusion Group	Criteria	Care Setting	Principal Diagnosis Position	Evaluation Period Start	Evaluation Period End	Exclude Evidence of Days Supply if Event Washout Includes Dispensings	Number of Instances for the Condition
10	n/a	Yes	*End of exposure episode (up to 365 days) *Death *DP end date *Query end date *Occurrence of a DKA event *Switch to SGLT-2 inhibitor	Type 1 Diabetes (>50% of all diabetes codes are T1DM) [PLUS]	Inclusion	Any	n/a	-365	-5	No	1
				AND							
				Short- or rapid-acting insulin	Inclusion	Any	n/a	-365	-1	No	1
				AND NOT							
				Non-insulin antidiabetic (excluding Metformin)	Exclusion	Any	n/a	-365	-1	No	1
				OR							
				Washout (SGLT-2 + sitagliptin)	Exclusion	Any	n/a	-365	-1	No	1
11	n/a	Yes	*End of exposure episode (up to 365 days) *Death *DP end date *Query end date *Occurrence of a DKA event *Switch to sitagliptin	Type 2 Diabetes	Inclusion	Any	n/a	-365	-5	No	1
				AND							
				Any Insulin	Inclusion	Any	n/a	-365	-1	No	1
				AND NOT							
				Type 1 Diabetes	Exclusion	Any	n/a	-365	-5	No	1
				OR							
				Washout (SGLT-2 + sitagliptin)	Exclusion	Any	n/a	-365	-1	No	1

Appendix H. Specifications Defining Parameters Used in this Request (Continued)

	Exposure			Inclusion/Exclusion Criteria							
Scenario	Principal Diagnosis Position	Create Baseline Table (Y/N)	End At-Risk Period at Evidence of	Inclusion/ Exclusion Group	Criteria	Care Setting	Principal Diagnosis Position	Evaluation Period Start	Evaluation Period End	Exclude Evidence of Days Supply if Event Washout Includes Dispensings	Number of Instances for the Condition
12	n/a	Yes	*End of exposure episode (up to 365 days) *Death *DP end date *Query end date *Occurrence of a DKA event *Switch to SGLT-2 inhibitor	Type 2 Diabetes	Inclusion	Any	n/a	-365	-5	No	1
				AND							
				Any Insulin	Inclusion	Any	n/a	-365	-1	No	1
				AND NOT							
				Type 1 Diabetes	Exclusion	Any	n/a	-365	-5	No	1
				OR							
				Washout (SGLT-2 + sitagliptin)	Exclusion	Any	n/a	-365	-1	No	1
13	n/a	Yes	*End of exposure episode (up to 365 days) *Death *DP end date *Query end date *Occurrence of a DKA event *Switch to sitagliptin	Type 2 Diabetes	Inclusion	Any	n/a	-365	-5	No	1
				AND NOT							
				Any Insulin	Exclusion	Any	n/a	-365	-1	No	1
				OR							
				Type 1 Diabetes	Exclusion	Any	n/a	-365	-5	No	1
				OR							
				Washout (SGLT-2 + sitagliptin)	Exclusion	Any	n/a	-365	-1	No	1

Appendix H. Specifications Defining Parameters Used in this Request (Continued)

	Exposure			Inclusion/Exclusion Criteria							
Scenario	Principal Diagnosis Position	Create Baseline Table (Y/N)	End At-Risk Period at Evidence of	Inclusion/ Exclusion Group	Criteria	Care Setting	Principal Diagnosis Position	Evaluation Period Start	Evaluation Period End	Exclude Evidence of Days Supply if Event Washout Includes Dispensings	Number of Instances for the Condition
14	n/a	Yes	*End of exposure episode (up to 365 days) *Death *DP end date *Query end date *Occurrence of a DKA event *Switch to SGLT-2 inhibitor	Type 2 Diabetes	Inclusion	Any	n/a	-365	-5	No	1
				AND NOT							
				Any Insulin	Exclusion	Any	n/a	-365	-1	No	1
				OR							
				Type 1 Diabetes	Exclusion	Any	n/a	-365	-5	No	1
				OR							
				Washout (SGLT-2 + sitagliptin)	Exclusion	Any	n/a	-365	-1	No	1
15	n/a	Yes	*End of exposure episode (up to 365 days) *Death *DP end date *Query end date *Occurrence of a DKA event	Type 1 Diabetes (>50% of all diabetes codes are T1DM) [PLUS]	Inclusion	Any	n/a	-365	-5	No	1
				AND NOT							
				Non-insulin antidiabetic (excluding Metformin)	Exclusion	Any	n/a	-365	-1	No	1

