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

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

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

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Overview for Request cder_mpl1p_wp026

Request ID: cder_mpl1p_wp026

Request Description: The goal of this request was to estimate rates of Diabetic Ketoacidosis (DKA) among new users of Canagliflozin, Dapagliflozin, Empagliflozin or Sitagliptin in the Sentinel Distributed Database (SDD). Separate cohorts were examined to compare patients with 1) incident exposure-ONLY, 2) incident exposure AND prior Type 1 Diabetes Mellitus (T1DM) using a strict definition, 3) incident exposure AND T1DM using a broad definition, 4) incident exposure AND Type 2 Diabetes Mellitus (T2DM), 5) incident exposure AND T2DM patients with prior insulin exposure, and 6) incident exposure AND T2DM patients without prior insulin exposure.

Sentinel Modular Program Tool Used: Cohort Identification and Descriptive Analysis tool, version 6.0.0

Data Source: Data from March 1, 2013 through June 30, 2018 from 17 Data Partners (DPs) contributing to the SDD were included in this report. This request was distributed on November 28, 2018. See Appendix A for a list of the latest dates of available data for each DP.

Study Design: The request was designed to identify incident drug exposures and DKA outcomes. The number of qualifying patients with the exposures of interest were calculated overall and by sex, age group, year of exposure, sex and age group, and year of exposure and age group.

Exposures of Interest: The exposures of interest, which were defined using National Drug Codes (NDC) were: 1) incident Canagliflozin dispensings; 2) incident Dapagliflozin dispensings; 3) incident Empagliflozin dispensings; 4) incident Sitagliptin dispensings. Please see Appendix B for a list of generic and brand names used to define exposures. Only the first valid exposure episode (index dispensing) was included in the given cohort for each qualifying patient.

Cohort Eligibility Criteria: Members' first valid exposure that occurred between March 1, 2013 - June 30, 2018 were included. Those included in the cohorts were required to be continuously enrolled in plans with medical and drug coverage for at least 365 days prior to their index date, during which gaps in coverage of up to 45 days were allowed. The following age groups were included in the cohort: 0-11, 12-18, 19-24, 25-44, 45-64, 65+ years. For the Canagliflozin, Dapagliflozin and Empagliflozin cohorts, incident exposure was defined as no evidence of an SGLT-2 dispensing in the previous 365 days. For the Sitagliptin cohorts, incident exposure was defined as no evidence of a dipeptidyl peptidase-4 inhibitor (DPP-4i) in the previous 365 days. Six separate cohort groups were formed for each of the four exposures of interest based on the following:

1. Incident exposure cohorts: no additional cohort criteria applied
2. Incident exposure, T1DM Strict definition: Patients needed to have 1) >50% of all diabetes codes in a (-365, -5) day window needed to be for T1DM vs T2DM, 2) no evidence of oral antidiabetics in the 365 days prior to exposure, 3) evidence of a short/rapid-acting insulin in the 365 days prior to exposure
3. Incident exposure, T1DM Broad definition: Patients needed to have 1) >50% of all diabetes codes in a (-365, -5) day window needed to be for T1DM vs T2DM
4. Incident exposure, T2DM All definition: Patients needed to have 1) at least 1 T2DM code in the (-365, -5) days prior to exposure, 2) no evidence of any T1DM codes in the (-365, -5) days prior to exposure, 3) an oral antidiabetic dispensing in the 365 days prior to exposure
5. Incident exposure, T2DM with Insulin definition: Patients needed to have 1) at least 1 T2DM code in the (-365, -5) days prior to exposure, 2) no evidence of any T1DM codes in the (-365, -5) days prior to exposure, 3) an oral antidiabetic dispensing in the 365 days prior to exposure, 4) an insulin dispensing or procedure in the 365 days prior to exposure
6. Incident exposure, T2DM without Insulin definition: Patients needed to have 1) at least 1 T2DM code in the (-365, -5) days prior to exposure, 2) no evidence of any T1DM codes in the (-365, -5) days prior to exposure, 3) an oral antidiabetic dispensing in the 365 days prior to exposure, 4) no evidence of an insulin dispensing or procedure in the 365 days prior to exposure.

Overview for Request cder_mpl1p_wp026

See Appendix C for a list of the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), International Classification of Diseases Tenth Revision Clinical Modification (ICD-10-CM), and Healthcare Common Procedure Coding System (HCPCS) codes used to define inclusion and exclusion criteria.

See Appendix C.1 for a list of the generic and brand names used to define inclusion and exclusion criteria.

Outcomes of Interest: After incident exposure to one of the four drugs of interest, the following outcome was captured: Diabetic Ketoacidosis (DKA). See Appendix D for a list of the ICD-9-CM and ICD-10-CM codes used to define the outcome of interest.

Follow-Up Time: Follow-up time was determined by the length of the exposure episodes. Exposure episode lengths were defined using outpatient pharmacy dispensing days supplied to create a sequence of continuous exposure. Exposure episodes were considered continuous if gaps in days supplied were 10 days or less. The end date of each exposure episode was extended by 10 additional days. Follow-up began on the day after the first exposure of interest and continued until the first occurrence of any of the following: 1) disenrollment; 2) the end date of the data provided by each Data Partner (see Appendix A); 3) the end of the query period; 4) the end of the exposure episode; 5) occurrence of the outcome of interest, defined above; or 6) death. Only the first valid exposure episode that occurred during the study period was included per patient.

Characteristics of Interest: Among the 24 cohorts of interest, recorded history of DKA, insulin pump, and antidiabetic use by active ingredient were identified in the 365 days prior to index date. Antidiabetic use by active ingredient was also identified in the 365 days after index date. See Appendix E and E.1 for ICD-9-CM, ICD-10-CM, generic and brand names, and Healthcare Common Procedure Coding System (HCPCS) codes used to define characteristics of interest.

Limitations: Algorithms used to define the exposure, outcomes, exclusions, and characteristics are imperfect; thus, it is possible that there may be misclassification. Therefore, data should be interpreted with this limitation in mind.

Please see Appendices F.1-F.5 for the specifications of parameters used in the analyses for this request.

Notes: Please contact the Sentinel Operations Center (info@sentinelssystem.org) for questions and to provide comments/suggestions for future enhancements to this document.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

*all terms may not be used in this report

Table 1a. Baseline Characteristics of Canagliflozin, Dapagliflozin, Empagliflozin and Sitagliptin Users in the Sentinel Distributed Database (SDD), from March 1, 2013 to June 30, 2018

Characteristic	Canagliflozin		Dapagliflozin		Empagliflozin		Sitagliptin	
	Mean	Standard Deviation	Mean	Standard Deviation	Mean	Standard Deviation	Mean	Standard Deviation
Number of unique patients	297,633		79,311		98,583		667,468	
Demographics	Mean	Standard Deviation	Mean	Standard Deviation	Mean	Standard Deviation	Mean	Standard Deviation
Mean Age	61.8	10.6	58.9	10.2	59.5	10	67.2	11.7
Age (Years)	Number	Percent	Number	Percent	Number	Percent	Number	Percent
<12	*****	*****	*****	*****	*****	*****	*****	*****
12-18	*****	*****	*****	*****	*****	*****	*****	*****
19-24	521	0.2%	201	0.3%	212	0.2%	933	0.1%
25-44	27,949	9.4%	9,725	12.3%	10,563	10.7%	39,852	6.0%
45-64	134,159	45.1%	43,793	55.2%	54,865	55.7%	205,187	30.7%
>=65 years	134,902	45.3%	25,552	32.2%	32,907	33.4%	421,316	63.1%
Sex								
Female	142,526	47.9%	37,273	47.0%	43,347	44.0%	347,999	52.1%
Male	*****	*****	*****	*****	*****	*****	319,450	47.9%
Other	*****	*****	*****	*****	*****	*****	19	0.0%
Year								
2013	20,690	7.0%	0	0.0%	0	0.0%	122,005	18.3%
2014	73,202	24.6%	20,552	25.9%	2,691	2.7%	164,817	24.7%
2015	107,722	36.2%	24,302	30.6%	18,535	18.8%	164,156	24.6%
2016	78,522	26.4%	23,104	29.1%	37,694	38.2%	164,267	24.6%
2017	16,666	5.6%	10,338	13.0%	37,204	37.7%	48,715	7.3%
2018	831	0.3%	1,015	1.3%	2,459	2.5%	3,508	0.5%

Table 1a. Baseline Characteristics of Canagliflozin, Dapagliflozin, Empagliflozin and Sitagliptin Users in the Sentinel Distributed Database (SDD), from March 1, 2013 to June 30, 2018

History of Antidiabetic Drug Use up to 365 days prior to index	Canagliflozin		Dapagliflozin		Empagliflozin		Sitagliptin	
	Number	Percent	Number	Percent	Number	Percent	Number	Percent
Acarbose	2,677	0.9%	519	0.7%	539	0.5%	3,470	0.5%
Albiglutide	1,290	0.4%	590	0.7%	1,154	1.2%	635	0.1%
Alogliptin_Benzoate	987	0.3%	408	0.5%	546	0.6%	0	0.0%
Canagliflozin	0	0.0%	0	0.0%	0	0.0%	15,671	2.3%
Chlorpropamide	15	0.0%	*****	*****	*****	*****	45	0.0%
Dapagliflozin_Propoanediol	0	0.0%	0	0.0%	0	0.0%	3,956	0.6%
Dulaglutide	2,650	0.9%	1,500	1.9%	4,044	4.1%	1,884	0.3%
Empagliflozin	0	0.0%	0	0.0%	0	0.0%	2,774	0.4%
Ertugliflozin_Pidolate	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Exenatide	16,008	5.4%	4,930	6.2%	4,409	4.5%	8,197	1.2%
Glimiperide	59,984	20.2%	14,009	17.7%	18,025	18.3%	106,929	16.0%
Glipizide	59,019	19.8%	13,318	16.8%	16,798	17.0%	147,048	22.0%
Glyburide	23,378	7.9%	5,531	7.0%	5,319	5.4%	57,348	8.6%
Linagliptin	17,350	5.8%	4,636	5.8%	6,884	7.0%	0	0.0%
Liraglutide	35,555	11.9%	9,198	11.6%	10,638	10.8%	15,166	2.3%
Lixisenatide	11	0.0%	16	0.0%	48	0.0%	*****	*****
Metformin_HCl	229,546	77.1%	61,200	77.2%	77,484	78.6%	456,876	68.4%
Miglitol	152	0.1%	36	0.0%	35	0.0%	160	0.0%
Nateglinide	2,972	1.0%	682	0.9%	632	0.6%	4,949	0.7%
Pioglitazone_HCl	32,248	10.8%	8,137	10.3%	8,931	9.1%	49,194	7.4%
Repaglinide	3,662	1.2%	748	0.9%	916	0.9%	5,427	0.8%
Rosiglitazone_Maleate	69	0.0%	18	0.0%	19	0.0%	78	0.0%
Saxagliptin_HCl	18,720	6.3%	5,998	7.6%	4,734	4.8%	0	0.0%
Semaglutide	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Sitagliptin_Phosphate	78,170	26.3%	19,048	24.0%	21,207	21.5%	0	0.0%
Tolazamide	*****	*****	*****	*****	0	0.0%	26	0.0%
Tolbutamide	*****	*****	0	0.0%	0	0.0%	33	0.0%
Insulin lispro	24,494	8.2%	5,114	6.4%	8,928	9.1%	26,413	4.0%
Insulin regular, human	8,703	2.9%	1,771	2.2%	2,314	2.3%	17,515	2.6%

Table 1a. Baseline Characteristics of Canagliflozin, Dapagliflozin, Empagliflozin and Sitagliptin Users in the Sentinel Distributed Database (SDD), from March 1, 2013 to June 30, 2018

	Canagliflozin		Dapagliflozin		Empagliflozin		Sitagliptin	
History of Antidiabetic Drug Use up to 365 days prior to index	Number	Percent	Number	Percent	Number	Percent	Number	Percent
Insulin glulisine	2,049	0.7%	557	0.7%	501	0.5%	1,178	0.2%
Insulin aspart	30,157	10.1%	6,636	8.4%	7,177	7.3%	39,513	5.9%
Insulin lispro protamine	4,622	1.6%	976	1.2%	1,357	1.4%	4,740	0.7%
Insulin glargine, human recombinant analog	59,459	20.0%	13,080	16.5%	17,789	18.0%	81,334	12.2%
Insulin NPH human isophane	6,952	2.3%	1,399	1.8%	2,225	2.3%	13,453	2.0%
Insulin detemir	30,560	10.3%	7,221	9.1%	8,397	8.5%	34,037	5.1%
Insulin aspart protamine human	6,071	2.0%	1,363	1.7%	1,177	1.2%	8,178	1.2%
Insulin degludec	752	0.3%	561	0.7%	1,469	1.5%	874	0.1%
History of Antidiabetic Drug Use up to 365 days after index	Number	Percent	Number	Percent	Number	Percent	Number	Percent
Acarbose	2,494	0.8%	438	0.6%	513	0.5%	4,294	0.6%
Albiglutide	2,710	0.9%	1,096	1.4%	1,163	1.2%	1,224	0.2%
Alogliptin_Benzoate	1,150	0.4%	456	0.6%	423	0.4%	798	0.1%
Canagliflozin	297,621	100.0%	4,039	5.1%	1,970	2.0%	29,145	4.4%
Chlorpropamide	*****	*****	*****	*****	*****	*****	22	0.0%
Dapagliflozin_Propoanediol	3,830	1.3%	79,311	100.0%	1,083	1.1%	7,653	1.1%
Dulaglutide	8,455	2.8%	3,511	4.4%	6,683	6.8%	6,089	0.9%
Empagliflozin	5,122	1.7%	2,010	2.5%	98,582	100.0%	8,360	1.3%
Ertugliflozin_Pidolate	*****	*****	0	0.0%	0	0.0%	0	0.0%
Exenatide	14,466	4.9%	5,018	6.3%	3,539	3.6%	8,454	1.3%
Glimiperide	58,024	19.5%	13,482	17.0%	16,714	17.0%	118,950	17.8%
Glipizide	54,868	18.4%	12,210	15.4%	14,621	14.8%	152,698	22.9%
Glyburide	15,085	5.1%	3,888	4.9%	3,557	3.6%	37,448	5.6%
Linagliptin	19,413	6.5%	5,049	6.4%	14,943	15.2%	16,931	2.5%
Liraglutide	34,233	11.5%	8,799	11.1%	10,236	10.4%	18,871	2.8%
Lixisenatide	58	0.0%	79	0.1%	137	0.1%	64	0.0%
Metformin_HCl	224,509	75.4%	61,375	77.4%	74,236	75.3%	476,119	71.3%
Miglitol	114	0.0%	35	0.0%	27	0.0%	165	0.0%

Table 1a. Baseline Characteristics of Canagliflozin, Dapagliflozin, Empagliflozin and Sitagliptin Users in the Sentinel Distributed Database (SDD), from March 1, 2013 to June 30, 2018

	Canagliflozin		Dapagliflozin		Empagliflozin		Sitagliptin	
History of Antidiabetic Drug Use up to 365 days after index	Number	Percent	Number	Percent	Number	Percent	Number	Percent
Nateglinide	2,625	0.9%	618	0.8%	574	0.6%	5,998	0.9%
Pioglitazone_HCl	30,131	10.1%	7,906	10.0%	8,329	8.4%	49,499	7.4%
Repaglinide	3,496	1.2%	729	0.9%	890	0.9%	7,475	1.1%
Rosiglitazone_Maleate	64	0.0%	22	0.0%	16	0.0%	86	0.0%
Saxagliptin_HCl	14,938	5.0%	4,983	6.3%	3,375	3.4%	6,873	1.0%
Semaglutide	*****	*****	*****	*****	12	0.0%	*****	*****
Sitagliptin_Phosphate	69,559	23.4%	17,311	21.8%	18,131	18.4%	667,369	100.0%
Tolazamide	*****	*****	*****	*****	0	0.0%	14	0.0%
Tolbutamide	*****	*****	0	0.0%	0	0.0%	20	0.0%
Insulin lispro	25,929	8.7%	5,407	6.8%	8,749	8.9%	34,025	5.1%
Insulin regular, human	8,214	2.8%	1,623	2.0%	1,930	2.0%	17,653	2.6%
Insulin glulisine	1,617	0.5%	469	0.6%	338	0.3%	1,129	0.2%
Insulin aspart	29,664	10.0%	6,349	8.0%	5,786	5.9%	46,910	7.0%
Insulin lispro protamine	4,588	1.5%	933	1.2%	1,238	1.3%	5,164	0.8%
Insulin glargine,human recombinant analog	63,002	21.2%	13,682	17.3%	17,490	17.7%	106,272	15.9%
Insulin NPH human isophane	6,181	2.1%	1,170	1.5%	1,823	1.8%	12,573	1.9%
Insulin detemir	32,893	11.1%	7,557	9.5%	7,570	7.7%	46,939	7.0%
Insulin aspart protamine human	5,401	1.8%	1,148	1.4%	879	0.9%	8,084	1.2%
Insulin degludec	3,033	1.0%	1,460	1.8%	2,757	2.8%	3,349	0.5%
History of Diabetic Ketoacidosis Diagnosis up to 365 days prior to index	Number	Percent	Number	Percent	Number	Percent	Number	Percent
Diabetic Ketoacidosis diagnosis	1,416	0.5%	335	0.4%	437	0.4%	4,292	0.6%
History of Insulin Pump Use up to 365 days prior to index	Number	Percent	Number	Percent	Number	Percent	Number	Percent
Insulin Pump Use	1,795	0.6%	549	0.7%	757	0.8%	873	0.1%

*****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 1b. Baseline Characteristics of Canagliflozin, Dapagliflozin, Empagliflozin and Sitagliptin Users with a Prior Type 1 Diabetes Mellitus Diagnosis in the Sentinel Distributed Database (SDD), from March 1, 2013 to June 30, 2018

Characteristic	Canagliflozin		Dapagliflozin		Empagliflozin		Sitagliptin	
	Mean	Standard Deviation	Mean	Standard Deviation	Mean	Standard Deviation	Mean	Standard Deviation
Number of unique patients	1,520		391		468		791	
Demographics	Mean	Standard Deviation	Mean	Standard Deviation	Mean	Standard Deviation	Mean	Standard Deviation
Mean Age	52.3	12.9	51	11.9	52	12.1	61.5	14.4
Age (Years)	Number	Percent	Number	Percent	Number	Percent	Number	Percent
<12	*****	*****	*****	*****	*****	*****	*****	*****
12-18	*****	*****	*****	*****	*****	*****	*****	*****
19-24	*****	*****	*****	*****	*****	*****	*****	*****
25-44	431	28.4%	112	28.6%	136	29.1%	126	15.9%
45-64	708	46.6%	212	54.2%	243	51.9%	266	33.6%
>=65 years	330	21.7%	54	13.8%	78	16.7%	385	48.7%
Sex								
Female	820	53.9%	220	56.3%	226	48.3%	453	57.3%
Male	700	46.1%	171	43.7%	242	51.7%	338	42.7%
Other	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Year								
2013	150	9.9%	0	0.0%	0	0.0%	165	20.9%
2014	486	32.0%	141	36.1%	30	6.4%	227	28.7%
2015	589	38.8%	141	36.1%	131	28.0%	209	26.4%
2016	246	16.2%	67	17.1%	155	33.1%	147	18.6%
2017	*****	*****	*****	*****	140	29.9%	*****	*****
2018	*****	*****	*****	*****	12	2.6%	*****	*****

Table 1b. Baseline Characteristics of Canagliflozin, Dapagliflozin, Empagliflozin and Sitagliptin Users with a Prior Type 1 Diabetes Mellitus Diagnosis in the Sentinel Distributed Database (SDD), from March 1, 2013 to June 30, 2018

History of Antidiabetic Drug Use up to 365 days prior to index	Canagliflozin		Dapagliflozin		Empagliflozin		Sitagliptin	
	Number	Percent	Number	Percent	Number	Percent	Number	Percent
Acarbose	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Albiglutide	*****	*****	0	0.0%	*****	*****	*****	*****
Alogliptin_Benzoate	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Canagliflozin	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Chlorpropamide	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Dapagliflozin_Propanediol	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Dulaglutide	*****	*****	*****	*****	14	3.0%	*****	*****
Empagliflozin	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Ertugliflozin_Pidolate	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Exenatide	38	2.5%	*****	*****	12	2.6%	16	2.0%
Glimiperide	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Glipizide	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Glyburide	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Linagliptin	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Liraglutide	171	11.3%	41	10.5%	41	8.8%	27	3.4%
Lixisenatide	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Metformin_HCl	468	30.8%	91	23.3%	131	28.0%	321	40.6%
Miglitol	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Nateglinide	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Pioglitazone_HCl	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Repaglinide	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Rosiglitazone_Maleate	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Saxagliptin_HCl	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Semaglutide	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Sitagliptin_Phosphate	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Tolazamide	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Tolbutamide	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Insulin lispro	789	51.9%	209	53.5%	297	63.5%	352	44.5%

Table 1b. Baseline Characteristics of Canagliflozin, Dapagliflozin, Empagliflozin and Sitagliptin Users with a Prior Type 1 Diabetes Mellitus Diagnosis in the Sentinel Distributed Database (SDD), from March 1, 2013 to June 30, 2018

	Canagliflozin		Dapagliflozin		Empagliflozin		Sitagliptin	
History of Antidiabetic Drug Use up to 365 days prior to index	Number	Percent	Number	Percent	Number	Percent	Number	Percent
Insulin regular, human	114	7.5%	34	8.7%	35	7.5%	133	16.8%
Insulin glulisine	105	6.9%	45	11.5%	25	5.3%	25	3.2%
Insulin aspart	684	45.0%	157	40.2%	192	41.0%	406	51.3%
Insulin lispro protamine	45	3.0%	*****	*****	11	2.4%	72	9.1%
Insulin glargine,human recombinant analog	579	38.1%	154	39.4%	180	38.5%	433	54.7%
Insulin NPH human isophane	64	4.2%	15	3.8%	*****	*****	75	9.5%
Insulin detemir	267	17.6%	63	16.1%	63	13.5%	175	22.1%
Insulin aspart protamine human	23	1.5%	*****	*****	*****	*****	43	5.4%
Insulin degludec	14	0.9%	*****	*****	17	3.6%	*****	*****
History of Antidiabetic Drug Use up to 365 days after index	Number	Percent	Number	Percent	Number	Percent	Number	Percent
Acarbose	*****	*****	*****	*****	*****	*****	*****	*****
Albiglutide	*****	*****	*****	*****	*****	*****	*****	*****
Alogliptin_Benzoate	*****	*****	0	0.0%	0	0.0%	*****	*****
Canagliflozin	1,520	100.0%	21	5.4%	*****	*****	27	3.4%
Chlorpropamide	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Dapagliflozin_Propoanediol	14	0.9%	391	100.0%	*****	*****	*****	*****
Dulaglutide	27	1.8%	11	2.8%	19	4.1%	*****	*****
Empagliflozin	19	1.3%	*****	*****	468	100.0%	*****	*****
Ertugliflozin_Pidolate	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Exenatide	29	1.9%	17	4.3%	12	2.6%	12	1.5%
Glimiperide	11	0.7%	*****	*****	*****	*****	29	3.7%
Glipizide	*****	*****	*****	*****	*****	*****	22	2.8%
Glyburide	0	0.0%	*****	*****	*****	*****	*****	*****
Linagliptin	*****	*****	*****	*****	16	3.4%	32	4.0%
Liraglutide	150	9.9%	42	10.7%	38	8.1%	27	3.4%
Lixisenatide	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Metformin_HCl	458	30.1%	95	24.3%	121	25.9%	447	56.5%

Table 1b. Baseline Characteristics of Canagliflozin, Dapagliflozin, Empagliflozin and Sitagliptin Users with a Prior Type 1 Diabetes Mellitus Diagnosis in the Sentinel Distributed Database (SDD), from March 1, 2013 to June 30, 2018

	Canagliflozin		Dapagliflozin		Empagliflozin		Sitagliptin	
History of Antidiabetic Drug Use up to 365 days after index	Number	Percent	Number	Percent	Number	Percent	Number	Percent
Miglitol	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Nateglinide	****	****	0	0.0%	0	0.0%	****	****
Pioglitazone_HCl	21	1.4%	****	****	****	****	19	2.4%
Repaglinide	****	****	0	0.0%	0	0.0%	****	****
Rosiglitazone_Maleate	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Saxagliptin_HCl	****	****	****	****	0	0.0%	****	0.0%
Semaglutide	0	0.0%	0	0.0%	0	0.0%	0	****
Sitagliptin_Phosphate	17	1.1%	****	****	****	****	791	100.0%
Tolazamide	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Tolbutamide	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Insulin lispro	802	52.8%	219	56.0%	280	59.8%	300	37.9%
Insulin regular, human	87	5.7%	36	9.2%	29	6.2%	87	11.0%
Insulin glulisine	80	5.3%	34	8.7%	18	3.8%	16	2.0%
Insulin aspart	589	38.8%	131	33.5%	150	32.1%	342	43.2%
Insulin lispro protamine	38	2.5%	****	****	12	2.6%	57	7.2%
Insulin glargine,human recombinant analog	528	34.7%	132	33.8%	158	33.8%	401	50.7%
Insulin NPH human isophane	48	3.2%	11	2.8%	****	****	43	5.4%
Insulin detemir	234	15.4%	60	15.3%	53	11.3%	182	23.0%
Insulin aspart protamine human	13	0.9%	****	****	****	****	38	4.8%
Insulin degludec	27	1.8%	12	3.1%	29	6.2%	14	1.8%
History of Diabetic Ketoacidosis								
Diagnosis up to 365 days prior to index	Number	Percent	Number	Percent	Number	Percent	Number	Percent
Diabetic Ketoacidosis diagnosis	85	5.6%	21	5.4%	19	4.1%	53	6.7%
History of Insulin Pump Use up to 365 days prior to index								
Insulin Pump Use	Number	Percent	Number	Percent	Number	Percent	Number	Percent
Insulin Pump Use	465	30.6%	143	36.6%	193	41.2%	30	3.8%

****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 1c. Baseline Characteristics of Canagliflozin, Dapagliflozin, Empagliflozin and Sitagliptin Users with a Prior Type 1 Diabetes Mellitus Diagnosis (Using Broad Definition) in the Sentinel Distributed Database (SDD), from March 1, 2013 to June 30, 2018

Characteristic	Canagliflozin		Dapagliflozin		Empagliflozin		Sitagliptin	
	Mean	Standard Deviation	Mean	Standard Deviation	Mean	Standard Deviation	Mean	Standard Deviation
Number of unique patients	2,907		734		734		2,909	
Demographics	Mean	Standard Deviation	Mean	Standard Deviation	Mean	Standard Deviation	Mean	Standard Deviation
Mean Age	56.9	12.6	55.1	11.5	54.5	12	65.8	13.4
Age (Years)	Number	Percent	Number	Percent	Number	Percent	Number	Percent
<12	*****	*****	*****	*****	*****	*****	*****	*****
12-18	*****	*****	*****	*****	*****	*****	*****	*****
19-24	*****	*****	*****	*****	*****	*****	*****	*****
25-44	566	19.5%	148	20.2%	173	23.6%	256	8.8%
45-64	1,303	44.8%	395	53.8%	389	53.0%	893	30.7%
>=65 years	977	33.6%	177	24.1%	160	21.8%	1,734	59.6%
Sex								
Female	1,442	49.6%	372	50.7%	357	48.6%	1,521	52.3%
Male	1,465	50.4%	362	49.3%	377	51.4%	1,388	47.7%
Other	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Year								
2013	314	10.8%	0	0.0%	0	0.0%	693	23.8%
2014	902	31.0%	268	36.5%	48	6.5%	850	29.2%
2015	1,119	38.5%	251	34.2%	218	29.7%	741	25.5%
2016	487	16.8%	144	19.6%	248	33.8%	489	16.8%
2017	*****	*****	*****	*****	204	27.8%	*****	*****
2018	*****	*****	*****	*****	16	2.2%	*****	*****

Table 1c. Baseline Characteristics of Canagliflozin, Dapagliflozin, Empagliflozin and Sitagliptin Users with a Prior Type 1 Diabetes Mellitus Diagnosis (Using Broad Definition) in the Sentinel Distributed Database (SDD), from March 1, 2013 to June 30, 2018

History of Antidiabetic Drug Use up to 365 days prior to index	Canagliflozin		Dapagliflozin		Empagliflozin		Sitagliptin	
	Number	Percent	Number	Percent	Number	Percent	Number	Percent
Acarbose	11	0.4%	*****	*****	*****	*****	15	0.5%
Albiglutide	*****	*****	*****	*****	*****	*****	*****	*****
Alogliptin_Benzoate	*****	*****	*****	*****	*****	*****	0	0.0%
Canagliflozin	0	0.0%	0	0.0%	0	0.0%	65	2.2%
Chlorpropamide	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Dapagliflozin_Propoanediol	0	0.0%	0	0.0%	0	0.0%	12	0.4%
Dulaglutide	12	0.4%	*****	*****	30	4.1%	*****	*****
Empagliflozin	0	0.0%	0	0.0%	0	0.0%	*****	*****
Ertugliflozin_Pidolate	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Exenatide	124	4.3%	25	3.4%	23	3.1%	48	1.7%
Glimiperide	260	8.9%	47	6.4%	43	5.9%	342	11.8%
Glipizide	236	8.1%	46	6.3%	33	4.5%	470	16.2%
Glyburide	109	3.7%	20	2.7%	14	1.9%	228	7.8%
Linagliptin	62	2.1%	17	2.3%	14	1.9%	0	0.0%
Liraglutide	348	12.0%	93	12.7%	74	10.1%	76	2.6%
Lixisenatide	0	0.0%	*****	*****	0	0.0%	0	0.0%
Metformin_HCl	1,394	48.0%	325	44.3%	320	43.6%	1,603	55.1%
Miglitol	0	0.0%	*****	*****	0	0.0%	*****	*****
Nateglinide	24	0.8%	*****	*****	*****	*****	30	1.0%
Pioglitazone_HCl	179	6.2%	47	6.4%	28	3.8%	198	6.8%
Repaglinide	27	0.9%	*****	*****	*****	*****	36	1.2%
Rosiglitazone_Maleate	*****	*****	0	0.0%	0	0.0%	*****	*****
Saxagliptin_HCl	89	3.1%	33	4.5%	12	1.6%	0	0.0%
Semaglutide	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Sitagliptin_Phosphate	350	12.0%	82	11.2%	59	8.0%	0	0.0%
Tolazamide	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Tolbutamide	0	0.0%	0	0.0%	0	0.0%	*****	*****
Insulin lispro	971	33.4%	255	34.7%	344	46.9%	475	16.3%
Insulin regular, human	230	7.9%	59	8.0%	49	6.7%	298	10.2%

Table 1c. Baseline Characteristics of Canagliflozin, Dapagliflozin, Empagliflozin and Sitagliptin Users with a Prior Type 1 Diabetes Mellitus Diagnosis (Using Broad Definition) in the Sentinel Distributed Database (SDD), from March 1, 2013 to June 30, 2018

	Canagliflozin		Dapagliflozin		Empagliflozin		Sitagliptin	
History of Antidiabetic Drug Use up to 365 days prior to index	Number	Percent	Number	Percent	Number	Percent	Number	Percent
Insulin glulisine	122	4.2%	47	6.4%	29	4.0%	35	1.2%
Insulin aspart	942	32.4%	215	29.3%	226	30.8%	627	21.6%
Insulin lispro protamine	82	2.8%	19	2.6%	21	2.9%	104	3.6%
Insulin glargine,human recombinant analog	1,125	38.7%	284	38.7%	291	39.6%	1,071	36.8%
Insulin NPH human isophane	174	6.0%	33	4.5%	26	3.5%	257	8.8%
Insulin detemir	549	18.9%	137	18.7%	113	15.4%	430	14.8%
Insulin aspart protamine human	119	4.1%	29	4.0%	18	2.5%	145	5.0%
Insulin degludec	17	0.6%	*****	*****	24	3.3%	13	0.4%
History of Antidiabetic Drug Use up to 365 days after index	Number	Percent	Number	Percent	Number	Percent	Number	Percent
Acarbose	17	0.6%	*****	*****	*****	*****	20	0.7%
Albiglutide	15	0.5%	*****	*****	*****	*****	*****	*****
Alogliptin_Benzoate	*****	*****	*****	*****	*****	*****	*****	*****
Canagliflozin	2,907	100.0%	43	5.9%	12	1.6%	119	4.1%
Chlorpropamide	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Dapagliflozin_Propoanediol	30	1.0%	734	100.0%	11	1.5%	26	0.9%
Dulaglutide	51	1.8%	16	2.2%	48	6.5%	18	0.6%
Empagliflozin	46	1.6%	*****	*****	734	100.0%	29	1.0%
Ertugliflozin_Pidolate	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Exenatide	103	3.5%	40	5.4%	21	2.9%	43	1.5%
Glimiperide	231	7.9%	47	6.4%	32	4.4%	391	13.4%
Glipizide	217	7.5%	42	5.7%	30	4.1%	496	17.1%
Glyburide	69	2.4%	19	2.6%	13	1.8%	156	5.4%
Linagliptin	83	2.9%	18	2.5%	60	8.2%	96	3.3%
Liraglutide	311	10.7%	93	12.7%	57	7.8%	101	3.5%
Lixisenatide	0	0.0%	*****	*****	0	0.0%	*****	*****
Metformin_HCl	1,373	47.2%	327	44.6%	303	41.3%	1,868	64.2%
Miglitol	*****	*****	0	0.0%	0	0.0%	*****	*****

Table 1c. Baseline Characteristics of Canagliflozin, Dapagliflozin, Empagliflozin and Sitagliptin Users with a Prior Type 1 Diabetes Mellitus Diagnosis (Using Broad Definition) in the Sentinel Distributed Database (SDD), from March 1, 2013 to June 30, 2018

	Canagliflozin		Dapagliflozin		Empagliflozin		Sitagliptin	
History of Antidiabetic Drug Use up to 365 days after index	Number	Percent	Number	Percent	Number	Percent	Number	Percent
Nateglinide	20	0.7%	*****	*****	*****	*****	38	1.3%
Pioglitazone_HCl	183	6.3%	37	5.0%	28	3.8%	207	7.1%
Repaglinide	20	0.7%	*****	*****	*****	*****	45	1.5%
Rosiglitazone_Maleate	*****	*****	0	0.0%	0	0.0%	*****	*****
Saxagliptin_HCl	60	2.1%	24	3.3%	*****	*****	23	0.8%
Semaglutide	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Sitagliptin_Phosphate	309	10.6%	82	11.2%	46	6.3%	2,908	100.0%
Tolazamide	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Tolbutamide	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Insulin lispro	1,022	35.2%	281	38.3%	334	45.5%	474	16.3%
Insulin regular, human	203	7.0%	58	7.9%	42	5.7%	240	8.3%
Insulin glulisine	102	3.5%	36	4.9%	21	2.9%	30	1.0%
Insulin aspart	857	29.5%	190	25.9%	187	25.5%	618	21.2%
Insulin lispro protamine	75	2.6%	21	2.9%	24	3.3%	97	3.3%
Insulin glargine,human recombinant analog	1,052	36.2%	266	36.2%	258	35.1%	1,091	37.5%
Insulin NPH human isophane	145	5.0%	23	3.1%	22	3.0%	194	6.7%
Insulin detemir	523	18.0%	123	16.8%	95	12.9%	461	15.8%
Insulin aspart protamine human	103	3.5%	21	2.9%	13	1.8%	138	4.7%
Insulin degludec	42	1.4%	18	2.5%	39	5.3%	30	1.0%
History of Diabetic Ketoacidosis Diagnosis up to 365 days prior to index	Number	Percent	Number	Percent	Number	Percent	Number	Percent
Diabetic Ketoacidosis diagnosis	104	3.6%	25	3.4%	21	2.9%	75	2.6%
History of Insulin Pump Use up to 365 days prior to index	Number	Percent	Number	Percent	Number	Percent	Number	Percent
Insulin Pump Use	504	17.3%	156	21.3%	203	27.7%	46	1.6%

*****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. Baseline Characteristics of Canagliflozin, Dapagliflozin, Empagliflozin and Sitagliptin Users with a Prior Type 2 Diabetes Mellitus Diagnosis in the Sentinel Distributed Database (SDD), from March 1, 2013 to June 30, 2018

Characteristic	Canagliflozin		Dapagliflozin		Empagliflozin		Sitagliptin	
	Mean	Standard Deviation	Mean	Standard Deviation	Mean	Standard Deviation	Mean	Standard Deviation
Number of unique patients	229,836		60,910		78,420		482,451	
Demographics	Mean	Standard Deviation	Mean	Standard Deviation	Mean	Standard Deviation	Mean	Standard Deviation
Mean Age	62.1	10.3	59.3	10	59.8	9.8	67.2	11.3
Age (Years)	Number	Percent	Number	Percent	Number	Percent	Number	Percent
<12	*****	*****	*****	*****	*****	*****	*****	*****
12-18	*****	*****	*****	*****	*****	*****	*****	*****
19-24	275	0.1%	101	0.2%	115	0.1%	514	0.1%
25-44	20,003	8.7%	6,863	11.3%	7,864	10.0%	26,955	5.6%
45-64	102,555	44.6%	33,775	55.5%	43,896	56.0%	148,258	30.7%
>=65 years	106,969	46.5%	20,156	33.1%	26,527	33.8%	306,642	63.6%
Sex								
Female	108,055	47.0%	27,929	45.9%	33,707	43.0%	250,673	52.0%
Male	*****	*****	*****	*****	*****	*****	231,762	48.0%
Other	*****	*****	*****	*****	*****	*****	16	0.0%
Year								
2013	15,443	6.7%	0	0.0%	0	0.0%	85,868	17.8%
2014	56,005	24.4%	15,782	25.9%	2,003	2.6%	117,568	24.4%
2015	82,941	36.1%	18,822	30.9%	14,371	18.3%	118,190	24.5%
2016	61,707	26.8%	17,646	29.0%	29,830	38.0%	120,791	25.0%
2017	13,079	5.7%	7,867	12.9%	30,265	38.6%	37,375	7.7%
2018	661	0.3%	793	1.3%	1,951	2.5%	2,659	0.6%

Table 1d. Baseline Characteristics of Canagliflozin, Dapagliflozin, Empagliflozin and Sitagliptin Users with a Prior Type 2 Diabetes Mellitus Diagnosis in the Sentinel Distributed Database (SDD), from March 1, 2013 to June 30, 2018

History of Antidiabetic Drug Use up to 365 days prior to index	Canagliflozin		Dapagliflozin		Empagliflozin		Sitagliptin	
	Number	Percent	Number	Percent	Number	Percent	Number	Percent
Acarbose	2,279	1.0%	434	0.7%	462	0.6%	2,971	0.6%
Albiglutide	957	0.4%	459	0.8%	922	1.2%	488	0.1%
Alogliptin_Benzoate	874	0.4%	362	0.6%	493	0.6%	0	0.0%
Canagliflozin	0	0.0%	0	0.0%	0	0.0%	14,017	2.9%
Chlorpropamide	13	0.0%	*****	*****	*****	*****	37	0.0%
Dapagliflozin_Propoanediol	0	0.0%	0	0.0%	0	0.0%	3,604	0.7%
Dulaglutide	2,091	0.9%	1,157	1.9%	3,233	4.1%	1,492	0.3%
Empagliflozin	0	0.0%	0	0.0%	0	0.0%	2,586	0.5%
Ertugliflozin_Pidolate	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Exenatide	12,149	5.3%	3,851	6.3%	3,533	4.5%	6,206	1.3%
Glimiperide	53,372	23.2%	12,595	20.7%	16,578	21.1%	95,887	19.9%
Glipizide	52,667	22.9%	11,998	19.7%	15,424	19.7%	131,700	27.3%
Glyburide	20,722	9.0%	4,954	8.1%	4,869	6.2%	50,921	10.6%
Linagliptin	15,270	6.6%	4,074	6.7%	6,261	8.0%	0	0.0%
Liraglutide	26,562	11.6%	6,956	11.4%	8,301	10.6%	11,276	2.3%
Lixisenatide	*****	*****	*****	*****	40	0.1%	*****	*****
Metformin_HCl	201,197	87.5%	54,158	88.9%	69,916	89.2%	407,143	84.4%
Miglitol	131	0.1%	26	0.0%	30	0.0%	131	0.0%
Nateglinide	2,553	1.1%	593	1.0%	573	0.7%	4,160	0.9%
Pioglitazone_HCl	28,338	12.3%	7,254	11.9%	8,142	10.4%	43,574	9.0%
Repaglinide	3,028	1.3%	620	1.0%	793	1.0%	4,476	0.9%
Rosiglitazone_Maleate	59	0.0%	14	0.0%	18	0.0%	67	0.0%
Saxagliptin_HCl	16,838	7.3%	5,362	8.8%	4,341	5.5%	0	0.0%
Semaglutide	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Sitagliptin_Phosphate	69,503	30.2%	17,095	28.1%	19,397	24.7%	0	0.0%
Tolazamide	*****	*****	*****	*****	0	0.0%	21	0.0%
Tolbutamide	*****	*****	0	0.0%	0	0.0%	29	0.0%
Insulin lispro	12,879	5.6%	2,691	4.4%	5,203	6.6%	12,128	2.5%
Insulin regular, human	4,450	1.9%	921	1.5%	1,402	1.8%	8,185	1.7%

Table 1d. Baseline Characteristics of Canagliflozin, Dapagliflozin, Empagliflozin and Sitagliptin Users with a Prior Type 2 Diabetes Mellitus Diagnosis in the Sentinel Distributed Database (SDD), from March 1, 2013 to June 30, 2018

	Canagliflozin		Dapagliflozin		Empagliflozin		Sitagliptin	
History of Antidiabetic Drug Use up to 365 days prior to index	Number	Percent	Number	Percent	Number	Percent	Number	Percent
Insulin glulisine	1,008	0.4%	275	0.5%	254	0.3%	550	0.1%
Insulin aspart	15,980	7.0%	3,552	5.8%	4,135	5.3%	17,957	3.7%
Insulin lispro protamine	2,654	1.2%	576	0.9%	844	1.1%	2,162	0.4%
Insulin glargine,human recombinant analog	37,883	16.5%	8,507	14.0%	12,228	15.6%	45,101	9.3%
Insulin NPH human isophane	3,838	1.7%	810	1.3%	1,545	2.0%	6,405	1.3%
Insulin detemir	19,561	8.5%	4,741	7.8%	5,865	7.5%	18,835	3.9%
Insulin aspart protamine human	3,374	1.5%	757	1.2%	751	1.0%	3,800	0.8%
Insulin degludec	492	0.2%	352	0.6%	1,022	1.3%	551	0.1%
History of Antidiabetic Drug Use up to 365 days after index	Number	Percent	Number	Percent	Number	Percent	Number	Percent
Acarbose	2,110	0.9%	360	0.6%	435	0.6%	3,483	0.7%
Albiglutide	2,040	0.9%	856	1.4%	925	1.2%	903	0.2%
Alogliptin_Benzoate	957	0.4%	378	0.6%	358	0.5%	574	0.1%
Canagliflozin	229,828	100.0%	3,195	5.2%	1,555	2.0%	23,171	4.8%
Chlorpropamide	*****	*****	*****	*****	*****	*****	20	0.0%
Dapagliflozin_Propoanediol	2,938	1.3%	60,910	100.0%	860	1.1%	6,123	1.3%
Dulaglutide	6,533	2.8%	2,699	4.4%	5,298	6.8%	4,801	1.0%
Empagliflozin	4,053	1.8%	1,611	2.6%	78,420	100.0%	6,739	1.4%
Ertugliflozin_Pidolate	*****	*****	0	0.0%	0	0.0%	0	0.0%
Exenatide	10,994	4.8%	3,866	6.3%	2,791	3.6%	6,391	1.3%
Glimiperide	50,898	22.1%	11,879	19.5%	15,142	19.3%	100,642	20.9%
Glipizide	48,477	21.1%	10,835	17.8%	13,276	16.9%	130,665	27.1%
Glyburide	13,273	5.8%	3,443	5.7%	3,230	4.1%	32,153	6.7%
Linagliptin	16,340	7.1%	4,249	7.0%	12,256	15.6%	12,085	2.5%
Liraglutide	25,735	11.2%	6,661	10.9%	7,951	10.1%	14,154	2.9%
Lixisenatide	44	0.0%	61	0.1%	112	0.1%	50	0.0%
Metformin_HCl	188,086	81.8%	50,924	83.6%	64,145	81.8%	376,820	78.1%
Miglitol	97	0.0%	25	0.0%	23	0.0%	121	0.0%

