Disclaimer

The following report(s) provides findings from an FDA-initiated query using Sentinel. While Sentinel queries may be undertaken to assess potential medical product safety risks, they may also be initiated for various other reasons. Some examples include determining a rate or count of an identified health outcome of interest, examining medical product use, exploring the feasibility of future, more detailed analyses within Sentinel, and seeking to better understand Sentinel capabilities.

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

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

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

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Request ID: cder_mpl1p_wp101

Request Description: In this report we described characteristics of individuals with dispensings of short/rapid-acting insulin and a history of type 1 diabetes in the Sentinel Distributed Database (SDD). Among these cohorts, we assessed occurrence of diabetic ketoacidosis (DKA) by chronic kidney disease (CKD) stage and calculated incidence rates.

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

Data Source: We distributed this query to six Data Partners on September 10, 2024. These six Data Partners are a subset of the SDD. Data from Medicare patients having both fee-for-service medical coverage and Part D drug coverage are included. The study period included data from March 1, 2013 through February 29, 2024. Please see Appendix A for a list of dates of available data for each Data Partner.

Study Design: We identified individuals with prevalent use of short/rapid-acting insulin. We evaluated the occurrence of diabetic ketoacidosis within 365 days among a cohort of users of any age who had evidence of type 1 diabetes, by chronic kidney disease stage.

Exposures of Interest: We defined the exposure of interest, short/rapid-acting insulin, using outpatient dispensing data and National Drug Codes (NDCs) and Healthcare Common Procedure Coding System (HCPCS) procedure codes. Please see Appendix B for a list of generic and brand names of medical products and Appendix C for a list of HCPCS used to define exposure in this request.

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

Cohort Eligibility Criteria: We required members to be enrolled in health plans with medical and drug coverage in the 365 days prior to their index date in order to be included in the cohort; a gap in coverage of up to 45 days was allowed and treated as continuous enrollment. The following age groups were included in the cohort: <12, 12-18, 19-24, 25-44, 45-64, ≥65 years. We required all patients to have evidence of type 1 diabetes, which we defined as: in the 365 days to five days prior to the index dispensing, the proportion of type 1 diabetes codes to type 2 diabetes codes is greater than 50% AND in the 365 days to one day prior to the index dispensing there is evidence of short/rapid-acting insulin AND NO evidence of non-insulin antidiabetics (excluding metformin).

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

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

Baseline Characteristics: We assessed the following characteristics on the date of the index dispensing: age, sex, race, ethnicity, and year. We assessed characteristics based on the chronic kidney disease (CKD) stage algorithm components in the 365 days prior to and including the index dispensing, including: CKD stage 4 or 5 diagnoses, dialysis, CKD stage 3 diagnoses, any CKD diagnosis code at least three times, renal failure or CKD AND evidence of a CKD treatment, renal failure, CKD stage 1 diagnoses, CKD stage 2 diagnoses, CKD stage 3 diagnoses, CKD stage 4 diagnoses, CKD stage 5 diagnoses, unspecified CKD diagnoses, and end stage renal disease (ESRD). We assessed the following characteristics in the 365 days prior to and excluding the index dispensing: history of diabetic ketoacidosis, metformin, sulfonylureas, thiazolidinediones, alpha-glucosidase inhibitors, meglitinides, dipeptidyl peptidase-4 (DPP-4) inhibitors, sodium-glucose cotransporter-2 (SGLT-2) inhibitors, glucagon-like peptide-1 receptor agonists (GLP-1 RAs), other oral antidiabetic drugs, short/rapid-acting insulin, long/intermediate-acting insulin, combination insulin, and insulin pump. We assessed the following characteristics on the day after the index dispensing and following 365 days: number of diabetic ketoacidosis events (1, 2, 3, 4, or 5+).

Evidence of CKD stage was defined using a validated, hierarchical algorithm[1] which required the following in the proceeding 365 days:

-CKD stage 4 or 5 including dialysis: Code for CKD stage 4 or 5 OR dialysis code
-CKD stage 3: Code for CKD stage 3 OR any three CKD codes OR renal failure or CKD code and drug purchase
-CKD stage 2: Code for renal failure or renal impairment
-CKD stage 1: None of the above

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

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

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

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

[1]Friberg G, Gasparini A, Carrero JJ. A scheme based on ICD-10 diagnoses and drug prescriptions to stage chronic kidney disease severity in healthcare administrative records. Clin Kidney J. 2018; 11(2):254-258

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

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

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

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

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

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

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

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

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

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

Code Days - the minimum number of times the diagnosis must be found during the evaluation period in order to fulfill the algorithm to identify the corresponding patient characteristic.

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

Computed Start Marketing Date - represents the first observed dispensing date among all valid users within a GROUP (scenario) within each Data Partner site.

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

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

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

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

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

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

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

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

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

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

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.

Switch Evaluation Step Value - value used to differentiate evaluation step. Each switch pattern can support up to 2 evaluation steps (0 = switch pattern evaluation start; 1 = first evaluation; 2 = second evaluation).

Switch Gap Inclusion Indicator - indicator for whether gaps in treatment episodes that are included in a switch episode will be counted as part of the switch episode duration.

Switch Pattern Cohort Inclusion Date - indicates which date to use for inclusion into the switch pattern cohort of interest as well as optionally as the index date of the treatment episode initiating the switch pattern. Valid options are the product approval date, product marketing date, other requester defined date, or computed start marketing date.

Switch Pattern Cohort Inclusion Strategy - indicates how the switch pattern cohort inclusion date will be used: 01: used only as a switch cohort entry date. First treatment episode dispensing date is used as index for computing time to first switch; 02: used as switch cohort entry date and as initial switch step index date for computing time to first switch.

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

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

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

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

*all terms may not be used in this report

Table 1a. Aggregated Characteristics of Short/Rapid-Acting Insulin Users, with Type 1 Diabetes and Chronic Kidney Disease (CKD) Stage 1 in the Sentinel Distributed Database (SDD) from March 1, 2013 to February 29, 2024

Patient Characteristics	Number	Percent
Unique patients with type 1 diabetes	683,436	
Unique patients with chronic kidney disease stage 1	562,905	82.4%
Demographic Characteristics	**Number**	**Percent**
Age		
0-11 years	50,111	8.9%
12-18 years	78,058	13.9%
19-24 years	56,565	10.0%
25-44 years	166,531	29.6%
45-64 years	120,971	21.5%
≥ 65 years	90,669	16.1%
Sex		
Female	282,057	50.1%
Male	280,848	49.9%
Race[1]		
American Indian or Alaska Native	3,081	0.5%
Asian	5,688	1.0%
Black or African American	47,025	8.4%
Multi-racial	4,382	0.8%
Native Hawaiian or Other Pacific Islander	838	0.1%
Unknown	215,513	38.3%
White	286,378	50.9%
Hispanic origin		
Yes	38,655	6.9%
No	322,549	57.3%
Unknown	201,701	35.8%
Year		
2013	76,990	13.7%
2014	45,166	8.0%
2015	51,616	9.2%
2016	57,870	10.3%
2017	78,778	14.0%
2018	58,102	10.3%
2019	48,124	8.5%
2020	48,353	8.6%
2021	55,871	9.9%
2022	20,872	3.7%
2023	19,404	3.4%
2024	1,759	0.3%

Table 1a. Aggregated Characteristics of Short/Rapid-Acting Insulin Users, with Type 1 Diabetes and Chronic Kidney Disease (CKD) Stage 1 in the Sentinel Distributed Database (SDD) from March 1, 2013 to February 29, 2024

Chronic Kidney Disease Definition Components [-365, 0]	Number	Percent
CKD 4/5 Component: CKD 4/5 Diagnosis Code (N18.4, N18.5, 585.4, 585.5)	0	0.0%
CKD 4/5 Component: Dialysis	0	0.0%
CKD 3 Component: CKD 3 Diagnosis Code (N18.3*, 585.3)	0	0.0%
CKD 3 Component: Any CKD Diagnosis Code 3 Times	0	0.0%
CKD 3 Component: CKD/Renal Failure and Treatment	0	0.0%
CKD 2 Component: Renal Failure	0	0.0%
CKD 2 Component: CKD 1 Diagnosis Code (N18.1, 585.1)	0	0.0%
CKD 2 Component: CKD 2 Diagnosis Code (N18.2, 585.2)	0	0.0%
CKD 2 Component: CKD 3 Diagnosis Code (N18.3*, 585.3)	0	0.0%
CKD 2 Component: CKD 4 Diagnosis Code (N18.4, 585.4)	0	0.0%
CKD 2 Component: CKD 5 Diagnosis Code (N18.5, 585.5)	0	0.0%
CKD 2 Component: Unspecified CKD Diagnosis Code (N18.9, 583.6, 583.7, 585.9)	0	0.0%
CKD 2 Component: End-Stage Renal Disease (ESRD)	0	0.0%
Diabetic Ketoacidosis (DKA)		
History of DKA [-365, -1]	56,970	10.1%
At Least 1 DKA Event Post-Exposure [1, 365]	37,910	6.7%
Exactly 1 DKA Event Post-Exposure [1, 365]	13,399	2.4%
Exactly 2 DKA Events Post-Exposure [1, 365]	7,049	1.3%
Exactly 3 DKA Events Post-Exposure [1, 365]	5,240	0.9%
Exactly 4 DKA Events Post-Exposure [1, 365]	3,193	0.6%
At Least 5 DKA Events Post-Exposure [1, 365]	9,029	1.6%
Anti-Diabetic Treatments by Active Ingredient [-365, -1]		
Metformin	47,777	8.5%
Sulfonylureas	0	0.0%
Thiazolidinediones	0	0.0%
Alpha-glucosidase Inhibitors	0	0.0%
Meglitinides	0	0.0%
Dipeptidyl Peptidase-4 (DPP-4) Inhibitors	0	0.0%
Sodium-Glucose Cotransporter-2 (SGLT-2) Inhibitors	0	0.0%
Glucagon-Like Peptide-1 Receptor Agonists (GLP-1 RAs)	0	0.0%
Other Oral Antidiabetes Drugs	0	0.0%
Insulin Products [-365, -1]		
Short/Rapid-Acting Insulin	493,879	87.7%
Long/Intermediate-Acting Insulin	389,176	69.1%
Combination Insulin	14,501	2.6%
Insulin Pump	128,399	22.8%