Appendix H. Specifications Defining Parameters Used in this Request (Continued)

	Health Outcomes of Interest (HOI)							
Scenario	Event	HOI Washout Period	Care Setting	Principal Diagnosis Position	Exclude Evidence of Days Supply if Event Washout Includes Dispensings	Event De-Duplication	Blackout Period	At Risk Period Start
1	DKA	0	Inpatient (IP), Emergency Department (ED)	n/a	No	**1:** de-duplicates occurrences of the same HOI code and code type on the same day	1	n/a
2	DKA	0	IP, ED	n/a	No	**1:** de-duplicates occurrences of the same HOI code and code type on the same day	1	n/a
3	DKA	0	IP, ED	n/a	No	**1:** de-duplicates occurrences of the same HOI code and code type on the same day	1	n/a
4	DKA	0	IP, ED	n/a	No	**1:** de-duplicates occurrences of the same HOI code and code type on the same day	1	n/a

Appendix H. Specifications Defining Parameters Used in this Request (Continued)

	Health Outcomes of Interest (HOI)							
Scenario	Event	HOI Washout Period	Care Setting	Principal Diagnosis Position	Exclude Evidence of Days Supply if Event Washout Includes Dispensings	Event De-Duplication	Blackout Period	At Risk Period Start
5	DKA	0	IP, ED	n/a	No	**1:** de-duplicates occurrences of the same HOI code and code type on the same day	n/a	1
6	DKA	0	IP, ED	n/a	No	**1:** de-duplicates occurrences of the same HOI code and code type on the same day	n/a	1
7	DKA	0	IP, ED	n/a	No	**1:** de-duplicates occurrences of the same HOI code and code type on the same day	1	n/a

Appendix H. Specifications Defining Parameters Used in this Request (Continued)								
		Health Outcomes of Interest (HOI)						
Scenario	Event	HOI Washout Period	Care Setting	Principal Diagnosis Position	Exclude Evidence of Days Supply if Event Washout Includes Dispensings	Event De-Duplication	Blackout Period	At Risk Period Start
8	DKA	0	IP, ED	n/a	No	**1:** de-duplicates occurrences of the same HOI code and code type on the same day	1	n/a
9	DKA	0	IP, ED	n/a	No	**1:** de-duplicates occurrences of the same HOI code and code type on the same day	n/a	1
10	DKA	0	IP, ED	n/a	No	**1:** de-duplicates occurrences of the same HOI code and code type on the same day	n/a	1
11	DKA	0	IP, ED	n/a	No	**1:** de-duplicates occurrences of the same HOI code and code type on the same day	1	n/a
12	DKA	0	IP, ED	n/a	No	**1:** de-duplicates occurrences of the same HOI code and code type on the same day	1	n/a

Appendix H. Specifications Defining Parameters Used in this Request (Continued)

		Health Outcomes of Interest (HOI)						
Scenario	Event	HOI Washout Period	Care Setting	Principal Diagnosis Position	Exclude Evidence of Days Supply if Event Washout Includes Dispensings	Event De-Duplication	Blackout Period	At Risk Period Start
13	DKA	0	IP, ED	n/a	No	**1:** de-duplicates occurrences of the same HOI code and code type on the same day	1	n/a
14	DKA	0	IP, ED	n/a	No	**1:** de-duplicates occurrences of the same HOI code and code type on the same day	1	n/a
15	DKA	0	IP, ED	n/a	No	**1:** de-duplicates occurrences of the same HOI code and code type on the same day	1	n/a

[1]N/A: Not Applicable

International Classification of Diseases, Ninth Revision (ICD-9), International Classification of Diseases, Tenth Revision (ICD-10), Healthcare Common Procedure Coding System (HCPCS), and CPT (Current Procedural Terminology) codes are provided by Optum360. National Drug Codes (NDCs) are checked against FirstDataBank's FDBMedKnowledge®.