Table 1d. Baseline Characteristics of Canagliflozin, Dapagliflozin, Empagliflozin and Sitagliptin Users with a Prior Type 2 Diabetes Mellitus Diagnosis in the Sentinel Distributed Database (SDD), from March 1, 2013 to June 30, 2018

	Canagliflozin		Dapagliflozin		Empagliflozin		Sitagliptin	
History of Antidiabetic Drug Use up to 365 days after index	Number	Percent	Number	Percent	Number	Percent	Number	Percent
Nateglinide	2,234	1.0%	527	0.9%	508	0.6%	4,667	1.0%
Pioglitazone_HCl	26,012	11.3%	6,869	11.3%	7,347	9.4%	41,494	8.6%
Repaglinide	2,889	1.3%	599	1.0%	761	1.0%	5,560	1.2%
Rosiglitazone_Maleate	56	0.0%	15	0.0%	15	0.0%	65	0.0%
Saxagliptin_HCl	13,297	5.8%	4,376	7.2%	3,068	3.9%	4,931	1.0%
Semaglutide	****	****	****	****	****	****	****	****
Sitagliptin_Phosphate	60,409	26.3%	15,142	24.9%	16,176	20.6%	482,401	100.0%
Tolazamide	****	****	0	0.0%	0	0.0%	11	0.0%
Tolbutamide	****	****	0	0.0%	0	0.0%	19	0.0%
Insulin lispro	14,259	6.2%	2,966	4.9%	5,263	6.7%	18,013	3.7%
Insulin regular, human	4,376	1.9%	846	1.4%	1,185	1.5%	9,144	1.9%
Insulin glulisine	799	0.3%	245	0.4%	167	0.2%	600	0.1%
Insulin aspart	16,448	7.2%	3,549	5.8%	3,370	4.3%	24,531	5.1%
Insulin lispro protamine	2,744	1.2%	555	0.9%	795	1.0%	2,749	0.6%
Insulin glargine,human recombinant analog	41,898	18.2%	9,209	15.1%	12,273	15.7%	65,805	13.6%
Insulin NPH human isophane	3,572	1.6%	698	1.1%	1,285	1.6%	6,812	1.4%
Insulin detemir	21,997	9.6%	5,203	8.5%	5,353	6.8%	28,676	5.9%
Insulin aspart protamine human	3,149	1.4%	656	1.1%	575	0.7%	4,306	0.9%
Insulin degludec	2,054	0.9%	976	1.6%	1,941	2.5%	2,212	0.5%
History of Diabetic Ketoacidosis Diagnosis up to 365 days prior to index	Number	Percent	Number	Percent	Number	Percent	Number	Percent
Diabetic Ketoacidosis diagnosis	460	0.2%	104	0.2%	171	0.2%	1,406	0.3%
History of Insulin Pump Use up to 365 days prior to index	Number	Percent	Number	Percent	Number	Percent	Number	Percent
Insulin Pump Use	372	0.2%	106	0.2%	170	0.2%	452	0.1%

****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 1e. Baseline Characteristics of Canagliflozin, Dapagliflozin, Empagliflozin and Sitagliptin Users with a Prior Type 2 Diabetes Mellitus Diagnosis and History of Insulin Use in the Sentinel Distributed Database (SDD), from March 1, 2013 to June 30, 2018

Characteristic	Canagliflozin		Dapagliflozin		Empagliflozin		Sitagliptin	
	Mean	Standard Deviation	Mean	Standard Deviation	Mean	Standard Deviation	Mean	Standard Deviation
Number of unique patients	63,256		14,533		20,491		75,736	
Demographics	Mean	Standard Deviation	Mean	Standard Deviation	Mean	Standard Deviation	Mean	Standard Deviation
Mean Age	61.3	10.5	59.1	10.1	59.8	9.7	66.5	11.7
Age (Years)	Number	Percent	Number	Percent	Number	Percent	Number	Percent
<12	*****	*****	*****	*****	*****	*****	*****	*****
12-18	*****	*****	*****	*****	*****	*****	*****	*****
19-24	*****	*****	*****	*****	*****	*****	*****	*****
25-44	5,618	8.9%	1,567	10.8%	1,889	9.2%	4,369	5.8%
45-64	30,602	48.4%	8,250	56.8%	11,759	57.4%	25,568	33.8%
>=65 years	26,935	42.6%	4,686	32.2%	6,811	33.2%	45,705	60.3%
Sex								
Female	30,949	48.9%	6,967	47.9%	9,257	45.2%	41,755	55.1%
Male	*****	*****	7,566	52.1%	11,234	54.8%	*****	*****
Other	*****	*****	0	0.0%	0	0.0%	*****	*****
Year								
2013	4,746	7.5%	0	0.0%	0	0.0%	12,410	16.4%
2014	17,026	26.9%	4,417	30.4%	594	2.9%	18,355	24.2%
2015	23,365	36.9%	4,505	31.0%	3,960	19.3%	19,468	25.7%
2016	15,266	24.1%	3,927	27.0%	7,775	37.9%	19,819	26.2%
2017	2,716	4.3%	1,500	10.3%	7,568	36.9%	5,298	7.0%
2018	137	0.2%	184	1.3%	594	2.9%	386	0.5%

Table 1e. Baseline Characteristics of Canagliflozin, Dapagliflozin, Empagliflozin and Sitagliptin Users with a Prior Type 2 Diabetes Mellitus Diagnosis and History of Insulin Use in the Sentinel Distributed Database (SDD), from March 1, 2013 to June 30, 2018

History of Antidiabetic Drug Use up to 365 days prior to index	Canagliflozin		Dapagliflozin		Empagliflozin		Sitagliptin	
	Number	Percent	Number	Percent	Number	Percent	Number	Percent
Acarbose	694	1.1%	122	0.8%	127	0.6%	655	0.9%
Albiglutide	383	0.6%	179	1.2%	372	1.8%	164	0.2%
Alogliptin_Benzoate	160	0.3%	75	0.5%	95	0.5%	0	0.0%
Canagliflozin	0	0.0%	0	0.0%	0	0.0%	3,445	4.5%
Chlorpropamide	*****	*****	*****	*****	*****	*****	*****	*****
Dapagliflozin_Propoanediol	0	0.0%	0	0.0%	0	0.0%	717	0.9%
Dulaglutide	835	1.3%	405	2.8%	1,282	6.3%	471	0.6%
Empagliflozin	0	0.0%	0	0.0%	0	0.0%	547	0.7%
Ertugliflozin_Pidolate	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Exenatide	4,865	7.7%	1,391	9.6%	1,345	6.6%	1,914	2.5%
Glimiperide	12,481	19.7%	2,740	18.9%	3,775	18.4%	14,453	19.1%
Glipizide	12,010	19.0%	2,495	17.2%	3,636	17.7%	19,510	25.8%
Glyburide	4,853	7.7%	1,028	7.1%	1,116	5.4%	7,030	9.3%
Linagliptin	3,705	5.9%	848	5.8%	1,436	7.0%	0	0.0%
Liraglutide	11,485	18.2%	2,752	18.9%	3,551	17.3%	3,674	4.9%
Lixisenatide	*****	*****	*****	*****	*****	*****	*****	*****
Metformin_HCl	54,100	85.5%	12,638	87.0%	17,935	87.5%	60,768	80.2%
Miglitol	42	0.1%	*****	*****	*****	*****	33	0.0%
Nateglinide	787	1.2%	151	1.0%	174	0.8%	962	1.3%
Pioglitazone_HCl	7,106	11.2%	1,717	11.8%	1,938	9.5%	6,834	9.0%
Repaglinide	963	1.5%	187	1.3%	245	1.2%	1,121	1.5%
Rosiglitazone_Maleate	12	0.0%	*****	*****	*****	*****	*****	*****
Saxagliptin_HCl	3,373	5.3%	1,060	7.3%	821	4.0%	0	0.0%
Semaglutide	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Sitagliptin_Phosphate	15,808	25.0%	3,442	23.7%	4,059	19.8%	0	0.0%
Tolazamide	*****	*****	0	0.0%	0	0.0%	*****	*****
Tolbutamide	0	0.0%	0	0.0%	0	0.0%	*****	*****
Insulin lispro	12,916	20.4%	2,696	18.6%	5,212	25.4%	12,230	16.1%
Insulin regular, human	4,458	7.0%	921	6.3%	1,402	6.8%	8,226	10.9%

Table 1e. Baseline Characteristics of Canagliflozin, Dapagliflozin, Empagliflozin and Sitagliptin Users with a Prior Type 2 Diabetes Mellitus Diagnosis and History of Insulin Use in the Sentinel Distributed Database (SDD), from March 1, 2013 to June 30, 2018

	Canagliflozin		Dapagliflozin		Empagliflozin		Sitagliptin	
History of Antidiabetic Drug Use up to 365 days prior to index	Number	Percent	Number	Percent	Number	Percent	Number	Percent
Insulin glulisine	1,010	1.6%	275	1.9%	254	1.2%	553	0.7%
Insulin aspart	16,012	25.3%	3,554	24.5%	4,136	20.2%	18,071	23.9%
Insulin lispro protamine	2,662	4.2%	577	4.0%	846	4.1%	2,172	2.9%
Insulin glargine, human recombinant analog	37,996	60.1%	8,529	58.7%	12,243	59.7%	45,582	60.2%
Insulin NPH human isophane	3,850	6.1%	810	5.6%	1,545	7.5%	6,436	8.5%
Insulin detemir	19,637	31.0%	4,763	32.8%	5,869	28.6%	19,091	25.2%
Insulin aspart protamine human	3,380	5.3%	757	5.2%	751	3.7%	3,819	5.0%
Insulin degludec	500	0.8%	356	2.4%	1,027	5.0%	564	0.7%
History of Antidiabetic Drug Use up to 365 days after index	Number	Percent	Number	Percent	Number	Percent	Number	Percent
Acarbose	563	0.9%	91	0.6%	101	0.5%	630	0.8%
Albiglutide	750	1.2%	308	2.1%	352	1.7%	237	0.3%
Alogliptin_Benzoate	177	0.3%	68	0.5%	69	0.3%	74	0.1%
Canagliflozin	63,253	100.0%	859	5.9%	422	2.1%	4,538	6.0%
Chlorpropamide	0	0.0%	0	0.0%	0	0.0%	*****	*****
Dapagliflozin_Propoanediol	774	1.2%	14,533	100.0%	200	1.0%	1,028	1.4%
Dulaglutide	2,286	3.6%	826	5.7%	1,848	9.0%	1,102	1.5%
Empagliflozin	1,064	1.7%	359	2.5%	20,491	100.0%	1,170	1.5%
Ertugliflozin_Pidolate	*****	*****	0	0.0%	0	0.0%	0	0.0%
Exenatide	4,143	6.5%	1,313	9.0%	955	4.7%	1,558	2.1%
Glimiperide	10,675	16.9%	2,286	15.7%	3,030	14.8%	13,160	17.4%
Glipizide	9,722	15.4%	1,984	13.7%	2,682	13.1%	16,816	22.2%
Glyburide	2,817	4.5%	612	4.2%	620	3.0%	3,742	4.9%
Linagliptin	3,737	5.9%	847	5.8%	2,690	13.1%	2,104	2.8%
Liraglutide	10,502	16.6%	2,415	16.6%	3,210	15.7%	3,601	4.8%
Lixisenatide	21	0.0%	24	0.2%	80	0.4%	27	0.0%
Metformin_HCl	49,782	78.7%	11,756	80.9%	16,283	79.5%	55,552	73.3%
Miglitol	27	0.0%	*****	*****	*****	*****	25	0.0%

Table 1e. Baseline Characteristics of Canagliflozin, Dapagliflozin, Empagliflozin and Sitagliptin Users with a Prior Type 2 Diabetes Mellitus Diagnosis and History of Insulin Use in the Sentinel Distributed Database (SDD), from March 1, 2013 to June 30, 2018

	Canagliflozin		Dapagliflozin		Empagliflozin		Sitagliptin	
History of Antidiabetic Drug Use up to 365 days after index	Number	Percent	Number	Percent	Number	Percent	Number	Percent
Nateglinide	603	1.0%	114	0.8%	144	0.7%	896	1.2%
Pioglitazone_HCl	6,172	9.8%	1,500	10.3%	1,679	8.2%	5,730	7.6%
Repaglinide	846	1.3%	153	1.1%	223	1.1%	1,087	1.4%
Rosiglitazone_Maleate	12	0.0%	*****	*****	*****	*****	*****	*****
Saxagliptin_HCl	2,352	3.7%	773	5.3%	496	2.4%	679	0.9%
Semaglutide	*****	*****	*****	*****	*****	*****	*****	*****
Sitagliptin_Phosphate	12,644	20.0%	2,730	18.8%	3,006	14.7%	75,725	100.0%
Tolazamide	*****	*****	0	0.0%	0	0.0%	0	0.0%
Tolbutamide	0	0.0%	0	0.0%	0	0.0%	*****	*****
Insulin lispro	12,427	19.6%	2,580	17.8%	4,764	23.2%	11,988	15.8%
Insulin regular, human	3,846	6.1%	731	5.0%	1,079	5.3%	6,543	8.6%
Insulin glulisine	741	1.2%	226	1.6%	*****	*****	444	0.6%
Insulin aspart	14,431	22.8%	3,075	21.2%	3,072	15.0%	16,638	22.0%
Insulin lispro protamine	2,408	3.8%	494	3.4%	695	3.4%	1,974	2.6%
Insulin glargine,human recombinant analog	33,501	53.0%	7,364	50.7%	10,340	50.5%	40,234	53.1%
Insulin NPH human isophane	3,088	4.9%	594	4.1%	1,152	5.6%	4,970	6.6%
Insulin detemir	17,455	27.6%	4,135	28.5%	4,650	22.7%	17,255	22.8%
Insulin aspart protamine human	2,786	4.4%	569	3.9%	533	2.6%	3,209	4.2%
Insulin degludec	1,426	2.3%	696	4.8%	1,490	7.3%	1,200	1.6%
History of Diabetic Ketoacidosis Diagnosis up to 365 days prior to index	Number	Percent	Number	Percent	Number	Percent	Number	Percent
Diabetic Ketoacidosis diagnosis	310	0.5%	77	0.5%	135	0.7%	710	0.9%
History of Insulin Pump Use up to 365 days prior to index	Number	Percent	Number	Percent	Number	Percent	Number	Percent
Insulin Pump Use	373	0.6%	106	0.7%	170	0.8%	456	0.6%

*****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 1f. Baseline Characteristics of Canagliflozin, Dapagliflozin, Empagliflozin and Sitagliptin Users with a Prior Type 2 Diabetes Mellitus Diagnosis and No Prior History of Insulin Use in the Sentinel Distributed Database (SDD), from March 1, 2013 through June 30, 2018

Characteristic	Canagliflozin		Dapagliflozin		Empagliflozin		Sitagliptin	
	Mean	Standard Deviation	Mean	Standard Deviation	Mean	Standard Deviation	Mean	Standard Deviation
Number of unique patients	166,866		46,434		57,971		407,759	
Demographics	Mean	Standard Deviation	Mean	Standard Deviation	Mean	Standard Deviation	Mean	Standard Deviation
Mean Age	62.5	10.2	59.3	9.9	59.7	9.8	67.3	11.2
Age (Years)	Number	Percent	Number	Percent	Number	Percent	Number	Percent
<12	*****	*****	*****	*****	*****	*****	*****	*****
12-18	*****	*****	*****	*****	*****	*****	*****	*****
19-24	*****	*****	*****	*****	*****	*****	*****	*****
25-44	14,423	8.6%	5,307	11.4%	5,977	10.3%	22,642	5.6%
45-64	72,075	43.2%	25,548	55.0%	32,162	55.5%	123,003	30.2%
>=65 years	80,160	48.0%	15,493	33.4%	19,731	34.0%	261,611	64.2%
Sex								
Female	77,247	46.3%	20,987	45.2%	24,466	42.2%	209,469	51.4%
Male	*****	*****	*****	*****	*****	*****	*****	*****
Other	*****	*****	*****	*****	*****	*****	*****	*****
Year								
2013	10,697	6.4%	0	0.0%	0	0.0%	73,458	18.0%
2014	38,985	23.4%	11,365	24.5%	1,409	2.4%	99,262	24.3%
2015	59,642	35.7%	14,318	30.8%	10,411	18.0%	98,987	24.3%
2016	46,595	27.9%	13,746	29.6%	22,063	38.1%	101,497	24.9%
2017	10,420	6.2%	6,391	13.8%	22,729	39.2%	32,266	7.9%
2018	527	0.3%	614	1.3%	1,359	2.3%	2,289	0.6%

Table 1f. Baseline Characteristics of Canagliflozin, Dapagliflozin, Empagliflozin and Sitagliptin Users with a Prior Type 2 Diabetes Mellitus Diagnosis and No Prior History of Insulin Use in the Sentinel Distributed Database (SDD), from March 1, 2013 through June 30, 2018

History of Antidiabetic Drug Use up to 365 days prior to index	Canagliflozin		Dapagliflozin		Empagliflozin		Sitagliptin	
	Number	Percent	Number	Percent	Number	Percent	Number	Percent
Acarbose	1,589	1.0%	312	0.7%	336	0.6%	2,328	0.6%
Albiglutide	585	0.4%	283	0.6%	551	1.0%	325	0.1%
Alogliptin_Benzoate	716	0.4%	287	0.6%	398	0.7%	0	0.0%
Canagliflozin	0	0.0%	0	0.0%	0	0.0%	10,642	2.6%
Chlorpropamide	*****	*****	*****	*****	*****	*****	34	0.0%
Dapagliflozin_Propoanediol	0	0.0%	0	0.0%	0	0.0%	2,894	0.7%
Dulaglutide	1,273	0.8%	757	1.6%	1,960	3.4%	1,034	0.3%
Empagliflozin	0	0.0%	0	0.0%	0	0.0%	2,052	0.5%
Ertugliflozin_Pidolate	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Exenatide	7,298	4.4%	2,468	5.3%	2,190	3.8%	4,318	1.1%
Glimiperide	40,957	24.5%	9,870	21.3%	12,811	22.1%	81,719	20.0%
Glipizide	40,720	24.4%	9,517	20.5%	11,800	20.4%	112,532	27.6%
Glyburide	15,889	9.5%	3,931	8.5%	3,757	6.5%	43,964	10.8%
Linagliptin	11,577	6.9%	3,228	7.0%	4,829	8.3%	0	0.0%
Liraglutide	15,126	9.1%	4,209	9.1%	4,759	8.2%	7,658	1.9%
Lixisenatide	*****	*****	*****	*****	*****	*****	*****	*****
Metformin_HCl	147,350	88.3%	41,567	89.5%	52,017	89.7%	347,126	85.1%
Miglitol	89	0.1%	23	0.0%	21	0.0%	100	0.0%
Nateglinide	1,772	1.1%	443	1.0%	399	0.7%	3,213	0.8%
Pioglitazone_HCl	21,267	12.7%	5,551	12.0%	6,208	10.7%	36,835	9.0%
Repaglinide	2,068	1.2%	434	0.9%	548	0.9%	3,374	0.8%
Rosiglitazone_Maleate	47	0.0%	12	0.0%	15	0.0%	61	0.0%
Saxagliptin_HCl	13,485	8.1%	4,307	9.3%	3,522	6.1%	0	0.0%
Semaglutide	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Sitagliptin_Phosphate	53,777	32.2%	13,668	29.4%	15,349	26.5%	0	0.0%
Tolazamide	*****	*****	*****	*****	0	0.0%	18	0.0%
Tolbutamide	*****	*****	0	0.0%	0	0.0%	23	0.0%
Insulin lispro	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Insulin regular, human	0	0.0%	0	0.0%	0	0.0%	0	0.0%

Table 1f. Baseline Characteristics of Canagliflozin, Dapagliflozin, Empagliflozin and Sitagliptin Users with a Prior Type 2 Diabetes Mellitus Diagnosis and No Prior History of Insulin Use in the Sentinel Distributed Database (SDD), from March 1, 2013 through June 30, 2018

	Canagliflozin		Dapagliflozin		Empagliflozin		Sitagliptin	
History of Antidiabetic Drug Use up to 365 days prior to index	Number	Percent	Number	Percent	Number	Percent	Number	Percent
Insulin glulisine	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Insulin aspart	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Insulin lispro protamine	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Insulin glargine,human recombinant analog	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Insulin NPH human isophane	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Insulin detemir	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Insulin aspart protamine human	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Insulin degludec	0	0.0%	0	0.0%	0	0.0%	0	0.0%
History of Antidiabetic Drug Use up to 365 days after index	Number	Percent	Number	Percent	Number	Percent	Number	Percent
Acarbose	1,550	0.9%	269	0.6%	335	0.6%	2,858	0.7%
Albiglutide	1,300	0.8%	551	1.2%	574	1.0%	667	0.2%
Alogliptin_Benzoate	784	0.5%	310	0.7%	289	0.5%	500	0.1%
Canagliflozin	166,861	100.0%	2,337	5.0%	1,133	2.0%	18,692	4.6%
Chlorpropamide	*****	*****	*****	*****	*****	*****	*****	*****
Dapagliflozin_Propoanediol	2,164	1.3%	46,434	100.0%	660	1.1%	5,105	1.3%
Dulaglutide	4,268	2.6%	1,881	4.1%	3,459	6.0%	3,719	0.9%
Empagliflozin	3,001	1.8%	1,253	2.7%	57,971	100.0%	5,592	1.4%
Ertugliflozin_Pidolate	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Exenatide	6,862	4.1%	2,555	5.5%	1,836	3.2%	4,850	1.2%
Glimiperide	40,285	24.1%	9,603	20.7%	12,118	20.9%	87,729	21.5%
Glipizide	38,803	23.3%	8,865	19.1%	10,603	18.3%	114,156	28.0%
Glyburide	10,466	6.3%	2,835	6.1%	2,613	4.5%	28,455	7.0%
Linagliptin	12,615	7.6%	3,404	7.3%	9,573	16.5%	10,002	2.5%
Liraglutide	15,279	9.2%	4,251	9.2%	4,750	8.2%	10,590	2.6%
Lixisenatide	23	0.0%	38	0.1%	32	0.1%	24	0.0%
Metformin_HCl	138,532	83.0%	39,212	84.4%	47,894	82.6%	322,000	79.0%
Miglitol	70	0.0%	23	0.0%	16	0.0%	98	0.0%

Table 1f. Baseline Characteristics of Canagliflozin, Dapagliflozin, Empagliflozin and Sitagliptin Users with a Prior Type 2 Diabetes Mellitus Diagnosis and No Prior History of Insulin Use in the Sentinel Distributed Database (SDD), from March 1, 2013 through June 30, 2018

	Canagliflozin		Dapagliflozin		Empagliflozin		Sitagliptin	
History of Antidiabetic Drug Use up to 365 days after index	Number	Percent	Number	Percent	Number	Percent	Number	Percent
Nateglinide	1,635	1.0%	414	0.9%	364	0.6%	3,784	0.9%
Pioglitazone_HCl	19,867	11.9%	5,378	11.6%	5,672	9.8%	35,851	8.8%
Repaglinide	2,046	1.2%	447	1.0%	538	0.9%	4,490	1.1%
Rosiglitazone_Maleate	44	0.0%	13	0.0%	13	0.0%	58	0.0%
Saxagliptin_HCl	10,961	6.6%	3,605	7.8%	2,574	4.4%	4,256	1.0%
Semaglutide	0	0.0%	*****	*****	*****	*****	*****	*****
Sitagliptin_Phosphate	47,831	28.7%	12,425	26.8%	13,179	22.7%	407,720	100.0%
Tolazamide	*****	*****	0	0.0%	0	0.0%	11	0.0%
Tolbutamide	*****	*****	0	0.0%	0	0.0%	15	0.0%
Insulin lispro	1,866	1.1%	393	0.8%	507	0.9%	6,133	1.5%
Insulin regular, human	537	0.3%	115	0.2%	106	0.2%	2,638	0.6%
Insulin glulisine	60	0.0%	19	0.0%	*****	*****	157	0.0%
Insulin aspart	2,040	1.2%	476	1.0%	299	0.5%	8,001	2.0%
Insulin lispro protamine	344	0.2%	62	0.1%	101	0.2%	787	0.2%
Insulin glargine,human recombinant analog	8,501	5.1%	1,860	4.0%	1,947	3.4%	25,991	6.4%
Insulin NPH human isophane	490	0.3%	104	0.2%	134	0.2%	1,869	0.5%
Insulin detemir	4,605	2.8%	1,083	2.3%	706	1.2%	11,650	2.9%
Insulin aspart protamine human	365	0.2%	88	0.2%	42	0.1%	1,112	0.3%
Insulin degludec	642	0.4%	284	0.6%	458	0.8%	1,037	0.3%
History of Diabetic Ketoacidosis Diagnosis up to 365 days prior to index	Number	Percent	Number	Percent	Number	Percent	Number	Percent
Diabetic Ketoacidosis diagnosis	152	0.1%	27	0.1%	37	0.1%	701	0.2%
History of Insulin Pump Use up to 365 days prior to index	Number	Percent	Number	Percent	Number	Percent	Number	Percent
Insulin Pump Use	0	0.0%	0	0.0%	0	0.0%	0	0.0%

*****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 2a. Summary of Diabetic Ketoacidosis Events after Incident Exposure to Canagliflozin, Dapagliflozin, Empagliflozin, or Sitagliptin in the Sentinel Distributed Database (SDD) between March 1, 2013 and June 30, 2018, Overall

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	New Episodes with an Event	Number of Exposed Members per 1,000 Eligible Members ¹	Years at Risk	Eligible Member Years ¹	Incidence Rate per 1,000 Years at Risk	All Events	Number of Events per Patient with an Event
Incident Exposure												
Canagliflozin	297,633	297,633	1,307,542	48,685,848	51,583,854	895	3.03	135,262.7	228,346,622.6	6.62	2,092	2.34
Dapagliflozin	79,311	79,311	301,248	10,853,692	11,290,128	161	0.81	30,551.5	228,391,329.4	5.27	296	1.84
Empagliflozin	98,583	98,583	343,336	12,584,513	12,918,331	181	1.00	35,129.7	228,399,840.9	5.15	326	1.80
Sitagliptin	667,468	667,468	2,891,091	106,694,887	119,942,949	1,420	6.84	296,936.8	225,017,510.0	4.78	3,221	2.27
Incident Exposure and Prior Type 1 Diabetes Mellitus												
Canagliflozin	1,520	1,520	7,226	267,425	277,324	57	.	723.3	.	78.81	123	2.16
Dapagliflozin	391	391	1,418	53,204	54,958	*****	.	*****	.	61.31	*****	2.56
Empagliflozin	468	468	1,770	67,368	67,354	11	.	184.2	.	59.72	20	1.82
Sitagliptin	791	791	3,797	115,295	130,978	18	.	324.0	.	55.56	39	2.17
Incident Exposure and Prior Type 1 Diabetes Mellitus - Broad Definition												
Canagliflozin	2,907	2,907	13,414	502,008	522,359	65	.	1,371.7	.	47.39	141	2.17
Dapagliflozin	734	734	2,830	106,879	111,603	*****	.	*****	.	33.67	*****	2.50
Empagliflozin	734	734	2,751	101,696	102,160	12	.	281.9	.	42.57	21	1.75
Sitagliptin	2,909	2,909	13,910	464,684	534,154	23	.	1,299.3	.	17.70	48	2.09
Incident Exposure and Prior Type 2 Diabetes Mellitus												
Canagliflozin	229,836	229,836	1,022,219	38,348,644	40,566,825	468	24.57	106,465.0	18,343,523.7	4.40	1,062	2.27
Dapagliflozin	60,910	60,910	235,753	8,526,810	8,853,705	77	6.51	23,977.0	18,369,699.2	3.21	148	1.92
Empagliflozin	78,420	78,420	276,591	10,172,717	10,420,336	108	8.38	28,362.7	18,374,492.6	3.81	181	1.68
Sitagliptin	482,451	482,451	2,094,865	79,623,457	89,089,771	761	57.25	221,120.9	15,480,602.4	3.44	1,567	2.06
Incident Exposure and Prior Type 2 Diabetes Mellitus with History of Insulin Use												
Canagliflozin	63,256	63,256	283,690	10,472,555	11,070,580	209	25.91	29,016.4	3,433,693.5	7.20	535	2.56
Dapagliflozin	14,533	14,533	55,863	2,026,016	2,117,707	35	5.95	5,681.7	3,439,587.4	6.16	73	2.09
Empagliflozin	20,491	20,491	70,566	2,607,825	2,657,231	47	8.39	7,259.0	3,440,547.9	6.47	77	1.64
Sitagliptin	75,736	75,736	341,319	11,374,163	12,818,644	252	36.41	31,744.4	2,827,354.3	7.94	589	2.34

Table 2a. Summary of Diabetic Ketoacidosis Events after Incident Exposure to Canagliflozin, Dapagliflozin, Empagliflozin, or Sitagliptin in the Sentinel Distributed Database (SDD) between March 1, 2013 and June 30, 2018, Overall

	New Users	New Episodes	Days Supplied	Amount Supplied	New Episodes with an Event	Number of Exposed Members per 1,000 Eligible Members ¹	Years at Risk	Eligible Member Years ¹	Incidence Rate per 1,000 Years at Risk	All Events	Number of Events per Patient with an Event	
Incident Exposure and Prior Type 2 Diabetes Mellitus without History of Insulin Use												
Canagliflozin	166,866	166,866	739,417	27,908,079	29,532,816	261	21.19	77,538.2	14,917,033.8	3.37	532	2.04
Dapagliflozin	46,434	46,434	180,045	6,506,509	6,742,318	42	5.90	18,311.4	14,931,438.2	2.29	75	1.79
Empagliflozin	57,971	57,971	206,117	7,568,483	7,766,772	61	7.36	21,113.7	14,934,444.1	2.89	104	1.70
Sitagliptin	407,759	407,759	1,756,415	68,351,754	76,384,494	510	57.54	189,669.2	12,671,963.2	2.69	980	1.92

¹Data not available for the T1DM subgroups

*****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 2b. Summary of Diabetic Ketoacidosis Events after Incident Exposure to Canagliflozin, Dapagliflozin, Empagliflozin, or Sitagliptin in the Sentinel Distributed Database (SDD) between March 1, 2013 and June 30, 2018, by Year of Exposure

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	New Episodes with an Event	Number of Exposed Members per 1,000 Eligible Members ¹	Years at Risk	Eligible Member Years ¹	Incident Rate per 1,000 Years at Risk	All Events	Number of Events per Patient with an Event
Incident Exposure												
Canagliflozin												
2013	20,690	20,690	117,886	4,179,685	4,223,321	76	0.39	11,550.1	39,639,031.2	6.58	160	2.11
2014	73,202	73,202	387,541	14,621,979	15,007,472	272	1.27	40,373.9	50,117,710.2	6.74	641	2.36
2015	107,722	107,722	495,832	18,663,531	20,085,616	337	1.80	51,939.4	52,160,210.0	6.49	767	2.28
2016	78,522	78,522	259,617	9,508,292	10,342,781	174	1.21	26,589.2	53,894,555.7	6.54	459	2.64
2017	16,666	16,666	45,543	1,683,719	1,892,901	36	0.44	4,731.2	30,362,294.4	7.61	65	1.81
2018	831	831	1,123	28,642	31,763	0	0.08	79.0	2,172,821.0	0.00	0	.
Dapagliflozin												
2013	0	0	0	0	0	0	0.00	0.0	39,639,031.2	.	0	.
2014	20,552	20,552	89,463	3,239,836	3,289,577	47	0.36	9,119.5	50,118,220.3	5.15	74	1.57
2015	24,302	24,302	105,770	3,812,157	3,961,426	58	0.41	10,741.9	52,166,932.5	5.40	106	1.83
2016	23,104	23,104	75,392	2,717,952	2,877,141	42	0.36	7,650.3	53,918,999.4	5.49	99	2.36
2017	10,338	10,338	29,199	1,048,575	1,124,638	14	0.27	2,943.6	30,374,174.0	4.76	17	1.21
2018	1,015	1,015	1,424	35,172	37,346	0	0.10	96.2	2,173,972.0	0.00	0	.
Empagliflozin												
2013	0	0	0	0	0	0	0.00	0.0	39,639,031.2	.	0	.
2014	2,691	2,691	12,967	456,186	457,377	*****	0.05	*****	50,118,220.3	5.46	*****	1.14
2015	18,535	18,535	84,224	3,124,583	3,140,607	47	0.31	8,774.6	52,167,894.0	5.36	95	2.02
2016	37,694	37,694	136,648	5,065,370	5,235,958	65	0.58	14,161.4	53,924,076.5	4.59	141	2.17
2017	37,204	37,204	105,991	3,849,714	3,998,156	57	0.97	10,673.8	30,376,577.6	5.34	72	1.26
2018	2,459	2,459	3,506	88,660	86,233	*****	0.24	*****	2,174,041.2	21.00	*****	2.00
Sitagliptin												
2013	122,005	122,005	640,060	22,548,060	25,430,949	309	2.33	62,948.2	38,954,419.8	4.91	652	2.11
2014	164,817	164,817	816,443	30,390,273	34,188,440	401	2.90	84,471.6	49,241,461.8	4.75	919	2.29
2015	164,156	164,156	752,150	28,361,305	31,750,526	370	2.78	78,893.7	51,338,344.8	4.69	875	2.36
2016	164,267	164,267	539,740	19,988,993	22,394,638	285	2.56	55,585.4	53,098,626.9	5.13	661	2.32
2017	48,715	48,715	137,922	5,289,750	6,042,953	*****	1.28	*****	30,222,366.3	3.46	*****	2.16
2018	3,508	3,508	4,776	116,506	135,443	*****	0.34	*****	2,162,290.3	12.73	*****	1.00

Table 2b. Summary of Diabetic Ketoacidosis Events after Incident Exposure to Canagliflozin, Dapagliflozin, Empagliflozin, or Sitagliptin in the Sentinel Distributed Database (SDD) between March 1, 2013 and June 30, 2018, by Year of Exposure

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	New Episodes with an Event	Number of Exposed Members per 1,000 Eligible Members ¹	Years at Risk	Eligible Member Years ¹	Incident Rate per 1,000 Years at Risk	All Events	Number of Events per Patient with an Event
Incident Exposure and Prior Type 1 Diabetes Mellitus												
Canagliflozin												
2013	150	150	840	27,253	27,369	*****	.	*****	.	95.63	*****	2.00
2014	486	486	2,697	100,361	102,047	23	.	268.4	.	85.69	39	1.70
2015	589	589	2,643	100,638	106,346	21	.	273.2	.	76.87	44	2.10
2016	246	246	903	34,114	36,348	*****	.	*****	.	42.37	*****	6.00
2017	*****	*****	*****	4,982	5,137	*****	.	*****	.	143.88	*****	1.00
2018	*****	*****	*****	77	77	0	.	0.2	.	0.00	0	.
Dapagliflozin												
2013	0	0	0	0	0	0	.	0.0	.	.	0	.
2014	141	141	549	19,845	20,786	*****	.	*****	.	73.39	*****	2.00
2015	141	141	555	22,647	22,707	*****	.	*****	.	48.78	*****	2.00
2016	67	67	224	7,544	8,237	*****	.	*****	.	45.87	*****	8.00
2017	*****	*****	*****	3,048	3,108	*****	.	*****	.	116.28	*****	1.00
2018	*****	*****	*****	120	120	0	.	0.3	.	0.00	0	.
Empagliflozin												
2013	0	0	0	0	0	0	.	0.0	.	.	0	.
2014	30	30	159	5,089	5,089	0	.	14.4	.	0.00	0	.
2015	131	131	553	20,820	20,820	*****	.	*****	.	105.63	*****	2.00
2016	155	155	638	26,601	26,646	*****	.	*****	.	56.10	*****	1.75
2017	140	140	406	14,436	14,353	*****	.	*****	.	24.63	*****	1.00
2018	12	12	14	422	447	0	.	1.1	.	0.00	0	.
Sitagliptin												
2013	165	165	913	25,469	28,089	*****	.	*****	.	68.97	*****	1.60
2014	227	227	1,263	41,068	46,725	*****	.	*****	.	35.06	*****	3.25
2015	209	209	1,078	30,888	36,283	*****	.	*****	.	68.18	*****	1.33
2016	147	147	452	14,299	15,938	*****	.	*****	.	50.89	*****	4.50
2017	*****	*****	*****	3,452	3,794	*****	.	*****	.	102.04	*****	1.00
2018	*****	*****	*****	119	149	0	.	0.3	.	0.00	0	.

Table 2b. Summary of Diabetic Ketoacidosis Events after Incident Exposure to Canagliflozin, Dapagliflozin, Empagliflozin, or Sitagliptin in the Sentinel Distributed Database (SDD) between March 1, 2013 and June 30, 2018, by Year of Exposure

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	New Episodes with an Event	Number of Exposed Members per 1,000 Eligible Members ¹	Years at Risk	Eligible Member Years ¹	Incident Rate per 1,000 Years at Risk	All Events	Number of Events per Patient with an Event
Incident Exposure and Prior Type 1 Diabetes Mellitus - Broad Definition												
Canagliflozin												
2013	314	314	1,702	59,393	59,878	*****	.	*****	.	50.19	*****	2.00
2014	902	902	5,011	186,937	189,921	26	.	507.0	.	51.28	47	1.81
2015	1,119	1,119	4,855	188,588	200,130	23	.	518.1	.	44.39	50	2.17
2016	487	487	1,623	59,190	63,894	*****	.	*****	.	30.32	*****	5.00
2017	*****	*****	*****	7,763	8,339	*****	.	*****	.	136.99	*****	1.00
2018	*****	*****	*****	137	197	0	.	0.4	.	0.00	0	.
Dapagliflozin												
2013	0	0	0	0	0	0	.	0.0	.	.	0	.
2014	268	268	1,122	42,327	43,975	*****	.	*****	.	42.70	*****	2.00
2015	251	251	1,046	40,556	42,012	*****	.	*****	.	26.81	*****	2.00
2016	144	144	491	17,586	18,834	*****	.	*****	.	20.00	*****	8.00
2017	*****	*****	*****	6,290	6,662	*****	.	*****	.	56.50	*****	1.00
2018	*****	*****	*****	120	120	0	.	0.3	.	0.00	0	.
Empagliflozin												
2013	0	0	0	0	0	0	.	0.0	.	.	0	.
2014	48	48	253	8,222	8,222	*****	.	*****	.	43.10	*****	1.00
2015	218	218	899	33,116	33,163	*****	.	*****	.	65.01	*****	2.00
2016	248	248	983	39,339	39,725	*****	.	*****	.	37.17	*****	1.75
2017	204	204	595	20,341	20,318	*****	.	*****	.	17.54	*****	1.00
2018	16	16	21	678	733	0	.	1.8	.	0.00	0	.
Sitagliptin												
2013	693	693	4,099	126,816	146,728	*****	.	*****	.	16.84	*****	1.50
2014	850	850	4,473	152,347	173,800	*****	.	*****	.	14.18	*****	2.83
2015	741	741	3,421	119,929	139,923	*****	.	*****	.	17.84	*****	1.33
2016	489	489	1,607	52,477	58,074	*****	.	*****	.	27.17	*****	3.25
2017	*****	*****	296	12,736	15,184	*****	.	*****	.	28.25	*****	1.00
2018	*****	*****	14	379	446	0	.	1.0	.	0.00	0	.