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

Table 1b. Aggregated Characteristics of Short/Rapid-Acting Insulin Users, with Type 1 Diabetes and Chronic Kidney Disease (CKD) Stage 2 in the Sentinel Distributed Database (SDD) from March 1, 2013 to February 29, 2024

Patient Characteristics	Number	Percent
Unique patients with type 1 diabetes	683,436	
Unique patients with chronic kidney disease stage 2	45,557	6.7%
Demographic Characteristics	**Number**	**Percent**
Age		
0-11 years	1,711	3.8%
12-18 years	2,773	6.1%
19-24 years	4,136	9.1%
25-44 years	14,899	32.7%
45-64 years	11,876	26.1%
≥ 65 years	10,162	22.3%
Sex		
Female	21,162	46.5%
Male	24,395	53.5%
Race[1]		
American Indian or Alaska Native	413	0.9%
Asian	411	0.9%
Black or African American	7,503	16.5%
Multi-racial	228	0.5%
Native Hawaiian or Other Pacific Islander	84	0.2%
Unknown	10,942	24.0%
White	25,976	57.0%
Hispanic origin		
Yes	2,983	6.5%
No	33,497	73.5%
Unknown	9,077	19.9%
Year		
2013	5,269	11.6%
2014	3,253	7.1%
2015	3,547	7.8%
2016	4,590	10.1%
2017	6,591	14.5%
2018	5,084	11.2%
2019	4,197	9.2%
2020	4,515	9.9%
2021	5,318	11.7%
2022	1,641	3.6%
2023	1,455	3.2%
2024	97	0.2%

Table 1b. Aggregated Characteristics of Short/Rapid-Acting Insulin Users, with Type 1 Diabetes and Chronic Kidney Disease (CKD) Stage 2 in the Sentinel Distributed Database (SDD) from March 1, 2013 to February 29, 2024

Chronic Kidney Disease Definition Components [-365, 0]	Number	Percent
CKD 4/5 Component: CKD 4/5 Diagnosis Code (N18.4, N18.5, 585.4, 585.5)	0	0.0%
CKD 4/5 Component: Dialysis	0	0.0%
CKD 3 Component: CKD 3 Diagnosis Code (N18.3*, 585.3)	0	0.0%
CKD 3 Component: Any CKD Diagnosis Code 3 Times	0	0.0%
CKD 3 Component: CKD/Renal Failure and Treatment	0	0.0%
CKD 2 Component: Renal Failure	35,802	78.6%
CKD 2 Component: CKD 1 Diagnosis Code (N18.1, 585.1)	1,791	3.9%
CKD 2 Component: CKD 2 Diagnosis Code (N18.2, 585.2)	3,664	8.0%
CKD 2 Component: CKD 3 Diagnosis Code (N18.3*, 585.3)	0	0.0%
CKD 2 Component: CKD 4 Diagnosis Code (N18.4, 585.4)	0	0.0%
CKD 2 Component: CKD 5 Diagnosis Code (N18.5, 585.5)	0	0.0%
CKD 2 Component: Unspecified CKD Diagnosis Code (N18.9, 583.6, 583.7, 585.9)	8,391	18.4%
CKD 2 Component: End-Stage Renal Disease (ESRD)	529	1.2%
Diabetic Ketoacidosis (DKA)		
History of DKA [-365, -1]	25,300	55.5%
At Least 1 DKA Event Post-Exposure [1, 365]	11,448	25.1%
Exactly 1 DKA Event Post-Exposure [1, 365]	2,144	4.7%
Exactly 2 DKA Events Post-Exposure [1, 365]	1,411	3.1%
Exactly 3 DKA Events Post-Exposure [1, 365]	1,288	2.8%
Exactly 4 DKA Events Post-Exposure [1, 365]	999	2.2%
At Least 5 DKA Events Post-Exposure [1, 365]	5,606	12.3%
Anti-Diabetic Treatments by Active Ingredient [-365, -1]		
Metformin	4,509	9.9%
Sulfonylureas	0	0.0%
Thiazolidinediones	0	0.0%
Alpha-glucosidase Inhibitors	0	0.0%
Meglitinides	0	0.0%
Dipeptidyl Peptidase-4 (DPP-4) Inhibitors	0	0.0%
Sodium-Glucose Cotransporter-2 (SGLT-2) Inhibitors	0	0.0%
Glucagon-Like Peptide-1 Receptor Agonists (GLP-1 RAs)	0	0.0%
Other Oral Antidiabetes Drugs	0	0.0%
Insulin Products [-365, -1]		
Short/Rapid-Acting Insulin	38,396	84.3%
Long/Intermediate-Acting Insulin	35,565	78.1%
Combination Insulin	2,459	5.4%
Insulin Pump	5,184	11.4%

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

Table 1c. Aggregated Characteristics of Short/Rapid-Acting Insulin Users, with Type 1 Diabetes and Chronic Kidney Disease (CKD) Stage 3 in the Sentinel Distributed Database (SDD) from March 1, 2013 to February 29, 2024

Patient Characteristics	Number	Percent
Unique patients with type 1 diabetes	683,436	
Unique patients with chronic kidney disease stage 3	38,583	5.6%
Demographic Characteristics	**Number**	**Percent**
Age		
0-11 years	30	0.1%
12-18 years	110	0.3%
19-24 years	320	0.8%
25-44 years	5,947	15.4%
45-64 years	12,166	31.5%
≥ 65 years	20,010	51.9%
Sex		
Female	19,869	51.5%
Male	18,714	48.5%
Race[1]		
American Indian or Alaska Native	221	0.6%
Asian	368	1.0%
Black or African American	4,485	11.6%
Multi-racial	77	0.2%
Native Hawaiian or Other Pacific Islander	67	0.2%
Unknown	5,826	15.1%
White	27,539	71.4%
Hispanic origin		
Yes	1,143	3.0%
No	31,258	81.0%
Unknown	6,182	16.0%
Year		
2013	6,491	16.8%
2014	4,121	10.7%
2015	3,559	9.2%
2016	3,560	9.2%
2017	3,995	10.4%
2018	3,370	8.7%
2019	2,924	7.6%
2020	3,032	7.9%
2021	3,215	8.3%
2022	2,296	6.0%
2023	1,929	5.0%
2024	91	0.2%

Table 1c. Aggregated Characteristics of Short/Rapid-Acting Insulin Users, with Type 1 Diabetes and Chronic Kidney Disease (CKD) Stage 3 in the Sentinel Distributed Database (SDD) from March 1, 2013 to February 29, 2024

Chronic Kidney Disease Definition Components [-365, 0]		
CKD 4/5 Component: CKD 4/5 Diagnosis Code (N18.4, N18.5, 585.4, 585.5)	0	0.0%
CKD 4/5 Component: Dialysis	0	0.0%
CKD 3 Component: CKD 3 Diagnosis Code (N18.3*, 585.3)	31,978	82.9%
CKD 3 Component: Any CKD Diagnosis Code 3 Times	27,629	71.6%
CKD 3 Component: CKD/Renal Failure and Treatment	1,296	3.4%
CKD 2 Component: Renal Failure	12,975	33.6%
CKD 2 Component: CKD 1 Diagnosis Code (N18.1, 585.1)	1,891	4.9%
CKD 2 Component: CKD 2 Diagnosis Code (N18.2, 585.2)	6,682	17.3%
CKD 2 Component: CKD 3 Diagnosis Code (N18.3*, 585.3)	31,978	82.9%
CKD 2 Component: CKD 4 Diagnosis Code (N18.4, 585.4)	0	0.0%
CKD 2 Component: CKD 5 Diagnosis Code (N18.5, 585.5)	0	0.0%
CKD 2 Component: Unspecified CKD Diagnosis Code (N18.9, 583.6, 583.7, 585.9)	15,347	39.8%
CKD 2 Component: End-Stage Renal Disease (ESRD)	1,236	3.2%
Diabetic Ketoacidosis (DKA)		
History of DKA [-365, -1]	4,924	12.8%
At Least 1 DKA Event Post-Exposure [1, 365]	3,704	9.6%
Exactly 1 DKA Event Post-Exposure [1, 365]	881	2.3%
Exactly 2 DKA Events Post-Exposure [1, 365]	490	1.3%
Exactly 3 DKA Events Post-Exposure [1, 365]	404	1.0%
Exactly 4 DKA Events Post-Exposure [1, 365]	327	0.8%
At Least 5 DKA Events Post-Exposure [1, 365]	1,602	4.2%
Anti-Diabetic Treatments by Active Ingredient [-365, -1]		
Metformin	3,062	7.9%
Sulfonylureas	0	0.0%
Thiazolidinediones	0	0.0%
Alpha-glucosidase Inhibitors	0	0.0%
Meglitinides	0	0.0%
Dipeptidyl Peptidase-4 (DPP-4) Inhibitors	0	0.0%
Sodium-Glucose Cotransporter-2 (SGLT-2) Inhibitors	0	0.0%
Glucagon-Like Peptide-1 Receptor Agonists (GLP-1 RAs)	0	0.0%
Other Oral Antidiabetes Drugs	0	0.0%
Insulin Products [-365, -1]		
Short/Rapid-Acting Insulin	32,057	83.1%
Long/Intermediate-Acting Insulin	27,011	70.0%
Combination Insulin	1,799	4.7%
Insulin Pump	4,179	10.8%