Appendix I. Specifications Defining Baseline Characteristic Parameters Used in this Request							
Baseline Characteristics							
Characteristic Name	**Characteristic Number**	**Combo Logic**	**Code Category**	**Care Setting**	**Principal Diagnosis Position**	**Characteristic Evaluation Period Start**	**Characteristic Evaluation Period End**
Chronic Kidney Disease (CKD) Definition Components							
CKD Stage 4 or 5 Diagnosis Code	1		Diagnosis	Any	n/a[1]	-365	0
Dialysis	2		Diagnosis, Procedure	Any	n/a	-365	0
CKD Stage 3 Diagnosis Code	3		Diagnosis	Any	n/a	-365	0
Any CKD code at least 3 times	4		Diagnosis	Any	n/a	-365	0
Renal Failure or CKD	5		Diagnosis	Any	n/a	-365	0
CKD treatment	6		Dispensing, Procedure	Any	n/a	-365	0
Chronic Kidney Disease Stages							
CKD Stage 4 or 5	26	1 or 2	Combo covariate				
CKD Stage 3	27	(3 or 4 or (5 and 6)) and not 26	Combo covariate				
CKD Stage 2	28	5 and not (27 or 26)	Combo covariate				
CKD Stage 1	29	not (28 or 27 or 26)	Combo covariate				

Appendix I. Specifications Defining Baseline Characteristic Parameters Used in this Request							
Baseline Characteristics							
Characteristic Name	**Characteristic Number**	**Combo Logic**	**Code Category**	**Care Setting**	**Principal Diagnosis Position**	**Characteristic Evaluation Period Start**	**Characteristic Evaluation Period End**
Diabetic ketoacidosis (DKA)							
History of DKA	7		Diagnosis	IP, ED[2]	n/a	-365	-1
At least 1 DKA event	8		Diagnosis	IP, ED	n/a	1	365
At least 2 DKA events	9		Diagnosis	IP, ED	n/a	1	365
At least 3 DKA events	10		Diagnosis	IP, ED	n/a	1	365
At least 4 DKA events	11		Diagnosis	IP, ED	n/a	1	365
At least 5 DKA events	12		Diagnosis	IP, ED	n/a	1	365
Exactly 1 DKA event	30	8 and not 9	Combo covariate				
Exactly 2 DKA events	31	9 and not 10	Combo covariate				
Exactly 3 DKA events	32	10 and not 11	Combo covariate				
Exactly 4 DKA events	33	11 and not 12	Combo covariate				
Baseline Diabetes Treatments by Active Ingredient							
Metformin	13		Dispensing	Any	n/a	-365	-1
Sulfonylureas	14		Dispensing	Any	n/a	-365	-1
Thiazolidinediones	15		Dispensing	Any	n/a	-365	-1
Alpha-glucosidase inhibitors	16		Dispensing	Any	n/a	-365	-1
Meglitinides	17		Dispensing	Any	n/a	-365	-1
Dipeptidyl peptidase-4 (DPP-4) inhibitors	18		Dispensing	Any	n/a	-365	-1
Sodium-glucose cotransporter-2 (SGLT-2) inhibitors	19		Dispensing	Any	n/a	-365	-1
Glucagon-like peptide-1 receptor agonists (GLP-1 RAs)	20		Dispensing, Procedure	Any	n/a	-365	-1

Appendix I. Specifications Defining Baseline Characteristic Parameters Used in this Request							
Baseline Characteristics							
Characteristic Name	**Characteristic Number**	**Combo Logic**	**Code Category**	**Care Setting**	**Principal Diagnosis Position**	**Characteristic Evaluation Period Start**	**Characteristic Evaluation Period End**
Other oral diabetes drugs (bromocriptine and colesevelam)	21		Dispensing	Any	n/a	-365	-1
Insulin Products							
Short/rapid acting insulin	22		Dispensing, Procedure	Any	n/a	-365	-1
Long/intermediate acting insulin	23		Dispensing, Procedure	Any	n/a	-365	-1
Combination insulin	24		Dispensing, Procedure	Any	n/a	-365	-1
Insulin pump	25		Dispensing, Procedure	Any	n/a	-365	-1