Table 2b. Summary of Diabetic Ketoacidosis Events after Incident Exposure to Canagliflozin, Dapagliflozin, Empagliflozin, or Sitagliptin in the Sentinel Distributed Database (SDD) between March 1, 2013 and June 30, 2018, by Year of Exposure

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	New Episodes with an Event	Number of Exposed Members per 1,000 Eligible Members ¹	Years at Risk	Eligible Member Years ¹	Incident Rate per 1,000 Years at Risk	All Events	Number of Events per Patient with an Event
Incident Exposure and Prior Type 2 Diabetes Mellitus												
Canagliflozin												
2013	15,443	15,443	90,150	3,203,956	3,234,186	30	3.22	8,855.7	3,256,488.7	3.39	50	1.67
2014	56,005	56,005	302,178	11,462,673	11,772,212	141	10.21	31,641.6	4,289,958.5	4.46	321	2.28
2015	82,941	82,941	387,441	14,701,493	15,798,411	175	14.54	40,880.0	4,447,821.5	4.28	397	2.27
2016	61,707	61,707	205,110	7,597,669	8,228,067	95	10.16	21,210.9	4,664,401.4	4.48	239	2.52
2017	13,079	13,079	36,446	1,360,321	1,509,490	27	6.24	3,814.8	1,557,579.1	7.08	55	2.04
2018	661	661	894	22,532	24,458	0	0.80	62.0	127,274.4	0.00	0	.
Dapagliflozin												
2013	0	0	0	0	0	0	0.00	0.0	3,256,488.7	.	0	.
2014	15,782	15,782	70,103	2,541,211	2,577,343	24	2.88	7,153.4	4,290,257.1	3.36	36	1.50
2015	18,822	18,822	83,610	3,020,117	3,140,697	27	3.30	8,506.1	4,451,659.1	3.17	59	2.19
2016	17,646	17,646	58,469	2,119,556	2,232,035	*****	2.89	*****	4,678,547.9	3.36	*****	2.20
2017	7,867	7,867	22,469	818,869	875,055	*****	3.73	*****	1,564,749.4	2.62	*****	1.50
2018	793	793	1,102	27,057	28,575	0	0.95	73.7	127,996.9	0.00	0	.
Empagliflozin												
2013	0	0	0	0	0	0	0.00	0.0	3,256,488.7	.	0	.
2014	2,003	2,003	9,816	348,937	349,861	*****	0.36	*****	4,290,257.1	3.06	*****	1.33
2015	14,371	14,371	67,098	2,483,766	2,496,610	*****	2.52	*****	4,452,201.7	3.73	*****	1.77
2016	29,830	29,830	109,766	4,092,676	4,219,975	43	4.89	11,427.2	4,681,510.8	3.76	82	1.91
2017	30,265	30,265	87,086	3,176,126	3,285,527	36	14.35	8,796.9	1,566,017.7	4.09	49	1.36
2018	1,951	1,951	2,825	71,212	68,364	0	2.35	190.9	128,016.6	0.00	0	.
Sitagliptin												
2013	85,868	85,868	454,253	16,555,315	18,577,838	151	21.11	46,118.6	2,675,973.2	3.27	292	1.93
2014	117,568	117,568	585,667	22,560,779	25,317,456	215	25.19	62,584.8	3,536,386.1	3.44	414	1.93
2015	118,190	118,190	545,025	21,158,586	23,600,758	193	24.07	58,736.6	3,739,272.5	3.29	406	2.10
2016	120,791	120,791	399,085	15,119,021	16,824,479	165	22.77	41,943.6	3,979,154.3	3.93	371	2.25
2017	37,375	37,375	107,237	4,142,512	4,670,440	*****	19.15	*****	1,431,936.0	3.04	*****	2.34
2018	2,659	2,659	3,598	87,244	98,799	*****	3.53	*****	117,880.3	8.51	*****	1.00

Table 2b. Summary of Diabetic Ketoacidosis Events after Incident Exposure to Canagliflozin, Dapagliflozin, Empagliflozin, or Sitagliptin in the Sentinel Distributed Database (SDD) between March 1, 2013 and June 30, 2018, by Year of Exposure

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	New Episodes with an Event	Number of Exposed Members per 1,000 Eligible Members ¹	Years at Risk	Eligible Member Years ¹	Incident Rate per 1,000 Years at Risk	All Events	Number of Events per Patient with an Event
Incident Exposure and Prior Type 2 Diabetes Mellitus with History of Insulin Use												
Canagliflozin												
2013	4,746	4,746	27,355	958,987	971,683	13	4.47	2,651.7	600,482.4	4.90	27	2.08
2014	17,026	17,026	89,855	3,369,625	3,460,411	56	13.71	9,293.2	801,890.6	6.03	141	2.52
2015	23,365	23,365	109,257	4,059,655	4,372,958	81	18.28	11,261.5	833,616.5	7.19	202	2.49
2016	15,266	15,266	49,811	1,805,759	1,957,206	45	11.24	5,030.2	885,061.7	8.95	142	3.16
2017	2,716	2,716	7,226	273,715	303,095	14	6.33	766.7	288,405.8	18.26	23	1.64
2018	137	137	186	4,814	5,228	0	0.87	13.2	24,236.6	0.00	0	.
Dapagliflozin												
2013	0	0	0	0	0	0	0.00	0.0	600,482.4	.	0	.
2014	4,417	4,417	19,361	703,498	717,017	16	3.56	1,974.0	801,954.5	8.11	26	1.63
2015	4,505	4,505	19,773	720,244	755,974	*****	3.52	*****	834,446.3	5.93	*****	2.33
2016	3,927	3,927	12,344	438,393	464,676	*****	2.88	*****	888,387.3	3.25	*****	3.25
2017	1,500	1,500	4,128	157,456	173,092	*****	3.47	*****	289,935.1	6.87	*****	2.00
2018	184	184	257	6,425	6,950	0	1.17	17.3	24,382.0	0.00	0	.
Empagliflozin												
2013	0	0	0	0	0	0	0.00	0.0	600,482.4	.	0	.
2014	594	594	2,840	100,183	100,557	0	0.48	281.3	801,954.5	0.00	0	.
2015	3,960	3,960	18,159	673,498	677,959	11	3.09	1,887.1	834,559.9	5.83	16	1.45
2016	7,775	7,775	27,180	1,012,700	1,038,980	20	5.69	2,827.3	888,993.4	7.07	39	1.95
2017	7,568	7,568	21,501	797,915	818,005	16	17.51	2,200.8	290,169.3	7.27	22	1.38
2018	594	594	886	23,529	21,730	0	3.76	62.6	24,388.5	0.00	0	.
Sitagliptin												
2013	12,410	12,410	72,450	2,253,356	2,555,856	55	14.61	6,288.0	469,949.8	8.75	124	2.25
2014	18,355	18,355	96,357	3,187,049	3,597,565	59	18.27	8,879.7	634,546.4	6.64	129	2.19
2015	19,468	19,468	92,209	3,142,386	3,531,897	68	18.32	8,780.8	685,391.8	7.74	158	2.32
2016	19,819	19,819	65,362	2,233,767	2,503,539	56	17.16	6,236.3	743,154.6	8.98	150	2.68
2017	5,298	5,298	14,455	545,608	615,930	*****	13.12	*****	271,230.9	8.51	*****	2.08
2018	386	386	486	11,997	13,857	*****	2.67	*****	23,080.9	31.06	*****	1.00

Table 2b. Summary of Diabetic Ketoacidosis Events after Incident Exposure to Canagliflozin, Dapagliflozin, Empagliflozin, or Sitagliptin in the Sentinel Distributed Database (SDD) between March 1, 2013 and June 30, 2018, by Year of Exposure

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	New Episodes with an Event	Number of Exposed Members per 1,000 Eligible Members ¹	Years at Risk	Eligible Member Years ¹	Incident Rate per 1,000 Years at Risk	All Events	Number of Events per Patient with an Event
Incident Exposure and Prior Type 2 Diabetes Mellitus without History of Insulin Use												
Canagliflozin												
2013	10,697	10,697	62,795	2,244,969	2,262,503	17	2.72	6,204.0	2,656,006.4	2.74	23	1.35
2014	38,985	38,985	212,338	8,093,498	8,312,251	85	8.67	22,349.8	3,488,129.3	3.80	180	2.12
2015	59,642	59,642	278,489	10,651,969	11,437,864	94	12.76	29,647.1	3,615,140.1	3.17	195	2.07
2016	46,595	46,595	155,716	5,807,667	6,288,026	51	9.37	16,224.8	3,783,126.1	3.14	101	1.98
2017	10,420	10,420	29,366	1,092,150	1,212,834	14	5.96	3,063.5	1,271,393.0	4.57	33	2.36
2018	527	527	713	17,826	19,338	0	0.78	49.1	103,238.9	0.00	0	.
Dapagliflozin												
2013	0	0	0	0	0	0	0.00	0.0	2,656,006.4	.	0	.
2014	11,365	11,365	50,742	1,837,713	1,860,327	*****	2.53	*****	3,488,302.7	1.54	*****	1.25
2015	14,318	14,318	63,838	2,299,888	2,384,738	15	3.06	6,483.4	3,617,303.3	2.31	31	2.07
2016	13,746	13,746	46,207	1,684,367	1,771,020	16	2.76	4,731.8	3,790,822.1	3.38	31	1.94
2017	6,391	6,391	18,406	663,766	704,435	*****	3.64	*****	1,275,350.7	1.61	*****	1.00
2018	614	614	852	20,775	21,799	0	0.90	56.9	103,653.1	0.00	0	.
Empagliflozin												
2013	0	0	0	0	0	0	0.00	0.0	2,656,006.4	.	0	.
2014	1,409	1,409	6,976	248,754	249,304	*****	0.31	*****	3,488,302.7	4.30	*****	1.33
2015	10,411	10,411	48,939	1,810,268	1,818,651	*****	2.23	*****	3,617,643.7	2.95	*****	2.00
2016	22,063	22,063	82,608	3,080,872	3,181,891	23	4.42	8,602.4	3,792,668.3	2.67	43	1.87
2017	22,729	22,729	65,653	2,380,859	2,470,244	20	12.93	6,603.4	1,276,161.6	3.03	27	1.35
2018	1,359	1,359	1,941	47,730	46,681	0	2.00	128.4	103,661.5	0.00	0	.
Sitagliptin												
2013	73,458	73,458	381,803	14,301,959	16,021,982	96	21.84	39,830.5	2,206,023.4	2.41	168	1.75
2014	99,262	99,262	489,485	19,379,864	21,726,009	156	25.82	53,723.0	2,902,559.8	2.90	285	1.83
2015	98,987	98,987	453,817	18,051,793	20,109,186	126	24.49	50,056.8	3,058,122.5	2.52	250	1.98
2016	101,497	101,497	334,951	12,929,308	14,368,971	109	23.27	35,833.6	3,245,544.4	3.04	221	2.03
2017	32,266	32,266	93,227	3,613,054	4,072,700	*****	19.87	*****	1,164,572.1	2.20	*****	2.50
2018	2,289	2,289	3,132	75,776	85,646	*****	3.70	*****	95,141.1	4.90	*****	1.00

¹Data not available for the T1DM subgroups

*****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 2c. Summary of Diabetic Ketoacidosis Events after Incident Exposure to Canagliflozin, Dapagliflozin, Empagliflozin, or Sitagliptin in the Sentinel Distributed Database (SDD) between March 1, 2013 and June 30, 2018, by Sex

	New Users	New Episodes	Days Dispensings	Days Supplied	Amount Supplied	New Episodes with an Event	Number of Exposed Members per 1,000 Eligible Members ¹	Years at Risk	Eligible Member Years ¹	Incidence Rate per 1,000 Years at Risk	All Events	Number of Events per Patient with an Event
Incident Exposure												
Canagliflozin												
Female	142,526	142,526	593,853	21,640,800	22,882,762	502	2.75	60,424.2	122,351,970.1	8.31	1,144	2.28
Male	155,094	155,094	713,605	27,041,704	28,697,478	393	3.33	74,829.3	105,987,220.7	5.25	948	2.41
Other	13	13	84	3,344	3,614	0	4.08	9.2	7,431.8	0.00	0	.
Dapagliflozin												
Female	37,273	37,273	133,752	4,756,562	4,929,571	89	0.72	13,445.8	122,376,628.2	6.62	183	2.06
Male	*****	*****	*****	6,096,902	6,360,239	72	0.90	17,105.0	106,007,263.7	4.21	113	1.57
Other	*****	*****	*****	228	318	0	1.26	0.7	7,437.5	0.00	0	.
Empagliflozin												
Female	43,347	43,347	144,305	5,194,641	5,323,815	88	0.84	14,585.9	122,381,170.5	6.03	164	1.86
Male	*****	*****	*****	7,389,435	7,594,079	93	1.19	20,542.6	106,011,232.8	4.53	162	1.74
Other	*****	*****	*****	437	437	0	0.31	1.2	7,437.5	0.00	0	.
Sitagliptin												
Female	347,999	347,999	1,540,219	54,973,215	61,219,905	887	6.77	153,118.2	120,608,439.8	5.79	2,049	2.31
Male	319,450	319,450	1,350,800	51,719,022	58,719,975	533	6.92	143,811.6	104,401,763.0	3.71	1,172	2.20
Other	19	19	72	2,650	3,069	0	6.00	7.0	7,307.1	0.00	0	.
Incident Exposure and Prior Type 1 Diabetes Mellitus												
Canagliflozin												
Female	820	820	3,626	131,887	135,203	36	.	356.3	.	101.04	65	1.81
Male	700	700	3,600	135,538	142,121	21	.	367.1	.	57.21	58	2.76
Other	0	0	0	0	0	0	.	0.0	.	.	0	.
Dapagliflozin												
Female	220	220	820	29,706	29,856	*****	.	*****	.	73.44	*****	2.83
Male	171	171	598	23,498	25,102	*****	.	*****	.	46.15	*****	2.00
Other	0	0	0	0	0	0	.	0.0	.	.	0	.
Empagliflozin												
Female	226	226	796	30,057	30,052	*****	.	*****	.	48.96	*****	2.00
Male	242	242	974	37,311	37,302	*****	.	*****	.	68.36	*****	1.71
Other	0	0	0	0	0	0	.	0.0	.	.	0	.

Table 2c. Summary of Diabetic Ketoacidosis Events after Incident Exposure to Canagliflozin, Dapagliflozin, Empagliflozin, or Sitagliptin in the Sentinel Distributed Database (SDD) between March 1, 2013 and June 30, 2018, by Sex

	New Users	New Episodes	Days Supplied	Amount Supplied	New Episodes with an Event	Number of Exposed Members per 1,000 Eligible Members ¹	Years at Risk	Eligible Member Years ¹	Incidence Rate per 1,000 Years at Risk	All Events	Number of Events per Patient with an Event	
Sitagliptin												
Female	453	453	2,234	66,074	74,159	*****	.	*****	.	70.12	*****	2.54
Male	338	338	1,563	49,221	56,819	*****	.	*****	.	36.08	*****	1.20
Other	0	0	0	0	0	0	.	0.0	.	.	0	.
Incident Exposure and Prior Type 1 Diabetes Mellitus - Broad Definition												
Canagliflozin												
Female	1,442	1,442	6,296	229,277	236,168	42	.	627.1	.	66.97	78	1.86
Male	1,465	1,465	7,118	272,731	286,191	23	.	744.6	.	30.89	63	2.74
Other	0	0	0	0	0	0	.	0.0	.	.	0	.
Dapagliflozin												
Female	372	372	1,451	52,715	54,623	*****	.	*****	.	47.68	*****	2.71
Male	362	362	1,379	54,164	56,980	*****	.	*****	.	19.97	*****	2.00
Other	0	0	0	0	0	0	.	0.0	.	.	0	.
Empagliflozin												
Female	357	357	1,291	47,565	47,763	*****	.	*****	.	38.08	*****	1.80
Male	377	377	1,460	54,131	54,397	*****	.	*****	.	46.48	*****	1.71
Other	0	0	0	0	0	0	.	0.0	.	.	0	.
Sitagliptin												
Female	1,521	1,521	7,849	246,211	278,336	*****	.	*****	.	24.67	*****	2.41
Male	1,388	1,388	6,061	218,473	255,819	*****	.	*****	.	9.83	*****	1.17
Other	0	0	0	0	0	0	.	0.0	.	.	0	.
Incident Exposure and Prior Type 2 Diabetes Mellitus												
Canagliflozin												
Female	108,055	108,055	455,601	16,754,516	17,695,323	244	22.43	46,753.0	9,553,709.2	5.22	543	2.23
Male	*****	*****	566,582	21,592,224	22,869,387	224	26.84	59,706.8	8,789,234.8	3.75	519	2.32
Other	*****	*****	36	1,904	2,114	0	33.21	5.2	579.7	0.00	0	.
Dapagliflozin												
Female	27,929	27,929	101,634	3,629,453	3,759,228	40	5.80	10,249.5	9,568,014.0	3.90	91	2.28
Male	*****	*****	*****	4,897,237	5,094,267	37	7.27	13,727.1	8,801,100.9	2.70	57	1.54
Other	*****	*****	*****	120	210	0	7.38	0.4	584.3	0.00	0	.

Table 2c. Summary of Diabetic Ketoacidosis Events after Incident Exposure to Canagliflozin, Dapagliflozin, Empagliflozin, or Sitagliptin in the Sentinel Distributed Database (SDD) between March 1, 2013 and June 30, 2018, by Sex

	New Users	New Episodes	Days Supplied	Amount Supplied	New Episodes with an Event	Number of Exposed Members per 1,000 Eligible Members ¹	Years at Risk	Eligible Member Years ¹	Incidence Rate per 1,000 Years at Risk	All Events	Number of Events per Patient with an Event	
Empagliflozin												
Female	33,707	33,707	113,655	4,101,921	4,200,914	53	7.00	11,507.4	9,570,517.7	4.61	94	1.77
Male	*****	*****	*****	6,070,359	6,218,985	55	9.85	16,854.1	8,803,390.6	3.26	87	1.58
Other	*****	*****	*****	437	437	0	3.69	1.2	584.3	0.00	0	.
Sitagliptin												
Female	250,673	250,673	1,104,158	40,711,243	45,228,952	471	57.67	113,195.1	8,059,409.8	4.16	1,029	2.18
Male	231,762	231,762	990,638	38,909,634	43,857,850	290	56.80	107,919.0	7,420,720.1	2.69	538	1.86
Other	16	16	69	2,580	2,969	0	64.00	6.8	472.5	0.00	0	.
Incident Exposure and Prior Type 2 Diabetes Mellitus with History of Insulin Use												
Canagliflozin												
Female	30,949	30,949	130,852	4,718,479	4,983,539	109	24.45	13,155.9	1,784,819.2	8.29	269	2.47
Male	*****	*****	*****	5,753,776	6,086,532	100	27.49	15,859.6	1,648,758.1	6.31	266	2.66
Other	*****	*****	*****	300	510	0	58.82	0.9	116.3	0.00	0	.
Dapagliflozin												
Female	6,967	6,967	24,983	889,887	930,038	17	5.50	2,506.0	1,788,112.7	6.78	47	2.76
Male	7,566	7,566	30,880	1,136,129	1,187,669	18	6.44	3,175.7	1,651,355.3	5.67	26	1.44
Other	0	0	0	0	0	0	0.00	0.0	119.5	.	0	.
Empagliflozin												
Female	9,257	9,257	30,180	1,092,493	1,111,617	29	7.31	3,065.1	1,788,632.3	9.46	47	1.62
Male	11,234	11,234	40,386	1,515,332	1,545,614	18	9.56	4,193.8	1,651,796.0	4.29	30	1.67
Other	0	0	0	0	0	0	0.00	0.0	119.5	.	0	.
Sitagliptin												
Female	41,755	41,755	192,897	6,151,961	6,879,847	152	38.94	17,209.8	1,453,241.7	8.83	378	2.49
Male	*****	*****	*****	5,221,962	5,938,527	100	33.72	14,533.8	1,374,012.6	6.88	211	2.11
Other	*****	*****	*****	240	270	0	41.10	0.8	100.0	0.00	0	.
Incident Exposure and Prior Type 2 Diabetes Mellitus without History of Insulin Use												
Canagliflozin												
Female	77,247	77,247	325,171	12,050,765	12,727,783	136	19.10	33,638.4	7,772,821.4	4.04	278	2.04
Male	*****	*****	414,220	15,855,710	16,803,429	125	23.40	43,895.5	7,143,749.0	2.85	254	2.03
Other	*****	*****	26	1,604	1,604	0	17.24	4.3	463.4	0.00	0	.

Table 2c. Summary of Diabetic Ketoacidosis Events after Incident Exposure to Canagliflozin, Dapagliflozin, Empagliflozin, or Sitagliptin in the Sentinel Distributed Database (SDD) between March 1, 2013 and June 30, 2018, by Sex

	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	New Episodes with an Event	Number of Exposed Members per 1,000 Eligible Members ¹	Years at Risk	Eligible Member Years ¹	Incidence Rate per 1,000 Years at Risk	All Events	Number of Events per Patient with an Event
Dapagliflozin												
Female	20,987	20,987	76,733	2,741,969	2,832,049	23	5.19	7,750.3	7,780,600.7	2.97	44	1.91
Male	*****	*****	*****	3,764,420	3,910,059	19	6.64	10,560.7	7,150,372.7	1.80	31	1.63
Other	*****	*****	*****	120	210	0	8.62	0.4	464.9	0.00	0	.
Empagliflozin												
Female	24,466	24,466	83,497	3,010,049	3,089,948	24	6.05	8,444.2	7,782,141.8	2.84	47	1.96
Male	*****	*****	*****	4,557,997	4,676,386	37	8.75	12,668.3	7,151,837.4	2.92	57	1.54
Other	*****	*****	*****	437	437	0	4.31	1.2	464.9	0.00	0	.
Sitagliptin												
Female	209,469	209,469	912,795	34,612,886	38,407,191	319	57.38	96,138.2	6,616,028.2	3.32	651	2.04
Male	198,277	198,277	843,559	33,736,528	37,974,604	191	57.71	93,525.0	6,055,561.9	2.04	329	1.72
Other	13	13	61	2,340	2,699	0	61.61	6.0	373.2	0.00	0	.

¹Data not available for the T1DM subgroups

*****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 2d. Summary of Diabetic Ketoacidosis Events after Incident Exposure to Canagliflozin, Dapagliflozin, Empagliflozin, or Sitagliptin in the Sentinel Distributed Database (SDD) between March 1, 2013 and June 30, 2018, by Age Group (Years)

Age Group	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	New Episodes with an Event	Number of Exposed Members per 1,000 Eligible Members ¹	Years at Risk	Eligible Member Years ¹	Incident Rate per 1,000 Years at Risk	All Events	Number of Events per Patient with an Event
Incident Exposure												
Canagliflozin												
<12	*****	*****	16	630	660	0	0.00	2.0	18,907,529.2	0.00	0	.
12-18	*****	*****	268	9,073	9,868	*****	0.01	*****	14,026,948.3	40.16	*****	6.00
19-24	521	521	1,942	67,047	71,413	*****	0.06	*****	12,678,574.9	26.40	*****	1.00
25-44	27,949	27,949	117,279	3,926,446	4,240,851	*****	1.10	*****	44,179,032.6	15.30	*****	2.16
45-64	134,159	134,159	650,613	23,010,429	24,587,030	427	4.99	63,987.5	58,334,963.0	6.67	998	2.34
>=65	134,902	134,902	537,424	21,672,223	22,674,031	292	4.41	59,947.8	80,219,574.4	4.87	716	2.45
Dapagliflozin												
<12	*****	*****	*****	100	100	0	0.00	0.2	18,907,535.3	0.00	0	.
12-18	*****	*****	*****	2,551	2,821	*****	0.00	*****	14,026,960.6	142.86	*****	2.00
19-24	201	201	470	16,239	17,431	0	0.02	48.1	12,678,636.0	0.00	0	.
25-44	9,725	9,725	32,691	1,077,007	1,140,687	*****	0.38	*****	44,181,427.7	9.69	*****	2.20
45-64	43,793	43,793	178,514	6,201,942	6,491,411	83	1.63	17,503.4	58,351,301.1	4.74	128	1.54
>=65	25,552	25,552	89,489	3,555,853	3,637,679	47	0.84	9,896.7	80,245,468.8	4.75	100	2.13
Empagliflozin												
<12	0	0	0	0	0	0	0.00	0.0	18,907,535.3	.	0	.
12-18	36	36	111	3,835	3,889	0	0.00	10.6	14,026,959.1	0.00	0	.
19-24	212	212	522	16,880	18,147	*****	0.03	*****	12,678,672.5	20.41	*****	2.00
25-44	10,563	10,563	34,682	1,158,621	1,211,464	*****	0.42	*****	44,182,366.0	8.47	*****	1.29
45-64	54,865	54,865	209,795	7,414,501	7,644,332	106	2.04	20,678.6	58,355,886.7	5.13	182	1.72
>=65	32,907	32,907	98,226	3,990,676	4,040,500	46	1.08	11,084.1	80,248,421.3	4.15	106	2.30
Sitagliptin												
<12	16	16	31	1,035	1,246	0	0.00	3.4	18,907,501.0	0.00	0	.
12-18	164	164	397	13,601	17,775	0	0.02	39.9	14,026,762.5	0.00	0	.
19-24	933	933	2,765	94,650	116,065	*****	0.11	*****	12,677,147.5	22.26	*****	1.00
25-44	39,852	39,852	147,582	5,074,138	6,108,279	*****	1.57	*****	44,084,502.2	7.55	*****	2.28
45-64	205,187	205,187	874,806	31,662,209	36,853,743	466	7.70	88,520.1	57,580,449.4	5.26	1,154	2.48
>=65	421,316	421,316	1,865,510	69,849,254	76,845,841	839	14.04	193,658.9	77,741,147.3	4.33	1,812	2.16

Table 2d. Summary of Diabetic Ketoacidosis Events after Incident Exposure to Canagliflozin, Dapagliflozin, Empagliflozin, or Sitagliptin in the Sentinel Distributed Database (SDD) between March 1, 2013 and June 30, 2018, by Age Group (Years)

Age Group	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	New Episodes with an Event	Number of Exposed Members per 1,000 Eligible Members ¹	Years at Risk	Eligible Member Years ¹	Incident Rate per 1,000 Years at Risk	All Events	Number of Events per Patient with an Event
Incident Exposure and Prior Type 1 Diabetes Mellitus												
Canagliflozin												
<12	0	0	0	0	0	0	.	0.0	.	.	0	.
12-18	*****	*****	84	2,767	2,767	*****	.	*****	.	153.85	*****	6.00
19-24	*****	*****	175	5,514	5,604	*****	.	*****	.	64.10	*****	1.00
25-44	431	431	2,003	72,437	73,648	33	.	191.1	.	172.68	64	1.94
45-64	708	708	3,668	133,001	139,680	*****	.	*****	.	44.05	*****	2.38
>=65	330	330	1,296	53,706	55,625	*****	.	*****	.	40.84	*****	2.33
Dapagliflozin												
<12	0	0	0	0	0	0	.	0.0	.	.	0	.
12-18	*****	*****	*****	120	120	0	.	0.3	.	0.00	0	.
19-24	*****	*****	*****	900	900	0	.	2.7	.	0.00	0	.
25-44	112	112	345	12,586	12,706	*****	.	*****	.	84.99	*****	2.00
45-64	212	212	852	32,208	33,302	*****	.	*****	.	45.40	*****	1.75
>=65	54	54	195	7,390	7,930	*****	.	*****	.	98.04	*****	5.00
Empagliflozin												
<12	0	0	0	0	0	0	.	0.0	.	.	0	.
12-18	*****	*****	14	424	424	0	.	1.1	.	0.00	0	.
19-24	*****	*****	29	888	913	0	.	2.4	.	0.00	0	.
25-44	136	136	511	17,528	17,501	*****	.	*****	.	61.60	*****	1.33
45-64	243	243	1,025	40,087	40,027	*****	.	*****	.	64.40	*****	1.86
>=65	78	78	191	8,441	8,489	*****	.	*****	.	43.10	*****	3.00
Sitagliptin												
<12	0	0	0	0	0	0	.	0.0	.	.	0	.
12-18	*****	*****	*****	60	60	0	.	0.2	.	0.00	0	.
19-24	*****	*****	*****	710	830	*****	.	*****	.	500.00	*****	1.00
25-44	126	126	388	13,723	16,045	*****	.	*****	.	102.56	*****	1.75
45-64	266	266	1,203	38,038	42,079	*****	.	*****	.	36.97	*****	1.25
>=65	385	385	2,180	62,764	71,964	*****	.	*****	.	51.58	*****	2.89

Table 2d. Summary of Diabetic Ketoacidosis Events after Incident Exposure to Canagliflozin, Dapagliflozin, Empagliflozin, or Sitagliptin in the Sentinel Distributed Database (SDD) between March 1, 2013 and June 30, 2018, by Age Group (Years)

Age Group	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	New Episodes with an Event	Number of Exposed Members per 1,000 Eligible Members ¹	Years at Risk	Eligible Member Years ¹	Incident Rate per 1,000 Years at Risk	All Events	Number of Events per Patient with an Event
Incident Exposure and Prior Type 1 Diabetes Mellitus - Broad Definition												
Canagliflozin												
<12	0	0	0	0	0	0	.	0.0	.	.	0	.
12-18	13	13	88	2,947	2,977	*****	.	*****	.	142.86	*****	6.00
19-24	48	48	197	6,199	6,289	*****	.	*****	.	114.29	*****	1.00
25-44	566	566	2,650	94,511	97,148	34	.	252.0	.	134.92	65	1.91
45-64	1,303	1,303	6,616	239,651	251,771	18	.	657.5	.	27.38	42	2.33
>=65	977	977	3,863	158,700	164,174	*****	.	*****	.	22.85	*****	2.60
Dapagliflozin												
<12	0	0	0	0	0	0	.	0.0	.	.	0	.
12-18	*****	*****	*****	300	480	0	.	0.8	.	0.00	0	.
19-24	*****	*****	*****	900	900	0	.	2.7	.	0.00	0	.
25-44	148	148	478	17,782	18,202	*****	.	*****	.	81.14	*****	2.00
45-64	395	395	1,669	61,582	65,121	*****	.	*****	.	23.34	*****	1.75
>=65	177	177	651	26,315	26,900	*****	.	*****	.	27.51	*****	5.00
Empagliflozin												
<12	0	0	0	0	0	0	.	0.0	.	.	0	.
12-18	*****	*****	14	424	424	0	.	1.1	.	0.00	0	.
19-24	*****	*****	30	911	936	0	.	2.5	.	0.00	0	.
25-44	173	173	691	23,581	23,601	*****	.	*****	.	45.52	*****	1.33
45-64	389	389	1,572	59,155	59,435	*****	.	*****	.	49.14	*****	1.75
>=65	160	160	444	17,625	17,764	*****	.	*****	.	20.12	*****	3.00
Sitagliptin												
<12	0	0	0	0	0	0	.	0.0	.	.	0	.
12-18	*****	*****	15	402	462	0	.	1.1	.	0.00	0	.
19-24	*****	*****	37	1,353	1,473	*****	.	*****	.	263.16	*****	1.00
25-44	256	256	913	32,010	38,292	*****	.	*****	.	43.91	*****	1.75
45-64	893	893	4,089	137,499	164,317	*****	.	*****	.	15.52	*****	1.17
>=65	1,734	1,734	8,856	293,420	329,610	12	.	816.9	.	14.69	33	2.75

Table 2d. Summary of Diabetic Ketoacidosis Events after Incident Exposure to Canagliflozin, Dapagliflozin, Empagliflozin, or Sitagliptin in the Sentinel Distributed Database (SDD) between March 1, 2013 and June 30, 2018, by Age Group (Years)

Age Group	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	New Episodes with an Event	Number of Exposed Members per 1,000 Eligible Members ¹	Years at Risk	Eligible Member Years ¹	Incident Rate per 1,000 Years at Risk	All Events	Number of Events per Patient with an Event
Incident Exposure and Prior Type 2 Diabetes Mellitus												
Canagliflozin												
<12	****	****	****	240	240	0	1.33	0.7	555.4	0.00	0	.
12-18	****	****	****	2,815	3,340	0	4.11	8.1	7,159.8	0.00	0	.
19-24	275	275	1,156	39,144	41,272	****	12.46	****	19,078.6	9.04	****	1.00
25-44	20,003	20,003	86,593	2,908,394	3,129,576	****	31.68	****	800,308.6	6.80	****	2.23
45-64	102,555	102,555	507,127	18,035,796	19,237,666	233	33.06	50,106.0	5,059,097.9	4.65	503	2.16
>=65	106,969	106,969	427,254	17,362,255	18,154,731	178	17.70	48,005.4	12,457,323.4	3.71	433	2.43
Dapagliflozin												
<12	0	0	0	0	0	0	0.00	0.0	555.4	.	0	.
12-18	15	15	42	1,219	1,219	0	1.87	3.4	7,161.2	0.00	0	.
19-24	101	101	222	7,590	8,692	0	4.58	22.4	19,091.1	0.00	0	.
25-44	6,863	6,863	23,819	786,705	832,616	****	10.87	****	801,433.7	3.55	****	3.50
45-64	33,775	33,775	140,730	4,901,230	5,117,086	****	10.89	****	5,068,312.3	2.89	****	1.38
>=65	20,156	20,156	70,940	2,830,066	2,894,092	29	3.33	7,874.6	12,473,145.5	3.68	65	2.24
Empagliflozin												
<12	0	0	0	0	0	0	0.00	0.0	555.4	.	0	.
12-18	18	18	65	2,059	2,083	0	2.24	5.7	7,160.9	0.00	0	.
19-24	115	115	285	9,439	10,014	0	5.21	27.4	19,097.2	0.00	0	.
25-44	7,864	7,864	26,320	880,196	915,542	14	12.45	2,510.6	801,843.8	5.58	15	1.07
45-64	43,896	43,896	170,401	6,036,474	6,210,347	67	14.15	16,813.0	5,070,884.1	3.99	106	1.58
>=65	26,527	26,527	79,520	3,244,549	3,282,350	27	4.39	9,006.0	12,474,951.2	3.00	60	2.22
Sitagliptin												
<12	****	****	****	180	286	0	5.36	0.6	537.7	0.00	0	.
12-18	****	****	****	6,891	8,842	0	9.81	20.1	7,060.8	0.00	0	.
19-24	514	514	1,558	53,715	66,737	****	24.09	****	17,928.4	19.69	****	1.00
25-44	26,955	26,955	104,822	3,628,308	4,310,248	****	45.53	****	719,697.8	4.47	****	1.93
45-64	148,258	148,258	644,758	23,724,111	27,334,661	230	52.32	66,177.9	4,408,781.2	3.48	513	2.23
>=65	306,642	306,642	1,343,515	52,210,252	57,368,997	482	57.16	144,472.1	10,326,596.5	3.34	962	2.00

Table 2d. Summary of Diabetic Ketoacidosis Events after Incident Exposure to Canagliflozin, Dapagliflozin, Empagliflozin, or Sitagliptin in the Sentinel Distributed Database (SDD) between March 1, 2013 and June 30, 2018, by Age Group (Years)

Age Group	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	New Episodes with an Event	Number of Exposed Members per 1,000 Eligible Members ¹	Years at Risk	Eligible Member Years ¹	Incident Rate per 1,000 Years at Risk	All Events	Number of Events per Patient with an Event
Incident Exposure and Prior Type 2 Diabetes Mellitus with History of Insulin Use												
Canagliflozin												
<12	0	0	0	0	0	0	0.00	0.0	76.5	.	0	.
12-18	14	14	33	1,040	1,460	0	8.87	3.1	1,156.0	0.00	0	.
19-24	87	87	303	11,333	12,302	*****	19.78	*****	3,044.9	31.45	*****	1.00
25-44	5,618	5,618	24,433	828,428	887,009	*****	37.64	*****	154,795.4	11.62	*****	2.22
45-64	30,602	30,602	150,010	5,353,841	5,691,212	120	36.37	14,813.7	1,109,328.2	8.10	331	2.76
>=65	26,935	26,935	108,911	4,277,913	4,478,597	61	17.39	11,843.9	2,165,292.4	5.15	143	2.34
Dapagliflozin												
<12	0	0	0	0	0	0	0.00	0.0	76.5	.	0	.
12-18	*****	*****	*****	118	118	0	1.90	0.3	1,156.1	0.00	0	.
19-24	*****	*****	*****	1,545	1,799	0	6.13	4.7	3,049.8	0.00	0	.
25-44	1,567	1,567	5,446	185,512	197,687	*****	10.50	*****	155,066.8	7.59	*****	4.50
45-64	8,250	8,250	33,419	1,183,525	1,245,702	19	9.80	3,324.8	1,111,671.2	5.71	29	1.53
>=65	4,686	4,686	16,945	655,316	672,401	*****	3.02	*****	2,168,567.0	6.57	*****	2.17
Empagliflozin												
<12	0	0	0	0	0	0	0.00	0.0	76.5	.	0	.
12-18	*****	*****	11	330	330	0	2.53	1.0	1,155.8	0.00	0	.
19-24	*****	*****	68	2,434	2,439	0	6.36	7.0	3,050.8	0.00	0	.
25-44	1,889	1,889	6,236	212,202	221,791	*****	12.65	*****	155,132.4	10.03	*****	1.00
45-64	11,759	11,759	44,528	1,599,959	1,634,519	28	13.97	4,444.2	1,112,228.9	6.30	43	1.54
>=65	6,811	6,811	19,723	792,900	798,152	*****	4.40	*****	2,168,903.4	5.89	*****	2.15
Sitagliptin												
<12	0	0	0	0	0	0	0.00	0.0	72.2	.	0	.
12-18	*****	*****	20	824	1,087	0	6.49	2.4	1,130.7	0.00	0	.
19-24	*****	*****	203	7,416	9,865	0	20.62	21.6	2,784.8	0.00	0	.
25-44	4,369	4,369	16,275	544,430	649,483	19	32.40	1,547.2	137,961.7	12.28	49	2.58
45-64	25,568	25,568	110,680	3,822,631	4,426,471	97	34.42	10,678.7	966,482.7	9.08	245	2.53
>=65	45,705	45,705	214,141	6,998,862	7,731,738	136	35.54	19,494.6	1,718,922.3	6.98	295	2.17

Table 2d. Summary of Diabetic Ketoacidosis Events after Incident Exposure to Canagliflozin, Dapagliflozin, Empagliflozin, or Sitagliptin in the Sentinel Distributed Database (SDD) between March 1, 2013 and June 30, 2018, by Age Group (Years)

Age Group	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	New Episodes with an Event	Number of Exposed Members per 1,000 Eligible Members ¹	Years at Risk	Eligible Member Years ¹	Incident Rate per 1,000 Years at Risk	All Events	Number of Events per Patient with an Event
Incident Exposure and Prior Type 2 Diabetes Mellitus without History of Insulin Use												
Canagliflozin												
<12	****	****	****	240	240	0	1.51	0.7	478.9	0.00	0	.
12-18	****	****	****	1,775	1,880	0	2.69	5.0	6,004.7	0.00	0	.
19-24	188	188	853	27,811	28,970	0	9.62	78.8	16,035.7	0.00	0	.
25-44	14,423	14,423	62,265	2,083,211	2,246,145	29	26.39	5,919.6	645,933.0	4.90	65	2.24
45-64	72,075	72,075	357,586	12,698,380	13,565,623	114	28.14	35,338.0	3,952,543.9	3.23	176	1.54
>=65	80,160	80,160	318,657	13,096,662	13,689,958	118	15.74	36,196.0	10,296,037.5	3.26	291	2.47
Dapagliflozin												
<12	0	0	0	0	0	0	0.00	0.0	478.9	.	0	.
12-18	12	12	38	1,101	1,101	0	1.70	3.1	6,005.1	0.00	0	.
19-24	74	74	173	6,045	6,893	0	3.79	17.7	16,043.3	0.00	0	.
25-44	5,307	5,307	18,399	602,077	635,932	****	9.71	****	646,489.5	2.31	****	2.50
45-64	25,548	25,548	107,381	3,719,832	3,873,691	21	9.97	10,503.7	3,957,330.6	2.00	26	1.24
>=65	15,493	15,493	54,054	2,177,454	2,224,702	****	3.04	****	10,305,090.8	2.81	****	2.29
Empagliflozin												
<12	0	0	0	0	0	0	0.00	0.0	478.9	.	0	.
12-18	14	14	54	1,729	1,753	0	1.98	4.7	6,005.1	0.00	0	.
19-24	87	87	217	7,005	7,575	0	4.45	20.5	16,048.6	0.00	0	.
25-44	5,977	5,977	20,087	668,084	693,842	****	10.93	****	646,750.1	4.18	****	1.13
45-64	32,162	32,162	125,932	4,438,594	4,577,952	39	12.55	12,374.6	3,958,926.3	3.15	63	1.62
>=65	19,731	19,731	59,827	2,453,071	2,485,650	****	3.87	****	10,306,235.0	2.06	****	2.29
Sitagliptin												
<12	****	****	****	180	286	0	6.10	0.6	465.5	0.00	0	.
12-18	****	****	****	6,067	7,755	0	9.72	17.7	5,931.8	0.00	0	.
19-24	431	431	1,356	46,313	56,886	****	22.76	****	15,158.9	22.92	****	1.00
25-44	22,642	22,642	88,700	3,089,766	3,667,718	****	44.19	****	582,636.8	3.08	****	1.48
45-64	123,003	123,003	534,952	19,932,864	22,945,362	133	52.68	55,589.5	3,447,905.1	2.39	268	2.02
>=65	261,611	261,611	1,131,215	45,276,564	49,706,488	347	57.89	125,163.4	8,619,865.1	2.77	669	1.93

¹Data not available for the T1DM subgroups

****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 2e. Summary of Diabetic Ketoacidosis Events after Incident Exposure to Canagliflozin, Dapagliflozin, Empagliflozin, or Sitagliptin in the Sentinel Distributed Database (SDD) between March 1, 2013 and June 30, 2018, by Age Group (Years) and Year of Exposure

Age Group (Years)	Calendar Year	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	New Episodes with an Event	Number of Exposed Members per 1,000 Eligible Members ¹	Years at Risk	Eligible Member Years ¹	Incidence Rate per 1,000 Years at Risk	Number of Events per Patient with an Event	
												All Events	an Event
Incident Exposure													
Canagliflozin													
<12	2013	0	0	0	0	0	0	0.00	0.0	3,222,049.9	.	0	.
	2014	*****	*****	*****	180	180	0	0.00	0.6	3,939,536.6	0.00	0	.
	2015	*****	*****	*****	120	120	0	0.00	0.4	4,072,170.4	0.00	0	.
	2016	*****	*****	*****	330	360	0	0.00	1.0	4,131,010.0	0.00	0	.
	2017	0	0	0	0	0	0	0.00	0.0	3,325,427.6	.	0	.
	2018	0	0	0	0	0	0	0.00	0.0	217,334.6	.	0	.
12-18	2013	13	13	34	1,281	1,281	*****	0.00	*****	2,368,046.2	416.67	*****	6.00
	2014	*****	*****	*****	1,890	1,920	0	0.00	5.5	2,891,324.7	0.00	0	.
	2015	*****	*****	*****	3,747	4,347	0	0.01	10.8	2,999,545.6	0.00	0	.
	2016	*****	*****	*****	1,037	1,172	0	0.00	3.3	3,051,719.5	0.00	0	.
	2017	*****	*****	22	1,118	1,148	0	0.00	*****	2,554,669.8	0.00	0	.
	2018	0	0	0	0	0	0	0.00	0.0	161,642.6	.	0	.
19-24	2013	46	46	232	7,037	7,037	0	0.01	19.9	2,100,551.2	0.00	0	.
	2014	123	123	534	18,681	19,086	*****	0.03	*****	2,585,086.2	56.29	*****	1.00
	2015	181	181	655	23,301	25,497	0	0.05	65.5	2,739,038.8	0.00	0	.
	2016	121	121	391	13,606	14,458	*****	0.03	*****	2,753,350.7	25.91	*****	1.00
	2017	*****	*****	*****	4,373	5,237	*****	0.01	*****	2,339,473.7	83.33	*****	1.00
	2018	*****	*****	*****	49	98	0	0.00	0.2	161,074.2	0.00	0	.
25-44	2013	2,203	2,203	10,926	353,081	356,545	*****	0.20	*****	7,483,912.8	14.97	*****	1.47
	2014	6,687	6,687	33,882	1,129,398	1,169,779	*****	0.57	*****	9,057,976.2	17.05	*****	2.13
	2015	9,697	9,697	42,819	1,457,261	1,599,422	60	0.79	4,131.1	9,472,179.0	14.52	134	2.23
	2016	6,890	6,890	23,421	782,032	875,923	*****	0.51	*****	9,732,289.4	13.95	*****	2.68
	2017	*****	*****	*****	200,971	234,759	*****	0.21	*****	7,892,053.4	17.33	*****	1.30
	2018	*****	*****	*****	3,703	4,424	0	0.05	10.5	540,621.9	0.00	0	.

Table 2e. Summary of Diabetic Ketoacidosis Events after Incident Exposure to Canagliflozin, Dapagliflozin, Empagliflozin, or Sitagliptin in the Sentinel Distributed Database (SDD) between March 1, 2013 and June 30, 2018, by Age Group (Years) and Year of Exposure

Age Group (Years)	Calendar Year	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	New Episodes with an Event	Number of Exposed Members per 1,000 Eligible Members ¹	Years at Risk	Eligible Member Years ¹	Incidence Rate per 1,000 Years at Risk	All Events	Number of Events per Patient with an Event
45-64	2013	11,430	11,430	67,658	2,288,318	2,311,640	38	0.83	6,342.8	10,139,172.6	5.99	80	2.11
	2014	33,552	33,552	193,308	6,854,827	7,060,630	121	2.29	18,982.3	12,311,947.1	6.37	282	2.33
	2015	46,585	46,585	238,354	8,503,920	9,262,270	157	3.08	23,663.9	12,771,248.0	6.63	348	2.22
	2016	32,035	32,035	121,933	4,318,547	4,762,747	93	1.95	12,065.9	13,115,652.5	7.71	253	2.72
	2017	10,138	10,138	28,768	1,029,308	1,172,379	18	0.85	2,889.7	9,376,648.2	6.23	35	1.94
	2018	419	419	592	15,509	17,363	0	0.15	43.0	620,294.6	0.00	0	.
>=65	2013	6,998	6,998	39,036	1,529,968	1,546,818	*****	0.38	*****	14,325,298.6	5.26	*****	2.36
	2014	32,820	32,820	159,749	6,617,003	6,755,877	94	1.56	18,164.7	19,331,839.3	5.17	241	2.56
	2015	51,220	51,220	213,884	8,675,182	9,193,960	120	2.33	24,067.7	20,106,028.0	4.99	285	2.38
	2016	39,454	39,454	113,832	4,392,740	4,688,121	49	1.69	12,257.4	21,110,533.6	4.00	122	2.49
	2017	4,104	4,104	10,538	447,949	479,377	*****	0.74	*****	4,874,021.7	5.60	*****	2.29
	2018	306	306	385	9,381	9,878	0	0.09	25.4	471,853.2	0.00	0	.
Dapagliflozin													
<12	2013	0	0	0	0	0	0	0.00	0.0	3,222,049.9	.	0	.
	2014	0	0	0	0	0	0	0.00	0.0	3,939,536.6	.	0	.
	2015	0	0	0	0	0	0	0.00	0.0	4,072,171.7	.	0	.
	2016	0	0	0	0	0	0	0.00	0.0	4,131,012.2	.	0	.
	2017	*****	*****	*****	100	100	0	0.00	0.2	3,325,429.9	0.00	0	.
	2018	0	0	0	0	0	0	0.00	0.0	217,334.8	.	0	.
12-18	2013	0	0	0	0	0	0	0.00	0.0	2,368,046.2	.	0	.
	2014	*****	*****	*****	270	270	*****	0.00	*****	2,891,325.3	2,000.00	*****	2.00
	2015	14	14	40	1,214	1,244	0	0.00	3.5	2,999,549.0	0.00	0	.
	2016	*****	*****	11	450	480	0	0.00	1.3	3,051,724.0	0.00	0	.
	2017	11	11	19	553	763	0	0.00	1.6	2,554,673.2	0.00	0	.
	2018	*****	*****	*****	64	64	0	0.00	*****	161,642.9	0.00	0	.
19-24	2013	0	0	0	0	0	0	0.00	0.0	2,100,551.2	.	0	.
	2014	42	42	121	4,147	4,267	0	0.01	12.2	2,585,087.7	0.00	0	.
	2015	67	67	155	5,500	5,950	0	0.02	16.4	2,739,047.6	0.00	0	.
	2016	*****	*****	114	3,997	4,333	0	0.01	11.6	2,753,378.3	0.00	0	.
	2017	*****	*****	*****	2,504	2,790	0	0.01	7.5	2,339,496.0	0.00	0	.
	2018	*****	*****	*****	91	91	0	0.01	0.3	161,075.2	0.00	0	.