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

Table 1d. Aggregated Characteristics of Short/Rapid-Acting Insulin Users, with Type 1 Diabetes and Chronic Kidney Disease (CKD) Stage 4 or 5 including Dialysis in the Sentinel Distributed Database (SDD) from March 1, 2013 to February 29, 2024

Patient Characteristics	Number	Percent
Unique patients with type 1 diabetes	683,436	
Unique patients with chronic kidney disease stage 4 or 5	36,391	5.3%
Demographic Characteristics	**Number**	**Percent**
Age		
0-11 years	55	0.2%
12-18 years	166	0.5%
19-24 years	334	0.9%
25-44 years	11,465	31.5%
45-64 years	14,116	38.8%
≥ 65 years	10,255	28.2%
Sex		
Female	17,595	48.3%
Male	18,796	51.7%
Race[1]		
American Indian or Alaska Native	351	1.0%
Asian	568	1.6%
Black or African American	7,759	21.3%
Multi-racial	68	0.2%
Native Hawaiian or Other Pacific Islander	64	0.2%
Unknown	5,971	16.4%
White	21,610	59.4%
Hispanic origin		
Yes	2,340	6.4%
No	29,574	81.3%
Unknown	4,477	12.3%
Year		
2013	5,830	16.0%
2014	3,532	9.7%
2015	3,533	9.7%
2016	3,872	10.6%
2017	4,000	11.0%
2018	3,458	9.5%
2019	2,979	8.2%
2020	2,943	8.1%
2021	2,807	7.7%
2022	1,902	5.2%
2023	1,473	4.0%
2024	62	0.2%

Table 1d. Aggregated Characteristics of Short/Rapid-Acting Insulin Users, with Type 1 Diabetes and Chronic Kidney Disease (CKD) Stage 4 or 5 including Dialysis in the Sentinel Distributed Database (SDD) from March 1, 2013 to February 29, 2024

Chronic Kidney Disease Definition Components [-365, 0]	Number	Percent
CKD 4/5 Component: CKD 4/5 Diagnosis Code (N18.4, N18.5, 585.4, 585.5)	21,650	59.5%
CKD 4/5 Component: Dialysis	25,171	69.2%
CKD 3 Component: CKD 3 Diagnosis Code (N18.3*, 585.3)	12,800	35.2%
CKD 3 Component: Any CKD Diagnosis Code 3 Times	32,752	90.0%
CKD 3 Component: CKD/Renal Failure and Treatment	19,521	53.6%
CKD 2 Component: Renal Failure	18,248	50.1%
CKD 2 Component: CKD 1 Diagnosis Code (N18.1, 585.1)	989	2.7%
CKD 2 Component: CKD 2 Diagnosis Code (N18.2, 585.2)	2,210	6.1%
CKD 2 Component: CKD 3 Diagnosis Code (N18.3*, 585.3)	12,800	35.2%
CKD 2 Component: CKD 4 Diagnosis Code (N18.4, 585.4)	16,694	45.9%
CKD 2 Component: CKD 5 Diagnosis Code (N18.5, 585.5)	9,360	25.7%
CKD 2 Component: Unspecified CKD Diagnosis Code (N18.9, 583.6, 583.7, 585.9)	20,618	56.7%
CKD 2 Component: End-Stage Renal Disease (ESRD)	22,687	62.3%
Diabetic Ketoacidosis (DKA)		
History of DKA [-365, -1]	6,937	19.1%
At Least 1 DKA Event Post-Exposure [1, 365]	5,658	15.5%
Exactly 1 DKA Event Post-Exposure [1, 365]	1,303	3.6%
Exactly 2 DKA Events Post-Exposure [1, 365]	696	1.9%
Exactly 3 DKA Events Post-Exposure [1, 365]	509	1.4%
Exactly 4 DKA Events Post-Exposure [1, 365]	433	1.2%
At Least 5 DKA Events Post-Exposure [1, 365]	2,717	7.5%
Anti-Diabetic Treatments by Active Ingredient [-365, -1]		
Metformin	704	1.9%
Sulfonylureas	0	0.0%
Thiazolidinediones	0	0.0%
Alpha-glucosidase Inhibitors	0	0.0%
Meglitinides	0	0.0%
Dipeptidyl Peptidase-4 (DPP-4) Inhibitors	0	0.0%
Sodium-Glucose Cotransporter-2 (SGLT-2) Inhibitors	0	0.0%
Glucagon-Like Peptide-1 Receptor Agonists (GLP-1 RAs)	0	0.0%
Other Oral Antidiabetes Drugs	0	0.0%
Insulin Products [-365, -1]		
Short/Rapid-Acting Insulin	29,080	79.9%
Long/Intermediate-Acting Insulin	26,763	73.5%
Combination Insulin	1,653	4.5%
Insulin Pump	2,452	6.7%

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

Table 2a. Summary of Short/Rapid-Acting Insulin Users with Type 1 Diabetes in the Sentinel Distributed Database (SDD) from March 1, 2013 to February 29, 2024, by Chronic Kidney Disease Stage and Age Group

	Number of Patients	Number of Exposure Episodes with an Event	Total Years at Risk	Event Rate per 10,000 Patient-Years at Risk (95% Confidence Interval)
Short/Rapid-Acting Insulin Users				
Evidence of Chronic Kidney Disease Stage 1				
0-11 years	50,111	1,149	14,823.6	775.11 (731.57, 821.25)
12-18 years	78,058	2,645	22,468.9	1,177.18 (1,133.16, 1,222.91)
19-24 years	56,565	2,219	14,819.6	1,497.34 (1,436.32, 1,560.96)
25-44 years	166,531	4,251	44,717.6	950.63 (922.48, 979.64)
45-64 years	120,971	1,641	35,633.3	460.52 (438.77, 483.35)
≥ 65 years	90,669	771	25,871.9	298.01 (277.70, 319.80)
Evidence of Chronic Kidney Disease Stage 2				
0-11 years	1,711	63	436.8	1,442.16 (1,126.60, 1,846.11)
12-18 years	2,773	286	617.2	4,634.08 (4,126.96, 5,203.52)
19-24 years	4,136	878	791.0	11,099.17 (10,388.75, 11,858.1
25-44 years	14,899	2,474	2,993.8	8,263.65 (7,944.35, 8,595.78)
45-64 years	11,876	1,003	2,883.1	3,478.92 (3,270.15, 3,701.03)
≥ 65 years	10,162	280	2,433.5	1,150.62 (1,023.44, 1,293.61)
Evidence of Chronic Kidney Disease Stage 3				
0-11 years	30	*****	*****	1,366.44 (192.47, 9,700.82)
12-18 years	110	*****	*****	3,373.35 (1,686.99, 6,745.48)
19-24 years	320	*****	*****	6,449.71 (4,830.98, 8,610.84)
25-44 years	5,947	536	1,409.0	3,804.10 (3,495.31, 4,140.18)
45-64 years	12,166	511	3,343.2	1,528.49 (1,401.55, 1,666.94)
≥ 65 years	20,010	346	5,319.7	650.41 (585.36, 722.68)
Evidence of Chronic Kidney Disease Stage 4 or 5				
0-11 years	55	*****	*****	536.90 (75.63, 3,811.60)
12-18 years	166	*****	*****	2,252.31 (1,171.90, 4,328.80)
19-24 years	334	*****	*****	7,372.14 (5,673.42, 9,579.49)
25-44 years	11,465	1,364	2,610.0	5,226.15 (4,956.03, 5,510.99)
45-64 years	14,116	738	3,496.8	2,110.49 (1,963.58, 2,268.38)
≥ 65 years	10,255	216	2,446.1	883.05 (772.80, 1,009.03)

*****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 Short/Rapid-Acting Insulin Users with Type 1 Diabetes in the Sentinel Distributed Database (SDD) from March 1, 2013 to February 29, 2024, by Chronic Kidney Disease Stage and Sex

	Number of Patients	Number of Exposure Episodes with an Event	Total Years at Risk	Event Rate per 10,000 Patient-Years at Risk (95% Confidence Interval)
Short/Rapid-Acting Insulin Users				
Evidence of Chronic Kidney Disease Stage 1				
Female	282,057	7,196	78,366.2	918.25 (897.28, 939.72)
Male	280,848	5,480	79,968.7	685.27 (667.36, 703.65)
Evidence of Chronic Kidney Disease Stage 2				
Female	21,162	2,483	4,692.5	5,291.42 (5,087.33, 5,503.70)
Male	24,395	2,501	5,462.9	4,578.13 (4,402.17, 4,761.11)
Evidence of Chronic Kidney Disease Stage 3				
Female	19,869	803	5,183.2	1,549.25 (1,445.71, 1,660.19)
Male	18,714	645	4,991.1	1,292.30 (1,196.32, 1,395.99)
Evidence of Chronic Kidney Disease Stage 4 or 5				
Female	17,595	1,225	4,141.2	2,958.08 (2,796.98, 3,128.45)
Male	18,796	1,159	4,546.2	2,549.40 (2,406.77, 2,700.48)

Table 3. Summary of Patient Level Cohort Attrition in the Sentinel Distributed Database (SDD) from March 1, 2013 to February 29, 2024

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

[1]N/A: Not applicable

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

Appendix A. Dates of Available Data for Each Data Partner (DP) as of Request Distribution Date (September 10, 2024)