Appendix I. Specifications Defining Baseline Characteristic Parameters Used in this Request (Continued)			
Baseline Characteristics			
Characteristic Name	**Exclude Evidence of Days Supply if Event Washout Includes Dispensings**	**Number of Instances the Characteristic Should be Found in Evaluation Period**	**Output in Baseline Table (Y/N)**
Chronic Kidney Disease (CKD) Definition Components			
CKD Stage 4 or 5 Diagnosis Code	n/a	1	No
Dialysis	n/a	1	No
CKD Stage 3 Diagnosis Code	n/a	1	No
Any CKD code at least 3	n/a	3	No
Renal Failure or CKD	n/a	1	No
CKD treatment	No	1	No
Chronic Kidney Disease Stages			
CKD Stage 4 or 5		1	Yes
CKD Stage 3		1	Yes
CKD Stage 2		1	Yes
CKD Stage 1		1	Yes
Diabetic ketoacidosis (DKA)			
History of DKA	n/a	1	Yes
At least 1 DKA event	n/a	1	No
At least 2 DKA events	n/a	2	No
At least 3 DKA events	n/a	3	No
At least 4 DKA events	n/a	4	No
At least 5 DKA events	n/a	5	Yes
Exactly 1 DKA event		1	Yes
Exactly 2 DKA events		1	Yes
Exactly 3 DKA events		1	Yes
Exactly 4 DKA events		1	Yes

Appendix I. Specifications Defining Baseline Characteristic Parameters Used in this Request (Continued)			
Baseline Characteristics			
Characteristic Name	**Exclude Evidence of Days Supply if Event Washout Includes Dispensings**	**Number of Instances the Characteristic Should be Found in Evaluation Period**	**Output in Baseline Table (Y/N)**
Baseline Diabetes Treatments by Active Ingredient			
Metformin	No	1	Yes
Sulfonylureas	No	1	Yes
Thiazolidinediones	No	1	Yes
Alpha-glucosidase inhibitors	No	1	Yes
Meglitinides	No	1	Yes
DPP-4 inhibitors	No	1	Yes
SGLT-2 inhibitors	No	1	Yes
GLP-1 RAs	No	1	Yes
Other oral diabetes drugs (bromocriptine and colesevelam)	No	1	Yes
Insulin Products			
Short/rapid acting insulin	No	1	Yes
Long/intermediate acting insulin	No	1	Yes
Combination insulin	No	1	Yes
Insulin pump	No	1	Yes

[1]n/a: Not applicable
[2]IP: Inpatient; ED: Emergency Department

Appendix J. Specifications Defining Risk Score and Utilization Parameters Used in this Request