Table 2e. Summary of Diabetic Ketoacidosis Events after Incident Exposure to Canagliflozin, Dapagliflozin, Empagliflozin, or Sitagliptin in the Sentinel Distributed Database (SDD) between March 1, 2013 and June 30, 2018, by Age Group (Years) and Year of Exposure

Age Group (Years)	Calendar Year	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	New Episodes with an Event	Number of Exposed Members per 1,000 Eligible Members ¹		Eligible Member Years ¹	Incidence Rate per 1,000 Years at Risk	All Events	Number of Events per Patient with an Event
								Years at Risk	Members ¹				
25-44	2013	0	0	0	0	0	0	0.00	0.0	7,483,912.8	.	0	.
	2014	2,627	2,627	9,686	319,271	324,852	*****	0.22	*****	9,058,018.4	3.28	*****	1.67
	2015	2,951	2,951	11,167	366,481	384,583	13	0.24	1,055.0	9,472,573.4	12.32	36	2.77
	2016	2,480	2,480	7,624	253,478	280,524	*****	0.18	*****	9,733,386.0	12.32	*****	2.22
	2017	*****	*****	*****	133,263	145,626	*****	0.14	*****	7,892,861.2	13.08	*****	1.00
	2018	*****	*****	*****	4,514	5,102	0	0.06	12.4	540,675.9	0.00	0	.
45-64	2013	0	0	0	0	0	0	0.00	0.0	10,139,172.6	.	0	.
	2014	11,615	11,615	52,813	1,811,549	1,842,224	29	0.79	5,127.2	12,312,166.1	5.66	44	1.52
	2015	13,243	13,243	62,635	2,159,079	2,260,141	29	0.88	6,101.0	12,773,595.6	4.75	41	1.41
	2016	11,311	11,311	41,556	1,476,843	1,576,460	*****	0.69	*****	13,123,088.1	4.56	*****	1.79
	2017	7,073	7,073	20,715	734,849	791,682	*****	0.59	*****	9,382,498.0	2.92	*****	1.50
	2018	551	551	795	19,622	20,905	0	0.20	54.4	620,780.8	0.00	0	.
>=65	2013	0	0	0	0	0	0	0.00	0.0	14,325,298.6	.	0	.
	2014	6,263	6,263	26,834	1,104,599	1,117,965	*****	0.30	3,063.8	19,332,086.1	4.57	*****	1.64
	2015	8,027	8,027	31,773	1,279,883	1,309,509	16	0.36	3,565.9	20,109,995.2	4.49	29	1.81
	2016	9,254	9,254	26,087	983,184	1,015,344	14	0.40	2,741.6	21,126,410.9	5.11	45	3.21
	2017	1,680	1,680	4,371	177,306	183,677	*****	0.30	496.5	4,879,215.6	6.04	*****	1.00
	2018	328	328	424	10,881	11,185	0	0.10	28.9	472,462.4	0.00	0	.
Empagliflozin													
<12	2013	0	0	0	0	0	0	0.00	0.0	3,222,049.9	.	0	.
	2014	0	0	0	0	0	0	0.00	0.0	3,939,536.6	.	0	.
	2015	0	0	0	0	0	0	0.00	0.0	4,072,171.7	.	0	.
	2016	0	0	0	0	0	0	0.00	0.0	4,131,012.2	.	0	.
	2017	0	0	0	0	0	0	0.00	0.0	3,325,429.9	.	0	.
	2018	0	0	0	0	0	0	0.00	0.0	217,334.8	.	0	.
12-18	2013	0	0	0	0	0	0	0.00	0.0	2,368,046.2	.	0	.
	2014	*****	*****	*****	150	150	0	0.00	0.5	2,891,325.3	0.00	0	.
	2015	*****	*****	*****	934	934	0	0.00	2.5	2,999,549.1	0.00	0	.
	2016	*****	*****	43	1,459	1,459	0	0.00	4.0	3,051,723.8	0.00	0	.
	2017	15	15	39	1,241	1,295	0	0.00	3.5	2,554,671.9	0.00	0	.
	2018	*****	*****	*****	51	51	0	0.00	0.1	161,642.9	0.00	0	.

Table 2e. Summary of Diabetic Ketoacidosis Events after Incident Exposure to Canagliflozin, Dapagliflozin, Empagliflozin, or Sitagliptin in the Sentinel Distributed Database (SDD) between March 1, 2013 and June 30, 2018, by Age Group (Years) and Year of Exposure

Age Group (Years)	Calendar Year	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	New Episodes with an Event	Number of Exposed Members per 1,000 Eligible Members ¹	Years at Risk	Eligible Member Years ¹	Incidence Rate per 1,000 Years at Risk	Number of Events per Patient with	
												All Events	an Event
19-24	2013	0	0	0	0	0	0	0.00	0.0	2,100,551.2	.	0	.
	2014	****	****	****	363	363	0	0.00	1.2	2,585,087.7	0.00	0	.
	2015	****	****	****	3,035	3,065	0	0.01	9.4	2,739,051.9	0.00	0	.
	2016	****	****	189	6,239	6,884	****	0.02	18.2	2,753,394.7	54.95	****	2.00
	2017	88	88	214	7,076	7,613	0	0.03	19.8	2,339,510.7	0.00	0	.
	2018	****	****	****	167	222	0	0.01	0.5	161,076.4	0.00	0	.
25-44	2013	0	0	0	0	0	0	0.00	0.0	7,483,912.8	.	0	.
	2014	340	340	1,215	38,785	39,084	****	0.03	****	9,058,018.4	35.12	****	1.00
	2015	1,947	1,947	8,359	277,494	280,268	****	0.16	****	9,472,672.2	8.83	****	1.71
	2016	3,587	3,587	12,961	443,339	467,554	****	0.26	****	9,733,881.7	4.74	****	1.33
	2017	4,450	4,450	11,805	390,358	415,641	****	0.40	****	7,893,185.8	8.99	****	1.10
	2018	****	****	****	8,645	8,917	****	0.10	****	540,695.2	41.67	****	1.00
45-64	2013	0	0	0	0	0	0	0.00	0.0	10,139,172.6	.	0	.
	2014	1,669	1,669	8,918	301,058	301,935	****	0.11	****	12,312,166.1	3.55	****	1.33
	2015	9,561	9,561	49,436	1,732,328	1,740,381	****	0.63	****	12,774,000.1	6.17	****	2.17
	2016	18,378	18,378	78,616	2,831,140	2,940,110	33	1.11	7,917.8	13,125,280.1	4.17	62	1.88
	2017	23,833	23,833	70,705	2,496,463	2,608,364	38	1.99	6,905.4	9,384,410.4	5.50	49	1.29
	2018	1,424	1,424	2,120	53,512	53,542	****	0.52	****	620,857.5	13.83	****	1.00
>=65	2013	0	0	0	0	0	0	0.00	0.0	14,325,298.6	.	0	.
	2014	671	671	2,818	115,830	115,845	0	0.03	320.5	19,332,086.1	0.00	0	.
	2015	6,985	6,985	26,303	1,110,792	1,115,960	****	0.32	****	20,110,449.0	3.22	****	1.80
	2016	15,643	15,643	44,839	1,783,193	1,819,951	****	0.67	****	21,128,784.2	5.04	****	2.76
	2017	8,818	8,818	23,228	954,576	965,243	****	1.58	****	4,879,369.0	3.42	****	1.33
	2018	790	790	1,038	26,285	23,501	****	0.24	****	472,434.5	29.07	****	3.50
Sitagliptin													
<12	2013	****	****	****	135	226	0	0.00	0.5	3,222,044.9	0.00	0	.
	2014	****	****	18	660	690	0	0.00	2.1	3,939,525.4	0.00	0	.
	2015	****	****	****	90	120	0	0.00	0.3	4,072,158.3	0.00	0	.
	2016	****	****	****	60	60	0	0.00	0.2	4,131,007.8	0.00	0	.
	2017	****	****	****	90	150	0	0.00	0.3	3,325,430.1	0.00	0	.
	2018	0	0	0	0	0	0	0.00	0.0	217,334.6	.	0	.

Table 2e. Summary of Diabetic Ketoacidosis Events after Incident Exposure to Canagliflozin, Dapagliflozin, Empagliflozin, or Sitagliptin in the Sentinel Distributed Database (SDD) between March 1, 2013 and June 30, 2018, by Age Group (Years) and Year of Exposure

Age Group (Years)	Calendar Year	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	New Episodes with an Event	Number of Exposed Members per 1,000 Eligible Members ¹		Eligible Member Years ¹	Incidence Rate per 1,000 Years at Risk	All Events	Number of Events per Patient with an Event
								Years at Risk	Members ¹				
12-18	2013	*****	*****	*****	1,744	2,017	0	0.01	5.3	2,367,982.9	0.00	0	.
	2014	*****	*****	78	2,640	3,450	0	0.01	7.7	2,891,267.6	0.00	0	.
	2015	*****	*****	*****	3,383	4,433	0	0.01	9.9	2,999,513.9	0.00	0	.
	2016	*****	*****	*****	4,096	5,643	0	0.01	11.9	3,051,688.4	0.00	0	.
	2017	*****	*****	*****	1,721	2,215	0	0.01	5.0	2,554,666.2	0.00	0	.
	2018	*****	*****	*****	17	17	0	0.00	0.0	161,643.5	.	0	.
19-24	2013	152	152	496	16,701	20,623	*****	0.05	*****	2,100,118.7	20.62	*****	1.00
	2014	200	200	730	25,699	31,489	0	0.06	72.1	2,584,648.5	0.00	0	.
	2015	199	199	622	21,012	26,811	*****	0.05	*****	2,738,753.2	16.86	*****	1.00
	2016	230	230	612	20,958	24,873	*****	0.06	*****	2,753,135.6	33.84	*****	1.00
	2017	*****	*****	*****	9,825	11,735	*****	0.04	*****	2,339,418.6	68.26	*****	1.00
	2018	*****	*****	*****	455	534	0	0.01	1.3	161,072.8	0.00	0	.
25-44	2013	7,237	7,237	30,574	1,031,491	1,259,590	*****	0.66	*****	7,454,749.3	9.52	*****	2.00
	2014	9,792	9,792	39,155	1,366,444	1,655,232	25	0.83	3,892.6	9,028,203.1	6.42	62	2.48
	2015	8,899	8,899	36,336	1,255,627	1,494,630	*****	0.73	*****	9,452,130.6	8.13	*****	2.76
	2016	8,816	8,816	28,719	984,017	1,174,496	*****	0.65	*****	9,718,428.2	7.16	*****	2.20
	2017	*****	*****	*****	424,531	509,404	*****	0.43	*****	7,890,363.0	5.75	*****	1.00
	2018	*****	*****	*****	12,028	14,928	0	0.15	33.8	540,627.8	0.00	0	.
45-64	2013	35,935	35,935	174,732	6,127,116	7,187,842	86	2.64	17,202.3	9,946,887.4	5.00	195	2.27
	2014	48,677	48,677	233,472	8,471,609	9,884,559	132	3.37	23,666.9	12,100,030.1	5.58	355	2.69
	2015	46,935	46,935	219,835	8,056,229	9,325,104	116	3.14	22,498.6	12,601,256.2	5.16	285	2.46
	2016	47,279	47,279	172,509	6,310,612	7,296,678	107	2.90	17,626.4	12,975,322.9	6.07	278	2.60
	2017	24,846	24,846	72,049	2,640,677	3,092,334	*****	2.08	*****	9,338,258.2	2.98	*****	1.73
	2018	1,515	1,515	2,209	55,966	67,227	*****	0.55	*****	618,694.6	19.70	*****	1.00
>=65	2013	78,647	78,647	434,197	15,370,873	16,960,651	194	4.41	42,749.4	13,862,636.5	4.54	400	2.06
	2014	106,110	106,110	542,990	20,523,221	22,613,021	244	5.17	56,830.2	18,697,787.1	4.29	502	2.06
	2015	108,080	108,080	495,253	19,024,964	20,899,429	224	5.05	52,759.8	19,474,532.6	4.25	509	2.27
	2016	107,902	107,902	337,789	12,669,250	13,892,888	156	4.74	35,095.0	20,469,044.0	4.45	337	2.16
	2017	18,932	18,932	53,216	2,212,906	2,427,115	*****	3.47	*****	4,774,230.2	3.28	*****	3.15
	2018	1,645	1,645	2,065	48,040	52,737	*****	0.52	*****	462,916.9	7.89	*****	1.00

Table 2e. Summary of Diabetic Ketoacidosis Events after Incident Exposure to Canagliflozin, Dapagliflozin, Empagliflozin, or Sitagliptin in the Sentinel Distributed Database (SDD) between March 1, 2013 and June 30, 2018, by Age Group (Years) and Year of Exposure

Age Group (Years)	Calendar Year	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	New Episodes with an Event	Number of Exposed Members per 1,000 Eligible Members ¹	Years at Risk	Eligible Member Years ¹	Incidence Rate per 1,000 Years at Risk	All Events	Number of Events per Patient with an Event
Incident Exposure and Prior Type 1 Diabetes Mellitus													
Canagliflozin													
<12	2013	0	0	0	0	0	0	.	0.0	.	.	0	.
	2014	0	0	0	0	0	0	.	0.0	.	.	0	.
	2015	0	0	0	0	0	0	.	0.0	.	.	0	.
	2016	0	0	0	0	0	0	.	0.0	.	.	0	.
	2017	0	0	0	0	0	0	.	0.0	.	.	0	.
	2018	0	0	0	0	0	0	.	0.0	.	.	0	.
12-18	2013	*****	*****	*****	540	540	*****	.	*****	.	5,000.00	*****	6.00
	2014	*****	*****	25	750	750	0	.	2.1	.	0.00	0	.
	2015	*****	*****	43	1,327	1,327	0	.	3.8	.	0.00	0	.
	2016	*****	*****	*****	150	150	0	.	*****	.	0.00	0	.
	2017	0	0	0	0	0	0	.	0.0	.	.	0	.
	2018	0	0	0	0	0	0	.	0.0	.	.	0	.
19-24	2013	*****	*****	*****	2,190	2,190	0	.	6.0	.	0.00	0	.
	2014	*****	*****	32	1,020	1,020	*****	.	*****	.	344.83	*****	1.00
	2015	*****	*****	51	1,809	1,929	0	.	5.2	.	0.00	0	.
	2016	*****	*****	*****	430	400	0	.	1.3	.	0.00	0	.
	2017	*****	*****	*****	65	65	0	.	*****	.	0.00	0	.
	2018	0	0	0	0	0	0	.	0.0	.	.	0	.
25-44	2013	43	43	266	8,703	8,703	*****	.	*****	.	128.76	*****	1.00
	2014	153	153	769	28,094	28,700	15	.	70.3	.	213.37	23	1.53
	2015	148	148	640	23,251	23,611	*****	.	*****	.	155.76	*****	1.50
	2016	69	69	269	10,366	10,456	*****	.	*****	.	107.91	*****	7.00
	2017	*****	*****	*****	2,008	2,163	*****	.	*****	.	370.37	*****	1.00
	2018	*****	*****	*****	15	15	0	.	0.0	.	.	0	.
45-64	2013	73	73	361	11,389	11,449	*****	.	*****	.	63.29	*****	2.00
	2014	219	219	1,368	49,472	50,208	*****	.	*****	.	29.50	*****	1.75
	2015	273	273	1,405	52,254	56,687	*****	.	*****	.	64.19	*****	2.67
	2016	116	116	455	16,975	18,425	*****	.	*****	.	21.01	*****	3.00
	2017	*****	*****	*****	2,849	2,849	0	.	8.1	.	0.00	0	.
	2018	*****	*****	*****	62	62	0	.	0.2	.	0.00	0	.

Table 2e. Summary of Diabetic Ketoacidosis Events after Incident Exposure to Canagliflozin, Dapagliflozin, Empagliflozin, or Sitagliptin in the Sentinel Distributed Database (SDD) between March 1, 2013 and June 30, 2018, by Age Group (Years) and Year of Exposure

Age Group (Years)	Calendar Year	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	New Episodes with an Event	Number of Exposed Members per 1,000 Eligible Members ¹	Years at Risk	Eligible Member Years ¹	Incidence Rate per 1,000 Years at Risk	Number of Events per Patient with	
												All Events	an Event
>=65	2013	*****	*****	*****	4,431	4,487	*****	.	*****	.	82.64	*****	1.00
	2014	103	103	503	21,025	21,369	*****	.	*****	.	52.17	*****	2.67
	2015	145	145	504	21,997	22,792	*****	.	*****	.	33.44	*****	2.50
	2016	55	55	159	6,193	6,917	0	.	17.3	.	0.00	0	.
	2017	*****	*****	*****	60	60	0	.	0.2	.	0.00	0	.
	2018	0	0	0	0	0	0	.	0.0	.	.	0	.
Dapagliflozin													
<12	2013	0	0	0	0	0	0	.	0.0	.	.	0	.
	2014	0	0	0	0	0	0	.	0.0	.	.	0	.
	2015	0	0	0	0	0	0	.	0.0	.	.	0	.
	2016	0	0	0	0	0	0	.	0.0	.	.	0	.
	2017	0	0	0	0	0	0	.	0.0	.	.	0	.
	2018	0	0	0	0	0	0	.	0.0	.	.	0	.
12-18	2013	0	0	0	0	0	0	.	0.0	.	.	0	.
	2014	0	0	0	0	0	0	.	0.0	.	.	0	.
	2015	*****	*****	*****	120	120	0	.	0.3	.	0.00	0	.
	2016	0	0	0	0	0	0	.	0.0	.	.	0	.
	2017	0	0	0	0	0	0	.	0.0	.	.	0	.
	2018	0	0	0	0	0	0	.	0.0	.	.	0	.
19-24	2013	0	0	0	0	0	0	.	0.0	.	.	0	.
	2014	*****	*****	*****	630	630	0	.	1.8	.	0.00	0	.
	2015	*****	*****	*****	120	120	0	.	0.4	.	0.00	0	.
	2016	*****	*****	*****	90	90	0	.	0.3	.	0.00	0	.
	2017	*****	*****	*****	60	60	0	.	0.2	.	0.00	0	.
	2018	0	0	0	0	0	0	.	0.0	.	.	0	.
25-44	2013	0	0	0	0	0	0	.	0.0	.	.	0	.
	2014	38	38	105	3,930	3,930	*****	.	*****	.	93.46	*****	2.00
	2015	45	45	160	6,173	6,233	*****	.	*****	.	57.47	*****	3.00
	2016	14	14	42	1,325	1,325	0	.	4.0	.	0.00	0	.
	2017	15	15	38	1,158	1,218	*****	.	*****	.	312.50	*****	1.00
	2018	0	0	0	0	0	0	.	0.0	.	.	0	.

Table 2e. Summary of Diabetic Ketoacidosis Events after Incident Exposure to Canagliflozin, Dapagliflozin, Empagliflozin, or Sitagliptin in the Sentinel Distributed Database (SDD) between March 1, 2013 and June 30, 2018, by Age Group (Years) and Year of Exposure

Age Group (Years)	Calendar Year	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	New Episodes with an Event	Number of Exposed Members per 1,000 Eligible Members ¹	Years at Risk	Eligible Member Years ¹	Incidence Rate per 1,000 Years at Risk	Number of Events per Patient with an Event	
												All Events	an Event
45-64	2013	0	0	0	0	0	0	.	0.0	.	.	0	.
	2014	82	82	384	13,410	13,811	*****	.	*****	.	81.97	*****	2.00
	2015	71	71	301	12,696	12,696	*****	.	*****	.	29.50	*****	1.00
	2016	36	36	121	4,291	4,984	0	.	12.4	.	0.00	0	.
	2017	*****	*****	*****	1,710	1,710	0	.	4.9	.	0.00	0	.
	2018	*****	*****	*****	101	101	0	.	0.3	.	0.00	0	.
>=65	2013	0	0	0	0	0	0	.	0.0	.	.	0	.
	2014	16	16	45	1,875	2,415	0	.	5.4	.	0.00	0	.
	2015	*****	*****	*****	3,538	3,538	*****	.	*****	.	105.26	*****	2.00
	2016	*****	*****	*****	1,838	1,838	*****	.	*****	.	196.08	*****	8.00
	2017	*****	*****	*****	120	120	0	.	0.4	.	0.00	0	.
	2018	*****	*****	*****	19	19	0	.	0.0	.	.	0	.
Empagliflozin													
<12	2013	0	0	0	0	0	0	.	0.0	.	.	0	.
	2014	0	0	0	0	0	0	.	0.0	.	.	0	.
	2015	0	0	0	0	0	0	.	0.0	.	.	0	.
	2016	0	0	0	0	0	0	.	0.0	.	.	0	.
	2017	0	0	0	0	0	0	.	0.0	.	.	0	.
	2018	0	0	0	0	0	0	.	0.0	.	.	0	.
12-18	2013	0	0	0	0	0	0	.	0.0	.	.	0	.
	2014	0	0	0	0	0	0	.	0.0	.	.	0	.
	2015	*****	*****	*****	364	364	0	.	0.9	.	0.00	0	.
	2016	*****	*****	*****	60	60	0	.	0.2	.	0.00	0	.
	2017	0	0	0	0	0	0	.	0.0	.	.	0	.
	2018	0	0	0	0	0	0	.	0.0	.	.	0	.
19-24	2013	0	0	0	0	0	0	.	0.0	.	.	0	.
	2014	*****	*****	*****	90	90	0	.	0.3	.	0.00	0	.
	2015	*****	*****	*****	142	142	0	.	0.5	.	0.00	0	.
	2016	*****	*****	*****	240	240	0	.	0.7	.	0.00	0	.
	2017	*****	*****	11	339	339	0	.	0.8	.	0.00	0	.
	2018	*****	*****	*****	77	102	0	.	0.2	.	0.00	0	.

Table 2e. Summary of Diabetic Ketoacidosis Events after Incident Exposure to Canagliflozin, Dapagliflozin, Empagliflozin, or Sitagliptin in the Sentinel Distributed Database (SDD) between March 1, 2013 and June 30, 2018, by Age Group (Years) and Year of Exposure

Age Group (Years)	Calendar Year	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	New Episodes with an Event	Number of Exposed Members per 1,000 Eligible Members ¹	Years at Risk	Eligible Member Years ¹	Incidence Rate per 1,000 Years at Risk	Number of Events per Patient with an Event	
												All Events	an Event
25-44	2013	0	0	0	0	0	0	.	0.0	.	.	0	.
	2014	*****	*****	*****	720	720	0	.	2.2	.	0.00	0	.
	2015	*****	*****	163	5,267	5,267	*****	.	*****	.	66.23	*****	1.00
	2016	44	44	187	7,474	7,441	*****	.	*****	.	51.02	*****	2.00
	2017	42	42	135	4,024	4,031	*****	.	*****	.	85.47	*****	1.00
	2018	*****	*****	*****	43	43	0	.	0.1	.	0.00	0	.
45-64	2013	0	0	0	0	0	0	.	0.0	.	.	0	.
	2014	*****	*****	*****	3,709	3,709	0	.	10.3	.	0.00	0	.
	2015	57	57	298	11,930	11,930	*****	.	*****	.	159.74	*****	2.20
	2016	83	83	376	15,484	15,514	*****	.	*****	.	47.51	*****	1.00
	2017	79	79	228	8,692	8,602	0	.	24.3	.	0.00	0	.
	2018	*****	*****	*****	272	272	0	.	0.7	.	0.00	0	.
>=65	2013	0	0	0	0	0	0	.	0.0	.	.	0	.
	2014	*****	*****	*****	570	570	0	.	1.6	.	0.00	0	.
	2015	30	30	75	3,117	3,117	0	.	9.0	.	0.00	0	.
	2016	*****	*****	*****	3,343	3,391	*****	.	*****	.	113.64	*****	3.00
	2017	*****	*****	32	1,381	1,381	0	.	*****	.	0.00	0	.
	2018	*****	*****	*****	30	30	0	.	0.1	.	0.00	0	.
Sitagliptin													
<12	2013	0	0	0	0	0	0	.	0.0	.	.	0	.
	2014	0	0	0	0	0	0	.	0.0	.	.	0	.
	2015	0	0	0	0	0	0	.	0.0	.	.	0	.
	2016	0	0	0	0	0	0	.	0.0	.	.	0	.
	2017	0	0	0	0	0	0	.	0.0	.	.	0	.
	2018	0	0	0	0	0	0	.	0.0	.	.	0	.
12-18	2013	0	0	0	0	0	0	.	0.0	.	.	0	.
	2014	0	0	0	0	0	0	.	0.0	.	.	0	.
	2015	0	0	0	0	0	0	.	0.0	.	.	0	.
	2016	0	0	0	0	0	0	.	0.0	.	.	0	.
	2017	*****	*****	*****	60	60	0	.	0.2	.	0.00	0	.
	2018	0	0	0	0	0	0	.	0.0	.	.	0	.

Table 2e. Summary of Diabetic Ketoacidosis Events after Incident Exposure to Canagliflozin, Dapagliflozin, Empagliflozin, or Sitagliptin in the Sentinel Distributed Database (SDD) between March 1, 2013 and June 30, 2018, by Age Group (Years) and Year of Exposure

Age Group (Years)	Calendar Year	New Users	New Episodes	New Dispensings	Days Supplied	Amount Supplied	New Episodes with an Event	Number of Exposed Members per 1,000 Eligible Members ¹	Years at Risk	Eligible Member Years ¹	Incidence Rate per 1,000 Years at Risk	All Events	Number of Events per Patient with an Event
19-24	2013	*****	*****	*****	60	60	0	.	0.1	.	0.00	0	.
	2014	*****	*****	*****	300	330	0	.	0.8	.	0.00	0	.
	2015	0	0	0	0	0	0	.	0.0	.	.	0	.
	2016	*****	*****	*****	200	260	0	.	*****	.	0.00	0	.
	2017	*****	*****	*****	150	180	*****	.	*****	.	2,000.00	*****	1.00
	2018	0	0	0	0	0	0	.	0.0	.	.	0	.
25-44	2013	*****	*****	*****	2,134	3,079	*****	.	*****	.	307.69	*****	2.50
	2014	*****	*****	*****	4,285	4,789	0	.	12.1	.	0.00	0	.
	2015	29	29	107	3,420	3,660	*****	.	*****	.	206.19	*****	1.00
	2016	28	28	78	2,247	2,658	0	.	6.1	.	0.00	0	.
	2017	*****	*****	*****	1,607	1,799	0	.	4.5	.	0.00	0	.
	2018	*****	*****	*****	30	60	0	.	0.1	.	0.00	0	.
45-64	2013	49	49	165	5,708	6,008	*****	.	*****	.	60.61	*****	1.00
	2014	90	90	480	14,966	15,926	*****	.	*****	.	23.81	*****	1.00
	2015	70	70	401	11,775	13,986	*****	.	*****	.	59.35	*****	1.50
	2016	46	46	132	4,582	5,032	0	.	13.2	.	0.00	0	.
	2017	11	11	25	1,007	1,127	0	.	2.9	.	0.00	0	.
	2018	0	0	0	0	0	0	.	0.0	.	.	0	.
>=65	2013	89	89	678	17,567	18,942	*****	.	*****	.	40.49	*****	1.00
	2014	110	110	678	21,517	25,680	*****	.	*****	.	50.68	*****	4.00
	2015	110	110	570	15,693	18,637	*****	.	*****	.	44.94	*****	1.50
	2016	*****	*****	*****	7,270	7,988	*****	.	*****	.	102.56	*****	4.50
	2017	*****	*****	*****	628	628	0	.	1.7	.	0.00	0	.
	2018	*****	*****	*****	89	89	0	.	0.2	.	0.00	0	.
Incident Exposure and Prior Type 1 Diabetes Mellitus - Broad Definition													
Canagliflozin													
<12	2013	0	0	0	0	0	0	.	0.0	.	.	0	.
	2014	0	0	0	0	0	0	.	0.0	.	.	0	.
	2015	0	0	0	0	0	0	.	0.0	.	.	0	.
	2016	0	0	0	0	0	0	.	0.0	.	.	0	.
	2017	0	0	0	0	0	0	.	0.0	.	.	0	.
	2018	0	0	0	0	0	0	.	0.0	.	.	0	.

Table 2e. Summary of Diabetic Ketoacidosis Events after Incident Exposure to Canagliflozin, Dapagliflozin, Empagliflozin, or Sitagliptin in the Sentinel Distributed Database (SDD) between March 1, 2013 and June 30, 2018, by Age Group (Years) and Year of Exposure

Age Group (Years)	Calendar Year	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	New Episodes with an Event	Number of Exposed Members per 1,000 Eligible Members ¹	Years at Risk	Eligible Member Years ¹	Incidence Rate per 1,000 Years at Risk	Number of Events per Patient with an Event	
												All Events	an Event
12-18	2013	*****	*****	*****	570	570	*****	.	*****	.	2,500.00	*****	6.00
	2014	*****	*****	*****	780	810	0	.	2.2	.	0.00	0	.
	2015	*****	*****	*****	1,447	1,447	0	.	4.1	.	0.00	0	.
	2016	*****	*****	*****	150	150	0	.	*****	.	0.00	0	.
	2017	0	0	0	0	0	0	.	0.0	.	.	0	.
	2018	0	0	0	0	0	0	.	0.0	.	.	0	.
19-24	2013	*****	*****	*****	2,250	2,250	0	.	6.1	.	0.00	0	.
	2014	*****	*****	*****	1,450	1,450	*****	.	*****	.	243.90	*****	1.00
	2015	*****	*****	*****	1,959	2,079	0	.	5.7	.	0.00	0	.
	2016	*****	*****	*****	445	415	0	.	1.4	.	0.00	0	.
	2017	*****	*****	*****	95	95	*****	.	*****	.	5,000.00	*****	1.00
	2018	0	0	0	0	0	0	.	0.0	.	.	0	.
25-44	2013	61	61	310	9,992	9,992	*****	.	*****	.	110.70	.	1.00
	2014	190	190	982	36,252	36,858	15	.	92.9	.	161.46	23	1.53
	2015	189	189	911	32,265	33,555	*****	.	*****	.	112.99	*****	1.50
	2016	102	102	379	13,696	14,192	*****	.	*****	.	107.82	*****	5.50
	2017	*****	*****	*****	2,291	2,536	*****	.	*****	.	317.46	*****	1.00
	2018	*****	*****	*****	15	15	0	.	0.0	.	.	0	.
45-64	2013	167	167	867	29,499	29,838	*****	.	*****	.	25.16	*****	2.00
	2014	405	405	2,532	90,418	91,904	*****	.	*****	.	20.16	*****	1.80
	2015	497	497	2,406	90,120	97,777	*****	.	*****	.	40.55	*****	2.60
	2016	191	191	698	25,529	28,017	*****	.	*****	.	13.93	*****	3.00
	2017	*****	*****	*****	3,963	4,053	0	.	11.4	.	0.00	0	.
	2018	*****	*****	*****	122	182	0	.	0.3	.	0.00	0	.
>=65	2013	75	75	437	17,082	17,228	*****	.	*****	.	43.20	*****	1.50
	2014	293	293	1,424	58,037	58,899	*****	.	*****	.	31.29	*****	2.80
	2015	407	407	1,439	62,797	65,272	*****	.	*****	.	17.31	*****	3.00
	2016	187	187	525	19,370	21,120	0	.	54.2	.	0.00	0	.
	2017	15	15	38	1,414	1,655	0	.	4.1	.	0.00	0	.
	2018	0	0	0	0	0	0	.	0.0	.	.	0	.

Table 2e. Summary of Diabetic Ketoacidosis Events after Incident Exposure to Canagliflozin, Dapagliflozin, Empagliflozin, or Sitagliptin in the Sentinel Distributed Database (SDD) between March 1, 2013 and June 30, 2018, by Age Group (Years) and Year of Exposure

Age Group (Years)	Calendar Year	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	New Episodes with an Event	Number of Exposed Members per 1,000 Eligible Members ¹	Years at Risk	Eligible Member Years ¹	Incidence Rate per 1,000 Years at Risk	Number of Events per Patient with an Event	
												All Events	an Event
Dapagliflozin													
<12	2013	0	0	0	0	0	0	.	0.0	.	.	0	.
	2014	0	0	0	0	0	0	.	0.0	.	.	0	.
	2015	0	0	0	0	0	0	.	0.0	.	.	0	.
	2016	0	0	0	0	0	0	.	0.0	.	.	0	.
	2017	0	0	0	0	0	0	.	0.0	.	.	0	.
	2018	0	0	0	0	0	0	.	0.0	.	.	0	.
12-18	2013	0	0	0	0	0	0	.	0.0	.	.	0	.
	2014	0	0	0	0	0	0	.	0.0	.	.	0	.
	2015	*****	*****	*****	120	120	0	.	0.3	.	0.00	0	.
	2016	0	0	0	0	0	0	.	0.0	.	.	0	.
	2017	*****	*****	*****	180	360	0	.	0.5	.	0.00	0	.
	2018	0	0	0	0	0	0	.	0.0	.	.	0	.
19-24	2013	0	0	0	0	0	0	.	0.0	.	.	0	.
	2014	*****	*****	*****	630	630	0	.	1.8	.	0.00	0	.
	2015	*****	*****	*****	120	120	0	.	0.4	.	0.00	0	.
	2016	*****	*****	*****	90	90	0	.	0.3	.	0.00	0	.
	2017	*****	*****	*****	60	60	0	.	0.2	.	0.00	0	.
	2018	0	0	0	0	0	0	.	0.0	.	.	0	.
25-44	2013	0	0	0	0	0	0	.	0.0	.	.	0	.
	2014	*****	*****	*****	6,555	6,855	*****	.	*****	.	114.94	*****	2.00
	2015	*****	*****	*****	7,394	7,454	*****	.	*****	.	47.85	*****	3.00
	2016	*****	*****	*****	1,988	1,988	0	.	5.8	.	0.00	0	.
	2017	22	22	58	1,845	1,905	*****	.	*****	.	192.31	*****	1.00
	2018	0	0	0	0	0	0	.	0.0	.	.	0	.
45-64	2013	0	0	0	0	0	0	.	0.0	.	.	0	.
	2014	147	147	678	24,393	25,201	*****	.	*****	.	44.44	*****	2.00
	2015	140	140	641	24,198	25,564	*****	.	*****	.	14.99	*****	1.00
	2016	71	71	273	10,068	11,301	0	.	28.8	.	0.00	0	.
	2017	*****	*****	*****	2,822	2,954	0	.	8.1	.	0.00	0	.
	2018	*****	*****	*****	101	101	0	.	0.3	.	0.00	0	.

Table 2e. Summary of Diabetic Ketoacidosis Events after Incident Exposure to Canagliflozin, Dapagliflozin, Empagliflozin, or Sitagliptin in the Sentinel Distributed Database (SDD) between March 1, 2013 and June 30, 2018, by Age Group (Years) and Year of Exposure

Age Group (Years)	Calendar Year	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	New Episodes with an Event	Number of Exposed Members per 1,000 Eligible Members ¹	Years at Risk	Eligible Member Years ¹	Incidence Rate per 1,000 Years at Risk	All Events	Number of Events per Patient with an Event
								Members ¹			at Risk		
>=65	2013	0	0	0	0	0	0	.	0.0	.	.	0	.
	2014	64	64	262	10,749	11,289	0	.	30.4	.	0.00	0	.
	2015	51	51	201	8,724	8,754	*****	.	*****	.	42.37	*****	2.00
	2016	*****	*****	*****	5,440	5,455	*****	.	*****	.	66.23	*****	8.00
	2017	*****	*****	*****	1,383	1,383	0	.	3.6	.	0.00	0	.
	2018	*****	*****	*****	19	19	0	.	0.0	.	.	0	.
Empagliflozin													
<12	2013	0	0	0	0	0	0	.	0.0	.	.	0	.
	2014	0	0	0	0	0	0	.	0.0	.	.	0	.
	2015	0	0	0	0	0	0	.	0.0	.	.	0	.
	2016	0	0	0	0	0	0	.	0.0	.	.	0	.
	2017	0	0	0	0	0	0	.	0.0	.	.	0	.
	2018	0	0	0	0	0	0	.	0.0	.	.	0	.
12-18	2013	0	0	0	0	0	0	.	0.0	.	.	0	.
	2014	0	0	0	0	0	0	.	0.0	.	.	0	.
	2015	*****	*****	*****	364	364	0	.	0.9	.	0.00	0	.
	2016	*****	*****	*****	60	60	0	.	0.2	.	0.00	0	.
	2017	0	0	0	0	0	0	.	0.0	.	.	0	.
	2018	0	0	0	0	0	0	.	0.0	.	.	0	.
19-24	2013	0	0	0	0	0	0	.	0.0	.	.	0	.
	2014	*****	*****	*****	90	90	0	.	0.3	.	0.00	0	.
	2015	*****	*****	*****	142	142	0	.	0.5	.	0.00	0	.
	2016	*****	*****	*****	240	240	0	.	0.7	.	0.00	0	.
	2017	*****	*****	12	362	362	0	.	0.9	.	0.00	0	.
	2018	*****	*****	*****	77	102	0	.	0.2	.	0.00	0	.
25-44	2013	0	0	0	0	0	0	.	0.0	.	.	0	.
	2014	*****	*****	*****	1,312	1,312	0	.	3.9	.	0.00	0	.
	2015	*****	*****	*****	7,269	7,316	*****	.	*****	.	48.08	*****	1.00
	2016	*****	*****	*****	10,120	10,087	*****	.	*****	.	36.90	*****	2.00
	2017	53	53	162	4,837	4,844	*****	.	*****	.	70.92	*****	1.00
	2018	*****	*****	*****	43	43	0	.	0.1	.	0.00	0	.

Table 2e. Summary of Diabetic Ketoacidosis Events after Incident Exposure to Canagliflozin, Dapagliflozin, Empagliflozin, or Sitagliptin in the Sentinel Distributed Database (SDD) between March 1, 2013 and June 30, 2018, by Age Group (Years) and Year of Exposure

Age Group (Years)	Calendar Year	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	New Episodes with an Event	Number of Exposed Members per 1,000 Eligible Members ¹	Years at Risk	Eligible Member Years ¹	Incidence Rate per 1,000 Years at Risk	All Events	Number of Events per Patient with an Event
45-64	2013	0	0	0	0	0	0	.	0.0	.	.	0	.
	2014	*****	*****	163	5,407	5,407	*****	.	*****	.	66.23	*****	1.00
	2015	104	104	509	18,700	18,730	*****	.	*****	.	98.04	*****	2.20
	2016	128	128	522	21,702	21,937	*****	.	*****	.	33.44	*****	1.00
	2017	118	118	364	12,847	12,832	0	.	35.6	.	0.00	0	.
	2018	*****	*****	14	499	529	0	.	1.3	.	0.00	0	.
>=65	2013	0	0	0	0	0	0	.	0.0	.	.	0	.
	2014	*****	*****	*****	1,413	1,413	0	.	*****	.	0.00	0	.
	2015	58	58	156	6,641	6,611	0	.	19.2	.	0.00	0	.
	2016	64	64	182	7,217	7,401	*****	.	*****	.	50.25	*****	3.00
	2017	*****	*****	57	2,295	2,280	0	.	6.5	.	0.00	0	.
	2018	*****	*****	*****	59	59	0	.	0.1	.	0.00	0	.
Sitagliptin													
<12	2013	0	0	0	0	0	0	.	0.0	.	.	0	.
	2014	0	0	0	0	0	0	.	0.0	.	.	0	.
	2015	0	0	0	0	0	0	.	0.0	.	.	0	.
	2016	0	0	0	0	0	0	.	0.0	.	.	0	.
	2017	0	0	0	0	0	0	.	0.0	.	.	0	.
	2018	0	0	0	0	0	0	.	0.0	.	.	0	.
12-18	2013	*****	*****	*****	192	192	0	.	0.5	.	0.00	0	.
	2014	*****	*****	*****	30	60	0	.	0.1	.	0.00	0	.
	2015	*****	*****	*****	30	60	0	.	0.1	.	0.00	0	.
	2016	0	0	0	0	0	0	.	0.0	.	.	0	.
	2017	*****	*****	*****	150	150	0	.	0.5	.	0.00	0	.
	2018	0	0	0	0	0	0	.	0.0	.	.	0	.
19-24	2013	*****	*****	*****	450	450	0	.	1.2	.	0.00	0	.
	2014	*****	*****	*****	300	330	0	.	0.8	.	0.00	0	.
	2015	0	0	0	0	0	0	.	0.0	.	.	0	.
	2016	*****	*****	*****	339	399	0	.	*****	.	0.00	0	.
	2017	*****	*****	*****	264	294	*****	.	*****	.	1,250.00	*****	1.00
	2018	0	0	0	0	0	0	.	0.0	.	.	0	.

Table 2e. Summary of Diabetic Ketoacidosis Events after Incident Exposure to Canagliflozin, Dapagliflozin, Empagliflozin, or Sitagliptin in the Sentinel Distributed Database (SDD) between March 1, 2013 and June 30, 2018, by Age Group (Years) and Year of Exposure

Age Group (Years)	Calendar Year	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	New Episodes with an Event	Number of Exposed Members per 1,000 Eligible Members ¹		Eligible Member Years ¹	Incidence Rate per 1,000 Years at Risk	All Events	Number of Events per Patient with an Event
								Years at Risk	Members ¹				
25-44	2013	*****	*****	*****	5,921	7,878	*****	.	*****	.	114.29	*****	2.50
	2014	*****	*****	*****	10,931	13,536	0	.	30.9	.	0.00	0	.
	2015	*****	*****	*****	8,759	9,689	*****	.	*****	.	80.00	*****	1.00
	2016	*****	*****	*****	4,573	5,104	0	.	12.7	.	0.00	0	.
	2017	*****	*****	*****	1,740	1,932	0	.	4.8	.	0.00	0	.
	2018	*****	*****	*****	86	153	0	.	0.2	.	0.00	0	.
45-64	2013	177	177	823	25,551	32,257	*****	.	*****	.	13.81	*****	1.00
	2014	290	290	1,597	50,712	57,988	*****	.	*****	.	14.08	*****	1.00
	2015	232	232	1,078	40,135	49,031	*****	.	*****	.	17.79	*****	1.50
	2016	135	135	450	14,880	17,139	*****	.	*****	.	23.53	*****	1.00
	2017	*****	*****	*****	6,148	7,829	0	.	16.9	.	0.00	0	.
	2018	*****	*****	*****	73	73	0	.	0.2	.	0.00	0	.
>=65	2013	457	457	3,077	94,702	105,951	*****	.	*****	.	11.34	*****	1.00
	2014	492	492	2,584	90,374	101,886	*****	.	*****	.	16.04	*****	3.75
	2015	441	441	2,093	71,005	81,143	*****	.	*****	.	10.06	*****	1.50
	2016	298	298	997	32,685	35,432	*****	.	*****	.	32.93	*****	4.00
	2017	*****	*****	*****	4,434	4,979	0	.	12.4	.	0.00	0	.
	2018	*****	*****	*****	220	220	0	.	0.6	.	0.00	0	.
Incident Exposure and Prior Type 2 Diabetes Mellitus													
Canagliflozin													
<12	2013	0	0	0	0	0	0	0.00	0.0	104.8	.	0	.
	2014	0	0	0	0	0	0	0.00	0.0	120.1	.	0	.
	2015	0	0	0	0	0	0	0.00	0.0	118.6	.	0	.
	2016	*****	*****	*****	240	240	0	3.41	0.7	140.8	0.00	0	.
	2017	0	0	0	0	0	0	0.00	0.0	63.9	.	0	.
	2018	0	0	0	0	0	0	0.00	0.0	7.2	.	0	.
12-18	2013	*****	*****	12	410	410	0	1.15	1.1	1,208.0	0.00	0	.
	2014	*****	*****	*****	180	180	0	1.03	0.6	1,511.6	0.00	0	.
	2015	15	15	49	1,542	1,902	0	4.71	4.4	1,646.0	0.00	0	.
	2016	*****	*****	11	315	450	0	2.67	1.1	1,711.5	0.00	0	.
	2017	*****	*****	*****	368	398	0	1.48	1.0	1,015.4	0.00	0	.
	2018	0	0	0	0	0	0	0.00	0.0	67.3	.	0	.