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

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

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

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

Appendix C. List of Healthcare Common Procedure Coding System, Level II (HCPCS) Codes Used to Define Exposures in this Request

Code	Description	Code Category	Code Type
	Short/Rapid-Acting Insulin		
S5550	Insulin, rapid onset, 5 units	Procedure	HCPCS
S5551	Insulin, most rapid onset (Lispro or Aspart); 5 units	Procedure	HCPCS

Appendix 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) Codes Used to Define Outcomes in this Request

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

Appendix 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) Codes Used to Define Inclusion and Exclusion Criteria in this Request

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

Appendix 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) Codes Used to Define Inclusion and Exclusion Criteria in this Request

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

Appendix 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) Codes Used to Define Inclusion and Exclusion Criteria in this Request

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

Appendix 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) Codes Used to Define Inclusion and Exclusion Criteria in this Request

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

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

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

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) Codes Used to Define Inclusion and Exclusion Criteria in this Request

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

Appendix 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) Codes Used to Define Inclusion and Exclusion Criteria in this Request

Code	Description	Code Category	Code Type
E11.36	Type 2 diabetes mellitus with diabetic cataract	Diagnosis	ICD-10-CM
E11.37X1	Type 2 diabetes mellitus with diabetic macular edema, resolved following treatment, right eye	Diagnosis	ICD-10-CM
E11.37X2	Type 2 diabetes mellitus with diabetic macular edema, resolved following treatment, left eye	Diagnosis	ICD-10-CM
E11.37X3	Type 2 diabetes mellitus with diabetic macular edema, resolved following treatment, bilateral	Diagnosis	ICD-10-CM
E11.37X9	Type 2 diabetes mellitus with diabetic macular edema, resolved following treatment, unspecified eye	Diagnosis	ICD-10-CM
E11.39	Type 2 diabetes mellitus with other diabetic ophthalmic complication	Diagnosis	ICD-10-CM
E11.40	Type 2 diabetes mellitus with diabetic neuropathy, unspecified	Diagnosis	ICD-10-CM
E11.41	Type 2 diabetes mellitus with diabetic mononeuropathy	Diagnosis	ICD-10-CM
E11.42	Type 2 diabetes mellitus with diabetic polyneuropathy	Diagnosis	ICD-10-CM
E11.43	Type 2 diabetes mellitus with diabetic autonomic (poly)neuropathy	Diagnosis	ICD-10-CM
E11.44	Type 2 diabetes mellitus with diabetic amyotrophy	Diagnosis	ICD-10-CM
E11.49	Type 2 diabetes mellitus with other diabetic neurological complication	Diagnosis	ICD-10-CM
E11.51	Type 2 diabetes mellitus with diabetic peripheral angiopathy without gangrene	Diagnosis	ICD-10-CM
E11.52	Type 2 diabetes mellitus with diabetic peripheral angiopathy with gangrene	Diagnosis	ICD-10-CM
E11.59	Type 2 diabetes mellitus with other circulatory complications	Diagnosis	ICD-10-CM
E11.610	Type 2 diabetes mellitus with diabetic neuropathic arthropathy	Diagnosis	ICD-10-CM
E11.618	Type 2 diabetes mellitus with other diabetic arthropathy	Diagnosis	ICD-10-CM
E11.620	Type 2 diabetes mellitus with diabetic dermatitis	Diagnosis	ICD-10-CM
E11.621	Type 2 diabetes mellitus with foot ulcer	Diagnosis	ICD-10-CM
E11.622	Type 2 diabetes mellitus with other skin ulcer	Diagnosis	ICD-10-CM
E11.628	Type 2 diabetes mellitus with other skin complications	Diagnosis	ICD-10-CM
E11.630	Type 2 diabetes mellitus with periodontal disease	Diagnosis	ICD-10-CM
E11.638	Type 2 diabetes mellitus with other oral complications	Diagnosis	ICD-10-CM
E11.641	Type 2 diabetes mellitus with hypoglycemia with coma	Diagnosis	ICD-10-CM
E11.649	Type 2 diabetes mellitus with hypoglycemia without coma	Diagnosis	ICD-10-CM
E11.65	Type 2 diabetes mellitus with hyperglycemia	Diagnosis	ICD-10-CM
E11.69	Type 2 diabetes mellitus with other specified complication	Diagnosis	ICD-10-CM
E11.8	Type 2 diabetes mellitus with unspecified complications	Diagnosis	ICD-10-CM
E11.9	Type 2 diabetes mellitus without complications	Diagnosis	ICD-10-CM

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

Generic Name	Brand Name
Non-Insulin Antidiabetic	
acarbose	Precose
acarbose	acarbose
acarbose	acarbose (bulk)
albiglutide	Tanzeum
alogliptin benzoate	Nesina
alogliptin benzoate	alogliptin
alogliptin benzoate/metformin HCl	Kazano
alogliptin benzoate/metformin HCl	alogliptin-metformin
alogliptin benzoate/pioglitazone HCl	Oseni
alogliptin benzoate/pioglitazone HCl	alogliptin-pioglitazone
bexagliflozin	Brenzavvy
bexagliflozin	bexagliflozin
bromocriptine mesylate	Cycloset
bromocriptine mesylate	Parlodel
bromocriptine mesylate	bromocriptine
canagliflozin	INVOKANA
canagliflozin	Invokana
canagliflozin/metformin HCl	Invokamet
canagliflozin/metformin HCl	Invokamet XR
chlorpropamide	chlorpropamide
colesevelam HCl	WelChol
colesevelam HCl	colesevelam
dapagliflozin propanediol	Farxiga
dapagliflozin propanediol/metformin HCl	Xigduo XR
dulaglutide	Trulicity
empagliflozin	Jardiance
empagliflozin/metformin HCl	Synjardy
empagliflozin/metformin HCl	Synjardy XR
ertugliflozin pidolate	Steglatro
ertugliflozin pidolate/metformin HCl	Segluromet
exenatide	Byetta
exenatide microspheres	Bydureon
exenatide microspheres	Bydureon BCise
glimepiride	Amaryl
glimepiride	glimepiride
glipizide	Glucotrol
glipizide	Glucotrol XL
glipizide	glipizide
glipizide	glipizide (bulk)
glipizide/metformin HCl	glipizide-metformin
glyburide	Diabeta
glyburide	glyburide
glyburide	glyburide (bulk)
glyburide,micronized	Glynase
glyburide,micronized	glyburide micronized
glyburide/metformin HCl	Glucovance

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

Generic Name	Brand Name
glyburide/metformin HCl	glyburide-metformin
insulin degludec/liraglutide	Xultophy 100/3.6
insulin glargine and lixisenatide	Soliqua 100/33
insulin glargine,human recombinant analog/lixisenatide	Soliqua 100/33
linagliptin	Tradjenta
linagliptin/metformin HCl	Jentadueto
linagliptin/metformin HCl	Jentadueto XR
liraglutide	Saxenda
liraglutide	Victoza 2-Pak
liraglutide	Victoza 3-Pak
lixisenatide	Adlyxin
miglitol	Glyset
miglitol	miglitol
nateglinide	Starlix
nateglinide	nateglinide
pioglitazone HCl	Actos
pioglitazone HCl	pioglitazone
pioglitazone HCl/glimepiride	DUETACT
pioglitazone HCl/glimepiride	pioglitazone-glimepiride
pioglitazone HCl/metformin HCl	Actoplus MET
pioglitazone HCl/metformin HCl	Actoplus Met XR
pioglitazone HCl/metformin HCl	pioglitazone-metformin
repaglinide	Prandin
repaglinide	repaglinide
repaglinide/metformin HCl	Prandimet
repaglinide/metformin HCl	repaglinide-metformin
rosiglitazone maleate	Avandia
rosiglitazone maleate/glimepiride	Avandaryl
rosiglitazone maleate/metformin HCl	Avandamet
saxagliptin HCl	Onglyza
saxagliptin HCl	saxagliptin
saxagliptin HCl/metformin HCl	Kombiglyze XR
saxagliptin HCl/metformin HCl	saxagliptin-metformin
semaglutide	Ozempic
semaglutide	Rybelsus
semaglutide	Wegovy
sotagliflozin	Inpefa
tirzepatide	Mounjaro
tirzepatide	Zepbound
tolazamide	tolazamide
tolbutamide	tolbutamide