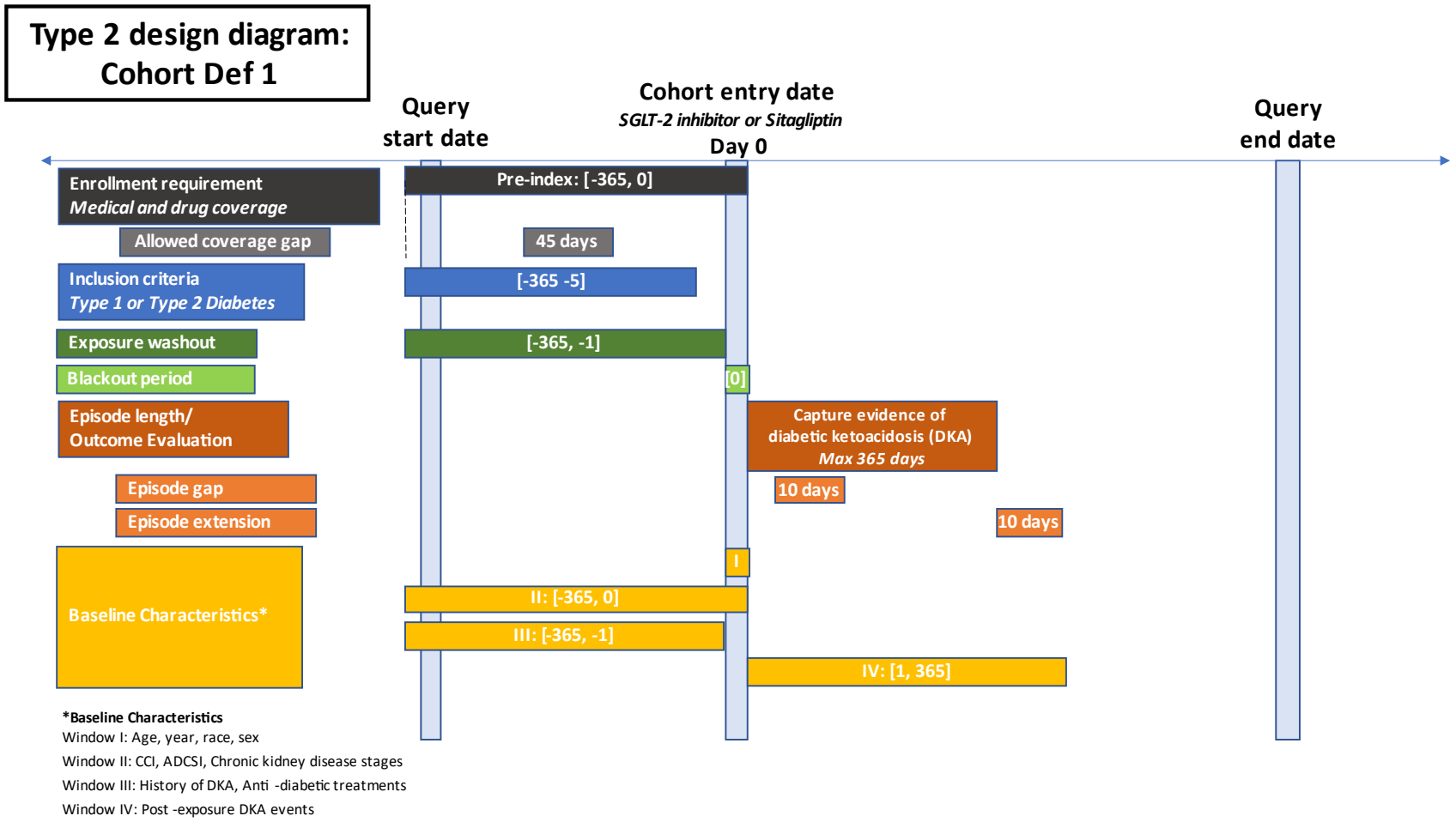
Risk Score

Risk Score	Evaluation Period Start	Evaluation Period End	Risk Score Categories
CCI: Combined comorbidity index **ADCSI:** Adapted Diabetes Complications Severity Index	-365	0	N/A[1]

Utilization

Medical Utilization Evaluation Period Start	Medical Utilization Evaluation Period End	Drug Utilization Evaluation Period Start	Drug Utilization Evaluation Period End
-365	0	-365	0

[1]N/A: Not applicable


Type 2 design diagram:
Cohort Def 1
Query
start date
Cohort entry date
SGLT-2 inhibitor or Sitagliptin
Day 0
Query
end date
Enrollment requirement
Medical and drug coverage
Pre-index: [-365, 0]
Allowed coverage gap
45 days
Inclusion criteria
Type 1 or Type 2 Diabetes
[-365 -5]
Exposure washout
[-365, -1]
Blackout period
[0]
Episode length/
Outcome Evaluation
Capture evidence of
diabetic ketoacidosis (DKA)
Max 365 days
Episode gap
10 days
Episode extension
10 days
I
Baseline Characteristics*
II: [-365, 0]
III: [-365, -1]
IV: [1, 365]
*Baseline Characteristics
Window I: Age, year, race, sex
Window II: CCI, ADCSI, Chronic kidney disease stages
Window III: History of DKA, Anti -diabetic treatments
Window IV: Post -exposure DKA events