Table 2e. Summary of Diabetic Ketoacidosis Events after Incident Exposure to Canagliflozin, Dapagliflozin, Empagliflozin, or Sitagliptin in the Sentinel Distributed Database (SDD) between March 1, 2013 and June 30, 2018, by Age Group (Years) and Year of Exposure

Age Group (Years)	Calendar Year	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	New Episodes with an Event	Number of Exposed Members per 1,000 Eligible Members ¹		Eligible Member Years ¹	Incidence Rate per 1,000 Years at Risk	All Events	Number of Events per Patient with an Event
								Years at Risk	Members ¹				
19-24	2013	*****	*****	106	3,222	3,222	0	2.94	9.0	3,237.7	0.00	0	.
	2014	*****	*****	*****	10,958	11,095	*****	8.07	*****	4,030.3	31.75	*****	1.00
	2015	97	97	404	13,473	14,511	0	11.46	37.6	4,311.2	0.00	0	.
	2016	*****	*****	258	8,858	9,432	0	7.22	25.0	4,614.8	0.00	0	.
	2017	*****	*****	*****	2,584	2,914	0	4.81	*****	2,719.4	0.00	0	.
	2018	*****	*****	*****	49	98	0	2.41	0.2	165.2	0.00	0	.
25-44	2013	1,539	1,539	8,127	265,251	268,337	*****	5.94	*****	149,584.5	2.66	*****	1.00
	2014	4,877	4,877	25,243	844,768	876,255	17	17.49	2,377.2	178,769.0	7.15	45	2.65
	2015	6,886	6,886	31,653	1,077,383	1,177,263	21	24.34	3,054.9	178,605.2	6.87	44	2.10
	2016	4,957	4,957	17,118	573,167	638,203	*****	16.72	*****	180,694.9	7.37	*****	2.33
	2017	*****	*****	*****	145,127	166,360	*****	9.23	*****	105,638.7	9.62	*****	1.50
	2018	*****	*****	*****	2,698	3,159	0	2.21	7.6	7,016.2	0.00	0	.
45-64	2013	8,670	8,670	52,453	1,779,100	1,796,254	19	6.14	4,934.5	898,500.5	3.85	30	1.58
	2014	25,606	25,606	150,768	5,367,385	5,530,713	61	16.57	14,855.8	1,109,436.3	4.11	113	1.85
	2015	35,425	35,425	184,922	6,637,461	7,225,552	82	22.15	18,451.2	1,143,540.9	4.44	182	2.22
	2016	24,604	24,604	95,464	3,411,830	3,741,429	54	14.40	9,512.4	1,183,475.8	5.68	144	2.67
	2017	7,916	7,916	23,048	827,671	930,303	17	7.94	2,317.9	677,707.5	7.33	34	2.00
	2018	334	334	472	12,349	13,415	0	1.36	34.2	46,437.0	0.00	0	.
>=65	2013	5,211	5,211	29,452	1,155,973	1,165,963	*****	1.63	*****	2,203,853.3	2.85	*****	2.00
	2014	25,456	25,456	125,855	5,239,382	5,353,969	62	6.80	14,376.5	2,996,091.2	4.31	162	2.61
	2015	40,518	40,518	170,413	6,971,634	7,379,183	72	10.38	19,331.9	3,119,599.5	3.72	171	2.38
	2016	32,070	32,070	92,255	3,603,259	3,838,314	29	7.72	10,043.7	3,293,763.6	2.89	67	2.31
	2017	3,463	3,463	8,962	384,571	409,516	*****	3.59	*****	770,434.2	5.59	*****	2.50
	2018	251	251	317	7,436	7,786	0	0.46	20.0	73,581.6	0.00	0	.
Dapagliflozin													
<12	2013	0	0	0	0	0	0	0.00	0.0	104.8	.	0	.
	2014	0	0	0	0	0	0	0.00	0.0	120.1	.	0	.
	2015	0	0	0	0	0	0	0.00	0.0	118.6	.	0	.
	2016	0	0	0	0	0	0	0.00	0.0	140.8	.	0	.
	2017	0	0	0	0	0	0	0.00	0.0	63.9	.	0	.
	2018	0	0	0	0	0	0	0.00	0.0	7.2	.	0	.

Table 2e. Summary of Diabetic Ketoacidosis Events after Incident Exposure to Canagliflozin, Dapagliflozin, Empagliflozin, or Sitagliptin in the Sentinel Distributed Database (SDD) between March 1, 2013 and June 30, 2018, by Age Group (Years) and Year of Exposure

Age Group (Years)	Calendar Year	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	New Episodes with an Event	Number of Exposed Members per 1,000 Eligible Members ¹	Years at Risk	Eligible Member Years ¹	Incidence Rate per 1,000 Years at Risk	Number of Events per Patient with an Event	
												All Events	an Event
12-18	2013	0	0	0	0	0	0	0.00	0.0	1,208.0	.	0	.
	2014	*****	*****	*****	30	30	0	0.34	0.1	1,511.6	0.00	0	.
	2015	*****	*****	28	809	809	0	1.57	2.3	1,646.8	0.00	0	.
	2016	*****	*****	*****	60	60	0	0.59	0.2	1,711.4	0.00	0	.
	2017	*****	*****	*****	256	256	0	2.95	0.7	1,016.2	0.00	0	.
	2018	*****	*****	*****	64	64	0	3.25	0.2	67.3	0.00	0	.
19-24	2013	0	0	0	0	0	0	0.00	0.0	3,237.7	.	0	.
	2014	*****	*****	*****	2,469	2,559	0	2.82	7.2	4,030.5	0.00	0	.
	2015	*****	*****	62	1,968	2,358	0	3.78	6.0	4,314.3	0.00	0	.
	2016	*****	*****	*****	1,654	1,990	0	2.84	4.8	4,618.5	0.00	0	.
	2017	*****	*****	*****	1,415	1,701	0	3.38	4.0	2,724.2	0.00	0	.
	2018	*****	*****	*****	84	84	0	2.40	0.3	165.9	0.00	0	.
25-44	2013	0	0	0	0	0	0	0.00	0.0	149,584.5	.	0	.
	2014	1,900	1,900	7,142	235,034	239,641	*****	6.81	*****	178,791.6	1.48	*****	1.00
	2015	2,086	2,086	8,215	270,197	283,481	*****	7.36	*****	178,782.7	3.87	*****	7.00
	2016	1,743	1,743	5,525	184,735	204,052	*****	5.86	*****	181,202.2	5.67	*****	1.67
	2017	1,047	1,047	2,812	93,922	102,231	*****	5.76	*****	106,028.2	3.74	*****	1.00
	2018	87	87	125	2,817	3,211	0	2.59	7.7	7,044.5	0.00	0	.
45-64	2013	0	0	0	0	0	0	0.00	0.0	898,500.5	.	0	.
	2014	8,998	8,998	41,805	1,433,075	1,455,622	15	5.82	4,057.9	1,109,566.5	3.70	19	1.27
	2015	10,408	10,408	50,291	1,736,075	1,818,445	13	6.50	4,902.1	1,144,842.1	2.65	19	1.46
	2016	8,500	8,500	31,954	1,139,525	1,206,815	*****	4.95	*****	1,187,486.0	2.80	*****	1.22
	2017	5,433	5,433	16,050	577,064	619,807	*****	5.42	*****	681,187.3	1.86	*****	2.00
	2018	436	436	630	15,491	16,398	0	1.77	42.8	46,729.9	0.00	0	.
>=65	2013	0	0	0	0	0	0	0.00	0.0	2,203,853.3	.	0	.
	2014	4,861	4,861	21,076	870,603	879,492	*****	1.30	*****	2,996,236.8	3.31	*****	2.00
	2015	6,291	6,291	25,014	1,011,068	1,035,604	11	1.61	2,819.9	3,121,954.7	3.90	19	1.73
	2016	7,375	7,375	20,944	793,582	819,118	*****	1.77	*****	3,303,388.9	3.62	*****	3.50
	2017	1,362	1,362	3,564	146,212	151,060	*****	1.41	*****	773,729.5	4.90	*****	1.00
	2018	267	267	342	8,601	8,819	0	0.48	22.8	73,982.2	0.00	0	.

Table 2e. Summary of Diabetic Ketoacidosis Events after Incident Exposure to Canagliflozin, Dapagliflozin, Empagliflozin, or Sitagliptin in the Sentinel Distributed Database (SDD) between March 1, 2013 and June 30, 2018, by Age Group (Years) and Year of Exposure

Age Group (Years)	Calendar Year	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	New Episodes with an Event	Number of Exposed	Years at Risk	Eligible Member Years ¹	Incidence	All Events	Number of Events per Patient with an Event
								Members per 1,000 Eligible Members ¹			Rate per 1,000 Years at Risk		
Empagliflozin													
<12	2013	0	0	0	0	0	0	0.00	0.0	104.8	.	0	.
	2014	0	0	0	0	0	0	0.00	0.0	120.1	.	0	.
	2015	0	0	0	0	0	0	0.00	0.0	118.6	.	0	.
	2016	0	0	0	0	0	0	0.00	0.0	140.8	.	0	.
	2017	0	0	0	0	0	0	0.00	0.0	63.9	.	0	.
	2018	0	0	0	0	0	0	0.00	0.0	7.2	.	0	.
12-18	2013	0	0	0	0	0	0	0.00	0.0	1,208.0	.	0	.
	2014	0	0	0	0	0	0	0.00	0.0	1,511.6	.	0	.
	2015	*****	*****	*****	120	120	0	0.94	0.3	1,646.8	0.00	0	.
	2016	*****	*****	37	1,279	1,279	0	1.78	3.4	1,711.5	0.00	0	.
	2017	*****	*****	*****	660	684	0	4.43	1.9	1,015.8	0.00	0	.
	2018	0	0	0	0	0	0	0.00	0.0	67.3	.	0	.
19-24	2013	0	0	0	0	0	0	0.00	0.0	3,237.7	.	0	.
	2014	*****	*****	*****	143	143	0	0.64	0.5	4,030.5	0.00	0	.
	2015	*****	*****	*****	1,698	1,728	0	2.01	5.3	4,314.8	0.00	0	.
	2016	*****	*****	111	3,610	4,030	0	4.15	10.6	4,623.0	0.00	0	.
	2017	*****	*****	*****	3,958	4,083	0	9.59	10.9	2,725.1	0.00	0	.
	2018	*****	*****	*****	30	30	0	1.20	0.1	166.0	0.00	0	.
25-44	2013	0	0	0	0	0	0	0.00	0.0	149,584.5	.	0	.
	2014	*****	*****	*****	28,851	29,150	*****	0.83	*****	178,791.6	23.72	*****	1.00
	2015	1,397	1,397	6,130	204,676	206,617	*****	4.93	*****	178,828.2	5.13	*****	1.00
	2016	2,654	2,654	9,947	339,798	355,276	*****	8.91	*****	181,423.2	3.10	*****	1.00
	2017	3,416	3,416	9,094	300,790	318,254	*****	18.78	*****	106,164.2	7.01	*****	1.17
	2018	*****	*****	*****	6,081	6,246	0	4.90	16.8	7,052.0	0.00	0	.
45-64	2013	0	0	0	0	0	0	0.00	0.0	898,500.5	.	0	.
	2014	1,279	1,279	6,881	233,345	234,000	*****	0.83	*****	1,109,566.5	1.53	*****	2.00
	2015	7,494	7,494	39,932	1,395,178	1,401,390	*****	4.68	*****	1,145,061.7	4.35	*****	1.76
	2016	14,526	14,526	63,435	2,295,169	2,378,140	23	8.45	6,410.4	1,188,738.1	3.59	39	1.70
	2017	19,448	19,448	58,423	2,069,232	2,153,859	26	19.35	5,717.7	682,250.0	4.55	35	1.35
	2018	1,149	1,149	1,730	43,550	42,958	0	4.65	117.3	46,767.4	0.00	0	.

Table 2e. Summary of Diabetic Ketoacidosis Events after Incident Exposure to Canagliflozin, Dapagliflozin, Empagliflozin, or Sitagliptin in the Sentinel Distributed Database (SDD) between March 1, 2013 and June 30, 2018, by Age Group (Years) and Year of Exposure

Age Group (Years)	Calendar Year	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	New Episodes with an Event	Number of Exposed Members per 1,000 Eligible Members ¹		Eligible Member Years ¹	Incidence Rate per 1,000 Years at Risk	All Events	Number of Events per Patient with an Event
								Years at Risk	Members ¹				
>=65	2013	0	0	0	0	0	0	0.00	0.0	2,203,853.3	.	0	.
	2014	487	487	2,026	86,598	86,568	0	0.13	239.4	2,996,236.8	0.00	0	.
	2015	5,460	5,460	20,974	882,094	886,756	*****	1.40	*****	3,122,231.6	2.43	*****	2.17
	2016	12,606	12,606	36,236	1,452,820	1,481,250	*****	3.02	*****	3,304,874.2	4.21	*****	2.35
	2017	7,338	7,338	19,435	801,486	808,647	*****	7.58	*****	773,798.6	1.81	*****	1.75
	2018	636	636	849	21,551	19,130	0	1.15	56.6	73,956.7	0.00	0	.
Sitagliptin													
<12	2013	*****	*****	*****	90	166	0	8.66	0.3	101.6	0.00	0	.
	2014	*****	*****	*****	30	60	0	4.08	0.1	113.0	0.00	0	.
	2015	0	0	0	0	0	0	0.00	0.0	111.0	.	0	.
	2016	*****	*****	*****	60	60	0	3.44	0.2	140.4	0.00	0	.
	2017	0	0	0	0	0	0	0.00	0.0	64.5	.	0	.
	2018	0	0	0	0	0	0	0.00	0.0	7.2	.	0	.
12-18	2013	*****	*****	*****	601	646	0	4.30	1.8	1,178.6	0.00	0	.
	2014	*****	*****	*****	1,140	1,530	0	4.85	3.3	1,481.5	0.00	0	.
	2015	22	22	60	1,853	2,393	0	6.97	5.4	1,629.4	0.00	0	.
	2016	*****	*****	*****	2,215	2,922	0	6.28	6.5	1,695.8	0.00	0	.
	2017	*****	*****	32	1,082	1,351	0	4.98	3.1	1,008.0	0.00	0	.
	2018	0	0	0	0	0	0	0.00	0.0	67.4	.	0	.
19-24	2013	81	81	267	9,350	12,100	0	12.84	26.9	2,919.0	0.00	0	.
	2014	107	107	403	13,669	16,248	0	14.57	37.8	3,696.9	0.00	0	.
	2015	102	102	308	10,341	14,476	0	12.60	30.3	4,083.6	0.00	0	.
	2016	137	137	401	14,282	16,979	*****	15.47	*****	4,413.1	50.38	*****	1.00
	2017	*****	*****	*****	5,829	6,690	*****	15.05	*****	2,654.5	58.48	*****	1.00
	2018	*****	*****	*****	244	244	0	4.93	0.6	161.4	0.00	0	.
25-44	2013	4,689	4,689	21,617	741,086	892,441	8	20.84	2,100.5	125,035.9	3.81	14	1.75
	2014	6,509	6,509	27,660	965,238	1,155,472	12	26.34	2,744.3	153,354.9	4.37	23	1.92
	2015	6,030	6,030	25,687	892,969	1,050,007	13	23.22	2,533.7	161,429.8	5.13	20	1.54
	2016	6,098	6,098	20,500	709,851	834,032	*****	21.70	*****	168,987.2	4.99	*****	2.90
	2017	*****	*****	*****	310,619	367,982	*****	19.07	*****	103,887.6	3.37	*****	1.00
	2018	*****	*****	*****	8,545	10,315	0	7.00	24.0	7,002.4	0.00	0	.

Table 2e. Summary of Diabetic Ketoacidosis Events after Incident Exposure to Canagliflozin, Dapagliflozin, Empagliflozin, or Sitagliptin in the Sentinel Distributed Database (SDD) between March 1, 2013 and June 30, 2018, by Age Group (Years) and Year of Exposure

Age Group (Years)	Calendar Year	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	New Episodes with an Event	Number of Exposed Members per 1,000 Eligible Members ¹	Years at Risk	Eligible Member Years ¹	Incidence Rate per 1,000 Years at Risk	Number of Events per Patient with	
												All Events	an Event
45-64	2013	24,944	24,944	125,269	4,475,417	5,186,931	36	20.89	12,529.8	734,725.1	2.87	64	1.78
	2014	34,467	34,467	169,769	6,288,908	7,277,367	63	25.94	17,529.7	926,711.6	3.59	131	2.08
	2015	33,715	33,715	161,760	6,031,380	6,928,836	57	23.77	16,806.1	996,972.3	3.39	146	2.56
	2016	34,897	34,897	129,995	4,821,763	5,512,351	59	22.36	13,443.4	1,062,991.4	4.39	152	2.58
	2017	19,096	19,096	56,304	2,064,894	2,380,525	*****	20.08	*****	642,414.0	2.26	*****	1.38
	2018	1,139	1,139	1,661	41,749	48,650	*****	4.85	*****	44,966.8	17.65	*****	1.00
>=65	2013	56,141	56,141	307,078	11,328,771	12,485,554	107	20.80	31,459.2	1,812,013.1	3.40	214	2.00
	2014	76,470	76,470	387,796	15,291,794	16,866,779	140	24.22	42,269.7	2,451,028.1	3.31	260	1.86
	2015	78,321	78,321	357,210	14,222,043	15,605,046	123	23.70	39,361.3	2,575,046.3	3.12	240	1.95
	2016	79,637	79,637	248,130	9,570,850	10,458,135	94	22.51	26,448.4	2,740,926.4	3.55	188	2.00
	2017	14,790	14,790	41,709	1,760,088	1,913,892	18	17.09	4,836.5	681,907.4	3.72	60	3.33
	2018	1,283	1,283	1,592	36,706	39,590	0	2.63	97.0	65,675.2	0.00	0	.
Incident Exposure and Prior Type 2 Diabetes Mellitus with History of Insulin Use													
Canagliflozin													
<12	2013	0	0	0	0	0	0	0.00	0.0	11.1	.	0	.
	2014	0	0	0	0	0	0	0.00	0.0	15.2	.	0	.
	2015	0	0	0	0	0	0	0.00	0.0	11.9	.	0	.
	2016	0	0	0	0	0	0	0.00	0.0	20.2	.	0	.
	2017	0	0	0	0	0	0	0.00	0.0	16.8	.	0	.
	2018	0	0	0	0	0	0	0.00	0.0	1.3	.	0	.
12-18	2013	*****	*****	*****	380	380	0	4.52	1.0	180.8	0.00	0	.
	2014	0	0	0	0	0	0	0.00	0.0	234.9	.	0	.
	2015	*****	*****	17	510	840	0	11.69	1.6	255.0	0.00	0	.
	2016	*****	*****	*****	120	180	0	6.23	0.4	275.6	0.00	0	.
	2017	*****	*****	*****	30	60	0	2.29	0.1	196.0	0.00	0	.
	2018	0	0	0	0	0	0	0.00	0.0	13.7	.	0	.
19-24	2013	*****	*****	*****	376	376	0	5.46	1.2	520.8	0.00	0	.
	2014	22	22	89	3,952	4,089	*****	14.80	*****	661.1	89.29	*****	1.00
	2015	*****	*****	154	5,311	5,701	0	21.78	14.4	679.7	0.00	0	.
	2016	*****	*****	45	1,634	2,016	0	13.41	4.8	717.4	0.00	0	.
	2017	*****	*****	*****	60	120	0	1.93	*****	437.8	0.00	0	.
	2018	0	0	0	0	0	0	0.00	0.0	28.1	.	0	.

Table 2e. Summary of Diabetic Ketoacidosis Events after Incident Exposure to Canagliflozin, Dapagliflozin, Empagliflozin, or Sitagliptin in the Sentinel Distributed Database (SDD) between March 1, 2013 and June 30, 2018, by Age Group (Years) and Year of Exposure

Age Group (Years)	Calendar Year	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	New Episodes with an Event	Number of Exposed	Years at Risk	Eligible Member Years ¹	Incidence Rate per 1,000 Years at Risk	All Events	Number of Events per Patient with an Event
								Members per 1,000 Eligible Members ¹					
25-44	2013	*****	*****	*****	81,233	81,983	0	8.88	228.9	29,718.2	0.00	0	.
	2014	1,509	1,509	7,820	265,273	274,498	*****	23.53	*****	35,842.3	8.12	*****	1.83
	2015	1,968	1,968	8,898	306,077	331,710	14	31.34	861.8	34,796.2	16.25	30	2.14
	2016	1,288	1,288	4,410	147,582	166,290	*****	20.00	*****	35,167.2	14.45	*****	3.00
	2017	*****	*****	*****	27,669	31,821	*****	9.33	*****	18,045.4	12.87	*****	1.00
	2018	17	17	25	594	707	0	2.82	1.6	1,226.1	0.00	0	.
45-64	2013	2,778	2,778	16,462	561,238	570,231	*****	7.75	*****	199,824.1	6.44	*****	2.00
	2014	8,514	8,514	48,347	1,739,506	1,793,110	24	21.24	4,802.7	251,591.9	5.00	65	2.71
	2015	10,862	10,862	55,914	2,004,017	2,181,849	44	26.78	5,544.9	255,800.5	7.94	120	2.73
	2016	6,762	6,762	24,618	877,414	954,572	32	15.87	2,434.1	264,387.0	13.15	108	3.38
	2017	1,618	1,618	4,575	168,784	188,381	*****	7.98	*****	128,456.1	21.27	*****	1.80
	2018	68	68	94	2,882	3,070	0	1.33	8.0	9,268.6	0.00	0	.
>=65	2013	1,437	1,437	8,401	315,760	318,713	*****	2.18	*****	370,227.3	3.46	*****	2.33
	2014	6,981	6,981	33,599	1,360,894	1,388,714	25	8.78	3,740.6	513,545.2	6.68	64	2.56
	2015	10,494	10,494	44,274	1,743,740	1,852,859	23	12.66	4,838.8	542,073.1	4.75	52	2.26
	2016	7,190	7,190	20,734	779,009	834,148	*****	8.09	*****	584,494.4	3.22	*****	2.29
	2017	781	781	1,836	77,172	82,713	*****	3.86	*****	141,253.7	13.72	*****	1.33
	2018	52	52	67	1,338	1,451	0	0.52	3.6	13,698.8	0.00	0	.
Dapagliflozin													
<12	2013	0	0	0	0	0	0	0.00	0.0	11.1	.	0	.
	2014	0	0	0	0	0	0	0.00	0.0	15.2	.	0	.
	2015	0	0	0	0	0	0	0.00	0.0	11.9	.	0	.
	2016	0	0	0	0	0	0	0.00	0.0	20.2	.	0	.
	2017	0	0	0	0	0	0	0.00	0.0	16.8	.	0	.
	2018	0	0	0	0	0	0	0.00	0.0	1.3	.	0	.
12-18	2013	0	0	0	0	0	0	0.00	0.0	180.8	.	0	.
	2014	0	0	0	0	0	0	0.00	0.0	234.9	.	0	.
	2015	*****	*****	*****	60	60	0	1.67	0.1	255.0	0.00	0	.
	2016	0	0	0	0	0	0	0.00	0.0	275.6	.	0	.
	2017	*****	*****	*****	58	58	0	4.58	0.2	196.2	0.00	0	.
	2018	0	0	0	0	0	0	0.00	0.0	13.7	.	0	.

Table 2e. Summary of Diabetic Ketoacidosis Events after Incident Exposure to Canagliflozin, Dapagliflozin, Empagliflozin, or Sitagliptin in the Sentinel Distributed Database (SDD) between March 1, 2013 and June 30, 2018, by Age Group (Years) and Year of Exposure

Age Group (Years)	Calendar Year	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	New Episodes with an Event	Number of Exposed Members per 1,000 Eligible Members ¹	Years at Risk	Eligible Member Years ¹	Incidence Rate per 1,000 Years at Risk	Number of Events per Patient with an Event	
												All Events	an Event
19-24	2013	0	0	0	0	0	0	0.00	0.0	520.8	.	0	.
	2014	*****	*****	17	549	549	0	5.38	1.7	661.1	0.00	0	.
	2015	*****	*****	*****	288	318	0	3.84	0.9	680.7	0.00	0	.
	2016	*****	*****	14	362	510	0	4.25	1.0	719.2	0.00	0	.
	2017	*****	*****	*****	346	422	0	5.77	1.1	439.5	0.00	0	.
	2018	0	0	0	0	0	0	0.00	0.0	28.4	.	0	.
25-44	2013	0	0	0	0	0	0	0.00	0.0	29,718.2	.	0	.
	2014	*****	*****	2,074	69,883	71,380	0	8.50	199.2	35,847.9	0.00	0	.
	2015	*****	*****	*****	61,063	64,906	*****	7.50	*****	34,842.9	11.50	*****	7.00
	2016	*****	*****	1,083	37,438	41,982	*****	5.64	*****	35,301.5	18.90	*****	2.00
	2017	*****	*****	*****	16,694	18,835	0	5.06	46.5	18,123.3	0.00	0	.
	2018	14	14	17	434	584	0	2.31	1.2	1,233.1	0.00	0	.
45-64	2013	0	0	0	0	0	0	0.00	0.0	199,824.1	.	0	.
	2014	2,607	2,607	11,730	409,789	418,057	*****	6.50	*****	251,625.3	8.65	*****	1.30
	2015	2,570	2,570	11,974	424,094	448,664	*****	6.32	*****	256,132.9	5.03	*****	1.50
	2016	1,959	1,959	6,698	237,339	253,952	*****	4.57	*****	265,526.1	1.50	*****	2.00
	2017	1,012	1,012	2,868	108,673	121,009	*****	4.96	*****	129,231.8	6.68	*****	2.50
	2018	102	102	149	3,630	4,021	0	1.97	9.9	9,330.9	0.00	0	.
>=65	2013	0	0	0	0	0	0	0.00	0.0	370,227.3	.	0	.
	2014	1,257	1,257	5,540	223,277	227,031	*****	1.58	*****	513,570.0	9.72	*****	2.17
	2015	1,456	1,456	6,002	234,739	242,026	*****	1.75	*****	542,522.8	6.11	*****	1.25
	2016	1,596	1,596	4,549	163,254	168,232	*****	1.79	*****	586,544.7	2.18	*****	7.00
	2017	309	309	763	31,685	32,768	*****	1.52	*****	141,927.6	11.21	*****	1.00
	2018	68	68	91	2,361	2,345	0	0.68	6.1	13,774.6	0.00	0	.
Empagliflozin													
<12	2013	0	0	0	0	0	0	0.00	0.0	11.1	.	0	.
	2014	0	0	0	0	0	0	0.00	0.0	15.2	.	0	.
	2015	0	0	0	0	0	0	0.00	0.0	11.9	.	0	.
	2016	0	0	0	0	0	0	0.00	0.0	20.2	.	0	.
	2017	0	0	0	0	0	0	0.00	0.0	16.8	.	0	.
	2018	0	0	0	0	0	0	0.00	0.0	1.3	.	0	.

Table 2e. Summary of Diabetic Ketoacidosis Events after Incident Exposure to Canagliflozin, Dapagliflozin, Empagliflozin, or Sitagliptin in the Sentinel Distributed Database (SDD) between March 1, 2013 and June 30, 2018, by Age Group (Years) and Year of Exposure

Age Group (Years)	Calendar Year	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	New Episodes with an Event	Number of Exposed Members per 1,000 Eligible Members ¹	Years at Risk	Eligible Member Years ¹	Incidence Rate per 1,000 Years at Risk	Number of Events per Patient with an Event	
												All Events	an Event
12-18	2013	0	0	0	0	0	0	0.00	0.0	180.8	.	0	.
	2014	0	0	0	0	0	0	0.00	0.0	234.9	.	0	.
	2015	0	0	0	0	0	0	0.00	0.0	255.0	.	0	.
	2016	*****	*****	*****	270	270	0	3.12	0.8	275.6	0.00	0	.
	2017	*****	*****	*****	60	60	0	4.59	0.2	195.9	0.00	0	.
	2018	0	0	0	0	0	0	0.00	0.0	13.7	.	0	.
19-24	2013	0	0	0	0	0	0	0.00	0.0	520.8	.	0	.
	2014	*****	*****	*****	90	90	0	2.02	0.3	661.1	0.00	0	.
	2015	*****	*****	*****	90	90	0	1.92	0.3	680.7	0.00	0	.
	2016	*****	*****	*****	1,452	1,452	0	6.67	4.0	720.2	0.00	0	.
	2017	*****	*****	*****	802	807	0	10.58	2.3	439.6	0.00	0	.
	2018	0	0	0	0	0	0	0.00	0.0	28.4	.	0	.
25-44	2013	0	0	0	0	0	0	0.00	0.0	29,718.2	.	0	.
	2014	*****	*****	*****	9,775	10,089	0	1.18	28.4	35,847.9	0.00	0	.
	2015	*****	*****	*****	55,362	56,052	*****	5.83	*****	34,850.0	12.86	*****	1.00
	2016	650	650	2,244	78,503	82,832	*****	10.03	*****	35,343.0	9.00	*****	1.00
	2017	751	751	1,981	67,107	71,339	*****	22.19	*****	18,140.1	10.62	*****	1.00
	2018	45	45	65	1,455	1,479	0	7.43	4.0	1,233.2	0.00	0	.
45-64	2013	0	0	0	0	0	0	0.00	0.0	199,824.1	.	0	.
	2014	362	362	1,890	62,927	62,987	0	0.90	177.2	251,625.3	0.00	0	.
	2015	2,166	2,166	11,329	401,969	403,490	*****	5.33	*****	256,184.7	4.44	*****	1.40
	2016	3,946	3,946	16,150	590,613	606,613	*****	9.20	*****	265,819.4	6.08	*****	2.00
	2017	4,942	4,942	14,645	531,076	548,411	13	24.17	1,461.3	129,433.6	8.90	16	1.23
	2018	343	343	514	13,374	13,018	0	6.63	35.9	9,341.8	0.00	0	.
>=65	2013	0	0	0	0	0	0	0.00	0.0	370,227.3	.	0	.
	2014	153	153	640	27,391	27,391	0	0.19	75.4	513,570.0	0.00	0	.
	2015	1,424	1,424	5,188	216,077	218,327	*****	1.72	*****	542,577.6	6.60	*****	1.75
	2016	3,166	3,166	8,738	341,862	347,813	*****	3.54	*****	586,815.1	8.37	*****	2.13
	2017	1,862	1,862	4,850	198,870	197,389	*****	9.16	*****	141,943.4	1.82	*****	4.00
	2018	206	206	307	8,700	7,233	0	2.05	22.7	13,770.0	0.00	0	.

Table 2e. Summary of Diabetic Ketoacidosis Events after Incident Exposure to Canagliflozin, Dapagliflozin, Empagliflozin, or Sitagliptin in the Sentinel Distributed Database (SDD) between March 1, 2013 and June 30, 2018, by Age Group (Years) and Year of Exposure

Age Group (Years)	Calendar Year	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	New Episodes with an Event	Number of Exposed Members per 1,000 Eligible Members ¹	Years at Risk	Eligible Member Years ¹	Incidence Rate per 1,000 Years at Risk	Number of Events per Patient with an Event	
												All Events	an Event
Sitagliptin													
<12	2013	0	0	0	0	0	0	0.00	0.0	9.6	.	0	.
	2014	0	0	0	0	0	0	0.00	0.0	13.4	.	0	.
	2015	0	0	0	0	0	0	0.00	0.0	10.9	.	0	.
	2016	0	0	0	0	0	0	0.00	0.0	20.1	.	0	.
	2017	0	0	0	0	0	0	0.00	0.0	16.8	.	0	.
	2018	0	0	0	0	0	0	0.00	0.0	1.3	.	0	.
12-18	2013	*****	*****	*****	30	30	0	2.37	0.1	174.1	0.00	0	.
	2014	*****	*****	*****	60	120	0	3.89	0.2	227.6	0.00	0	.
	2015	*****	*****	*****	168	168	0	6.87	0.5	249.9	0.00	0	.
	2016	*****	*****	*****	360	360	0	1.59	1.0	272.5	0.00	0	.
	2017	*****	*****	*****	206	409	0	4.63	0.6	193.0	0.00	0	.
	2018	0	0	0	0	0	0	0.00	0.0	13.6	.	0	.
19-24	2013	*****	*****	*****	1,858	2,743	0	14.25	5.2	444.5	0.00	0	.
	2014	*****	*****	*****	1,420	1,750	0	13.57	4.2	575.9	0.00	0	.
	2015	*****	*****	*****	1,260	1,890	0	9.60	3.7	629.7	0.00	0	.
	2016	*****	*****	*****	1,919	2,249	0	16.15	5.7	681.3	0.00	0	.
	2017	*****	*****	*****	959	1,233	0	10.95	2.8	425.6	0.00	0	.
	2018	0	0	0	0	0	0	0.00	0.0	27.9	.	0	.
25-44	2013	767	767	3,464	116,824	139,359	*****	15.85	*****	23,785.7	9.09	*****	1.67
	2014	1,092	1,092	4,425	150,842	183,591	*****	20.08	*****	29,827.0	14.02	*****	2.83
	2015	1,033	1,033	4,124	137,262	164,198	*****	18.22	*****	31,465.3	15.34	*****	1.83
	2016	1,042	1,042	3,202	103,239	119,645	*****	17.17	*****	33,183.4	10.19	*****	5.00
	2017	403	403	1,020	35,186	41,321	*****	11.92	*****	18,421.3	9.94	*****	1.00
	2018	32	32	40	1,077	1,369	0	5.14	3.0	1,278.9	0.00	0	.
45-64	2013	4,109	4,109	21,347	699,908	815,234	*****	14.14	*****	158,699.7	9.72	*****	2.00
	2014	6,126	6,126	31,076	1,059,468	1,230,718	*****	18.35	*****	206,244.7	7.10	*****	2.62
	2015	6,304	6,304	29,396	1,032,026	1,187,385	*****	17.75	*****	223,960.4	8.67	*****	2.92
	2016	6,311	6,311	21,462	760,712	882,274	*****	16.28	*****	240,238.5	11.28	*****	2.83
	2017	2,571	2,571	7,199	265,348	304,874	*****	12.86	*****	127,856.7	9.41	*****	1.43
	2018	147	147	200	5,169	5,986	*****	2.87	*****	9,482.7	71.43	*****	1.00

Table 2e. Summary of Diabetic Ketoacidosis Events after Incident Exposure to Canagliflozin, Dapagliflozin, Empagliflozin, or Sitagliptin in the Sentinel Distributed Database (SDD) between March 1, 2013 and June 30, 2018, by Age Group (Years) and Year of Exposure

Age Group (Years)	Calendar Year	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	New Episodes with an Event	Number of Exposed Members per 1,000 Eligible Members ¹		Eligible Member Years ¹	Incidence Rate per 1,000 Years at Risk	All Events	Number of Events per Patient with an Event
								Years at Risk	Members ¹				
>=65	2013	7,517	7,517	47,583	1,434,736	1,598,490	33	14.42	3,998.4	286,836.2	8.25	81	2.45
	2014	11,117	11,117	60,824	1,975,259	2,181,387	32	17.61	5,489.8	397,657.7	5.83	57	1.78
	2015	12,113	12,113	58,652	1,971,670	2,178,256	37	18.16	5,503.1	429,075.5	6.72	74	2.00
	2016	12,440	12,440	40,636	1,367,537	1,499,011	*****	17.18	*****	468,758.8	7.61	*****	2.31
	2017	2,311	2,311	6,200	243,909	268,093	*****	12.91	*****	124,317.6	7.36	*****	3.20
	2018	207	207	246	5,751	6,502	0	2.36	15.2	12,276.6	0.00	0	.
Incident Exposure and Prior Type 2 Diabetes Mellitus without History of Insulin Use													
Canagliflozin													
<12	2013	0	0	0	0	0	0	0.00	0.0	93.7	.	0	.
	2014	0	0	0	0	0	0	0.00	0.0	104.9	.	0	.
	2015	0	0	0	0	0	0	0.00	0.0	106.7	.	0	.
	2016	*****	*****	*****	240	240	0	4.05	0.7	120.6	0.00	0	.
	2017	0	0	0	0	0	0	0.00	0.0	47.1	.	0	.
	2018	0	0	0	0	0	0	0.00	0.0	5.9	.	0	.
12-18	2013	*****	*****	*****	30	30	0	0.44	0.1	1,027.2	0.00	0	.
	2014	*****	*****	*****	180	180	0	1.19	0.6	1,276.7	0.00	0	.
	2015	*****	*****	32	1,032	1,062	0	2.92	2.8	1,391.6	0.00	0	.
	2016	*****	*****	*****	195	270	0	1.74	0.7	1,435.9	0.00	0	.
	2017	*****	*****	*****	338	338	0	1.19	0.9	819.7	0.00	0	.
	2018	0	0	0	0	0	0	0.00	0.0	53.6	.	0	.
19-24	2013	*****	*****	*****	2,846	2,846	0	2.22	7.8	2,716.8	0.00	0	.
	2014	*****	*****	*****	7,006	7,006	0	6.09	20.2	3,369.1	0.00	0	.
	2015	*****	*****	250	8,162	8,810	0	8.63	23.2	3,631.6	0.00	0	.
	2016	*****	*****	*****	7,224	7,416	0	5.51	20.3	3,898.6	0.00	0	.
	2017	*****	*****	*****	2,524	2,794	0	5.13	7.1	2,282.5	0.00	0	.
	2018	*****	*****	*****	49	98	0	2.85	0.2	137.1	0.00	0	.
25-44	2013	1,017	1,017	5,659	184,018	186,354	*****	4.75	*****	119,866.4	3.83	*****	1.00
	2014	3,368	3,368	17,423	579,495	601,757	11	14.61	1,638.5	142,930.3	6.71	34	3.09
	2015	4,929	4,929	22,808	772,896	847,143	*****	20.94	*****	143,859.3	3.19	*****	2.00
	2016	3,689	3,689	12,741	426,660	473,276	*****	14.90	*****	145,719.2	4.93	*****	1.67
	2017	1,363	1,363	3,556	118,038	135,164	*****	8.75	*****	87,757.7	8.83	*****	1.67
	2018	57	57	78	2,104	2,452	0	2.03	6.0	5,800.0	0.00	0	.

Table 2e. Summary of Diabetic Ketoacidosis Events after Incident Exposure to Canagliflozin, Dapagliflozin, Empagliflozin, or Sitagliptin in the Sentinel Distributed Database (SDD) between March 1, 2013 and June 30, 2018, by Age Group (Years) and Year of Exposure

Age Group (Years)	Calendar Year	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	New Episodes with an Event	Number of Exposed Members per 1,000 Eligible Members ¹	Years at Risk	Eligible Member Years ¹	Incidence Rate per 1,000 Years at Risk	Number of Events per Patient with	
												All Events	an Event
45-64	2013	5,892	5,892	35,991	1,217,862	1,226,023	*****	5.28	*****	698,676.3	2.66	*****	1.11
	2014	17,094	17,094	102,425	3,627,999	3,737,723	37	14.02	10,053.6	857,866.7	3.68	48	1.30
	2015	24,582	24,582	129,149	4,637,918	5,049,707	*****	19.40	*****	888,059.7	2.94	*****	1.63
	2016	17,909	17,909	71,075	2,543,058	2,796,489	*****	13.17	*****	920,219.6	3.24	*****	1.74
	2017	6,331	6,331	18,565	662,007	745,267	*****	7.61	*****	550,459.6	3.77	*****	2.29
	2018	267	267	381	9,536	10,414	0	1.36	26.3	37,262.1	0.00	0	.
>=65	2013	3,774	3,774	21,051	840,213	847,250	*****	1.42	*****	1,833,625.9	2.62	*****	1.83
	2014	18,479	18,479	92,267	3,878,818	3,965,585	37	5.95	10,636.9	2,482,581.5	3.48	98	2.65
	2015	30,060	30,060	126,250	5,231,961	5,531,142	49	9.29	14,504.5	2,578,091.3	3.38	119	2.43
	2016	24,947	24,947	71,676	2,830,290	3,010,335	*****	7.27	*****	2,711,732.1	2.79	*****	2.32
	2017	2,699	2,699	7,161	309,243	329,271	*****	3.38	*****	630,026.4	4.66	*****	3.00
	2018	201	201	252	6,137	6,374	0	0.44	16.6	59,980.3	0.00	0	.
Dapagliflozin													
<12	2013	0	0	0	0	0	0	0.00	0.0	93.7	.	0	.
	2014	0	0	0	0	0	0	0.00	0.0	104.9	.	0	.
	2015	0	0	0	0	0	0	0.00	0.0	106.7	.	0	.
	2016	0	0	0	0	0	0	0.00	0.0	120.6	.	0	.
	2017	0	0	0	0	0	0	0.00	0.0	47.1	.	0	.
	2018	0	0	0	0	0	0	0.00	0.0	5.9	.	0	.
12-18	2013	0	0	0	0	0	0	0.00	0.0	1,027.2	.	0	.
	2014	*****	*****	*****	30	30	0	0.40	0.1	1,276.7	0.00	0	.
	2015	*****	*****	26	749	749	0	1.46	2.1	1,391.7	0.00	0	.
	2016	*****	*****	*****	60	60	0	0.70	0.2	1,435.9	0.00	0	.
	2017	*****	*****	*****	198	198	0	2.38	0.5	820.0	0.00	0	.
	2018	*****	*****	*****	64	64	0	4.00	0.2	53.6	0.00	0	.
19-24	2013	0	0	0	0	0	0	0.00	0.0	2,716.8	.	0	.
	2014	*****	*****	*****	1,920	2,010	0	2.08	5.5	3,369.4	0.00	0	.
	2015	*****	*****	52	1,680	2,040	0	3.56	5.1	3,633.6	0.00	0	.
	2016	*****	*****	*****	1,292	1,480	0	2.38	3.8	3,899.8	0.00	0	.
	2017	13	13	27	1,069	1,279	0	2.66	3.0	2,286.2	0.00	0	.
	2018	*****	*****	*****	84	84	0	2.85	0.3	137.5	0.00	0	.

Table 2e. Summary of Diabetic Ketoacidosis Events after Incident Exposure to Canagliflozin, Dapagliflozin, Empagliflozin, or Sitagliptin in the Sentinel Distributed Database (SDD) between March 1, 2013 and June 30, 2018, by Age Group (Years) and Year of Exposure

Age Group (Years)	Calendar Year	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	New Episodes with an Event	Number of	Years at Risk	Eligible Member Years ¹	Incidence Rate per 1,000 Years at Risk	All Events	Number of Events per Patient with an Event
								Exposed Members per 1,000 Eligible Members ¹					
25-44	2013	0	0	0	0	0	0	0.00	0.0	119,866.4	.	0	.
	2014	1,355	1,355	5,068	165,151	168,261	*****	5.88	*****	142,943.7	2.11	*****	1.00
	2015	1,615	1,615	6,431	209,149	218,590	*****	6.86	*****	143,948.8	1.66	*****	7.00
	2016	1,382	1,382	4,449	147,503	162,276	*****	5.57	*****	145,954.8	2.36	*****	1.00
	2017	*****	*****	*****	77,891	84,178	*****	5.64	*****	87,961.1	4.49	*****	1.00
	2018	*****	*****	*****	2,383	2,627	0	2.59	6.5	5,814.7	0.00	0	.
45-64	2013	0	0	0	0	0	0	0.00	0.0	698,676.3	.	0	.
	2014	6,391	6,391	30,075	1,023,286	1,037,565	*****	5.24	*****	857,941.2	1.72	*****	1.20
	2015	7,838	7,838	38,317	1,311,981	1,369,781	*****	6.18	*****	888,745.0	1.89	*****	1.43
	2016	6,547	6,547	25,282	902,999	953,826	*****	4.80	*****	922,221.5	3.14	*****	1.13
	2017	4,434	4,434	13,221	469,598	500,005	*****	5.31	*****	552,324.1	0.76	*****	1.00
	2018	338	338	486	11,968	12,514	0	1.71	33.2	37,422.5	0.00	0	.
>=65	2013	0	0	0	0	0	0	0.00	0.0	1,833,625.9	.	0	.
	2014	3,604	3,604	15,536	647,326	652,461	*****	1.16	*****	2,482,666.8	1.11	*****	1.50
	2015	4,835	4,835	19,012	776,329	793,578	*****	1.49	*****	2,579,477.5	3.23	*****	2.00
	2016	5,796	5,796	16,444	632,513	653,378	*****	1.68	*****	2,717,189.5	3.98	*****	3.00
	2017	1,058	1,058	2,809	115,010	118,775	*****	1.32	*****	631,912.1	3.12	*****	1.00
	2018	200	200	253	6,276	6,510	0	0.44	16.8	60,219.0	0.00	0	.
Empagliflozin													
<12	2013	0	0	0	0	0	0	0.00	0.0	93.7	.	0	.
	2014	0	0	0	0	0	0	0.00	0.0	104.9	.	0	.
	2015	0	0	0	0	0	0	0.00	0.0	106.7	.	0	.
	2016	0	0	0	0	0	0	0.00	0.0	120.6	.	0	.
	2017	0	0	0	0	0	0	0.00	0.0	47.1	.	0	.
	2018	0	0	0	0	0	0	0.00	0.0	5.9	.	0	.
12-18	2013	0	0	0	0	0	0	0.00	0.0	1,027.2	.	0	.
	2014	0	0	0	0	0	0	0.00	0.0	1,276.7	.	0	.
	2015	*****	*****	*****	120	120	0	1.10	0.3	1,391.7	0.00	0	.
	2016	*****	*****	28	1,009	1,009	0	1.39	2.7	1,435.9	0.00	0	.
	2017	*****	*****	*****	600	624	0	4.16	1.7	820.0	0.00	0	.
	2018	0	0	0	0	0	0	0.00	0.0	53.6	.	0	.