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

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

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

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

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

Code	Description	Code Category	Code Type
0842	CAPD outpatient-home supplies	Procedure	Revenue
0843	CAPD outpatient-home equipment	Procedure	Revenue
0844	CAPD outpatient-maintenance/100%	Procedure	Revenue
0845	CAPD outpatient-support services	Procedure	Revenue
0849	CAPD outpatient-other	Procedure	Revenue
0850	CCPD outpatient-general classification	Procedure	Revenue
0851	CCPD outpatient-CCPD/composite or other rate	Procedure	Revenue
0852	CCPD outpatient-home supplies	Procedure	Revenue
0853	CCPD outpatient-home equipment	Procedure	Revenue
0854	CCPD outpatient-maintenance/100%	Procedure	Revenue
0855	CCPD outpatient-support services	Procedure	Revenue
0859	CCPD outpatient-other	Procedure	Revenue
0880	Miscellaneous dialysis-general classification	Procedure	Revenue
0881	Miscellaneous dialysis-ultrafiltration	Procedure	Revenue
0882	Miscellaneous dialysis-home dialysis aide visit (eff 9/93)	Procedure	Revenue
0889	Miscellaneous dialysis-other	Procedure	Revenue
39.95	Hemodialysis	Procedure	ICD-9-CM
3E1M39Z	Irrigation of Peritoneal Cavity using Dialysate, Percutaneous Approach	Procedure	ICD-10-PCS
4052F	Hemodialysis via functioning arteriovenous (AV) fistula (ESRD)	Procedure	CPT-2
4053F	Hemodialysis via functioning arteriovenous (AV) graft (ESRD)	Procedure	CPT-2
4054F	Hemodialysis via catheter (ESRD)	Procedure	CPT-2
4055F	Patient receiving peritoneal dialysis (ESRD)	Procedure	CPT-2
458.21	Hypotension of hemodialysis	Diagnosis	ICD-9-CM
54.98	Peritoneal dialysis	Procedure	ICD-9-CM
75791	Angiography, arteriovenous shunt (eg, dialysis patient fistula/graft), complete evaluation of dialysis access, including fluoroscopy, image documentation and report (includes injections of contrast and all necessary imaging from the arterial anastomosis and adjacent artery through entire venous outflow including the inferior or superior vena cava), radiological supervision and interpretation	Procedure	CPT-4
792.5	Cloudy (hemodialysis) (peritoneal) dialysis affluent	Diagnosis	ICD-9-CM
90935	Hemodialysis procedure with single evaluation by a physician or other qualified health care professional	Procedure	CPT-4
90937	Hemodialysis procedure requiring repeated evaluation(s) with or without substantial revision of dialysis prescription	Procedure	CPT-4
90939	Hemodialysis access flow study to determine blood flow in grafts and arteriovenous fistulae by an indicator dilution method, hook-up; transcutaneous measurement and disconnection	Procedure	CPT-4
90940	Hemodialysis access flow study to determine blood flow in grafts and arteriovenous fistulae by an indicator method	Procedure	CPT-4
90941	Hemodialysis, For Acute Renal Failure And Or Intoxication,	Procedure	CPT-4
90942	Hemodialysis, For Acute Renal Failure And Or Intoxication,	Procedure	CPT-4
90943	Hemodialysis, For Acute Renal Failure And Or Intoxication,	Procedure	CPT-4
90944	Hemodialysis, For Acute Renal Failure And Or Intoxication,	Procedure	CPT-4

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

Code	Description	Code Category	Code Type
90945	Dialysis procedure other than hemodialysis (eg, peritoneal dialysis, hemofiltration, or other continuous renal replacement therapies), with single evaluation by a physician or other qualified health care professional	Procedure	CPT-4
90947	Dialysis procedure other than hemodialysis (eg, peritoneal dialysis, hemofiltration, or other continuous renal replacement therapies) requiring repeated evaluations by a physician or other qualified health care professional, with or without substantial revision of dialysis prescription	Procedure	CPT-4
90951	End-stage renal disease (ESRD) related services monthly, for patients younger than 2 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents; with 4 or more face-to-face visits by a physician or other qualified health care professional per month	Procedure	CPT-4
90952	End-stage renal disease (ESRD) related services monthly, for patients younger than 2 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents; with 2-3 face-to-face visits by a physician or other qualified health care professional per month	Procedure	CPT-4
90953	End-stage renal disease (ESRD) related services monthly, for patients younger than 2 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents; with 1 face-to-face visit by a physician or other qualified health care professional per month	Procedure	CPT-4
90954	End-stage renal disease (ESRD) related services monthly, for patients 2-11 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents; with 4 or more face-to-face visits by a physician or other qualified health care professional per month	Procedure	CPT-4
90955	End-stage renal disease (ESRD) related services monthly, for patients 2-11 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents; with 2-3 face-to-face visits by a physician or other qualified health care professional per month	Procedure	CPT-4
90956	End-stage renal disease (ESRD) related services monthly, for patients 2-11 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents; with 1 face-to-face visit by a physician or other qualified health care professional per month	Procedure	CPT-4
90957	End-stage renal disease (ESRD) related services monthly, for patients 12-19 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents; with 4 or more face-to-face visits by a physician or other qualified health care professional per month	Procedure	CPT-4
90958	End-stage renal disease (ESRD) related services monthly, for patients 12-19 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents; with 2-3 face-to-face visits by a physician or other qualified health care professional per month	Procedure	CPT-4
90959	End-stage renal disease (ESRD) related services monthly, for patients 12-19 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents; with 1 face-to-face visit by a physician or other qualified health care professional per month	Procedure	CPT-4

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

Code	Description	Code Category	Code Type
90960	End-stage renal disease (ESRD) related services monthly, for patients 20 years of age and older; with 4 or more face-to-face visits by a physician or other qualified health care professional per month	Procedure	CPT-4
90961	End-stage renal disease (ESRD) related services monthly, for patients 20 years of age and older; with 2-3 face-to-face visits by a physician or other qualified health care professional per month	Procedure	CPT-4
90962	End-stage renal disease (ESRD) related services monthly, for patients 20 years of age and older; with 1 face-to-face visit by a physician or other qualified health care professional per month	Procedure	CPT-4
90963	End-stage renal disease (ESRD) related services for home dialysis per full month, for patients younger than 2 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents	Procedure	CPT-4
90964	End-stage renal disease (ESRD) related services for home dialysis per full month, for patients 2-11 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents	Procedure	CPT-4
90965	End-stage renal disease (ESRD) related services for home dialysis per full month, for patients 12-19 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents	Procedure	CPT-4
90966	End-stage renal disease (ESRD) related services for home dialysis per full month, for patients 20 years of age and older	Procedure	CPT-4
90967	End-stage renal disease (ESRD) related services for dialysis less than a full month of service, per day; for patients younger than 2 years of age	Procedure	CPT-4
90968	End-stage renal disease (ESRD) related services for dialysis less than a full month of service, per day; for patients 2-11 years of age	Procedure	CPT-4
90969	End-stage renal disease (ESRD) related services for dialysis less than a full month of service, per day; for patients 12-19 years of age	Procedure	CPT-4
90970	End-stage renal disease (ESRD) related services for dialysis less than a full month of service, per day; for patients 20 years of age and older	Procedure	CPT-4
90976	Peritoneal Dialysis For End-stage Renal Disease (esrd),	Procedure	CPT-4
90977	Peritoneal Dialysis For End-stage Renal Disease (esrd),	Procedure	CPT-4
90978	Peritoneal Dialysis For End-stage Renal Disease (esrd),	Procedure	CPT-4
90979	Peritoneal Dialysis For End-stage Renal Disease (esrd),	Procedure	CPT-4
90982	Peritoneal Dialysis For End-stage Renal Disease (esrd),	Procedure	CPT-4
90983	Peritoneal Dialysis For End-stage Renal Disease (esrd),	Procedure	CPT-4
90984	Peritoneal Dialysis For End-stage Renal Disease (esrd),	Procedure	CPT-4
90985	Peritoneal Dialysis For End-stage Renal Disease (esrd),	Procedure	CPT-4
90988	Supervision Of Hemodialysis In Hospital Or Other Facility (excluding Home Dialysis), On Monthly Basis	Procedure	CPT-4
90989	Dialysis training, patient, including helper where applicable, any mode, completed course	Procedure	CPT-4
90990	Hemodialysis Training And/or Counseling	Procedure	CPT-4
90991	Home Hemodialysis Care, Outpatient, For Those Services Either Provided By The Physician Primarily Responsible	Procedure	CPT-4
90992	Peritoneal Dialysis Training And/or Counseling	Procedure	CPT-4

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

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

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

Code	Description	Code Category	Code Type
A4919	Dialyzer holder, each	Procedure	HCPCS
A4929	Tourniquet for dialysis, each	Procedure	HCPCS
B50W0ZZ	Plain Radiography of Dialysis Shunt/Fistula using High Osmolar Contrast	Procedure	ICD-10-PCS
B50W1ZZ	Plain Radiography of Dialysis Shunt/Fistula using Low Osmolar Contrast	Procedure	ICD-10-PCS
B50WYZZ	Plain Radiography of Dialysis Shunt/Fistula using Other Contrast	Procedure	ICD-10-PCS
B51W0ZA	Fluoroscopy of Dialysis Shunt/Fistula using High Osmolar Contrast, Guidance	Procedure	ICD-10-PCS
B51W0ZZ	Fluoroscopy of Dialysis Shunt/Fistula using High Osmolar Contrast	Procedure	ICD-10-PCS
B51W1ZA	Fluoroscopy of Dialysis Shunt/Fistula using Low Osmolar Contrast, Guidance	Procedure	ICD-10-PCS
B51W1ZZ	Fluoroscopy of Dialysis Shunt/Fistula using Low Osmolar Contrast	Procedure	ICD-10-PCS
B51WYZA	Fluoroscopy of Dialysis Shunt/Fistula using Other Contrast, Guidance	Procedure	ICD-10-PCS
B51WYZZ	Fluoroscopy of Dialysis Shunt/Fistula using Other Contrast	Procedure	ICD-10-PCS
B51WZZA	Fluoroscopy of Dialysis Shunt/Fistula, Guidance	Procedure	ICD-10-PCS
B51WZZZ	Fluoroscopy of Dialysis Shunt/Fistula	Procedure	ICD-10-PCS
C1037	Catheter, vaxcel chronic dialysis catheter, medcomp bio flex tesio catheter, medcomp silicone tesio catheter, medcomp hemo-cath long term silicone catheter, bard niagara dual lumen catheter, bard opti-flow dual lumen catheter, medcomp ash split catheter	Procedure	HCPCS
C1750	Catheter, hemodialysis/peritoneal, long-term	Procedure	HCPCS
C1752	Catheter, hemodialysis/peritoneal, short-term	Procedure	HCPCS
C1881	Dialysis access system (implantable)	Procedure	HCPCS
E1510	Kidney, dialysate delivery system kidney machine, pump recirculating, air removal system, flowrate meter, power off, heater and temperature control with alarm, IV poles, pressure gauge, concentrate container	Procedure	HCPCS
E1570	Adjustable chair, for ESRD patients	Procedure	HCPCS
E1590	Hemodialysis machine	Procedure	HCPCS
E1592	Automatic intermittent peritoneal dialysis system	Procedure	HCPCS
E1594	Cycler dialysis machine for peritoneal dialysis	Procedure	HCPCS
E1632	Wearable artificial kidney, each	Procedure	HCPCS
E1634	Peritoneal dialysis clamps, each	Procedure	HCPCS
E1635	Compact (portable) travel hemodialyzer system	Procedure	HCPCS
E1637	Hemostats, each	Procedure	HCPCS
E1638	Heating pad, for peritoneal dialysis, any size, each	Procedure	HCPCS
E1639	Scale, each	Procedure	HCPCS
E1699	Dialysis equipment, not otherwise specified	Procedure	HCPCS
E872.2	Failure of sterile precautions during kidney dialysis and other perfusion	Diagnosis	ICD-9-CM
E879.1	Kidney dialysis as the cause of abnormal reaction of patient, or of later complication, without mention of misadventure at time of procedure	Diagnosis	ICD-9-CM
G0257	Unscheduled or emergency dialysis treatment for an ESRD patient in a hospital outpatient department that is not certified as an ESRD facility	Procedure	HCPCS
G0321	ESRD related services for home dialysis patients per full month; for patients 2 to 11 years of age to include monitoring for adequacy of nutrition, assessment of growth and development, and counseling of parents	Procedure	HCPCS
G0322	End Stage Renal disease (ESRD) related services for home dialysis patients per full month; for patients 12 to 19 years of age to include monitoring for adequacy of nutrition, assessment of growth and development, and counseling of parents	Procedure	HCPCS