Table 2e. Summary of Diabetic Ketoacidosis Events after Incident Exposure to Canagliflozin, Dapagliflozin, Empagliflozin, or Sitagliptin in the Sentinel Distributed Database (SDD) between March 1, 2013 and June 30, 2018, by Age Group (Years) and Year of Exposure

Age Group (Years)	Calendar Year	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	New Episodes with an Event	Number of Exposed Members per 1,000 Eligible Members ¹		Eligible Member Years ¹	Incidence Rate per 1,000 Years at Risk	All Events	Number of Events per Patient with an Event
								Years at Risk	Members ¹				
19-24	2013	0	0	0	0	0	0	0.00	0.0	2,716.8	.	0	.
	2014	****	****	****	53	53	0	0.30	0.2	3,369.4	0.00	0	.
	2015	****	****	****	1,608	1,638	0	1.92	5.0	3,634.1	0.00	0	.
	2016	27	27	72	2,158	2,578	0	3.38	6.6	3,903.4	0.00	0	.
	2017	****	****	****	3,156	3,276	0	8.81	8.6	2,287.3	0.00	0	.
	2018	****	****	****	30	30	0	1.42	0.1	137.6	0.00	0	.
25-44	2013	0	0	0	0	0	0	0.00	0.0	119,866.4	.	0	.
	2014	****	****	****	19,076	19,061	****	0.68	****	142,943.7	35.71	****	1.00
	2015	1,030	1,030	4,491	149,314	150,565	****	4.37	****	143,978.5	2.33	****	1.00
	2016	2,005	2,005	7,705	261,355	272,504	****	8.07	****	146,091.6	1.34	****	1.00
	2017	2,666	2,666	7,114	233,713	246,945	****	17.04	****	88,049.9	5.99	****	1.25
	2018	****	****	****	4,626	4,767	0	4.26	12.9	5,820.1	0.00	0	.
45-64	2013	0	0	0	0	0	0	0.00	0.0	698,676.3	.	0	.
	2014	917	917	4,991	170,418	171,013	****	0.75	****	857,941.2	2.09	****	2.00
	2015	5,328	5,328	28,603	993,209	997,900	****	4.20	****	888,877.8	4.31	****	1.92
	2016	10,583	10,583	47,290	1,704,706	1,771,677	****	7.75	****	922,976.1	2.73	****	1.46
	2017	14,528	14,528	43,832	1,540,085	1,607,422	****	17.36	****	553,011.7	3.05	****	1.46
	2018	806	806	1,216	30,176	29,940	0	4.07	81.4	37,443.1	0.00	0	.
>=65	2013	0	0	0	0	0	0	0.00	0.0	1,833,625.9	.	0	.
	2014	334	334	1,386	59,207	59,177	0	0.11	163.9	2,482,666.8	0.00	0	.
	2015	4,036	4,036	15,786	666,017	668,429	****	1.25	****	2,579,654.8	1.08	****	3.00
	2016	9,444	9,444	27,513	1,111,644	1,134,124	****	2.74	****	2,718,140.7	2.92	****	2.56
	2017	5,485	5,485	14,598	603,305	611,977	****	6.84	****	631,945.5	1.80	****	1.00
	2018	432	432	544	12,898	11,944	0	0.95	34.1	60,201.2	0.00	0	.
Sitagliptin													
<12	2013	****	****	****	90	166	0	9.57	0.3	91.9	0.00	0	.
	2014	****	****	****	30	60	0	4.59	0.1	99.6	0.00	0	.
	2015	0	0	0	0	0	0	0.00	0.0	100.1	.	0	.
	2016	****	****	****	60	60	0	4.07	0.2	120.3	0.00	0	.
	2017	0	0	0	0	0	0	0.00	0.0	47.7	.	0	.
	2018	0	0	0	0	0	0	0.00	0.0	5.9	.	0	.

Table 2e. Summary of Diabetic Ketoacidosis Events after Incident Exposure to Canagliflozin, Dapagliflozin, Empagliflozin, or Sitagliptin in the Sentinel Distributed Database (SDD) between March 1, 2013 and June 30, 2018, by Age Group (Years) and Year of Exposure

Age Group (Years)	Calendar Year	New Users	New Episodes	New Dispensings	Days Supplied	Amount Supplied	New Episodes with an Event	Number of Exposed Members per 1,000 Eligible Members ¹		Eligible Member Years ¹	Incidence Rate per 1,000 Years at Risk	All Events	Number of Events per Patient with an Event
								Years at Risk	Members ¹				
12-18	2013	*****	*****	*****	571	616	0	4.52	1.7	1,004.5	0.00	0	.
	2014	*****	*****	*****	1,080	1,410	0	4.80	3.1	1,254.5	0.00	0	.
	2015	18	18	55	1,685	2,225	0	6.61	4.8	1,380.2	0.00	0	.
	2016	*****	*****	*****	1,855	2,562	0	7.01	5.5	1,423.6	0.00	0	.
	2017	*****	*****	*****	876	942	0	4.80	2.5	815.2	0.00	0	.
	2018	0	0	0	0	0	0	0.00	0.0	53.8	.	0	.
19-24	2013	65	65	212	7,492	9,357	0	11.87	21.7	2,474.5	0.00	0	.
	2014	89	89	373	12,249	14,498	0	13.99	33.6	3,123.1	0.00	0	.
	2015	88	88	276	9,081	12,586	0	12.54	26.6	3,458.4	0.00	0	.
	2016	112	112	343	12,363	14,730	*****	14.46	*****	3,737.4	58.82	*****	1.00
	2017	*****	*****	*****	4,884	5,471	*****	15.26	*****	2,231.8	69.44	*****	1.00
	2018	*****	*****	*****	244	244	0	5.85	0.6	133.6	0.00	0	.
25-44	2013	3,922	3,922	18,153	624,262	753,082	*****	20.97	*****	101,250.2	2.82	*****	1.80
	2014	5,420	5,420	23,242	814,585	972,071	*****	26.39	*****	123,567.2	2.59	*****	1.00
	2015	5,014	5,014	21,629	758,343	889,329	*****	23.18	*****	130,167.4	3.26	*****	1.29
	2016	5,076	5,076	17,343	608,487	716,292	*****	21.63	*****	136,220.3	4.08	*****	2.00
	2017	*****	*****	*****	276,621	327,999	*****	19.70	*****	85,692.0	2.52	*****	1.00
	2018	*****	*****	*****	7,468	8,946	0	7.25	21.0	5,739.7	0.00	0	.
45-64	2013	20,835	20,835	103,922	3,775,509	4,371,697	*****	21.96	*****	576,025.4	1.61	*****	1.53
	2014	28,354	28,354	138,722	5,230,899	6,048,108	*****	26.96	*****	720,673.4	2.88	*****	1.81
	2015	27,494	27,494	132,685	5,010,825	5,755,359	32	24.46	13,956.5	774,169.6	2.29	73	2.28
	2016	28,719	28,719	108,857	4,072,472	4,643,670	*****	23.17	*****	825,261.9	3.08	*****	2.40
	2017	16,605	16,605	49,299	1,806,435	2,083,613	*****	21.12	*****	516,168.7	1.19	*****	1.33
	2018	996	996	1,467	36,724	42,914	*****	5.33	*****	35,606.1	10.03	*****	1.00
>=65	2013	48,624	48,624	259,495	9,894,035	10,887,064	74	21.46	27,460.8	1,525,176.9	2.69	133	1.80
	2014	65,386	65,386	327,111	13,321,021	14,689,863	108	24.78	36,792.9	2,053,841.8	2.94	203	1.88
	2015	66,373	66,373	299,172	12,271,859	13,449,687	*****	24.08	*****	2,148,846.7	2.56	*****	1.93
	2016	67,569	67,569	208,353	8,234,071	8,991,656	65	22.95	22,728.4	2,278,780.9	2.86	121	1.86
	2017	12,571	12,571	35,724	1,524,238	1,654,675	*****	17.49	*****	559,616.7	3.11	*****	3.38
	2018	1,088	1,088	1,360	31,340	33,542	0	2.68	82.8	53,602.1	0.00	0	.

¹Data not available for the T1DM subgroups

*****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 2f. Summary of Diabetic Ketoacidosis Events after Incident Exposure to Canagliflozin, Dapagliflozin, Empagliflozin, or Sitagliptin in the Sentinel Distributed Database (SDD) between March 1, 2013 and June 30, 2018, by Age Group (Years) and Sex

Sex	Age Group (Years)	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	New Episodes with an Event	Number of Exposed Members per 1,000 Eligible Members ¹	Years at Risk	Eligible Member Years ¹	Incidence Rate per 1,000 Years at Risk	All Events	Number of Events per Patient with an Event
Incident Exposure													
Canagliflozin													
Female	<12	*****	*****	*****	360	360	0	0.00	1.1	9,232,682.7	0.00	0	.
	12-18	*****	*****	*****	6,218	6,953	*****	0.01	*****	6,874,539.4	59.88	*****	6.00
	19-24	323	323	1,127	37,787	40,042	*****	0.08	*****	6,230,435.9	37.45	*****	1.00
	25-44	13,420	13,420	52,595	1,757,220	1,889,831	*****	1.05	*****	22,439,982.7	22.33	*****	2.26
	45-64	62,168	62,168	282,597	9,897,942	10,556,307	222	4.51	27,646.5	30,064,822.3	8.03	516	2.32
	>=65	66,552	66,552	257,342	9,941,273	10,389,269	164	3.75	27,681.9	47,509,507.0	5.92	367	2.24
Male	<12	*****	*****	*****	270	300	0	0.00	0.9	9,674,496.6	0.00	0	.
	12-18	*****	*****	*****	2,855	2,915	0	0.01	8.2	7,152,124.8	0.00	0	.
	19-24	198	198	815	29,260	31,371	*****	0.05	*****	6,447,809.7	12.11	*****	1.00
	25-44	14,529	14,529	64,684	2,169,226	2,351,020	*****	1.16	*****	21,737,496.1	9.61	*****	1.97
	45-64	71,978	71,978	367,932	13,109,143	14,027,109	205	5.50	36,331.7	28,266,558.7	5.64	482	2.35
	>=65	68,350	68,350	280,082	11,730,950	12,284,762	128	5.34	32,265.9	32,708,734.9	3.97	349	2.73
Other	<12	0	0	0	0	0	0	0.00	0.0	349.9	.	0	.
	12-18	0	0	0	0	0	0	0.00	0.0	284.2	.	0	.
	19-24	0	0	0	0	0	0	0.00	0.0	329.3	.	0	.
	25-44	0	0	0	0	0	0	0.00	0.0	1,553.9	.	0	.
	45-64	13	13	84	3,344	3,614	0	9.86	9.2	3,582.1	0.00	0	.
	>=65	0	0	0	0	0	0	0.00	0.0	1,332.5	.	0	.
Dapagliflozin													
Female	<12	0	0	0	0	0	0	0.00	0.0	9,232,686.6	.	0	.
	12-18	*****	*****	*****	1,431	1,611	*****	0.01	*****	6,874,549.3	256.41	*****	2.00
	19-24	135	135	330	11,394	12,136	0	0.03	33.6	6,230,457.7	0.00	0	.
	25-44	4,630	4,630	14,473	475,880	499,530	*****	0.36	*****	22,441,444.1	16.79	*****	2.57
	45-64	19,975	19,975	76,409	2,632,999	2,742,371	34	1.45	7,460.0	30,073,833.9	4.56	58	1.71
	>=65	12,512	12,512	42,496	1,634,858	1,673,924	*****	0.70	*****	47,523,656.5	6.77	*****	2.06

Table 2f. Summary of Diabetic Ketoacidosis Events after Incident Exposure to Canagliflozin, Dapagliflozin, Empagliflozin, or Sitagliptin in the Sentinel Distributed Database (SDD) between March 1, 2013 and June 30, 2018, by Age Group (Years) and Sex

Sex	Age Group (Years)	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	New Episodes with an Event	Number of Exposed Members per 1,000 Eligible Members ¹	Years at Risk	Eligible Member Years ¹	Incidence		Number of Events per Patient with an Event
											Rate per 1,000 Years at Risk	All Events	
Male	<12	*****	*****	*****	100	100	0	0.00	0.2	9,674,498.7	0.00	0	.
	12-18	18	18	38	1,120	1,210	0	0.00	3.1	7,152,127.0	0.00	0	.
	19-24	66	66	140	4,845	5,295	0	0.02	14.4	6,447,849.0	0.00	0	.
	25-44	5,095	5,095	18,218	601,127	641,157	*****	0.41	*****	21,738,429.7	4.05	*****	1.00
	45-64	*****	*****	*****	3,568,715	3,748,723	49	1.82	10,042.7	28,273,879.4	4.88	70	1.43
	>=65	13,040	13,040	46,993	1,920,995	1,963,755	*****	1.02	*****	32,720,479.8	3.01	*****	2.25
Other	<12	0	0	0	0	0	0	0.00	0.0	349.9	.	0	.
	12-18	0	0	0	0	0	0	0.00	0.0	284.2	.	0	.
	19-24	0	0	0	0	0	0	0.00	0.0	329.3	.	0	.
	25-44	0	0	0	0	0	0	0.00	0.0	1,553.9	.	0	.
	45-64	*****	*****	*****	228	318	0	3.03	0.7	3,587.8	0.00	0	.
	>=65	0	0	0	0	0	0	0.00	0.0	1,332.5	.	0	.
Empagliflozin													
Female	<12	0	0	0	0	0	0	0.00	0.0	9,232,686.6	.	0	.
	12-18	20	20	65	2,116	2,131	0	0.01	5.8	6,874,546.6	0.00	0	.
	19-24	126	126	324	10,533	10,767	*****	0.03	*****	6,230,490.2	33.33	*****	2.00
	25-44	4,811	4,811	15,038	496,924	516,796	14	0.38	1,423.6	22,441,990.7	9.83	16	1.14
	45-64	*****	*****	*****	2,996,715	3,086,547	*****	1.70	*****	30,076,268.2	5.71	*****	1.63
	>=65	*****	*****	*****	1,688,353	1,707,574	*****	0.84	*****	47,525,188.1	5.29	*****	2.72
Male	<12	0	0	0	0	0	0	0.00	0.0	9,674,498.7	.	0	.
	12-18	16	16	46	1,719	1,758	0	0.00	4.8	7,152,128.3	0.00	0	.
	19-24	86	86	198	6,347	7,380	0	0.02	19.0	6,447,853.0	0.00	0	.
	25-44	5,752	5,752	19,644	661,697	694,668	14	0.46	1,883.8	21,738,821.4	7.43	20	1.43
	45-64	*****	*****	*****	4,417,349	4,557,348	*****	2.40	*****	28,276,030.6	4.72	*****	1.79
	>=65	*****	*****	*****	2,302,323	2,332,926	*****	1.40	*****	32,721,900.7	3.30	*****	1.81
Other	<12	0	0	0	0	0	0	0.00	0.0	349.9	.	0	.
	12-18	0	0	0	0	0	0	0.00	0.0	284.2	.	0	.
	19-24	0	0	0	0	0	0	0.00	0.0	329.3	.	0	.
	25-44	0	0	0	0	0	0	0.00	0.0	1,553.9	.	0	.
	45-64	*****	*****	*****	437	437	0	0.76	1.2	3,587.8	0.00	0	.
	>=65	0	0	0	0	0	0	0.00	0.0	1,332.5	.	0	.

Table 2f. Summary of Diabetic Ketoacidosis Events after Incident Exposure to Canagliflozin, Dapagliflozin, Empagliflozin, or Sitagliptin in the Sentinel Distributed Database (SDD) between March 1, 2013 and June 30, 2018, by Age Group (Years) and Sex

Sex	Age Group (Years)	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	New Episodes with an Event	Number of Exposed Members per 1,000 Eligible Members ¹	Years at Risk	Eligible Member Years ¹	Incidence		Number of Events per Patient with an Event
											Rate per 1,000 Years at Risk	All Events	
Sitagliptin													
Female	<12	*****	*****	*****	615	766	0	0.00	2.0	9,232,679.6	0.00	0	.
	12-18	105	105	243	8,302	10,902	0	0.03	24.3	6,874,431.2	0.00	0	.
	19-24	556	556	1,618	54,490	66,259	*****	0.13	*****	6,229,698.7	12.89	*****	1.00
	25-44	18,741	18,741	66,385	2,282,065	2,705,341	*****	1.47	*****	22,399,414.6	10.92	*****	2.27
	45-64	97,737	97,737	405,544	14,606,412	16,867,247	278	7.14	40,864.7	29,717,646.4	6.80	730	2.63
	>=65	230,853	230,853	1,066,408	38,021,331	41,569,391	536	13.22	105,569.7	46,154,569.3	5.08	1,156	2.16
Male	<12	*****	*****	*****	420	480	0	0.00	1.4	9,674,471.6	0.00	0	.
	12-18	59	59	154	5,299	6,873	0	0.01	15.5	7,152,047.2	0.00	0	.
	19-24	377	377	1,147	40,160	49,806	*****	0.09	*****	6,447,122.2	34.93	*****	1.00
	25-44	*****	*****	*****	2,791,893	3,402,758	*****	1.68	*****	21,683,544.5	4.78	*****	2.32
	45-64	*****	*****	*****	17,054,747	19,985,386	188	8.29	47,652.3	27,859,270.6	3.95	424	2.26
	>=65	*****	*****	*****	31,826,503	35,274,671	303	15.19	88,085.9	31,585,307.1	3.44	656	2.17
Other	<12	0	0	0	0	0	0	0.00	0.0	349.9	.	0	.
	12-18	0	0	0	0	0	0	0.00	0.0	284.2	.	0	.
	19-24	0	0	0	0	0	0	0.00	0.0	326.6	.	0	.
	25-44	*****	*****	*****	180	180	0	3.25	0.6	1,543.0	0.00	0	.
	45-64	*****	*****	*****	1,050	1,110	0	8.42	3.2	3,532.5	0.00	0	.
	>=65	*****	*****	*****	1,420	1,779	0	10.92	3.2	1,271.0	0.00	0	.
Incident Exposure and Prior Type 1 Diabetes Mellitus													
Canagliflozin													
Female	<12	0	0	0	0	0	0	.	0.0	.	.	0	.
	12-18	*****	*****	*****	2,100	2,100	*****	.	*****	.	217.39	*****	6.00
	19-24	*****	*****	*****	5,068	5,158	*****	.	*****	.	70.42	*****	1.00
	25-44	239	239	1,007	36,368	36,570	*****	.	*****	.	232.80	*****	1.50
	45-64	371	371	1,766	62,331	64,820	*****	.	*****	.	52.72	*****	2.33
	>=65	170	170	631	26,020	26,555	*****	.	*****	.	41.49	*****	1.33
Male	<12	0	0	0	0	0	0	.	0.0	.	.	0	.
	12-18	*****	*****	*****	667	667	0	.	1.9	.	0.00	0	.
	19-24	*****	*****	*****	446	446	0	.	1.4	.	0.00	0	.
	25-44	192	192	996	36,069	37,078	*****	.	*****	.	113.87	*****	2.82
	45-64	337	337	1,902	70,670	74,860	*****	.	*****	.	36.36	*****	2.43
	>=65	160	160	665	27,686	29,070	*****	.	*****	.	40.21	*****	3.33

Table 2f. Summary of Diabetic Ketoacidosis Events after Incident Exposure to Canagliflozin, Dapagliflozin, Empagliflozin, or Sitagliptin in the Sentinel Distributed Database (SDD) between March 1, 2013 and June 30, 2018, by Age Group (Years) and Sex

Sex	Age Group (Years)	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	New Episodes with an Event	Number of Exposed Members per 1,000 Eligible Members ¹	Years at Risk	Eligible Member Years ¹	Incidence Rate per 1,000 Years at Risk		Number of Events per Patient with an Event
											All Events		
Other	<12	0	0	0	0	0	0	.	0.0	.	.	0	.
	12-18	0	0	0	0	0	0	.	0.0	.	.	0	.
	19-24	0	0	0	0	0	0	.	0.0	.	.	0	.
	25-44	0	0	0	0	0	0	.	0.0	.	.	0	.
	45-64	0	0	0	0	0	0	.	0.0	.	.	0	.
	>=65	0	0	0	0	0	0	.	0.0	.	.	0	.
Dapagliflozin													
Female	<12	0	0	0	0	0	0	.	0.0	.	.	0	.
	12-18	*****	*****	*****	30	30	0	.	0.1	.	0.00	0	.
	19-24	*****	*****	*****	390	390	0	.	1.2	.	0.00	0	.
	25-44	68	68	192	7,154	7,184	*****	.	*****	.	153.06	*****	2.00
	45-64	118	118	525	18,695	18,815	*****	.	*****	.	19.49	*****	1.00
	>=65	*****	*****	91	3,437	3,437	*****	.	*****	.	212.77	*****	5.00
Male	<12	0	0	0	0	0	0	.	0.0	.	.	0	.
	12-18	*****	*****	*****	90	90	0	.	0.2	.	0.00	0	.
	19-24	*****	*****	*****	510	510	0	.	1.5	.	0.00	0	.
	25-44	44	44	153	5,432	5,522	0	.	15.7	.	0.00	0	.
	45-64	94	94	327	13,513	14,487	*****	.	*****	.	81.52	*****	2.00
	>=65	*****	*****	104	3,953	4,493	0	.	10.9	.	0.00	0	.
Other	<12	0	0	0	0	0	0	.	0.0	.	.	0	.
	12-18	0	0	0	0	0	0	.	0.0	.	.	0	.
	19-24	0	0	0	0	0	0	.	0.0	.	.	0	.
	25-44	0	0	0	0	0	0	.	0.0	.	.	0	.
	45-64	0	0	0	0	0	0	.	0.0	.	.	0	.
	>=65	0	0	0	0	0	0	.	0.0	.	.	0	.

Table 2f. Summary of Diabetic Ketoacidosis Events after Incident Exposure to Canagliflozin, Dapagliflozin, Empagliflozin, or Sitagliptin in the Sentinel Distributed Database (SDD) between March 1, 2013 and June 30, 2018, by Age Group (Years) and Sex

Sex	Age Group (Years)	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	New Episodes with an Event	Number of Exposed Members per 1,000 Eligible Members ¹	Years at Risk	Eligible Member Years ¹	Incidence		Number of Events per Patient with an Event
											Rate per 1,000 Years at Risk	All Events	
Empagliflozin													
Female	<12	0	0	0	0	0	0	.	0.0	.	.	0	.
	12-18	*****	*****	*****	364	364	0	.	0.9	.	0.00	0	.
	19-24	*****	*****	*****	623	648	0	.	1.6	.	0.00	0	.
	25-44	72	72	251	8,110	8,140	*****	.	*****	.	88.11	*****	1.00
	45-64	108	108	425	16,508	16,448	*****	.	*****	.	45.05	*****	3.00
	>=65	*****	*****	*****	4,452	4,452	0	.	12.1	.	0.00	0	.
Male	<12	0	0	0	0	0	0	.	0.0	.	.	0	.
	12-18	*****	*****	*****	60	60	0	.	0.2	.	0.00	0	.
	19-24	*****	*****	*****	265	265	0	.	0.8	.	0.00	0	.
	25-44	64	64	260	9,418	9,361	*****	.	*****	.	38.46	*****	2.00
	45-64	135	135	600	23,579	23,579	*****	.	*****	.	77.76	*****	1.40
	>=65	*****	*****	*****	3,989	4,037	*****	.	*****	.	90.09	*****	3.00
Other	<12	0	0	0	0	0	0	.	0.0	.	.	0	.
	12-18	0	0	0	0	0	0	.	0.0	.	.	0	.
	19-24	0	0	0	0	0	0	.	0.0	.	.	0	.
	25-44	0	0	0	0	0	0	.	0.0	.	.	0	.
	45-64	0	0	0	0	0	0	.	0.0	.	.	0	.
	>=65	0	0	0	0	0	0	.	0.0	.	.	0	.
Sitagliptin													
Female	<12	0	0	0	0	0	0	.	0.0	.	.	0	.
	12-18	*****	*****	*****	60	60	0	.	0.2	.	0.00	0	.
	19-24	*****	*****	*****	530	620	0	.	1.5	.	0.00	0	.
	25-44	*****	*****	*****	6,652	7,609	*****	.	*****	.	212.77	*****	1.75
	45-64	148	148	704	20,993	22,960	*****	.	*****	.	33.44	*****	1.00
	>=65	228	228	1,329	37,839	42,910	*****	.	*****	.	66.54	*****	3.43
Male	<12	0	0	0	0	0	0	.	0.0	.	.	0	.
	12-18	0	0	0	0	0	0	.	0.0	.	.	0	.
	19-24	*****	*****	*****	180	210	*****	.	*****	.	1,666.67	*****	1.00
	25-44	*****	*****	*****	7,071	8,436	0	.	20.2	.	0.00	0	.
	45-64	118	118	499	17,045	19,119	*****	.	*****	.	41.32	*****	1.50
	>=65	157	157	851	24,925	29,054	*****	.	*****	.	28.86	*****	1.00

Table 2f. Summary of Diabetic Ketoacidosis Events after Incident Exposure to Canagliflozin, Dapagliflozin, Empagliflozin, or Sitagliptin in the Sentinel Distributed Database (SDD) between March 1, 2013 and June 30, 2018, by Age Group (Years) and Sex

Sex	Age Group (Years)	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	New Episodes with an Event	Number of Exposed Members per 1,000 Eligible Members ¹	Years at Risk	Eligible Member Years ¹	Incidence Rate per 1,000 Years at Risk		Number of Events per Patient with an Event
											All Events		
Other	<12	0	0	0	0	0	0	.	0.0	.	.	0	.
	12-18	0	0	0	0	0	0	.	0.0	.	.	0	.
	19-24	0	0	0	0	0	0	.	0.0	.	.	0	.
	25-44	0	0	0	0	0	0	.	0.0	.	.	0	.
	45-64	0	0	0	0	0	0	.	0.0	.	.	0	.
	>=65	0	0	0	0	0	0	.	0.0	.	.	0	.
Incident Exposure and Prior Type 1 Diabetes Mellitus - Broad Definition													
Canagliflozin													
Female	<12	0	0	0	0	0	0	.	0.0	.	.	0	.
	12-18	*****	*****	66	2,250	2,250	*****	.	*****	.	200.00	*****	6.00
	19-24	*****	*****	165	5,293	5,383	*****	.	*****	.	67.57	*****	1.00
	25-44	304	304	1,320	46,408	47,376	23	.	121.8	.	188.83	34	1.48
	45-64	627	627	3,017	106,984	111,273	*****	.	*****	.	37.36	*****	2.27
	>=65	465	465	1,728	68,342	69,886	*****	.	*****	.	31.40	*****	2.00
Male	<12	0	0	0	0	0	0	.	0.0	.	.	0	.
	12-18	*****	*****	22	697	727	0	.	2.0	.	0.00	0	.
	19-24	*****	*****	32	906	906	*****	.	*****	.	384.62	*****	1.00
	25-44	262	262	1,330	48,103	49,772	11	.	130.1	.	84.55	31	2.82
	45-64	676	676	3,599	132,667	140,498	*****	.	*****	.	19.28	*****	2.43
	>=65	512	512	2,135	90,358	94,288	*****	.	*****	.	16.22	*****	3.50
Other	<12	0	0	0	0	0	0	.	0.0	.	.	0	.
	12-18	0	0	0	0	0	0	.	0.0	.	.	0	.
	19-24	0	0	0	0	0	0	.	0.0	.	.	0	.
	25-44	0	0	0	0	0	0	.	0.0	.	.	0	.
	45-64	0	0	0	0	0	0	.	0.0	.	.	0	.
	>=65	0	0	0	0	0	0	.	0.0	.	.	0	.

Table 2f. Summary of Diabetic Ketoacidosis Events after Incident Exposure to Canagliflozin, Dapagliflozin, Empagliflozin, or Sitagliptin in the Sentinel Distributed Database (SDD) between March 1, 2013 and June 30, 2018, by Age Group (Years) and Sex

Sex	Age Group (Years)	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	New Episodes with an Event	Number of Exposed Members per 1,000 Eligible Members ¹	Years at Risk	Eligible Member Years ¹	Incidence		Number of Events per Patient with an Event
											Rate per 1,000 Years at Risk	All Events	
Dapagliflozin													
Female	<12	0	0	0	0	0	0	.	0.0	.	.	0	.
	12-18	*****	*****	*****	210	390	0	.	0.6	.	0.00	0	.
	19-24	*****	*****	*****	390	390	0	.	1.2	.	0.00	0	.
	25-44	*****	*****	242	8,777	8,807	*****	.	*****	.	165.98	*****	2.00
	45-64	195	195	892	31,730	33,413	*****	.	*****	.	11.35	*****	1.00
	>=65	88	88	299	11,608	11,623	*****	.	*****	.	60.98	*****	5.00
Male	<12	0	0	0	0	0	0	.	0.0	.	.	0	.
	12-18	*****	*****	*****	90	90	0	.	0.2	.	0.00	0	.
	19-24	*****	*****	*****	510	510	0	.	1.5	.	0.00	0	.
	25-44	*****	*****	236	9,005	9,395	0	.	25.3	.	0.00	0	.
	45-64	200	200	777	29,852	31,708	*****	.	*****	.	36.06	*****	2.00
	>=65	89	89	352	14,707	15,277	0	.	40.0	.	0.00	0	.
Other	<12	0	0	0	0	0	0	.	0.0	.	.	0	.
	12-18	0	0	0	0	0	0	.	0.0	.	.	0	.
	19-24	0	0	0	0	0	0	.	0.0	.	.	0	.
	25-44	0	0	0	0	0	0	.	0.0	.	.	0	.
	45-64	0	0	0	0	0	0	.	0.0	.	.	0	.
	>=65	0	0	0	0	0	0	.	0.0	.	.	0	.
Empagliflozin													
Female	<12	0	0	0	0	0	0	.	0.0	.	.	0	.
	12-18	*****	*****	*****	364	364	0	.	0.9	.	0.00	0	.
	19-24	*****	*****	*****	646	671	0	.	1.7	.	0.00	0	.
	25-44	*****	*****	373	12,033	12,063	*****	.	*****	.	59.00	*****	1.00
	45-64	179	179	700	26,507	26,597	*****	.	*****	.	41.32	*****	2.33
	>=65	74	74	185	8,015	8,068	0	.	22.3	.	0.00	0	.
Male	<12	0	0	0	0	0	0	.	0.0	.	.	0	.
	12-18	*****	*****	*****	60	60	0	.	0.2	.	0.00	0	.
	19-24	*****	*****	*****	265	265	0	.	0.8	.	0.00	0	.
	25-44	*****	*****	318	11,548	11,538	*****	.	*****	.	31.15	*****	2.00
	45-64	210	210	872	32,648	32,838	*****	.	*****	.	55.43	*****	1.40
	>=65	86	86	259	9,610	9,696	*****	.	27.4	.	36.50	*****	3.00

Table 2f. Summary of Diabetic Ketoacidosis Events after Incident Exposure to Canagliflozin, Dapagliflozin, Empagliflozin, or Sitagliptin in the Sentinel Distributed Database (SDD) between March 1, 2013 and June 30, 2018, by Age Group (Years) and Sex

Sex	Age Group (Years)	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	New Episodes with an Event	Number of Exposed Members per 1,000 Eligible Members ¹	Years at Risk	Eligible Member Years ¹	Incidence Rate per 1,000 Years at Risk		Number of Events per Patient with an Event
											All Events		
Other	<12	0	0	0	0	0	0	.	0.0	.	.	0	.
	12-18	0	0	0	0	0	0	.	0.0	.	.	0	.
	19-24	0	0	0	0	0	0	.	0.0	.	.	0	.
	25-44	0	0	0	0	0	0	.	0.0	.	.	0	.
	45-64	0	0	0	0	0	0	.	0.0	.	.	0	.
	>=65	0	0	0	0	0	0	.	0.0	.	.	0	.
Sitagliptin													
Female	<12	0	0	0	0	0	0	.	0.0	.	.	0	.
	12-18	*****	*****	*****	312	372	0	.	0.9	.	0.00	0	.
	19-24	*****	*****	*****	1,173	1,263	0	.	3.2	.	0.00	0	.
	25-44	*****	*****	*****	13,457	15,114	*****	.	*****	.	104.71	*****	1.75
	45-64	423	423	1,959	65,249	75,316	*****	.	*****	.	16.35	*****	1.00
	>=65	952	952	5,473	166,020	186,271	*****	.	*****	.	21.58	*****	3.10
Male	<12	0	0	0	0	0	0	.	0.0	.	.	0	.
	12-18	*****	*****	*****	90	90	0	.	0.3	.	0.00	0	.
	19-24	*****	*****	*****	180	210	*****	.	*****	.	1,666.67	*****	1.00
	25-44	*****	*****	*****	18,553	23,178	0	.	52.9	.	0.00	0	.
	45-64	470	470	2,130	72,250	89,001	*****	.	*****	.	14.78	*****	1.33
	>=65	782	782	3,383	127,400	143,340	*****	.	*****	.	5.66	*****	1.00
Other	<12	0	0	0	0	0	0	.	0.0	.	.	0	.
	12-18	0	0	0	0	0	0	.	0.0	.	.	0	.
	19-24	0	0	0	0	0	0	.	0.0	.	.	0	.
	25-44	0	0	0	0	0	0	.	0.0	.	.	0	.
	45-64	0	0	0	0	0	0	.	0.0	.	.	0	.
	>=65	0	0	0	0	0	0	.	0.0	.	.	0	.

Table 2f. Summary of Diabetic Ketoacidosis Events after Incident Exposure to Canagliflozin, Dapagliflozin, Empagliflozin, or Sitagliptin in the Sentinel Distributed Database (SDD) between March 1, 2013 and June 30, 2018, by Age Group (Years) and Sex

Sex	Age Group (Years)	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	New Episodes with an Event	Number of Exposed Members per 1,000 Eligible Members ¹	Years at Risk	Eligible Member Years ¹	Incidence Rate per 1,000 Years at Risk		Number of Events per Patient with an Event
											All Events		
Incident Exposure and Prior Type 2 Diabetes Mellitus													
Canagliflozin													
Female	<12	*****	*****	*****	240	240	0	1.97	0.7	352.0	0.00	0	.
	12-18	*****	*****	*****	1,415	1,910	0	3.31	4.2	4,834.3	0.00	0	.
	19-24	175	175	629	20,506	21,429	*****	11.86	*****	12,409.1	17.12	*****	1.00
	25-44	9,247	9,247	37,488	1,256,456	1,351,382	*****	29.36	*****	394,623.1	9.56	*****	2.71
	45-64	46,258	46,258	214,216	7,548,344	8,037,776	107	31.60	21,066.6	2,392,586.8	5.08	225	2.10
	>=65	52,356	52,356	203,217	7,927,555	8,282,586	102	16.16	22,066.8	6,748,903.9	4.62	225	2.21
Male	<12	0	0	0	0	0	0	0.00	0.0	203.4	.	0	.
	12-18	*****	*****	*****	1,400	1,430	0	5.80	3.9	2,325.5	0.00	0	.
	19-24	100	100	527	18,638	19,843	0	13.69	52.3	6,666.6	0.00	0	.
	25-44	10,756	10,756	49,105	1,651,938	1,778,194	*****	34.00	*****	405,656.4	4.70	*****	1.50
	45-64	*****	*****	*****	10,485,548	11,197,776	126	34.37	29,034.2	2,666,181.4	4.34	278	2.21
	>=65	54,613	54,613	224,037	9,434,700	9,872,145	*****	19.48	*****	5,708,201.5	2.93	*****	2.74
Other	<12	0	0	0	0	0	0	.	0.0	0.0	.	0	.
	12-18	0	0	0	0	0	0	.	0.0	0.0	.	0	.
	19-24	0	0	0	0	0	0	0.00	0.0	2.9	.	0	.
	25-44	0	0	0	0	0	0	0.00	0.0	29.1	.	0	.
	45-64	*****	*****	*****	1,904	2,114	0	55.90	5.2	329.7	0.00	0	.
	>=65	0	0	0	0	0	0	0.00	0.0	218.1	.	0	.
Dapagliflozin													
Female	<12	0	0	0	0	0	0	0.00	0.0	352.0	.	0	.
	12-18	*****	*****	*****	504	504	0	1.10	1.4	4,835.7	0.00	0	.
	19-24	65	65	163	5,500	6,152	0	4.40	16.1	12,410.5	0.00	0	.
	25-44	3,112	3,112	9,986	331,070	348,659	*****	9.88	*****	395,314.2	6.33	*****	4.33
	45-64	15,010	15,010	58,374	2,011,795	2,092,385	*****	10.25	*****	2,397,581.3	2.98	*****	1.71
	>=65	9,736	9,736	33,093	1,280,584	1,311,529	17	3.00	3,586.3	6,757,520.4	4.74	36	2.12

Table 2f. Summary of Diabetic Ketoacidosis Events after Incident Exposure to Canagliflozin, Dapagliflozin, Empagliflozin, or Sitagliptin in the Sentinel Distributed Database (SDD) between March 1, 2013 and June 30, 2018, by Age Group (Years) and Sex

Sex	Age Group (Years)	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	New Episodes with an Event	Number of Exposed Members per 1,000 Eligible Members ¹	Years at Risk	Eligible Member Years ¹	Incidence Rate per 1,000 Years at Risk		Number of Events per Patient with an Event
											All Events		
Male	<12	0	0	0	0	0	0	0.00	0.0	203.4	.	0	.
	12-18	*****	*****	*****	715	715	0	3.48	2.0	2,325.6	0.00	0	.
	19-24	36	36	59	2,090	2,540	0	4.92	6.3	6,677.7	0.00	0	.
	25-44	3,751	3,751	13,833	455,635	483,957	*****	11.86	*****	406,090.4	1.53	*****	1.00
	45-64	*****	*****	*****	2,889,315	3,024,492	*****	11.45	*****	2,670,396.7	2.83	*****	1.13
	>=65	10,420	10,420	37,847	1,549,482	1,582,564	12	3.72	4,288.3	5,715,407.0	2.80	29	2.42
Other	<12	0	0	0	0	0	0	.	0.0	0.0	.	0	.
	12-18	0	0	0	0	0	0	.	0.0	0.0	.	0	.
	19-24	0	0	0	0	0	0	0.00	0.0	2.9	.	0	.
	25-44	0	0	0	0	0	0	0.00	0.0	29.1	.	0	.
	45-64	*****	*****	*****	120	210	0	12.42	0.4	334.3	0.00	0	.
	>=65	0	0	0	0	0	0	0.00	0.0	218.1	.	0	.
Empagliflozin													
Female	<12	0	0	0	0	0	0	0.00	0.0	352.0	.	0	.
	12-18	*****	*****	*****	1,401	1,386	0	2.02	3.8	4,835.3	0.00	0	.
	19-24	71	71	186	6,254	6,371	0	4.81	17.8	12,415.8	0.00	0	.
	25-44	3,439	3,439	10,856	360,465	373,288	*****	10.92	*****	395,536.7	5.81	*****	1.17
	45-64	*****	*****	*****	2,379,484	2,450,174	33	12.51	6,661.7	2,398,930.3	4.95	46	1.39
	>=65	11,869	11,869	34,379	1,354,317	1,369,696	*****	3.66	*****	6,758,447.5	3.69	*****	2.93
Male	<12	0	0	0	0	0	0	0.00	0.0	203.4	.	0	.
	12-18	*****	*****	*****	658	697	0	2.70	1.9	2,325.6	0.00	0	.
	19-24	44	44	99	3,185	3,643	0	6.02	9.7	6,678.5	0.00	0	.
	25-44	4,425	4,425	15,464	519,731	542,254	*****	13.99	*****	406,277.9	5.41	*****	1.00
	45-64	*****	*****	*****	3,656,553	3,759,736	34	15.61	10,150.1	2,671,619.6	3.35	60	1.76
	>=65	14,658	14,658	45,141	1,890,232	1,912,655	*****	5.23	*****	5,716,285.6	2.49	*****	1.46
Other	<12	0	0	0	0	0	0	.	0.0	0.0	.	0	.
	12-18	0	0	0	0	0	0	.	0.0	0.0	.	0	.
	19-24	0	0	0	0	0	0	0.00	0.0	2.9	.	0	.
	25-44	0	0	0	0	0	0	0.00	0.0	29.1	.	0	.
	45-64	*****	*****	*****	437	437	0	6.21	1.2	334.3	0.00	0	.
	>=65	0	0	0	0	0	0	0.00	0.0	218.1	.	0	.