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

Code	Description	Code Category	Code Type
G0323	End Stage Renal disease (ESRD) related services for home dialysis patients per full month; for patients 20 years of age and older	Procedure	HCPCS
G0324	ESRD related services for home dialysis (less than full month), per day; for patients under 2 years of age	Procedure	HCPCS
G0325	ESRD related services for home dialysis (less than full month), per day; for patients between 2 and 11 years of age	Procedure	HCPCS
G0326	ESRD related services for home dialysis (less than full month), per day; for patients between twelve and nineteen years of age	Procedure	HCPCS
G0327	ESRD related services for home dialysis (less than full month), per day; for patients twenty years of age and over	Procedure	HCPCS
G8075	ESRD patient with documented dialysis dose of URR greater than or equal to 65% (or Kt/ V greater than or equal to 1.2)	Procedure	HCPCS
G8076	ESRD patient with documented dialysis dose of URR less than 65% (or Kt/V less than 1.2)	Procedure	HCPCS
G8081	ESRD patient requiring hemodialysis vascular access documented to have received autogenous AV fistula	Procedure	HCPCS
G8082	ESRD patient requiring hemodialysis documented to have received vascular access other than autogenous AV fistula	Procedure	HCPCS
G8085	ESRD patient requiring hemodialysis vascular access was not an eligible candidate for autogenous AV fistula	Procedure	HCPCS
G8714	Hemodialysis treatment performed exactly 3 times per week > 90 days	Procedure	HCPCS
G8715	Hemodialysis treatment performed less than 3 times per week or greater than 3 times per week	Procedure	HCPCS
G8727	Patient receiving hemodialysis, peritoneal dialysis or kidney transplantation	Procedure	HCPCS
G9231	Documentation of end stage renal disease (ESRD), dialysis, renal transplant before or during the measurement period or pregnancy during the measurement period	Procedure	HCPCS
I95.3	Hypotension of hemodialysis	Diagnosis	ICD-10-CM
J0882	Injection, darbepoetin alfa, 1 mcg (for ESRD on dialysis)	Procedure	HCPCS
J0886	Injection, epoetin alfa, 1000 units (for ESRD on dialysis)	Procedure	HCPCS
J0887	Injection, epoetin beta, 1 mcg, (for ESRD on dialysis)	Procedure	HCPCS
K0610	Peritoneal dialysis clamp, each	Procedure	HCPCS
K0612	Drainage extension line, sterile, for dialysis, each	Procedure	HCPCS
Q0139	Injection, ferumoxytol, for treatment of iron deficiency anemia, 1 mg (for ESRD on dialysis)	Procedure	HCPCS
Q4054	Injection, darbepoetin alfa, 1 mcg (for ESRD on dialysis)	Procedure	HCPCS
Q4055	Injection, epoetin alfa, 1000 units (for ESRD on dialysis)	Procedure	HCPCS
Q4081	Injection, epoetin alfa, 100 units (for ESRD on dialysis)	Procedure	HCPCS
Q9972	Injection, epoetin beta, 1 microgram, (for ESRD on dialysis)	Procedure	HCPCS
R88.0	Cloudy (hemodialysis) (peritoneal) dialysis effluent	Diagnosis	ICD-10-CM
S9335	Home therapy, hemodialysis; administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing services coded separately), per diem	Procedure	HCPCS

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

Code	Description	Code Category	Code Type
S9339	Home therapy; peritoneal dialysis, administrative services, professional pharmacy services, care coordination and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem	Procedure	HCPCS
T81.502	Unspecified complication of foreign body accidentally left in body following kidney dialysis	Diagnosis	ICD-10-CM
T81.502A	Unspecified complication of foreign body accidentally left in body following kidney dialysis, initial encounter	Diagnosis	ICD-10-CM
T81.502D	Unspecified complication of foreign body accidentally left in body following kidney dialysis, subsequent encounter	Diagnosis	ICD-10-CM
T81.502S	Unspecified complication of foreign body accidentally left in body following kidney dialysis, sequela	Diagnosis	ICD-10-CM
T81.512	Adhesions due to foreign body accidentally left in body following kidney dialysis	Diagnosis	ICD-10-CM
T81.512A	Adhesions due to foreign body accidentally left in body following kidney dialysis, initial encounter	Diagnosis	ICD-10-CM
T81.512D	Adhesions due to foreign body accidentally left in body following kidney dialysis, subsequent encounter	Diagnosis	ICD-10-CM
T81.512S	Adhesions due to foreign body accidentally left in body following kidney dialysis, sequela	Diagnosis	ICD-10-CM
T81.522	Obstruction due to foreign body accidentally left in body following kidney dialysis	Diagnosis	ICD-10-CM
T81.522A	Obstruction due to foreign body accidentally left in body following kidney dialysis, initial encounter	Diagnosis	ICD-10-CM
T81.522D	Obstruction due to foreign body accidentally left in body following kidney dialysis, subsequent encounter	Diagnosis	ICD-10-CM
T81.522S	Obstruction due to foreign body accidentally left in body following kidney dialysis, sequela	Diagnosis	ICD-10-CM
T81.532	Perforation due to foreign body accidentally left in body following kidney dialysis	Diagnosis	ICD-10-CM
T81.532A	Perforation due to foreign body accidentally left in body following kidney dialysis, initial encounter	Diagnosis	ICD-10-CM
T81.532D	Perforation due to foreign body accidentally left in body following kidney dialysis, subsequent encounter	Diagnosis	ICD-10-CM
T81.532S	Perforation due to foreign body accidentally left in body following kidney dialysis, sequela	Diagnosis	ICD-10-CM
T81.592	Other complications of foreign body accidentally left in body following kidney dialysis	Diagnosis	ICD-10-CM
T81.592A	Other complications of foreign body accidentally left in body following kidney dialysis, initial encounter	Diagnosis	ICD-10-CM
T81.592D	Other complications of foreign body accidentally left in body following kidney dialysis, subsequent encounter	Diagnosis	ICD-10-CM
T81.592S	Other complications of foreign body accidentally left in body following kidney dialysis, sequela	Diagnosis	ICD-10-CM
T82.41XA	Breakdown (mechanical) of vascular dialysis catheter, initial encounter	Diagnosis	ICD-10-CM
T82.41XD	Breakdown (mechanical) of vascular dialysis catheter, subsequent encounter	Diagnosis	ICD-10-CM
T82.41XS	Breakdown (mechanical) of vascular dialysis catheter, sequela	Diagnosis	ICD-10-CM
T82.42XA	Displacement of vascular dialysis catheter, initial encounter	Diagnosis	ICD-10-CM
T82.42XD	Displacement of vascular dialysis catheter, subsequent encounter	Diagnosis	ICD-10-CM