Table 2f. Summary of Diabetic Ketoacidosis Events after Incident Exposure to Canagliflozin, Dapagliflozin, Empagliflozin, or Sitagliptin in the Sentinel Distributed Database (SDD) between March 1, 2013 and June 30, 2018, by Age Group (Years) and Sex

Sex	Age Group (Years)	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	New Episodes with an Event	Number of Exposed Members per 1,000 Eligible Members ¹	Years at Risk	Eligible Member Years ¹	Incidence Rate per 1,000 Years at Risk		Number of Events per Patient with an Event
											All Events		
Sitagliptin													
Female	<12	*****	*****	*****	90	166	0	3.96	0.3	346.7	0.00	0	.
	12-18	51	51	124	4,271	5,458	0	9.45	12.3	4,771.8	0.00	0	.
	19-24	321	321	928	31,636	38,808	*****	22.32	*****	11,818.2	11.17	*****	1.00
	25-44	12,793	12,793	47,174	1,632,103	1,913,875	*****	42.76	*****	360,126.8	6.25	*****	1.83
	45-64	*****	*****	*****	10,940,396	12,541,651	137	52.79	30,556.0	2,093,416.7	4.48	340	2.48
	>=65	166,564	166,564	756,682	28,102,747	30,728,993	304	57.90	77,898.8	5,588,929.6	3.90	635	2.09
Male	<12	*****	*****	*****	90	120	0	8.30	0.3	190.9	0.00	0	.
	12-18	27	27	82	2,620	3,384	0	10.56	7.7	2,289.0	0.00	0	.
	19-24	193	193	630	22,079	27,929	*****	27.77	*****	6,110.0	31.75	*****	1.00
	25-44	*****	*****	*****	1,996,055	2,396,223	*****	48.37	*****	359,549.8	3.00	*****	2.12
	45-64	77,306	77,306	345,479	12,782,695	14,791,960	93	51.89	35,618.7	2,315,080.6	2.61	173	1.86
	>=65	*****	*****	*****	24,106,095	26,638,234	178	56.29	66,570.1	4,737,499.9	2.67	327	1.84
Other	<12	0	0	0	0	0	0	.	0.0	0.0	.	0	.
	12-18	0	0	0	0	0	0	.	0.0	0.0	.	0	.
	19-24	0	0	0	0	0	0	0.00	0.0	0.2	.	0	.
	25-44	*****	*****	*****	150	150	0	117.65	0.5	21.2	0.00	0	.
	45-64	*****	*****	*****	1,020	1,050	0	66.23	3.1	284.0	0.00	0	.
	>=65	*****	*****	*****	1,410	1,769	0	40.82	3.2	167.1	0.00	0	.
Incident Exposure and Prior Type 2 Diabetes Mellitus with History of Insulin Use													
Canagliflozin													
Female	<12	0	0	0	0	0	0	0.00	0.0	49.5	.	0	.
	12-18	*****	*****	*****	800	1,190	0	8.19	2.3	725.9	0.00	0	.
	19-24	*****	*****	*****	4,811	5,373	*****	19.93	*****	1,861.5	71.94	*****	1.00
	25-44	2,807	2,807	11,412	391,007	417,110	*****	36.34	*****	79,887.6	13.70	*****	2.93
	45-64	14,658	14,658	66,990	2,365,653	2,513,846	59	36.38	6,585.3	535,006.3	8.96	153	2.59
	>=65	13,422	13,422	52,279	1,956,208	2,046,020	34	16.09	5,460.0	1,167,288.4	6.23	71	2.09

Table 2f. Summary of Diabetic Ketoacidosis Events after Incident Exposure to Canagliflozin, Dapagliflozin, Empagliflozin, or Sitagliptin in the Sentinel Distributed Database (SDD) between March 1, 2013 and June 30, 2018, by Age Group (Years) and Sex

Sex	Age Group (Years)	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	New Episodes with an Event	Number of Exposed Members per 1,000 Eligible Members ¹	Years at Risk	Eligible Member Years ¹	Incidence		Number of Events per Patient with an Event
											Rate per 1,000 Years at Risk	All Events	
Male	<12	0	0	0	0	0	0	0.00	0.0	27.0	.	0	.
	12-18	*****	*****	*****	240	270	0	9.98	0.8	430.1	0.00	0	.
	19-24	*****	*****	*****	6,522	6,929	0	19.54	18.0	1,183.5	0.00	0	.
	25-44	2,811	2,811	13,021	437,421	469,899	*****	39.03	*****	74,900.9	9.76	*****	1.33
	45-64	15,939	15,939	83,010	2,987,888	3,176,856	61	36.36	8,227.5	574,266.0	7.41	178	2.92
	>=65	13,513	13,513	56,632	2,321,705	2,432,577	*****	18.91	*****	997,950.7	4.23	*****	2.67
Other	<12	0	0	0	0	0	0	.	0.0	0.0	.	0	.
	12-18	0	0	0	0	0	0	.	0.0	0.0	.	0	.
	19-24	0	0	0	0	0	0	.	0.0	0.0	.	0	.
	25-44	0	0	0	0	0	0	0.00	0.0	6.9	.	0	.
	45-64	*****	*****	*****	300	510	0	135.14	0.9	56.0	0.00	0	.
	>=65	0	0	0	0	0	0	0.00	0.0	53.4	.	0	.
Dapagliflozin													
Female	<12	0	0	0	0	0	0	0.00	0.0	49.5	.	0	.
	12-18	*****	*****	*****	28	28	0	1.02	0.1	726.1	0.00	0	.
	19-24	*****	*****	*****	1,014	1,238	0	4.80	3.0	1,862.3	0.00	0	.
	25-44	760	760	2,399	83,930	87,442	*****	9.84	*****	80,055.5	12.64	*****	5.67
	45-64	3,864	3,864	14,674	512,439	539,006	*****	9.59	*****	536,279.7	4.84	*****	2.14
	>=65	2,329	2,329	7,876	292,476	302,324	*****	2.79	*****	1,169,139.5	8.55	*****	2.14
Male	<12	0	0	0	0	0	0	0.00	0.0	27.0	.	0	.
	12-18	*****	*****	*****	90	90	0	3.33	0.3	430.1	0.00	0	.
	19-24	*****	*****	*****	531	561	0	8.27	1.7	1,187.4	0.00	0	.
	25-44	807	807	3,047	101,582	110,245	*****	11.20	*****	75,004.4	3.46	*****	1.00
	45-64	4,386	4,386	18,745	671,086	706,697	*****	10.00	*****	575,332.3	6.39	*****	1.17
	>=65	2,357	2,357	9,069	362,840	370,077	*****	3.30	*****	999,374.1	4.97	*****	2.20
Other	<12	0	0	0	0	0	0	.	0.0	0.0	.	0	.
	12-18	0	0	0	0	0	0	.	0.0	0.0	.	0	.
	19-24	0	0	0	0	0	0	.	0.0	0.0	.	0	.
	25-44	0	0	0	0	0	0	0.00	0.0	6.9	.	0	.
	45-64	0	0	0	0	0	0	0.00	0.0	59.2	.	0	.
	>=65	0	0	0	0	0	0	0.00	0.0	53.4	.	0	.

Table 2f. Summary of Diabetic Ketoacidosis Events after Incident Exposure to Canagliflozin, Dapagliflozin, Empagliflozin, or Sitagliptin in the Sentinel Distributed Database (SDD) between March 1, 2013 and June 30, 2018, by Age Group (Years) and Sex

Sex	Age Group (Years)	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	New Episodes with an Event	Number of Exposed Members per 1,000 Eligible Members ¹	Years at Risk	Eligible Member Years ¹	Incidence		Number of Events per Patient with an Event
											Rate per 1,000 Years at Risk	All Events	
Empagliflozin													
Female	<12	0	0	0	0	0	0	0.00	0.0	49.5	.	0	.
	12-18	*****	*****	*****	270	270	0	2.05	0.8	725.7	0.00	0	.
	19-24	*****	*****	*****	2,246	2,243	0	8.49	6.3	1,863.0	0.00	0	.
	25-44	*****	*****	*****	95,697	100,029	*****	11.83	*****	80,102.7	11.07	*****	1.00
	45-64	5,195	5,195	18,555	657,855	670,837	*****	12.89	*****	536,591.1	9.24	*****	1.29
	>=65	3,123	3,123	8,721	336,425	338,239	*****	3.74	*****	1,169,300.3	9.50	*****	2.44
Male	<12	0	0	0	0	0	0	0.00	0.0	27.0	.	0	.
	12-18	*****	*****	*****	60	60	0	3.33	0.2	430.1	0.00	0	.
	19-24	*****	*****	*****	188	196	0	2.96	0.6	1,187.8	0.00	0	.
	25-44	*****	*****	*****	116,505	121,762	*****	13.54	*****	75,022.8	9.16	*****	1.00
	45-64	6,564	6,564	25,973	942,104	963,683	*****	14.97	*****	575,578.6	4.22	*****	1.91
	>=65	3,688	3,688	11,002	456,475	459,913	*****	5.16	*****	999,549.8	3.17	*****	1.50
Other	<12	0	0	0	0	0	0	.	0.0	0.0	.	0	.
	12-18	0	0	0	0	0	0	.	0.0	0.0	.	0	.
	19-24	0	0	0	0	0	0	.	0.0	0.0	.	0	.
	25-44	0	0	0	0	0	0	0.00	0.0	6.9	.	0	.
	45-64	0	0	0	0	0	0	0.00	0.0	59.2	.	0	.
	>=65	0	0	0	0	0	0	0.00	0.0	53.4	.	0	.
Sitagliptin													
Female	<12	0	0	0	0	0	0	0.00	0.0	49.5	.	0	.
	12-18	*****	*****	*****	570	630	0	7.35	1.7	705.7	0.00	0	.
	19-24	53	53	124	4,426	5,221	0	20.86	12.9	1,731.1	0.00	0	.
	25-44	*****	*****	*****	273,974	326,462	*****	32.29	*****	71,723.4	16.70	*****	2.23
	45-64	13,277	13,277	55,731	1,894,422	2,170,118	*****	37.41	*****	463,303.5	10.17	*****	2.70
	>=65	26,143	26,143	128,911	3,978,569	4,377,415	85	38.00	11,106.3	915,728.6	7.65	203	2.39
Male	<12	0	0	0	0	0	0	0.00	0.0	22.6	.	0	.
	12-18	*****	*****	*****	254	457	0	5.10	0.7	425.1	0.00	0	.
	19-24	31	31	79	2,990	4,644	0	20.23	8.7	1,053.6	0.00	0	.
	25-44	2,093	2,093	8,154	270,426	322,991	*****	32.50	*****	66,233.1	7.81	*****	3.33
	45-64	*****	*****	*****	1,927,999	2,256,113	*****	31.67	*****	503,128.5	8.01	*****	2.30
	>=65	19,562	19,562	85,230	3,020,293	3,354,323	51	32.70	8,388.3	803,149.6	6.08	92	1.80

Table 2f. Summary of Diabetic Ketoacidosis Events after Incident Exposure to Canagliflozin, Dapagliflozin, Empagliflozin, or Sitagliptin in the Sentinel Distributed Database (SDD) between March 1, 2013 and June 30, 2018, by Age Group (Years) and Sex

Sex	Age Group (Years)	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	New Episodes with an Event	Number of Exposed Members per 1,000 Eligible Members ¹	Years at Risk	Eligible Member Years ¹	Incidence Rate per 1,000 Years at Risk		Number of Events per Patient with an Event
											All Events		
Other	<12	0	0	0	0	0	0	.	0.0	0.0	.	0	.
	12-18	0	0	0	0	0	0	.	0.0	0.0	.	0	.
	19-24	0	0	0	0	0	0	.	0.0	0.0	.	0	.
	25-44	*****	*****	*****	30	30	0	200.00	0.1	5.2	0.00	0	.
	45-64	*****	*****	*****	210	240	0	57.14	0.7	50.8	0.00	0	.
	>=65	0	0	0	0	0	0	0.00	0.0	44.1	.	0	.
Incident Exposure and Prior Type 2 Diabetes Mellitus without History of Insulin Use													
Canagliflozin													
Female	<12	*****	*****	*****	240	240	0	2.25	0.7	302.5	0.00	0	.
	12-18	*****	*****	*****	615	720	0	2.07	1.9	4,109.3	0.00	0	.
	19-24	121	121	485	15,695	16,056	0	9.13	44.5	10,549.6	0.00	0	.
	25-44	6,461	6,461	26,131	867,096	936,079	*****	23.74	*****	315,012.5	7.70	*****	2.53
	45-64	31,658	31,658	147,443	5,190,718	5,532,707	*****	26.34	*****	1,859,118.5	3.38	*****	1.55
	>=65	38,996	38,996	151,088	5,976,401	6,241,980	68	14.32	16,621.7	5,583,728.9	4.09	154	2.26
Male	<12	0	0	0	0	0	0	0.00	0.0	176.4	.	0	.
	12-18	*****	*****	*****	1,160	1,160	0	4.06	3.1	1,895.4	0.00	0	.
	19-24	67	67	368	12,116	12,914	0	10.66	34.3	5,483.2	0.00	0	.
	25-44	7,962	7,962	36,134	1,216,115	1,310,066	*****	29.01	*****	330,898.3	2.90	*****	1.70
	45-64	*****	*****	*****	7,506,058	8,031,312	*****	29.73	*****	2,093,151.7	3.12	*****	1.54
	>=65	41,164	41,164	167,569	7,120,261	7,447,977	50	17.38	19,574.3	4,712,143.8	2.55	137	2.74
Other	<12	0	0	0	0	0	0	.	0.0	0.0	.	0	.
	12-18	0	0	0	0	0	0	.	0.0	0.0	.	0	.
	19-24	0	0	0	0	0	0	0.00	0.0	2.9	.	0	.
	25-44	0	0	0	0	0	0	0.00	0.0	22.2	.	0	.
	45-64	*****	*****	*****	1,604	1,604	0	28.78	4.3	273.7	0.00	0	.
	>=65	0	0	0	0	0	0	0.00	0.0	164.7	.	0	.

Table 2f. Summary of Diabetic Ketoacidosis Events after Incident Exposure to Canagliflozin, Dapagliflozin, Empagliflozin, or Sitagliptin in the Sentinel Distributed Database (SDD) between March 1, 2013 and June 30, 2018, by Age Group (Years) and Sex

Sex	Age Group (Years)	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	New Episodes with an Event	Number of Exposed Members per 1,000 Eligible Members ¹	Years at Risk	Eligible Member Years ¹	Incidence		Number of Events per Patient with an Event
											Rate per 1,000 Years at Risk	All Events	
Dapagliflozin													
Female	<12	0	0	0	0	0	0	0.00	0.0	302.5	.	0	.
	12-18	*****	*****	*****	476	476	0	1.03	1.4	4,109.6	0.00	0	.
	19-24	52	52	130	4,486	4,914	0	3.92	13.1	10,550.0	0.00	0	.
	25-44	2,359	2,359	7,603	247,601	261,678	*****	8.67	*****	315,330.4	4.21	*****	3.00
	45-64	*****	*****	*****	1,500,423	1,554,596	*****	9.28	*****	1,861,664.5	2.35	*****	1.40
	>=65	7,415	7,415	25,245	988,983	1,010,386	*****	2.72	*****	5,588,643.7	3.61	*****	2.10
Male	<12	0	0	0	0	0	0	0.00	0.0	176.4	.	0	.
	12-18	*****	*****	*****	625	625	0	3.16	1.8	1,895.5	0.00	0	.
	19-24	22	22	43	1,559	1,979	0	3.50	4.6	5,490.4	0.00	0	.
	25-44	2,948	2,948	10,796	354,476	374,254	*****	10.74	*****	331,136.9	0.98	*****	1.00
	45-64	*****	*****	*****	2,219,289	2,318,885	*****	10.58	*****	2,095,391.0	1.76	*****	1.09
	>=65	8,078	8,078	28,809	1,188,471	1,214,316	*****	3.41	*****	4,716,282.4	2.13	*****	2.57
Other	<12	0	0	0	0	0	0	.	0.0	0.0	.	0	.
	12-18	0	0	0	0	0	0	.	0.0	0.0	.	0	.
	19-24	0	0	0	0	0	0	0.00	0.0	2.9	.	0	.
	25-44	0	0	0	0	0	0	0.00	0.0	22.2	.	0	.
	45-64	*****	*****	*****	120	210	0	14.39	0.4	275.1	0.00	0	.
	>=65	0	0	0	0	0	0	0.00	0.0	164.7	.	0	.
Empagliflozin													
Female	<12	0	0	0	0	0	0	0.00	0.0	302.5	.	0	.
	12-18	*****	*****	*****	1,131	1,116	0	1.86	3.0	4,109.6	0.00	0	.
	19-24	48	48	123	4,008	4,128	0	3.62	11.4	10,553.8	0.00	0	.
	25-44	2,526	2,526	8,025	264,798	273,289	*****	9.28	*****	315,461.8	3.94	*****	1.33
	45-64	*****	*****	*****	1,722,132	1,779,870	16	10.92	4,823.8	1,862,474.1	3.32	24	1.50
	>=65	8,750	8,750	25,662	1,017,980	1,031,545	*****	3.21	*****	5,589,240.0	1.76	*****	3.80
Male	<12	0	0	0	0	0	0	0.00	0.0	176.4	.	0	.
	12-18	*****	*****	*****	598	637	0	2.26	1.7	1,895.5	0.00	0	.
	19-24	39	39	94	2,997	3,447	0	6.21	9.1	5,492.0	0.00	0	.
	25-44	3,451	3,451	12,062	403,286	420,553	*****	12.58	*****	331,266.1	4.35	*****	1.00
	45-64	*****	*****	*****	2,716,025	2,797,645	23	13.99	7,549.7	2,096,177.1	3.05	39	1.70
	>=65	10,981	10,981	34,165	1,435,091	1,454,105	*****	4.64	*****	4,716,830.3	2.27	*****	1.44

Table 2f. Summary of Diabetic Ketoacidosis Events after Incident Exposure to Canagliflozin, Dapagliflozin, Empagliflozin, or Sitagliptin in the Sentinel Distributed Database (SDD) between March 1, 2013 and June 30, 2018, by Age Group (Years) and Sex

Sex	Age Group (Years)	New Users	New Episodes	Dispensings	Days Supplied	Amount Supplied	New Episodes with an Event	Number of Exposed Members per 1,000 Eligible Members ¹	Years at Risk	Eligible Member Years ¹	Incidence Rate per 1,000 Years at Risk		Number of Events per Patient with an Event
											All Events		
Other	<12	0	0	0	0	0	0	.	0.0	0.0	.	0	.
	12-18	0	0	0	0	0	0	.	0.0	0.0	.	0	.
	19-24	0	0	0	0	0	0	0.00	0.0	2.9	.	0	.
	25-44	0	0	0	0	0	0	0.00	0.0	22.2	.	0	.
	45-64	*****	*****	*****	437	437	0	7.19	1.2	275.1	0.00	0	.
	>=65	0	0	0	0	0	0	0.00	0.0	164.7	.	0	.
Sitagliptin													
Female	<12	*****	*****	*****	90	166	0	4.51	0.3	297.2	0.00	0	.
	12-18	44	44	113	3,701	4,828	0	9.15	10.7	4,067.9	0.00	0	.
	19-24	269	269	805	27,224	33,601	*****	20.79	*****	10,097.7	13.05	*****	1.00
	25-44	*****	*****	*****	1,360,630	1,590,094	*****	40.76	*****	288,887.4	4.14	*****	1.50
	45-64	57,817	57,817	243,891	9,059,399	10,387,320	83	52.43	25,284.2	1,632,990.3	3.28	194	2.34
	>=65	140,790	140,790	628,867	24,161,842	26,391,182	219	58.15	66,899.4	4,679,687.6	3.27	432	1.97
Male	<12	*****	*****	*****	90	120	0	9.39	0.3	168.3	0.00	0	.
	12-18	24	24	73	2,366	2,927	0	10.96	7.0	1,863.9	0.00	0	.
	19-24	162	162	551	19,089	23,285	*****	27.03	*****	5,061.0	36.90	*****	1.00
	25-44	12,094	12,094	49,580	1,729,016	2,077,504	*****	47.69	*****	293,733.4	2.24	*****	1.45
	45-64	*****	*****	*****	10,872,655	12,557,232	50	52.90	30,302.9	1,814,680.8	1.65	74	1.48
	>=65	*****	*****	*****	21,113,312	23,313,536	128	57.59	58,260.8	3,940,054.5	2.20	237	1.85
Other	<12	0	0	0	0	0	0	.	0.0	0.0	.	0	.
	12-18	0	0	0	0	0	0	.	0.0	0.0	.	0	.
	19-24	0	0	0	0	0	0	0.00	0.0	0.2	.	0	.
	25-44	*****	*****	*****	120	120	0	71.43	0.4	16.0	0.00	0	.
	45-64	*****	*****	*****	810	810	0	62.02	2.4	234.0	0.00	0	.
	>=65	*****	*****	*****	1,410	1,769	0	50.63	3.2	123.0	0.00	0	.

¹Data not available for the T1DM subgroups

*****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 3. Summary of Follow-Up Time until Diabetic Ketoacidosis Events after Incident Exposure to Canagliflozin, Dapagliflozin, Empagliflozin, or Sitagliptin in the Sentinel Distributed Database (SDD) between March 1, 2013 and June 30, 2018, Overall

	Patients with an Event (N)	Mean (days)	Minimum (days)	Q1 (days)	Median (days)	Q3 (days)	Maximum (days)
Incident Exposure							
Canagliflozin	895	123	1	21	62	161	1,148
Dapagliflozin	161	109	1	18	54	131	907
Empagliflozin	181	84	1	10	36	131	780
Sitagliptin	1,420	133	1	22	61	159	1,327
Incident Exposure and Prior Type 1 Diabetes Mellitus							
Canagliflozin	57	133	3	25	77	170	572
Dapagliflozin	*****	99	5	23	64	197	214
Empagliflozin	11	156	26	93	157	215	273
Sitagliptin	18	102	3	15	35	120	795
Incident Exposure and Prior Type 1 Diabetes Mellitus - Broad Definition							
Canagliflozin	65	136	2	21	73	170	740
Dapagliflozin	*****	96	5	23	65	197	214
Empagliflozin	12	144	8	81	144	214	273
Sitagliptin	23	113	3	15	53	133	795
Incident Exposure and Prior Type 2 Diabetes Mellitus							
Canagliflozin	468	127	1	21	64	171	1,148
Dapagliflozin	77	136	3	26	57	160	907
Empagliflozin	108	93	1	10	35	139	780
Sitagliptin	761	150	1	28	69	186	1,327
Incident Exposure and Prior Type 2 Diabetes Mellitus with History of Insulin Use							
Canagliflozin	209	130	1	27	66	178	1,069
Dapagliflozin	35	157	3	28	99	215	844
Empagliflozin	47	90	2	20	49	143	472
Sitagliptin	252	132	1	26	63	159	916
Incident Exposure and Prior Type 2 Diabetes Mellitus without History of Insulin Use							
Canagliflozin	261	124	1	15	62	158	1,148
Dapagliflozin	42	119	4	22	57	116	907
Empagliflozin	61	95	1	8	34	135	780
Sitagliptin	510	159	1	28	72	225	1,327

*****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.

Appendix A. Start and End Dates for Data Partners (DP) in the Sentinel Distributed Database, as of Request Distribution Date (November 28, 2018)

Masked ID	DP Start Date	DP End Date
DP01	06/01/2007	01/31/2018
DP02	01/01/2000	10/31/2017
DP03	01/01/2000	06/30/2018
DP04	01/01/2008	03/31/2018
DP05	01/01/2006	12/31/2017
DP06	01/01/2000	12/31/2016
DP07	01/01/2008	09/30/2017
DP08	01/01/2010	12/31/2016
DP09	01/01/2005	12/17/2017
DP10	01/01/2000	03/31/2016
DP11	01/01/2000	05/31/2015
DP12	01/01/2000	03/31/2018
DP13	01/01/2000	12/31/2017
DP14	01/01/2000	06/30/2017
DP15	01/01/2004	05/31/2018
DP16	01/01/2000	03/31/2018
DP17	01/01/2012	06/30/2017

*Start Date and End Date are first calculated by individual table (enrollment, dispensing, etc). End Date is defined as the greatest year-month with a record count that is within 80% of the previous year-month. After Start Date and End Dates are calculated by individual tables, the overall DP End Date is the minimum of all the table End Dates.

Appendix B. List of Generic and Brand Names Used to Define Index-Defining Exposures

Generic Name	Brand Name
Canagliflozin	
canagliflozin/metformin HCl	Invokamet
canagliflozin/metformin HCl	Invokamet XR
canagliflozin	Invokana
Dapagliflozin	
dapagliflozin propanediol	Farxiga
dapagliflozin propanediol/saxagliptin HCl	Qtern
dapagliflozin propanediol/metformin HCl	Xigduo XR
Empagliflozin	
empagliflozin/linagliptin	Glyxambi
empagliflozin	Jardiance
empagliflozin/metformin HCl	Synjardy
empagliflozin/metformin HCl	Synjardy XR
Sitagliptin	
sitagliptin phosphate/metformin HCl	Janumet
sitagliptin phosphate/metformin HCl	Janumet XR
sitagliptin phosphate	Januvia
sitagliptin phosphate/simvastatin	Juvisync
ertugliflozin pidolate/sitagliptin phosphate	Steglujan

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) Diagnosis Codes and Healthcare Common Procedure Coding System (HCPCS) Codes Used to Define Inclusion and Exclusion Criteria in this Request

Code	Description	Code Type
Type 1 Diabetes Mellitus		
250.01	Diabetes mellitus without mention of complication, type I [juvenile type], not stated as uncontrolled	ICD-9-CM
250.03	Diabetes mellitus without mention of complication, type I [juvenile type], uncontrolled	ICD-9-CM
250.21	Diabetes with hyperosmolarity, type I [juvenile type], not stated as uncontrolled	ICD-9-CM
250.23	Diabetes with hyperosmolarity, type I [juvenile type], uncontrolled	ICD-9-CM
250.11	Diabetes with ketoacidosis, type I [juvenile type], not stated as uncontrolled	ICD-9-CM
250.13	Diabetes with ketoacidosis, type I [juvenile type], uncontrolled	ICD-9-CM
250.61	Diabetes with neurological manifestations, type I [juvenile type], not stated as uncontrolled	ICD-9-CM
250.63	Diabetes with neurological manifestations, type I [juvenile type], uncontrolled	ICD-9-CM
250.51	Diabetes with ophthalmic manifestations, type I [juvenile type], not stated as uncontrolled	ICD-9-CM
250.53	Diabetes with ophthalmic manifestations, type I [juvenile type], uncontrolled	ICD-9-CM
250.31	Diabetes with other coma, type I [juvenile type], not stated as uncontrolled	ICD-9-CM
250.33	Diabetes with other coma, type I [juvenile type], uncontrolled	ICD-9-CM
250.81	Diabetes with other specified manifestations, type I [juvenile type], not stated as uncontrolled	ICD-9-CM
250.83	Diabetes with other specified manifestations, type I [juvenile type], uncontrolled	ICD-9-CM
250.71	Diabetes with peripheral circulatory disorders, type I [juvenile type], not stated as uncontrolled	ICD-9-CM
250.73	Diabetes with peripheral circulatory disorders, type I [juvenile type], uncontrolled	ICD-9-CM
250.41	Diabetes with renal manifestations, type I [juvenile type], not stated as uncontrolled	ICD-9-CM
250.43	Diabetes with renal manifestations, type I [juvenile type], uncontrolled	ICD-9-CM
250.91	Diabetes with unspecified complication, type I [juvenile type], not stated as uncontrolled	ICD-9-CM
250.93	Diabetes with unspecified complication, type I [juvenile type], uncontrolled	ICD-9-CM
E10.3299	Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, unspecified eye	ICD-10-CM
E10.3319	Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema,	ICD-10-CM
E10.3499	Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema,	ICD-10-CM
E10.37	Type 1 diabetes mellitus with diabetic macular edema, resolved following treatment	ICD-10-CM
E10.37X9	Type 1 diabetes mellitus with diabetic macular edema, resolved following treatment, unspecified eye	ICD-10-CM
E10.3219	Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, unspecified eye	ICD-10-CM
E10.3213	Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, bilateral	ICD-10-CM
E10.3211	Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, right eye	ICD-10-CM
E10.3212	Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, left eye	ICD-10-CM
E10.3293	Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, bilateral	ICD-10-CM
E10.3291	Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, right eye	ICD-10-CM
E10.3292	Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, left eye	ICD-10-CM

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) Diagnosis Codes and Healthcare Common Procedure Coding System (HCPCS) Codes Used to Define Inclusion and Exclusion Criteria in this Request

Code	Description	Code Type
E10.3313	Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, bilateral	ICD-10-CM
E10.3311	Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, right eye	ICD-10-CM
E10.3312	Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, left eye	ICD-10-CM
E10.3399	Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema,	ICD-10-CM
E10.3393	Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema, bilateral	ICD-10-CM
E10.3391	Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema, right eye	ICD-10-CM
E10.3392	Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema, left eye	ICD-10-CM
E10.354	Type 1 diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment	ICD-10-CM
E10.3549	Type 1 diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, unspecified eye	ICD-10-CM
E10.3519	Type 1 diabetes mellitus with proliferative diabetic retinopathy with macular edema, unspecified eye	ICD-10-CM
E10.353	Type 1 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula	ICD-10-CM
E10.352	Type 1 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula	ICD-10-CM
E10.3529	Type 1 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, unspecified eye	ICD-10-CM
E10.3533	Type 1 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, bilateral	ICD-10-CM
E10.3531	Type 1 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, right eye	ICD-10-CM
E10.3532	Type 1 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, left eye	ICD-10-CM
E10.3539	Type 1 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, unspecified eye	ICD-10-CM
E10.3599	Type 1 diabetes mellitus with proliferative diabetic retinopathy without macular edema, unspecified eye	ICD-10-CM
E10.355	Type 1 diabetes mellitus with stable proliferative diabetic retinopathy	ICD-10-CM
E10.3419	Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, unspecified eye	ICD-10-CM
E10.3413	Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, bilateral	ICD-10-CM
E10.3411	Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, right eye	ICD-10-CM
E10.3412	Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, left eye	ICD-10-CM

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) Diagnosis Codes and Healthcare Common Procedure Coding System (HCPCS) Codes Used to Define Inclusion and Exclusion Criteria in this Request

Code	Description	Code Type
E10.3493	Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema, bilateral	ICD-10-CM
E10.3491	Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema, right eye	ICD-10-CM
E10.3492	Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema, left eye	ICD-10-CM
E10.39	Type 1 diabetes mellitus with other diabetic ophthalmic complication	ICD-10-CM
E10.35	Type 1 diabetes mellitus with proliferative diabetic retinopathy	ICD-10-CM
E10	Type 1 diabetes mellitus	ICD-10-CM
E10.37X3	Type 1 diabetes mellitus with diabetic macular edema, resolved following treatment, bilateral	ICD-10-CM
E10.37X1	Type 1 diabetes mellitus with diabetic macular edema, resolved following treatment, right eye	ICD-10-CM
E10.37X2	Type 1 diabetes mellitus with diabetic macular edema, resolved following treatment, left eye	ICD-10-CM
E10.3543	Type 1 diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, bilateral	ICD-10-CM
E10.3541	Type 1 diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, right eye	ICD-10-CM
E10.3542	Type 1 diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, left eye	ICD-10-CM
E10.3513	Type 1 diabetes mellitus with proliferative diabetic retinopathy with macular edema, bilateral	ICD-10-CM
E10.3511	Type 1 diabetes mellitus with proliferative diabetic retinopathy with macular edema, right eye	ICD-10-CM
E10.3512	Type 1 diabetes mellitus with proliferative diabetic retinopathy with macular edema, left eye	ICD-10-CM
E10.3523	Type 1 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, bilateral	ICD-10-CM
E10.3521	Type 1 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, right eye	ICD-10-CM
E10.3522	Type 1 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, left eye	ICD-10-CM
E10.3593	Type 1 diabetes mellitus with proliferative diabetic retinopathy without macular edema, bilateral	ICD-10-CM
E10.3591	Type 1 diabetes mellitus with proliferative diabetic retinopathy without macular edema, right eye	ICD-10-CM
E10.3592	Type 1 diabetes mellitus with proliferative diabetic retinopathy without macular edema, left eye	ICD-10-CM
E10.3553	Type 1 diabetes mellitus with stable proliferative diabetic retinopathy, bilateral	ICD-10-CM
E10.3552	Type 1 diabetes mellitus with stable proliferative diabetic retinopathy, left eye	ICD-10-CM
E10.3551	Type 1 diabetes mellitus with stable proliferative diabetic retinopathy, right eye	ICD-10-CM
E10.3559	Type 1 diabetes mellitus with stable proliferative diabetic retinopathy, unspecified eye	ICD-10-CM
E10.5	Type 1 diabetes mellitus with circulatory complications	ICD-10-CM
E10.22	Type 1 diabetes mellitus with diabetic chronic kidney disease	ICD-10-CM
E10.41	Type 1 diabetes mellitus with diabetic mononeuropathy	ICD-10-CM
E10.40	Type 1 diabetes mellitus with diabetic neuropathy, unspecified	ICD-10-CM
E10.42	Type 1 diabetes mellitus with diabetic polyneuropathy	ICD-10-CM
E10.44	Type 1 diabetes mellitus with diabetic amyotrophy	ICD-10-CM
E10.61	Type 1 diabetes mellitus with diabetic arthropathy	ICD-10-CM
E10.36	Type 1 diabetes mellitus with diabetic cataract	ICD-10-CM
E10.620	Type 1 diabetes mellitus with diabetic dermatitis	ICD-10-CM

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) Diagnosis Codes and Healthcare Common Procedure Coding System (HCPCS) Codes Used to Define Inclusion and Exclusion Criteria in this Request

Code	Description	Code Type
E10.21	Type 1 diabetes mellitus with diabetic nephropathy	ICD-10-CM
E10.641	Type 1 diabetes mellitus with hypoglycemia with coma	ICD-10-CM
E10.649	Type 1 diabetes mellitus with hypoglycemia without coma	ICD-10-CM
E10.11	Type 1 diabetes mellitus with ketoacidosis with coma	ICD-10-CM
E10.10	Type 1 diabetes mellitus with ketoacidosis without coma	ICD-10-CM
E10.2	Type 1 diabetes mellitus with kidney complications	ICD-10-CM
E10.4	Type 1 diabetes mellitus with neurological complications	ICD-10-CM
E10.3	Type 1 diabetes mellitus with ophthalmic complications	ICD-10-CM
E10.59	Type 1 diabetes mellitus with other circulatory complications	ICD-10-CM
E10.618	Type 1 diabetes mellitus with other diabetic arthropathy	ICD-10-CM
E10.29	Type 1 diabetes mellitus with other diabetic kidney complication	ICD-10-CM
E10.638	Type 1 diabetes mellitus with other oral complications	ICD-10-CM
E10.628	Type 1 diabetes mellitus with other skin complications	ICD-10-CM
E10.69	Type 1 diabetes mellitus with other specified complication	ICD-10-CM
E10.6	Type 1 diabetes mellitus with other specified complications	ICD-10-CM
E10.630	Type 1 diabetes mellitus with periodontal disease	ICD-10-CM
E10.31	Type 1 diabetes mellitus with unspecified diabetic retinopathy	ICD-10-CM
E10.8	Type 1 diabetes mellitus with unspecified complications	ICD-10-CM
E10.621	Type 1 diabetes mellitus with foot ulcer	ICD-10-CM
E10.65	Type 1 diabetes mellitus with hyperglycemia	ICD-10-CM
E10.64	Type 1 diabetes mellitus with hypoglycemia	ICD-10-CM
E10.1	Type 1 diabetes mellitus with ketoacidosis	ICD-10-CM
E10.63	Type 1 diabetes mellitus with oral complications	ICD-10-CM
E10.622	Type 1 diabetes mellitus with other skin ulcer	ICD-10-CM
E10.62	Type 1 diabetes mellitus with skin complications	ICD-10-CM
E10.9	Type 1 diabetes mellitus without complications	ICD-10-CM
E10.329	Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema	ICD-10-CM
E10.52	Type 1 diabetes mellitus with diabetic peripheral angiopathy with gangrene	ICD-10-CM
E10.51	Type 1 diabetes mellitus with diabetic peripheral angiopathy without gangrene	ICD-10-CM
E10.43	Type 1 diabetes mellitus with diabetic autonomic (poly)neuropathy	ICD-10-CM
E10.610	Type 1 diabetes mellitus with diabetic neuropathic arthropathy	ICD-10-CM
E10.321	Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema	ICD-10-CM
E10.32	Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy	ICD-10-CM
E10.339	Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema	ICD-10-CM
E10.331	Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema	ICD-10-CM
E10.33	Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy	ICD-10-CM
E10.49	Type 1 diabetes mellitus with other diabetic neurological complication	ICD-10-CM
E10.351	Type 1 diabetes mellitus with proliferative diabetic retinopathy with macular edema	ICD-10-CM
E10.349	Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema	ICD-10-CM
E10.341	Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema	ICD-10-CM
E10.34	Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy	ICD-10-CM

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) Diagnosis Codes and Healthcare Common Procedure Coding System (HCPCS) Codes Used to Define Inclusion and Exclusion Criteria in this Request

Code	Description	Code Type
E10.319	Type 1 diabetes mellitus with unspecified diabetic retinopathy without macular edema	ICD-10-CM
E10.311	Type 1 diabetes mellitus with unspecified diabetic retinopathy with macular edema	ICD-10-CM
E10.359	Type 1 diabetes mellitus with proliferative diabetic retinopathy without macular edema	ICD-10-CM
Type 2 Diabetes Mellitus		
250.00	Diabetes mellitus without mention of complication, type II or unspecified type, not stated as uncontrolled	ICD-9-CM
250.02	Diabetes mellitus without mention of complication, type II or unspecified type, uncontrolled	ICD-9-CM
250.20	Diabetes with hyperosmolarity, type II or unspecified type, not stated as uncontrolled	ICD-9-CM
250.22	Diabetes with hyperosmolarity, type II or unspecified type, uncontrolled	ICD-9-CM
250.10	Diabetes with ketoacidosis, type II or unspecified type, not stated as uncontrolled	ICD-9-CM
250.12	Diabetes with ketoacidosis, type II or unspecified type, uncontrolled	ICD-9-CM
250.60	Diabetes with neurological manifestations, type II or unspecified type, not stated as uncontrolled	ICD-9-CM
250.62	Diabetes with neurological manifestations, type II or unspecified type, uncontrolled	ICD-9-CM
250.50	Diabetes with ophthalmic manifestations, type II or unspecified type, not stated as uncontrolled	ICD-9-CM
250.52	Diabetes with ophthalmic manifestations, type II or unspecified type, uncontrolled	ICD-9-CM
250.30	Diabetes with other coma, type II or unspecified type, not stated as uncontrolled	ICD-9-CM
250.32	Diabetes with other coma, type II or unspecified type, uncontrolled	ICD-9-CM
250.80	Diabetes with other specified manifestations, type II or unspecified type, not stated as uncontrolled	ICD-9-CM
250.82	Diabetes with other specified manifestations, type II or unspecified type, uncontrolled	ICD-9-CM
250.70	Diabetes with peripheral circulatory disorders, type II or unspecified type, not stated as uncontrolled	ICD-9-CM
250.72	Diabetes with peripheral circulatory disorders, type II or unspecified type, uncontrolled	ICD-9-CM
250.40	Diabetes with renal manifestations, type II or unspecified type, not stated as uncontrolled	ICD-9-CM
250.42	Diabetes with renal manifestations, type II or unspecified type, uncontrolled	ICD-9-CM
250.90	Diabetes with unspecified complication, type II or unspecified type, not stated as uncontrolled	ICD-9-CM
250.92	Diabetes with unspecified complication, type II or unspecified type, uncontrolled	ICD-9-CM
E11.3539	Type 2 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, unspecified eye	ICD-10-CM
E11.37X9	Type 2 diabetes mellitus with diabetic macular edema, resolved following treatment, unspecified eye	ICD-10-CM
E11.37	Type 2 diabetes mellitus with diabetic macular edema, resolved following treatment	ICD-10-CM
E11.3219	Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, unspecified eye	ICD-10-CM
E11.354	Type 2 diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment	ICD-10-CM
E11.3549	Type 2 diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, unspecified eye	ICD-10-CM
E11.353	Type 2 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula	ICD-10-CM
E11.352	Type 2 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula	ICD-10-CM
E11.3529	Type 2 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, unspecified eye	ICD-10-CM

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) Diagnosis Codes and Healthcare Common Procedure Coding System (HCPCS) Codes Used to Define Inclusion and Exclusion Criteria in this Request

Code	Description	Code Type
E11.3533	Type 2 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, bilateral	ICD-10-CM
E11.3531	Type 2 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, right eye	ICD-10-CM
E11.3532	Type 2 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, left eye	ICD-10-CM
E11.355	Type 2 diabetes mellitus with stable proliferative diabetic retinopathy	ICD-10-CM
E11.01	Type 2 diabetes mellitus with hyperosmolarity with coma	ICD-10-CM
E11	Type 2 diabetes mellitus	ICD-10-CM
E11.37X3	Type 2 diabetes mellitus with diabetic macular edema, resolved following treatment, bilateral	ICD-10-CM
E11.37X1	Type 2 diabetes mellitus with diabetic macular edema, resolved following treatment, right eye	ICD-10-CM
E11.37X2	Type 2 diabetes mellitus with diabetic macular edema, resolved following treatment, left eye	ICD-10-CM
E11.3213	Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, bilateral	ICD-10-CM
E11.3211	Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, right eye	ICD-10-CM
E11.3212	Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema, left eye	ICD-10-CM
E11.3293	Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, bilateral	ICD-10-CM
E11.3291	Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, right eye	ICD-10-CM
E11.3292	Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, left eye	ICD-10-CM
E11.3299	Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema, unspecified eye	ICD-10-CM
E11.3319	Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, unspecified eye	ICD-10-CM
E11.3313	Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, bilateral	ICD-10-CM
E11.3311	Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, right eye	ICD-10-CM
E11.3312	Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema, left eye	ICD-10-CM
E11.3393	Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema, bilateral	ICD-10-CM
E11.3391	Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema, right eye	ICD-10-CM
E11.3392	Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema, left eye	ICD-10-CM
E11.3399	Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema, unspecified eye	ICD-10-CM
E11.39	Type 2 diabetes mellitus with other diabetic ophthalmic complication	ICD-10-CM

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Code	Description	Code Type
E11.3543	Type 2 diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, bilateral	ICD-10-CM
E11.3541	Type 2 diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, right eye	ICD-10-CM
E11.3542	Type 2 diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, left eye	ICD-10-CM
E11.3519	Type 2 diabetes mellitus with proliferative diabetic retinopathy with macular edema, unspecified eye	ICD-10-CM
E11.3513	Type 2 diabetes mellitus with proliferative diabetic retinopathy with macular edema, bilateral	ICD-10-CM
E11.3511	Type 2 diabetes mellitus with proliferative diabetic retinopathy with macular edema, right eye	ICD-10-CM
E11.3512	Type 2 diabetes mellitus with proliferative diabetic retinopathy with macular edema, left eye	ICD-10-CM
E11.3523	Type 2 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, bilateral	ICD-10-CM
E11.3521	Type 2 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, right eye	ICD-10-CM
E11.3522	Type 2 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula, left eye	ICD-10-CM
E11.3599	Type 2 diabetes mellitus with proliferative diabetic retinopathy without macular edema, unspecified eye	ICD-10-CM
E11.3593	Type 2 diabetes mellitus with proliferative diabetic retinopathy without macular edema, bilateral	ICD-10-CM
E11.3591	Type 2 diabetes mellitus with proliferative diabetic retinopathy without macular edema, right eye	ICD-10-CM
E11.3592	Type 2 diabetes mellitus with proliferative diabetic retinopathy without macular edema, left eye	ICD-10-CM
E11.3553	Type 2 diabetes mellitus with stable proliferative diabetic retinopathy, bilateral	ICD-10-CM
E11.3552	Type 2 diabetes mellitus with stable proliferative diabetic retinopathy, left eye	ICD-10-CM
E11.3551	Type 2 diabetes mellitus with stable proliferative diabetic retinopathy, right eye	ICD-10-CM
E11.3559	Type 2 diabetes mellitus with stable proliferative diabetic retinopathy, unspecified eye	ICD-10-CM
E11.3419	Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, unspecified eye	ICD-10-CM
E11.3413	Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, bilateral	ICD-10-CM
E11.3411	Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, right eye	ICD-10-CM
E11.3412	Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema, left eye	ICD-10-CM
E11.3493	Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema, bilateral	ICD-10-CM
E11.3491	Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema, right eye	ICD-10-CM
E11.3492	Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema, left eye	ICD-10-CM
E11.3499	Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema, unspecified eye	ICD-10-CM
E11.5	Type 2 diabetes mellitus with circulatory complications	ICD-10-CM
E11.22	Type 2 diabetes mellitus with diabetic chronic kidney disease	ICD-10-CM