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Code	Description	Code Category	Code Type
T82.42XS	Displacement of vascular dialysis catheter, sequela	Diagnosis	ICD-10-CM
T82.43XA	Leakage of vascular dialysis catheter, initial encounter	Diagnosis	ICD-10-CM
T82.43XD	Leakage of vascular dialysis catheter, subsequent encounter	Diagnosis	ICD-10-CM
T82.43XS	Leakage of vascular dialysis catheter, sequela	Diagnosis	ICD-10-CM
T82.49XA	Other complication of vascular dialysis catheter, initial encounter	Diagnosis	ICD-10-CM
T82.49XD	Other complication of vascular dialysis catheter, subsequent encounter	Diagnosis	ICD-10-CM
T82.49XS	Other complication of vascular dialysis catheter, sequela	Diagnosis	ICD-10-CM
T85.611	Breakdown (mechanical) of intraperitoneal dialysis catheter	Diagnosis	ICD-10-CM
T85.611A	Breakdown (mechanical) of intraperitoneal dialysis catheter, initial encounter	Diagnosis	ICD-10-CM
T85.611D	Breakdown (mechanical) of intraperitoneal dialysis catheter, subsequent encounter	Diagnosis	ICD-10-CM
T85.611S	Breakdown (mechanical) of intraperitoneal dialysis catheter, sequela	Diagnosis	ICD-10-CM
T85.621	Displacement of intraperitoneal dialysis catheter	Diagnosis	ICD-10-CM
T85.621A	Displacement of intraperitoneal dialysis catheter, initial encounter	Diagnosis	ICD-10-CM
T85.621D	Displacement of intraperitoneal dialysis catheter, subsequent encounter	Diagnosis	ICD-10-CM
T85.621S	Displacement of intraperitoneal dialysis catheter, sequela	Diagnosis	ICD-10-CM
T85.631	Leakage of intraperitoneal dialysis catheter	Diagnosis	ICD-10-CM
T85.631A	Leakage of intraperitoneal dialysis catheter, initial encounter	Diagnosis	ICD-10-CM
T85.631D	Leakage of intraperitoneal dialysis catheter, subsequent encounter	Diagnosis	ICD-10-CM
T85.631S	Leakage of intraperitoneal dialysis catheter, sequela	Diagnosis	ICD-10-CM
T85.691	Other mechanical complication of intraperitoneal dialysis catheter	Diagnosis	ICD-10-CM
T85.691A	Other mechanical complication of intraperitoneal dialysis catheter, initial encounter	Diagnosis	ICD-10-CM
T85.691D	Other mechanical complication of intraperitoneal dialysis catheter, subsequent encounter	Diagnosis	ICD-10-CM
T85.691S	Other mechanical complication of intraperitoneal dialysis catheter, sequela	Diagnosis	ICD-10-CM
T85.71XA	Infection and inflammatory reaction due to peritoneal dialysis catheter, initial encounter	Diagnosis	ICD-10-CM
T85.71XD	Infection and inflammatory reaction due to peritoneal dialysis catheter, subsequent encounter	Diagnosis	ICD-10-CM
T85.71XS	Infection and inflammatory reaction due to peritoneal dialysis catheter, sequela	Diagnosis	ICD-10-CM
V45.1	Renal dialysis status	Diagnosis	ICD-9-CM
V45.11	Renal dialysis status	Diagnosis	ICD-9-CM
V45.12	Noncompliance with renal dialysis	Diagnosis	ICD-9-CM
V56.0	Encounter for extracorporeal dialysis	Diagnosis	ICD-9-CM
V56.1	Fitting and adjustment of extracorporeal dialysis catheter	Diagnosis	ICD-9-CM
V56.2	Fitting and adjustment of peritoneal dialysis catheter	Diagnosis	ICD-9-CM
V56.3	Encounter for adequacy testing for dialysis	Diagnosis	ICD-9-CM
V56.31	Encounter for adequacy testing for hemodialysis	Diagnosis	ICD-9-CM
V56.32	Encounter for adequacy testing for peritoneal dialysis	Diagnosis	ICD-9-CM
V56.8	Encounter other dialysis	Diagnosis	ICD-9-CM
Y62.2	Failure of sterile precautions during kidney dialysis and other perfusion	Diagnosis	ICD-10-CM
Y84.1	Kidney dialysis as the cause of abnormal reaction of the patient, or of later complication, without mention of misadventure at the time of the procedure	Diagnosis	ICD-10-CM
Z49.01	Encounter for fitting and adjustment of extracorporeal dialysis catheter	Diagnosis	ICD-10-CM
Z49.02	Encounter for fitting and adjustment of peritoneal dialysis catheter	Diagnosis	ICD-10-CM

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Code	Description	Code Category	Code Type
Z49.31	Encounter for adequacy testing for hemodialysis	Diagnosis	ICD-10-CM
Z49.32	Encounter for adequacy testing for peritoneal dialysis	Diagnosis	ICD-10-CM
Z91.15	Patient's noncompliance with renal dialysis	Diagnosis	ICD-10-CM
Z94.0	Kidney transplant status	Diagnosis	ICD-10-CM
Z99.2	Dependence on renal dialysis	Diagnosis	ICD-10-CM
	Chronic Kidney Disease Treatment		
C1774	Injection, darbepoetin alfa (for non esrd use), per 1 mcg	Procedure	HCPCS
J0635	Injection, calcitriol, 1 mcg amp.	Procedure	HCPCS
J0636	Injection, calcitriol, 0.1 mcg	Procedure	HCPCS
J0880	Injection, darbepoetin alfa, 5 mcg	Procedure	HCPCS
J0881	Injection, darbepoetin alfa, 1 mcg (non-ESRD use)	Procedure	HCPCS
J0882	Injection, darbepoetin alfa, 1 mcg (for ESRD on dialysis)	Procedure	HCPCS
J0885	Injection, epoetin alfa, (for non-ESRD use), 1000 units	Procedure	HCPCS
J0886	Injection, epoetin alfa, 1000 units (for ESRD on dialysis)	Procedure	HCPCS
Q0137	Injection, darbepoetin alfa, 1 mcg (non-ESRD use)	Procedure	HCPCS
Q4054	Injection, darbepoetin alfa, 1 mcg (for ESRD on dialysis)	Procedure	HCPCS
Q4055	Injection, epoetin alfa, 1000 units (for ESRD on dialysis)	Procedure	HCPCS
Q4081	Injection, epoetin alfa, 100 units (for ESRD on dialysis)	Procedure	HCPCS
Q5105	Injection, epoetin alfa-epbx, biosimilar, (Retacrit) (for ESRD on dialysis), 100 units	Procedure	HCPCS
Q5106	Injection, epoetin alfa-epbx, biosimilar, (Retacrit) (for non-ESRD use), 1000 units	Procedure	HCPCS
S0112	INJECTION, DARBEPOETIN ALFA, 1 MCG	Procedure	HCPCS
S0169	Calcitriol, 0.25 mcg	Procedure	HCPCS
	Diabetic Ketoacidosis		
250.10	Diabetes with ketoacidosis, type II or unspecified type, not stated as uncontrolled	Diagnosis	ICD-9-CM
250.11	Diabetes with ketoacidosis, type I [juvenile type], not stated as uncontrolled	Diagnosis	ICD-9-CM
250.12	Diabetes with ketoacidosis, type II or unspecified type, uncontrolled	Diagnosis	ICD-9-CM
250.13	Diabetes with ketoacidosis, type I [juvenile type], uncontrolled	Diagnosis	ICD-9-CM
E10.10	Type 1 diabetes mellitus with ketoacidosis without coma	Diagnosis	ICD-10-CM
E10.11	Type 1 diabetes mellitus with ketoacidosis with coma	Diagnosis	ICD-10-CM
E11.10	Type 2 diabetes mellitus with ketoacidosis without coma	Diagnosis	ICD-10-CM
E11.11	Type 2 diabetes mellitus with ketoacidosis with coma	Diagnosis	ICD-10-CM
E13.10	Other specified diabetes mellitus with ketoacidosis without coma	Diagnosis	ICD-10-CM
E13.11	Other specified diabetes mellitus with ketoacidosis with coma	Diagnosis	ICD-10-CM
	Long/Intermediate-Acting Insulin		
S5552	Insulin, intermediate acting (NPH or LENTE); 5 units	Procedure	HCPCS
S5553	Insulin, long acting; 5 units	Procedure	HCPCS
	Short/Rapid-Acting Insulin		
S5550	Insulin, rapid onset, 5 units	Procedure	HCPCS
S5551	Insulin, most rapid onset (Lispro or Aspart); 5 units	Procedure	HCPCS
	Insulin Pump		
A4225	Supplies for external insulin infusion pump, syringe type cartridge, sterile, each	Procedure	HCPCS
A4230	Infusion set for external insulin pump, nonneedle cannula type	Procedure	HCPCS
A4231	Infusion set for external insulin pump, needle type	Procedure	HCPCS
A4232	Syringe with needle for external insulin pump, sterile, 3 cc	Procedure	HCPCS

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

Code	Description	Code Category	Code Type
E0784	External ambulatory infusion pump, insulin	Procedure	HCPCS
J1811	Insulin (Fiasp) for administration through DME (i.e., insulin pump) per 50 units	Procedure	HCPCS
J1813	Insulin (Lyumjev) for administration through DME (i.e., insulin pump) per 50 units	Procedure	HCPCS
J1817	Insulin for administration through DME (i.e., insulin pump) per 50 units	Procedure	HCPCS
S1034	Artificial pancreas device system (e.g., low glucose suspend [LGS] feature) including continuous glucose monitor, blood glucose device, insulin pump and computer algorithm that communicates with all of the devices	Procedure	HCPCS
S5565	Insulin cartridge for use in insulin delivery device other than pump; 150 units	Procedure	HCPCS
S5566	Insulin cartridge for use in insulin delivery device other than pump; 300 units	Procedure	HCPCS
S9145	Insulin pump initiation, instruction in initial use of pump (pump not included)	Procedure	HCPCS