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Code	Description	Code Type
E11.41	Type 2 diabetes mellitus with diabetic mononeuropathy	ICD-10-CM
E11.42	Type 2 diabetes mellitus with diabetic polyneuropathy	ICD-10-CM
E11.44	Type 2 diabetes mellitus with diabetic amyotrophy	ICD-10-CM
E11.61	Type 2 diabetes mellitus with diabetic arthropathy	ICD-10-CM
E11.620	Type 2 diabetes mellitus with diabetic dermatitis	ICD-10-CM
E11.21	Type 2 diabetes mellitus with diabetic nephropathy	ICD-10-CM
E11.641	Type 2 diabetes mellitus with hypoglycemia with coma	ICD-10-CM
E11.649	Type 2 diabetes mellitus with hypoglycemia without coma	ICD-10-CM
E11.10	Type 2 diabetes mellitus with ketoacidosis without coma	ICD-10-CM
E11.2	Type 2 diabetes mellitus with kidney complications	ICD-10-CM
E11.4	Type 2 diabetes mellitus with neurological complications	ICD-10-CM
E11.3	Type 2 diabetes mellitus with ophthalmic complications	ICD-10-CM
E11.59	Type 2 diabetes mellitus with other circulatory complications	ICD-10-CM
E11.618	Type 2 diabetes mellitus with other diabetic arthropathy	ICD-10-CM
E11.29	Type 2 diabetes mellitus with other diabetic kidney complication	ICD-10-CM
E11.49	Type 2 diabetes mellitus with other diabetic neurological complication	ICD-10-CM
E11.638	Type 2 diabetes mellitus with other oral complications	ICD-10-CM
E11.628	Type 2 diabetes mellitus with other skin complications	ICD-10-CM
E11.69	Type 2 diabetes mellitus with other specified complication	ICD-10-CM
E11.6	Type 2 diabetes mellitus with other specified complications	ICD-10-CM
E11.630	Type 2 diabetes mellitus with periodontal disease	ICD-10-CM
E11.8	Type 2 diabetes mellitus with unspecified complications	ICD-10-CM
E11.31	Type 2 diabetes mellitus with unspecified diabetic retinopathy	ICD-10-CM
E11.36	Type 2 diabetes mellitus with diabetic cataract	ICD-10-CM
E11.621	Type 2 diabetes mellitus with foot ulcer	ICD-10-CM
E11.65	Type 2 diabetes mellitus with hyperglycemia	ICD-10-CM
E11.0	Type 2 diabetes mellitus with hyperosmolarity	ICD-10-CM
E11.64	Type 2 diabetes mellitus with hypoglycemia	ICD-10-CM
E11.1	Type 2 diabetes mellitus with ketoacidosis	ICD-10-CM
E11.11	Type 2 diabetes mellitus with ketoacidosis with coma	ICD-10-CM
E11.63	Type 2 diabetes mellitus with oral complications	ICD-10-CM
E11.622	Type 2 diabetes mellitus with other skin ulcer	ICD-10-CM
E11.62	Type 2 diabetes mellitus with skin complications	ICD-10-CM
E11.9	Type 2 diabetes mellitus without complications	ICD-10-CM
E11.359	Type 2 diabetes mellitus with proliferative diabetic retinopathy without macular edema	ICD-10-CM
E11.52	Type 2 diabetes mellitus with diabetic peripheral angiopathy with gangrene	ICD-10-CM
E11.51	Type 2 diabetes mellitus with diabetic peripheral angiopathy without gangrene	ICD-10-CM
E11.43	Type 2 diabetes mellitus with diabetic autonomic (poly)neuropathy	ICD-10-CM
E11.610	Type 2 diabetes mellitus with diabetic neuropathic arthropathy	ICD-10-CM
E11.00	Type 2 diabetes mellitus with hyperosmolarity without nonketotic hyperglycemic-hyperosmolar coma (NKHHC)	ICD-10-CM
E11.321	Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema	ICD-10-CM
E11.329	Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema	ICD-10-CM
E11.32	Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy	ICD-10-CM

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) Diagnosis Codes and Healthcare Common Procedure Coding System (HCPCS) Codes Used to Define Inclusion and Exclusion Criteria in this Request

Code	Description	Code Type
E11.331	Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema	ICD-10-CM
E11.33	Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy	ICD-10-CM
E11.339	Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema	ICD-10-CM
E11.351	Type 2 diabetes mellitus with proliferative diabetic retinopathy with macular edema	ICD-10-CM
E11.35	Type 2 diabetes mellitus with proliferative diabetic retinopathy	ICD-10-CM
E11.349	Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema	ICD-10-CM
E11.341	Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema	ICD-10-CM
E11.34	Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy	ICD-10-CM
E11.319	Type 2 diabetes mellitus with unspecified diabetic retinopathy without macular edema	ICD-10-CM
E11.311	Type 2 diabetes mellitus with unspecified diabetic retinopathy with macular edema	ICD-10-CM
E11.40	Type 2 diabetes mellitus with diabetic neuropathy, unspecified	ICD-10-CM
Insulin Pumps		
A4230	Infusion set for external insulin pump, nonneedle cannula type	HCPCS
A4231	Infusion set for external insulin pump, needle type	HCPCS
A4232	Syringe with needle for external insulin pump, sterile, 3 cc	HCPCS
E0784	External ambulatory infusion pump, insulin	HCPCS
A4225	Supplies for external insulin infusion pump, syringe type cartridge, sterile, each	HCPCS
J1817	Insulin for administration through DME (i.e., insulin pump) per 50 units	HCPCS
S5565	Insulin cartridge for use in insulin delivery device other than pump; 150 units	HCPCS
S5566	Insulin cartridge for use in insulin delivery device other than pump; 300 units	HCPCS
S9145	Insulin pump initiation, instruction in initial use of pump (pump not included)	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	HCPCS
E0784	External ambulatory infusion pump, insulin	HCPCS

Appendix C.1. List of Generic and Brand Names Used to Define Inclusion and Exclusion Criteria for Index-Defining Events

Generic Name	Brand Name
Oral Anti-Diabetics	
alogliptin benzoate	alogliptin
alogliptin benzoate/metformin HCl	alogliptin-metformin
empagliflozin/linagliptin	Glyxambi
sitagliptin phosphate/metformin HCl	Janumet
sitagliptin phosphate/metformin HCl	Janumet XR
sitagliptin phosphate	Januvia
linagliptin/metformin HCl	Jentadueto
linagliptin/metformin HCl	Jentadueto XR
sitagliptin phosphate/simvastatin	Juvisync
alogliptin benzoate/metformin HCl	Kazano
saxagliptin HCl/metformin HCl	Kombiglyze XR
alogliptin benzoate	Nesina
saxagliptin HCl	Onglyza
dapagliflozin propanediol/saxagliptin HCl	Qtern
ertugliflozin pidolate/sitagliptin phosphate	Steglujan
linagliptin	Tradjenta
pioglitazone HCl/metformin HCl	Actoplus MET
pioglitazone HCl/metformin HCl	Actoplus Met XR
pioglitazone HCl	Actos
alogliptin benzoate/pioglitazone HCl	alogliptin-pioglitazone
rosiglitazone maleate/metformin HCl	Avandamet
rosiglitazone maleate/glimepiride	Avandaryl
rosiglitazone maleate	Avandia
pioglitazone HCl/glimepiride	DUETACT
alogliptin benzoate/pioglitazone HCl	Oseni
pioglitazone HCl	pioglitazone
pioglitazone HCl/glimepiride	pioglitazone-glimepiride
pioglitazone HCl/metformin HCl	pioglitazone-metformin
glimepiride	Amaryl
chlorpropamide	chlorpropamide
glyburide	Diabeta
glimepiride	glimepiride
glipizide	glipizide
glipizide	glipizide
glipizide/metformin HCl	glipizide-metformin
glipizide	Glucotrol
glipizide	Glucotrol XL
glyburide/metformin HCl	Glucovance
glyburide	glyburide
glyburide/metformin HCl	glyburide-metformin
glyburide,micronized	glyburide micronized
glyburide,micronized	Glynase
tolazamide	tolazamide
tolbutamide	tolbutamide
acarbose	acarbose

Appendix C.1. List of Generic and Brand Names Used to Define Inclusion and Exclusion Criteria for Index-Defining Events

Generic Name	Brand Name
miglitol	Glyset
miglitol	miglitol
acarbose	Precose
metformin HCl/blood sugar diagnostic	DM2
metformin HCl	Fortamet
metformin HCl	Glucophage
metformin HCl	Glucophage XR
metformin HCl	Glumetza
canagliflozin/metformin HCl	Invokamet
canagliflozin/metformin HCl	Invokamet XR
metformin HCl	metformin
metformin HCl	metformin (bulk)
repaglinide/metformin HCl	Prandimet
repaglinide/metformin HCl	repaglinide-metformin
metformin HCl	Riomet
ertugliflozin pidolate/metformin HCl	Segluromet
empagliflozin/metformin HCl	Synjardy
empagliflozin/metformin HCl	Synjardy XR
dapagliflozin propanediol/metformin HCl	Xigduo XR
nateglinide	nateglinide
repaglinide	Prandin
repaglinide	repaglinide
nateglinide	Starlix
dapagliflozin propanediol	Farxiga
canagliflozin	Invokana
empagliflozin	Jardiance
ertugliflozin pidolate	Steglatro
Short-/Rapid-Acting Insulin	
insulin lispro	Admelog SoloStar U-100 Insulin
insulin lispro	Admelog U-100 Insulin lispro
insulin regular, human	Afrezza
insulin glulisine	Apidra SoloStar U-100 Insulin
insulin glulisine	Apidra U-100 Insulin
insulin aspart (niacinamide)	Fiasp FlexTouch U-100 Insulin
insulin aspart (niacinamide)	Fiasp U-100 Insulin
insulin lispro	Humalog Junior KwikPen U-100
insulin lispro	Humalog KwikPen Insulin
insulin lispro	Humalog U-100 Insulin
insulin regular, human	Humulin R Regular U-100 Insulin
insulin regular, human	Humulin R U-500 (Conc) Insulin
insulin regular, human	Humulin R U-500 (Conc) Kwikpen
insulin regular, human	Novolin R Regular 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 lispro protamine and insulin lispro	Humalog Mix 50-50 Insulin U-100

Appendix C.1. List of Generic and Brand Names Used to Define Inclusion and Exclusion Criteria for Index-Defining Events

Generic Name	Brand Name
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
Long-/Intermediate-Acting Insulin	
insulin glargine,human recombinant analog	Basaglar KwikPen 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	Humulin N NPH Insulin KwikPen
insulin NPH human isophane	Humulin N NPH U-100 Insulin
insulin NPH human isophane	Humulin N Pen
insulin glargine,human recombinant analog	Lantus Solostar U-100 Insulin
insulin glargine,human recombinant analog	Lantus U-100 Insulin
insulin detemir	Levemir Flexpen
insulin detemir	Levemir FlexTouch U-100 Insuln
insulin detemir	Levemir U-100 Insulin
insulin NPH human isophane/insulin regular, human	Novolin 70/30 U-100 Insulin
insulin NPH human isophane	Novolin N NPH 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 glargine,human recombinant analog	Toujeo Max U-300 SoloStar
insulin glargine,human recombinant analog	Toujeo SoloStar U-300 Insulin
insulin degludec	Tresiba FlexTouch U-100
insulin degludec	Tresiba FlexTouch U-200

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

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

Appendix E. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) and International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) Diagnosis Codes and Healthcare Common Procedure Coding System (HCPCS) Procedure Codes Used to Define Characteristics in this Request

Code	Description	Code Type
Insulin Pumps		
A4230	Infusion set for external insulin pump, nonneedle cannula type	HCPCS
A4231	Infusion set for external insulin pump, needle type	HCPCS
A4232	Syringe with needle for external insulin pump, sterile, 3 cc	HCPCS
E0784	External ambulatory infusion pump, insulin	HCPCS
A4225	Supplies for external insulin infusion pump, syringe type cartridge, sterile, each	HCPCS
J1817	Insulin for administration through DME (i.e., insulin pump) per 50 units	HCPCS
S5565	Insulin cartridge for use in insulin delivery device other than pump; 150 units	HCPCS
S5566	Insulin cartridge for use in insulin delivery device other than pump; 300 units	HCPCS
S9145	Insulin pump initiation, instruction in initial use of pump (pump not included)	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	HCPCS
E0784	External ambulatory infusion pump, insulin	HCPCS
Diabetic Ketoacidosis		
250.11	Diabetes with ketoacidosis, type I [juvenile type], not stated as uncontrolled	ICD-9-CM
250.13	Diabetes with ketoacidosis, type I [juvenile type], uncontrolled	ICD-9-CM
250.10	Diabetes with ketoacidosis, type II or unspecified type, not stated as uncontrolled	ICD-9-CM
250.12	Diabetes with ketoacidosis, type II or unspecified type, uncontrolled	ICD-9-CM
E13.11	Other specified diabetes mellitus with ketoacidosis with coma	ICD-10-CM
E13.10	Other specified diabetes mellitus with ketoacidosis without coma	ICD-10-CM
E10.11	Type 1 diabetes mellitus with ketoacidosis with coma	ICD-10-CM
E10.10	Type 1 diabetes mellitus with ketoacidosis without coma	ICD-10-CM
E11.10	Type 2 diabetes mellitus with ketoacidosis without coma	ICD-10-CM
E11.11	Type 2 diabetes mellitus with ketoacidosis with coma	ICD-10-CM

Appendix E.1. Generic and Brand Drug Names Used to Define Characteristics in this Request

Generic Name	Brand Name
Anti-Diabetics	
alogliptin benzoate	alogliptin
alogliptin benzoate/metformin HCl	alogliptin-metformin
empagliflozin/linagliptin	Glyxambi
sitagliptin phosphate/metformin HCl	Janumet
sitagliptin phosphate/metformin HCl	Janumet XR
sitagliptin phosphate	Januvia
linagliptin/metformin HCl	Jentadueto
linagliptin/metformin HCl	Jentadueto XR
sitagliptin phosphate/simvastatin	Juvisync
alogliptin benzoate/metformin HCl	Kazano
saxagliptin HCl/metformin HCl	Kombiglyze XR
alogliptin benzoate	Nesina
saxagliptin HCl	Onglyza
dapagliflozin propanediol/saxagliptin HCl	Qtern
ertugliflozin pidolate/sitagliptin phosphate	Steglujan
linagliptin	Tradjenta
pioglitazone HCl/metformin HCl	Actoplus MET
pioglitazone HCl/metformin HCl	Actoplus Met XR
pioglitazone HCl	Actos
alogliptin benzoate/pioglitazone HCl	alogliptin-pioglitazone
rosiglitazone maleate/metformin HCl	Avandamet
rosiglitazone maleate/glimepiride	Avandaryl
rosiglitazone maleate	Avandia
pioglitazone HCl/glimepiride	DUETACT
alogliptin benzoate/pioglitazone HCl	Oseni
pioglitazone HCl	pioglitazone
pioglitazone HCl/glimepiride	pioglitazone-glimepiride
pioglitazone HCl/metformin HCl	pioglitazone-metformin
glimepiride	Amaryl
chlorpropamide	chlorpropamide
glyburide	Diabeta
glimepiride	glimepiride
glipizide	glipizide
glipizide/metformin HCl	glipizide-metformin
glipizide	Glucotrol
glipizide	Glucotrol XL
glyburide/metformin HCl	Glucovance
glyburide	glyburide
glyburide/metformin HCl	glyburide-metformin
glyburide,micronized	glyburide micronized
glyburide,micronized	Glynase
tolazamide	tolazamide
tolbutamide	tolbutamide
acarbose	acarbose
miglitol	Glyset

Appendix E.1. Generic and Brand Drug Names Used to Define Characteristics in this Request

Generic Name	Brand Name
miglitol	miglitol
acarbose	Precose
metformin HCl/blood sugar diagnostic	DM2
metformin HCl	Fortamet
metformin HCl	Glucophage
metformin HCl	Glucophage XR
metformin HCl	Glumetza
canagliflozin/metformin HCl	Invokamet
canagliflozin/metformin HCl	Invokamet XR
metformin HCl	metformin
metformin HCl	metformin (bulk)
repaglinide/metformin HCl	Prandimet
repaglinide/metformin HCl	repaglinide-metformin
metformin HCl	Riomet
ertugliflozin pidolate/metformin HCl	Segluromet
empagliflozin/metformin HCl	Synjardy
empagliflozin/metformin HCl	Synjardy XR
dapagliflozin propanediol/metformin HCl	Xigduo XR
lixisenatide	Adlyxin
exenatide microspheres	Bydureon
exenatide microspheres	Bydureon BCise
exenatide	Byetta
semaglutide	Ozempic
insulin glargine, human recombinant analog/lixisenatide	Soliqua 100/33
albiglutide	Tanzeum
dulaglutide	Trulicity
liraglutide	Victoza 2-Pak
liraglutide	Victoza 3-Pak
insulin degludec/liraglutide	Xultophy 100/3.6
nateglinide	nateglinide
repaglinide	Prandin
repaglinide	repaglinide
nateglinide	Starlix
dapagliflozin propanediol	Farxiga
canagliflozin	Invokana
empagliflozin	Jardiance
ertugliflozin pidolate	Steglatro
insulin lispro	Admelog SoloStar U-100 Insulin
insulin lispro	Admelog U-100 Insulin lispro
insulin regular, human	Afrezza
insulin glulisine	Apidra SoloStar U-100 Insulin
insulin glulisine	Apidra U-100 Insulin
insulin aspart (niacinamide)	Fiasp FlexTouch U-100 Insulin
insulin aspart (niacinamide)	Fiasp U-100 Insulin
insulin lispro	Humalog Junior KwikPen U-100
insulin lispro	Humalog KwikPen Insulin

Appendix E.1. Generic and Brand Drug Names Used to Define Characteristics in this Request

Generic Name	Brand Name
insulin lispro	Humalog U-100 Insulin
insulin regular, human	Humulin R Regular U-100 Insulin
insulin regular, human	Humulin R U-500 (Conc) Insulin
insulin regular, human	Humulin R U-500 (Conc) Kwikpen
insulin regular, human	Novolin R Regular 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 lispro protamine and insulin lispro	Humalog Mix 50-50 Insulin U-100
insulin lispro protamine and insulin lispro	Humalog Mix 50-50 KwikPen
insulin lispro protamine and insulin lispro	Humalog Mix 75-25 KwikPen
insulin lispro protamine and insulin lispro	Humalog Mix 75-25(U-100)Insulin
insulin glargine,human recombinant analog	Basaglar KwikPen 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	Humulin N NPH Insulin KwikPen
insulin NPH human isophane	Humulin N NPH U-100 Insulin
insulin NPH human isophane	Humulin N Pen
insulin glargine,human recombinant analog	Lantus Solostar U-100 Insulin
insulin glargine,human recombinant analog	Lantus U-100 Insulin
insulin detemir	Levemir Flexpen
insulin detemir	Levemir FlexTouch U-100 Insulin
insulin detemir	Levemir U-100 Insulin
insulin NPH human isophane/insulin regular, human	Novolin 70/30 U-100 Insulin
insulin NPH human isophane	Novolin N NPH U-100 Insulin
insulin aspart protamine human/insulin aspart	Novolog Mix 70-30 U-100 Insulin
insulin aspart protamine human/insulin aspart	Novolog Mix 70-30FlexPen U-100
insulin glargine,human recombinant analog	Toujeo Max U-300 SoloStar
insulin glargine,human recombinant analog	Toujeo SoloStar U-300 Insulin
insulin degludec	Tresiba FlexTouch U-100
insulin degludec	Tresiba FlexTouch U-200

Appendix F.1. Specifications Defining Exposure Parameters for this Request

This request executed the Cohort Identification and Descriptive Analysis (CIDA) module, version 6.0.0 to estimate rates of SGLT-2 Inhibitor use with prior Type 1 or Type 2 Diabetes and Diabetic Ketoacidosis events in the Sentinel Distributed Database (SDD).

Query period: March 1, 2013 -June 30, 2018
Coverage requirement: Medical & Drug Coverage
Pre-index enrollment requirement: 365 days
Age groups: <12, 12-18, 19-24, 25-44, 45-64, 65+ years
Stratifications: Age group, Sex, Calendar year, Age group * Sex, Age group * Calendar year

Exposure

Scenario	Index Exposure	Cohort definition	Incident exposure washout period	Incident with respect to:	Treatment episode gap	Exposure episode extension	Minimum exposure episode duration	Minimum days supplied	Maximum exposure episode duration	Censor treatment episode at evidence of:
1	Canagliflozin (Includes combination meds)	First valid exposure episodes during query period	365	Canagliflozin Dapagliflozin Empagliflozin Ertugliflozin (include SGLT-2/DPP-4i combos)	10 days	10 days	0	0	0	*Death; *DP end date; *Query end date; *Occurrence of a DKA event
2	Dapagliflozin (includes combination meds)	First valid exposure episodes during query period	365	Canagliflozin Dapagliflozin Empagliflozin Ertugliflozin (include SGLT-2/DPP-4i combos)	10 days	10 days	0	0	0	*Death; *DP end date; *Query end date; *Occurrence of a DKA event
3	Empagliflozin (includes combination meds)	First valid exposure episodes during query period	365	Canagliflozin Dapagliflozin Empagliflozin Ertugliflozin (include SGLT-2/DPP-4i combos)	10 days	10 days	0	0	0	*Death; *DP end date; *Query end date; *Occurrence of a DKA event

Appendix F.1. Specifications Defining Exposure Parameters for this Request

Exposure										
Scenario	Index Exposure	Cohort definition	Incident exposure washout period	Incident with respect to:	Treatment episode gap	Exposure episode extension	Minimum exposure episode duration	Minimum days supplied	Maximum exposure episode duration	Censor treatment episode at evidence of:
4	Sitagliptin (includes combination meds)	First valid exposure episodes during query period	365	DPP-4is (include SGLT-2/DPP-4i combos)	10 days	10 days	0	0	0	*Death; *DP end date; *Query end date; *Occurrence of a DKA event
5	Canagliflozin (Includes combination meds)	First valid exposure episodes during query period	365	Canagliflozin Dapagliflozin Empagliflozin Ertugliflozin (include SGLT-2/DPP-4i combos)	10 days	10 days	0	0	0	*Death; *DP end date; *Query end date; *Occurrence of a DKA event
6	Dapagliflozin (includes combination meds)	First valid exposure episodes during query period	365	Canagliflozin Dapagliflozin Empagliflozin Ertugliflozin (include SGLT-2/DPP-4i combos)	10 days	10 days	0	0	0	*Death; *DP end date; *Query end date; *Occurrence of a DKA event
7	Empagliflozin (includes combination meds)	First valid exposure episodes during query period	365	Canagliflozin Dapagliflozin Empagliflozin Ertugliflozin (include SGLT-2/DPP-4i combos)	10 days	10 days	0	0	0	*Death; *DP end date; *Query end date; *Occurrence of a DKA event

Appendix F.1. Specifications Defining Exposure Parameters for this Request

Exposure										
Scenario	Index Exposure	Cohort definition	Incident exposure washout period	Incident with respect to:	Treatment episode gap	Exposure episode extension	Minimum exposure episode duration	Minimum days supplied	Maximum exposure episode duration	Censor treatment episode at evidence of:
8	Sitagliptin (includes combination meds)	First valid exposure episodes during query period	365	DPP-4is (include SGLT-2/DPP-4i combos)	10 days	10 days	0	0	0	*Death; *DP end date; *Query end date; *Occurrence of a DKA event
9	Canagliflozin (Includes combination meds)	First valid exposure episodes during query period	365	Canagliflozin Dapagliflozin Empagliflozin Ertugliflozin (include SGLT-2/DPP-4i combos)	10 days	10 days	0	0	0	*Death; *DP end date; *Query end date; *Occurrence of a DKA event
10	Dapagliflozin (includes combination meds)	First valid exposure episodes during query period	365	Canagliflozin Dapagliflozin Empagliflozin Ertugliflozin (include SGLT-2/DPP-4i combos)	10 days	10 days	0	0	0	*Death; *DP end date; *Query end date; *Occurrence of a DKA event
11	Empagliflozin (includes combination meds)	First valid exposure episodes during query period	365	Canagliflozin Dapagliflozin Empagliflozin Ertugliflozin (include SGLT-2/DPP-4i combos)	10 days	10 days	0	0	0	*Death; *DP end date; *Query end date; *Occurrence of a DKA event

Appendix F.1. Specifications Defining Exposure Parameters for this Request

Exposure										
Scenario	Index Exposure	Cohort definition	Incident exposure washout period	Incident with respect to:	Treatment episode gap	Exposure episode extension	Minimum exposure episode duration	Minimum days supplied	Maximum exposure episode duration	Censor treatment episode at evidence of:
12	Sitagliptin (includes combination meds)	First valid exposure episodes during query period	365	DPP-4is (include SGLT-2/DPP-4i combos)	10 days	10 days	0	0	0	*Death; *DP end date; *Query end date; *Occurrence of a DKA event
13	Canagliflozin (Includes combination meds)	First valid exposure episodes during query period	365	Canagliflozin Dapagliflozin Empagliflozin Ertugliflozin (include SGLT-2/DPP-4i combos)	10 days	10 days	0	0	0	*Death; *DP end date; *Query end date; *Occurrence of a DKA event
14	Dapagliflozin (includes combination meds)	First valid exposure episodes during query period	365	Canagliflozin Dapagliflozin Empagliflozin Ertugliflozin (include SGLT-2/DPP-4i combos)	10 days	10 days	0	0	0	*Death; *DP end date; *Query end date; *Occurrence of a DKA event
15	Empagliflozin (includes combination meds)	First valid exposure episodes during query period	365	Canagliflozin Dapagliflozin Empagliflozin Ertugliflozin (include SGLT-2/DPP-4i combos)	10 days	10 days	0	0	0	*Death; *DP end date; *Query end date; *Occurrence of a DKA event

Appendix F.1. Specifications Defining Exposure Parameters for this Request

Exposure										
Scenario	Index Exposure	Cohort definition	Incident exposure washout period	Incident with respect to:	Treatment episode gap	Exposure episode extension	Minimum exposure episode duration	Minimum days supplied	Maximum exposure episode duration	Censor treatment episode at evidence of:
16	Sitagliptin (includes combination meds)	First valid exposure episodes during query period	365	DPP-4is (include SGLT-2/DPP-4i combos)	10 days	10 days	0	0	0	*Death; *DP end date; *Query end date; *Occurrence of a DKA event
17	Canagliflozin (Includes combination meds)	First valid exposure episodes during query period	365	Canagliflozin Dapagliflozin Empagliflozin Ertugliflozin (include SGLT-2/DPP-4i combos)	10 days	10 days	0	0	0	*Death; *DP end date; *Query end date; *Occurrence of a DKA event
18	Dapagliflozin (includes combination meds)	First valid exposure episodes during query period	365	Canagliflozin Dapagliflozin Empagliflozin Ertugliflozin (include SGLT-2/DPP-4i combos)	10 days	10 days	0	0	0	*Death; *DP end date; *Query end date; *Occurrence of a DKA event
19	Empagliflozin (includes combination meds)	First valid exposure episodes during query period	365	Canagliflozin Dapagliflozin Empagliflozin Ertugliflozin (include SGLT-2/DPP-4i combos)	10 days	10 days	0	0	0	*Death; *DP end date; *Query end date; *Occurrence of a DKA event

Appendix F.1. Specifications Defining Exposure Parameters for this Request

Exposure										
Scenario	Index Exposure	Cohort definition	Incident exposure washout period	Incident with respect to:	Treatment episode gap	Exposure episode extension	Minimum exposure episode duration	Minimum days supplied	Maximum exposure episode duration	Censor treatment episode at evidence of:
20	Sitagliptin (includes combination meds)	First valid exposure episodes during query period	365	DPP-4is (include SGLT-2/DPP-4i combos)	10 days	10 days	0	0	0	*Death; *DP end date; *Query end date; *Occurrence of a DKA event
21	Canagliflozin (Includes combination meds)	First valid exposure episodes during query period	365	Canagliflozin Dapagliflozin Empagliflozin Ertugliflozin (include SGLT-2/DPP-4i combos)	10 days	10 days	0	0	0	*Death; *DP end date; *Query end date; *Occurrence of a DKA event
22	Dapagliflozin (includes combination meds)	First valid exposure episodes during query period	365	Canagliflozin Dapagliflozin Empagliflozin Ertugliflozin (include SGLT-2/DPP-4i combos)	10 days	10 days	0	0	0	*Death; *DP end date; *Query end date; *Occurrence of a DKA event
23	Empagliflozin (includes combination meds)	First valid exposure episodes during query period	365	Canagliflozin Dapagliflozin Empagliflozin Ertugliflozin (include SGLT-2/DPP-4i combos)	10 days	10 days	0	0	0	*Death; *DP end date; *Query end date; *Occurrence of a DKA event
24	Sitagliptin (includes combination meds)	First valid exposure episodes during query period	365	DPP-4is (include SGLT-2/DPP-4i combos)	10 days	10 days	0	0	0	*Death; *DP end date; *Query end date; *Occurrence of a DKA event

International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), ICD-10-CM, Healthcare Common Procedure Coding System (HCPCS), and Current Procedural Terminology (CPT) codes are provided by Optum360.

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

Appendix F.2. Specifications Defining Inclusion and Exclusion Criteria Parameters for this Request

This request executed the Cohort Identification and Descriptive Analysis (CIDA) module, version 6.0.0 to estimate rates of SGLT-2 Inhibitor use with prior Type 1 or Type 2 Diabetes and Diabetic Ketoacidosis events in the Sentinel Distributed Database (SDD).

Query period: March 1, 2013 -June 30, 2018
Coverage requirement: Medical & Drug Coverage
Pre-index enrollment requirement: 365 days
Age groups: <12, 12-18, 19-24, 25-44, 45-64, 65+ years
Stratifications: Age group, Sex, Calendar year, Age group * Sex, Age group * Calendar year

Inclusion/Exclusion Criteria

Scenario	Inclusion/ Exclusion group	Criteria	Care setting	Principal diagnosis position	Evaluation period start (days)	Evaluation period end (days)	Number of instances the criteria should be found in evaluation period
1	None						
2	None						
3	None						
4	None						
5	1. Type 1 Diabetes algorithm AND	Inclusion	*Any care setting	Any Diagnosis Position	-365	-5	Algorithmic (RADAR)
	2. Short-/Rapid-Acting Insulin AND	Inclusion	*Any care setting	N/A	-365	-1	1
	3. Oral Antidiabetic Drug (excluding Metformin)	Exclusion	N/A	N/A	-365	-1	1
6	1. Type 1 Diabetes Algorithm AND	Inclusion	*Any care setting	Any Diagnosis Position	-365	-5	Algorithmic (RADAR)
	2. Short-/Rapid-Acting Insulin AND	Inclusion	*Any care setting	N/A	-365	-1	1
	3. Oral Antidiabetic Drug (excluding Metformin)	Exclusion	N/A	N/A	-365	-1	1

Appendix F.2. Specifications Defining Inclusion and Exclusion Criteria Parameters for this Request

Inclusion/Exclusion Criteria							
Scenario	Inclusion/ Exclusion group	Criteria	Care setting	Principal diagnosis position	Evaluation period start (days)	Evaluation period end (days)	Number of instances the criteria should be found in evaluation period
7	1. Type 1 Diabetes Algorithm AND	Inclusion	*Any care setting	Any Diagnosis Position	-365	-5	Algorithmic (RADAR)
	2. Short-/Rapid-Acting Insulin AND	Inclusion	*Any care setting	N/A	-365	-1	1
	3. Oral Antidiabetic Drug (excluding Metformin)	Exclusion	N/A	N/A	-365	-1	1
8	1. Type 1 Diabetes Algorithm AND	Inclusion	*Any care setting	Any Diagnosis Position	-365	-5	Algorithmic (RADAR)
	2. Short-/Rapid-Acting Insulin AND	Inclusion	*Any care setting	N/A	-365	-1	1
	3. Oral Antidiabetic Drug (excluding Metformin)	Exclusion	N/A	N/A	-365	-1	1
9	1. Type 2 Diabetes AND	Inclusion	*Any care setting	Any Diagnosis Position	-365	-5	1
	2. Type 1 Diabetes AND	Exclusion	*Any care setting	Any Diagnosis Position	-365	-5	1
	3. Oral Antidiabetic Drug	Inclusion	N/A	N/A	-365	-1	1
10	1. Type 2 Diabetes AND	Inclusion	*Any care setting	Any Diagnosis Position	-365	-5	1
	2. Type 1 Diabetes AND	Exclusion	*Any care setting	Any Diagnosis Position	-365	-5	1
	3. Oral Antidiabetic Drug	Inclusion	N/A	N/A	-365	-1	1

Appendix F.2. Specifications Defining Inclusion and Exclusion Criteria Parameters for this Request

Inclusion/Exclusion Criteria							
Scenario	Inclusion/ Exclusion group	Criteria	Care setting	Principal diagnosis position	Evaluation period start (days)	Evaluation period end (days)	Number of instances the criteria should be found in evaluation period
11	1. Type 2 Diabetes AND	Inclusion	*Any care setting	Any Diagnosis Position	-365	-5	1
	2. Type 1 Diabetes AND	Exclusion	*Any care setting	Any Diagnosis Position	-365	-5	1
	3. Oral Antidiabetic Drug	Inclusion	N/A	N/A	-365	-1	1
12	1. Type 2 Diabetes AND	Inclusion	*Any care setting	Any Diagnosis Position	-365	-5	1
	2. Type 1 Diabetes AND	Exclusion	*Any care setting	Any Diagnosis Position	-365	-5	1
	3. Oral Antidiabetic Drug	Inclusion	N/A	N/A	-365	-1	1
13	1. Type 2 Diabetes AND	Inclusion	*Any care setting	Any Diagnosis Position	-365	-5	1
	2. Type 1 Diabetes AND	Exclusion	*Any care setting	Any Diagnosis Position	-365	-5	1
	3. Insulin AND	Inclusion	*Any care setting	N/A	-365	-1	1
	4. Oral Antidiabetic Drug	Inclusion	N/A	N/A	-365	-1	1
14	1. Type 2 Diabetes AND	Inclusion	*Any care setting	Any Diagnosis Position	-365	-5	1
	2. Type 1 Diabetes AND	Exclusion	*Any care setting	Any Diagnosis Position	-365	-5	1
	3. Insulin AND	Inclusion	*Any care setting	N/A	-365	-1	1
	4. Oral Antidiabetic Drug	Inclusion	N/A	N/A	-365	-1	1

Appendix F.2. Specifications Defining Inclusion and Exclusion Criteria Parameters for this Request

Inclusion/Exclusion Criteria							
Scenario	Inclusion/ Exclusion group	Criteria	Care setting	Principal diagnosis position	Evaluation period start (days)	Evaluation period end (days)	Number of instances the criteria should be found in evaluation period
15	1. Type 2 Diabetes AND	Inclusion	*Any care setting	Any Diagnosis Position	-365	-5	1
	2. Type 1 Diabetes AND	Exclusion	*Any care setting	Any Diagnosis Position	-365	-5	1
	3. Insulin AND	Inclusion	*Any care setting	N/A	-365	-1	1
	4. Oral Antidiabetic Drug	Inclusion	N/A	N/A	-365	-1	1
16	1. Type 2 Diabetes AND	Inclusion	*Any care setting	Any Diagnosis Position	-365	-5	1
	2. Type 1 Diabetes AND	Exclusion	*Any care setting	Any Diagnosis Position	-365	-5	1
	3. Insulin AND	Inclusion	*Any care setting	N/A	-365	-1	1
	4. Oral Antidiabetic Drug	Inclusion	N/A	N/A	-365	-1	1
17	1. Type 2 Diabetes AND	Inclusion	*Any care setting	Any Diagnosis Position	-365	-5	1
	2. Type 1 Diabetes AND	Exclusion	*Any care setting	Any Diagnosis Position	-365	-5	1
	3. Insulin AND	Exclusion	*Any care setting	N/A	-365	-1	1
	4. Oral Antidiabetic Drug	Inclusion	N/A	N/A	-365	-1	1
18	1. Type 2 Diabetes AND	Inclusion	*Any care setting	Any Diagnosis Position	-365	-5	1
	2. Type 1 Diabetes AND	Exclusion	*Any care setting	Any Diagnosis Position	-365	-5	1
	3. Insulin AND	Exclusion	*Any care setting	N/A	-365	-1	1
	4. Oral Antidiabetic Drug	Inclusion	N/A	N/A	-365	-1	1

Appendix F.2. Specifications Defining Inclusion and Exclusion Criteria Parameters for this Request

Inclusion/Exclusion Criteria							
Scenario	Inclusion/ Exclusion group	Criteria	Care setting	Principal diagnosis position	Evaluation period start (days)	Evaluation period end (days)	Number of instances the criteria should be found in evaluation period
19	1. Type 2 Diabetes AND	Inclusion	*Any care setting	Any Diagnosis Position	-365	-5	1
	2. Type 1 Diabetes AND	Exclusion	*Any care setting	Any Diagnosis Position	-365	-5	1
	3. Insulin AND	Exclusion	*Any care setting	N/A	-365	-1	1
	4. Oral Antidiabetic Drug	Inclusion	N/A	N/A	-365	-1	1
20	1. Type 2 Diabetes AND	Inclusion	*Any care setting	Any Diagnosis Position	-365	-5	1
	2. Type 1 Diabetes AND	Exclusion	*Any care setting	Any Diagnosis Position	-365	-5	1
	3. Insulin AND	Exclusion	*Any care setting	N/A	-365	-1	1
	4. Oral Antidiabetic Drug	Inclusion	N/A	N/A	-365	-1	1
21	1. Type 1 Diabetes algorithm	Inclusion	*Any care setting	Any Diagnosis Position	-365	-5	Algorithmic (RADAR)
22	1. Type 1 Diabetes Algorithm	Inclusion	*Any care setting	Any Diagnosis Position	-365	-5	Algorithmic (RADAR)
23	1. Type 1 Diabetes Algorithm	Inclusion	*Any care setting	Any Diagnosis Position	-365	-5	Algorithmic (RADAR)
24	1. Type 1 Diabetes Algorithm	Inclusion	*Any care setting	Any Diagnosis Position	-365	-5	Algorithmic (RADAR)

International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), ICD-10-CM, Healthcare Common Procedure Coding System (HCPCS), and Current Procedural Terminology (CPT) codes are provided by Optum360.

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

Appendix F.3. Specifications Defining Event Outcome Parameters for this Request

This request executed the Cohort Identification and Descriptive Analysis (CIDA) module, version 6.0.0 to estimate rates of SGLT-2 Inhibitor use with prior Type 1 or Type 2 Diabetes and Diabetic Ketoacidosis events in the Sentinel Distributed Database (SDD).

Query period: March 1, 2013 -June 30, 2018
Coverage requirement: Medical & Drug Coverage
Pre-index enrollment requirement: 365 days
Age groups: <12, 12-18, 19-24, 25-44, 45-64, 65+ years
Stratifications: Age group, Sex, Calendar year, Age group * Sex, Age group * Calendar year

Event Outcome

Scenario	Event	Event washout period	Care setting	Principal diagnosis position	Event de-duplication	Blackout period
1	Diabetic Ketoacidosis (DKA)	0	*Inpatient hospital stay; *Emergency department encounter;	Any Diagnosis Position	*De-duplicates occurrences of the same event group on the same day	1 day
2	Diabetic Ketoacidosis (DKA)	0	*Inpatient hospital stay; *Emergency department encounter;	Any Diagnosis Position	*De-duplicates occurrences of the same event group on the same day	1 day
3	Diabetic Ketoacidosis (DKA)	0	*Inpatient hospital stay; *Emergency department encounter;	Any Diagnosis Position	*De-duplicates occurrences of the same event group on the same day	1 day
4	Diabetic Ketoacidosis (DKA)	0	*Inpatient hospital stay; *Emergency department encounter;	Any Diagnosis Position	*De-duplicates occurrences of the same event group on the same day	1 day
5	Diabetic Ketoacidosis (DKA)	0	*Inpatient hospital stay; *Emergency department encounter;	Any Diagnosis Position	*De-duplicates occurrences of the same event group on the same day	1 day
6	Diabetic Ketoacidosis (DKA)	0	*Inpatient hospital stay; *Emergency department encounter;	Any Diagnosis Position	*De-duplicates occurrences of the same event group on the same day	1 day

Appendix F.3. Specifications Defining Event Outcome Parameters for this Request

Event Outcome						
Scenario	Event	Event washout period	Care setting	Principal diagnosis position	Event de-duplication	Blackout period
7	Diabetic Ketoacidosis (DKA)	0	*Inpatient hospital stay; *Emergency department encounter;	Any Diagnosis Position	*De-duplicates occurrences of the same event group on the same day	1 day
8	Diabetic Ketoacidosis (DKA)	0	*Inpatient hospital stay; *Emergency department encounter;	Any Diagnosis Position	*De-duplicates occurrences of the same event group on the same day	1 day
9	Diabetic Ketoacidosis (DKA)	0	*Inpatient hospital stay; *Emergency department encounter;	Any Diagnosis Position	*De-duplicates occurrences of the same event group on the same day	1 day
10	Diabetic Ketoacidosis (DKA)	0	*Inpatient hospital stay; *Emergency department encounter;	Any Diagnosis Position	*De-duplicates occurrences of the same event group on the same day	1 day
11	Diabetic Ketoacidosis (DKA)	0	*Inpatient hospital stay; *Emergency department encounter;	Any Diagnosis Position	*De-duplicates occurrences of the same event group on the same day	1 day
12	Diabetic Ketoacidosis (DKA)	0	*Inpatient hospital stay; *Emergency department encounter;	Any Diagnosis Position	*De-duplicates occurrences of the same event group on the same day	1 day
13	Diabetic Ketoacidosis (DKA)	0	*Inpatient hospital stay; *Emergency department encounter;	Any Diagnosis Position	*De-duplicates occurrences of the same event group on the same day	1 day

Appendix F.3. Specifications Defining Event Outcome Parameters for this Request

Event Outcome						
Scenario	Event	Event washout period	Care setting	Principal diagnosis position	Event de-duplication	Blackout period
14	Diabetic Ketoacidosis (DKA)	0	*Inpatient hospital stay; *Emergency department encounter;	Any Diagnosis Position	*De-duplicates occurrences of the same event group on the same day	1 day
15	Diabetic Ketoacidosis (DKA)	0	*Inpatient hospital stay; *Emergency department encounter;	Any Diagnosis Position	*De-duplicates occurrences of the same event group on the same day	1 day
16	Diabetic Ketoacidosis (DKA)	0	*Inpatient hospital stay; *Emergency department encounter;	Any Diagnosis Position	*De-duplicates occurrences of the same event group on the same day	1 day
17	Diabetic Ketoacidosis (DKA)	0	*Inpatient hospital stay; *Emergency department encounter;	Any Diagnosis Position	*De-duplicates occurrences of the same event group on the same day	1 day
18	Diabetic Ketoacidosis (DKA)	0	*Inpatient hospital stay; *Emergency department encounter;	Any Diagnosis Position	*De-duplicates occurrences of the same event group on the same day	1 day
19	Diabetic Ketoacidosis (DKA)	0	*Inpatient hospital stay; *Emergency department encounter;	Any Diagnosis Position	*De-duplicates occurrences of the same event group on the same day	1 day
20	Diabetic Ketoacidosis (DKA)	0	*Inpatient hospital stay; *Emergency department encounter;	Any Diagnosis Position	*De-duplicates occurrences of the same event group on the same day	1 day

Appendix F.3. Specifications Defining Event Outcome Parameters for this Request

Event Outcome						
Scenario	Event	Event washout period	Care setting	Principal diagnosis position	Event de-duplication	Blackout period
21	Diabetic Ketoacidosis (DKA)	0	*Inpatient hospital stay; *Emergency department encounter;	Any Diagnosis Position	*De-duplicates occurrences of the same event group on the same day	1 day
22	Diabetic Ketoacidosis (DKA)	0	*Inpatient hospital stay; *Emergency department encounter;	Any Diagnosis Position	*De-duplicates occurrences of the same event group on the same day	1 day
23	Diabetic Ketoacidosis (DKA)	0	*Inpatient hospital stay; *Emergency department encounter;	Any Diagnosis Position	*De-duplicates occurrences of the same event group on the same day	1 day
24	Diabetic Ketoacidosis (DKA)	0	*Inpatient hospital stay; *Emergency department encounter;	Any Diagnosis Position	*De-duplicates occurrences of the same event group on the same day	1 day
International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), ICD-10-CM, Healthcare Common Procedure Coding System (HCPCS), and Current Procedural Terminology (CPT) codes are provided by Optum360.						
National Drug Codes (NDCs) are checked against First Data Bank's "National Drug Data File (NDDF®) Plus."						

Appendix F.4. Specifications Defining Characteristics Parameters for this Request

Covariates

Characteristic	Care setting	Principal diagnosis position	Evaluation period start	Evaluation period end	Number of instances the covariate should be found in evaluation period
Antidiabetic Drug Use (break down by active ingredient)	N/A	N/A	-365	-1	1
Diabetic Ketoacidosis	Inpatient OR Emergency Department	Any Dx Position	-365	-1	1
Insulin Pump Use	N/A	N/A	-365	-1	1
Antidiabetic Drug Use (break down by active ingredient)	N/A	N/A	1	365	1

Appendix F.5. Specifications Defining Stockpiling Parameters for this Request

Stockpiling

Stockpiling group	Same day dispensing processing for days supplied	Same day dispensing processing for amount supplied	Range of allowable days supplied values	Range of allowable amount supplied values	Overlap percentage*
Group used to adjust dispensing dates by stockpiling algorithm	*Adds all	Adds all	100 maximum	Allow all amounts	0%