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

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

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

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

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

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

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

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

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

Generic Name	Brand Name
Short/Rapid-Acting Insulin	
insulin aspart	Novolog FlexPen U-100 Insulin
insulin aspart	Novolog PenFill U-100 Insulin
insulin aspart	Novolog U-100 Insulin aspart
insulin aspart	insulin aspart U-100
insulin aspart (niacinamide)	Fiasp FlexTouch U-100 Insulin
insulin aspart (niacinamide)	Fiasp Penfill U-100 Insulin
insulin aspart (niacinamide)	Fiasp U-100 Insulin
insulin aspart (niacinamide)/pump cartridge	Fiasp Pumpcart
insulin glulisine	Apidra SoloStar U-100 Insulin
insulin glulisine	Apidra U-100 Insulin
insulin lispro	Admelog SoloStar U-100 Insulin
insulin lispro	Admelog U-100 Insulin lispro
insulin lispro	Humalog Junior KwikPen U-100
insulin lispro	Humalog KwikPen Insulin
insulin lispro	Humalog Tempo Pen(U-100)Insuln
insulin lispro	Humalog U-100 Insulin
insulin lispro	insulin lispro
insulin lispro-aabc	Lyumjev KwikPen U-100 Insulin
insulin lispro-aabc	Lyumjev KwikPen U-200 Insulin
insulin lispro-aabc	Lyumjev Tempo Pen(U-100)Insuln
insulin lispro-aabc	Lyumjev U-100 Insulin
insulin regular, human	Afrezza
insulin regular, human	Humulin R Regular U-100 Insuln
insulin regular, human	Humulin R U-500 (Conc) Insulin
insulin regular, human	Humulin R U-500 (Conc) Kwikpen
insulin regular, human	Novolin R FlexPen
insulin regular, human	Novolin R Regular U100 Insulin
insulin regular, human in 0.9 % sodium chloride	Myxredlin
Combination Insulin	
insulin NPH human isophane/insulin regular, human	Humulin 70/30 Insulin Pen
insulin NPH human isophane/insulin regular, human	Humulin 70/30 U-100 Insulin
insulin NPH human isophane/insulin regular, human	Humulin 70/30 U-100 KwikPen
insulin NPH human isophane/insulin regular, human	Novolin 70-30 FlexPen U-100
insulin NPH human isophane/insulin regular, human	Novolin 70/30 U-100 Insulin
insulin aspart protamine human/insulin aspart	Novolog Mix 70-30 U-100 Insuln
insulin aspart protamine human/insulin aspart	Novolog Mix 70-30FlexPen U-100
insulin aspart protamine human/insulin aspart	insulin asp prt-insulin aspart
insulin lispro protamine and insulin lispro	Humalog Mix 50-50 Insuln U-100
insulin lispro protamine and insulin lispro	Humalog Mix 50-50 KwikPen
insulin lispro protamine and insulin lispro	Humalog Mix 75-25 KwikPen
insulin lispro protamine and insulin lispro	Humalog Mix 75-25(U-100)Insuln
insulin lispro protamine and insulin lispro	insulin lispro protamin-lispro

Appendix I. Specifications Used to Define Parameters in this Request

This request executed the Cohort Identification and Descriptive Analysis (CIDA) tool [version 13.2.0] to estimate rates of diabetic ketoacidosis (DKA) among patients with short/rapid-acting insulin exposure and a history of type 1 diabetes in the Sentinel Distributed Database (SDD).

Query Period:	March 1, 2013 - Most recently available data (January 31, 2024)
Coverage requirement:	Medical & Drug Coverage
Pre-index enrollment requirement:	365 days
Post-index requirement:	0 days
Enrollment gap:	45 days
Age groups:	<12, 12-18, 19-24, 25-44, 45-64, ≥65 years
Strata:	Chronic kidney disease (CKD) definition (covar 35, 36, 37, 38) cross stratified by Age, Sex, Year, Race, Ethnicity
Restrictions:	M/F sex
Envelope macro:	Reclassify encounters during inpatient stay as inpatient
Freeze data:	No

Exposure

Scenario	Index Exposure	Cohort Definition	Incident Exposure Washout Period	Incident with Respect to:	Exclude Evidence of Days Supply if Event Washout Includes Dispensings	Treatment Episode Gap Type	Treatment Episode Gap	Exposure Episode Extension Period	Maximum Exposure Episode Duration	Care Setting	Principal Diagnosis Position	Create Baseline Table (Y/N)
15	Short/Rapid-Acting Insulin	**01:** Cohort includes only the first valid exposure episode during the query period	0	n/a[1]	No	**F:** Fixed episode gap.	10	10	365	n/a	n/a	Yes

Appendix I. Specifications Used to Define Parameters in this Request (Continued)

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

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

[1]n/a: Not applicable

[2] IP: Inpatient; ED: Emergency Department

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

Baseline Characteristics

Characteristic Name	Characteristic Number	Combo Logic	Code Category	Care Setting	Principal Diagnosis Position	Characteristic Evaluation Period Start	Characteristic Evaluation Period End	Exclude Evidence of Days Supply if Event Washout Includes Dispensings	Number of Instances the Characteristic Should be Found in Evaluation Period	Output in Baseline Table (Y/N)
Chronic Kidney Disease (CKD) Definition Components										
CKD 4/5: Diagnosis Code	1		Diagnosis	Any	n/a[1]	-365	0	n/a	1	No
CKD 4/5: Dialysis	2		Diagnosis, Procedure	Any	n/a	-365	0	n/a	1	No
CKD 3: Diagnosis Code	3		Diagnosis	Any	n/a	-365	0	n/a	1	No
CKD 3: Any CKD x3	4		Diagnosis	Any	n/a	-365	0	n/a	3	No
Renal Failure or CKD	5		Diagnosis	Any	n/a	-365	0	n/a	1	No
CKD treatment	6		Dispensing, Procedure	Any	n/a	-365	0	No	1	No
CKD 3: CKD and treatment	34	5 and 6	Combo covariate	Any	n/a				1	No
CKD 2: Renal failure	7		Diagnosis	Any	n/a	-365	0	No	1	No
CKD 2: CKD Stage 1	8		Diagnosis	Any	n/a	-365	0	No	1	No
CKD 2: CKD Stage 2	9		Diagnosis	Any	n/a	-365	0	No	1	No
CKD 2: CKD Stage 3	10		Diagnosis	Any	n/a	-365	0	No	1	No
CKD 2: CKD Stage 4	11		Diagnosis	Any	n/a	-365	0	No	1	No
CKD 2: CKD Stage 5	12		Diagnosis	Any	n/a	-365	0	No	1	No
CKD 2: Unspecified CKD	13		Diagnosis	Any	n/a	-365	0	No	1	No
CKD 2: End Stage Renal Disease (ESRD)	14		Diagnosis	Any	n/a	-365	0	No	1	No

Baseline Characteristics

Characteristic Name	Characteristic Number	Combo Logic	Code Category	Care Setting	Principal Diagnosis Position	Characteristic Evaluation Period Start	Characteristic Evaluation Period End	Exclude Evidence of Days Supply if Event Washout Includes Dispensings	Number of Instances the Characteristic Should be Found in Evaluation Period	Output in Baseline Table (Y/N)
Chronic Kidney Disease Stages										
CKD Stage 4 or 5	35	1 or 2	Combo covariate						1	Yes
CKD Stage 3	36	(3 or 4 or (5 and 6)) and not 35	Combo covariate						1	Yes
CKD Stage 2	37	5 and not (36 or 35)	Combo covariate						1	Yes
CKD Stage 1	38	not (37 or 36 or 35)	Combo covariate						1	Yes
Diabetic Ketoacidosis (DKA)										
History of DKA	15		Diagnosis	IP, ED[2]	n/a	-365	-1	n/a	1	No
At least 1 DKA event	16		Diagnosis	IP, ED	n/a	1	365	n/a	1	No
At least 2 DKA events	17		Diagnosis	IP, ED	n/a	1	365	n/a	2	No
At least 3 DKA events	18		Diagnosis	IP, ED	n/a	1	365	n/a	3	No
At least 4 DKA events	19		Diagnosis	IP, ED	n/a	1	365	n/a	4	No
At least 5 DKA events	20		Diagnosis	IP, ED	n/a	1	365	n/a	5	No
Exactly 1 DKA event	39	16 and not 17	Combo covariate						1	No
Exactly 2 DKA events	40	17 and not 18	Combo covariate						1	No
Exactly 3 DKA events	41	18 and not 19	Combo covariate						1	No
Exactly 4 DKA events	42	19 and not 20	Combo covariate						1	No

Appendix J. Specifications Used to Define Baseline Characteristic Parameters in this Request

Baseline Characteristics

Characteristic Name	Characteristic Number	Combo Logic	Code Category	Care Setting	Principal Diagnosis Position	Characteristic Evaluation Period Start	Characteristic Evaluation Period End	Exclude Evidence of Days Supply if Event Washout Includes Dispensings	Number of Instances the Characteristic Should be Found in Evaluation Period	Output in Baseline Table (Y/N)
Baseline Diabetes Treatments by Active Ingredient										
Metformin	21		Dispensing	Any	n/a	-365	-1	No	1	No
Sulfonylureas	22		Dispensing	Any	n/a	-365	-1	No	1	No
Thiazolidinediones	23		Dispensing	Any	n/a	-365	-1	No	1	No
Alpha-glucosidase inhibitors	24		Dispensing	Any	n/a	-365	-1	No	1	No
Meglitinides	25		Dispensing	Any	n/a	-365	-1	No	1	No
Dipeptidyl Peptidase-4 (DPP-4) Inhibitors	26		Dispensing	Any	n/a	-365	-1	No	1	No
Sodium-Glucose Cotransporter-2 (SGLT-2) Inhibitors	27		Dispensing	Any	n/a	-365	-1	No	1	No
Glucagon-Like Peptide-1 Receptor Agonists (GLP-1 RAs)	28		Dispensing, Procedure	Any	n/a	-365	-1	No	1	No
Other oral diabetes drugs (bromocriptine and colesevelam)	29		Dispensing	Any	n/a	-365	-1	No	1	No
Insulin Products										
Short/rapid acting insulin	30		Dispensing, Procedure	Any	n/a	-365	-1	No	1	No
Long/intermediate acting insulin	31		Dispensing, Procedure	Any	n/a	-365	-1	No	1	No
Combination insulin	32		Dispensing, Procedure	Any	n/a	-365	-1	No	1	No
Insulin pump	33		Dispensing, Procedure	Any	n/a	-365	-1	No	1	No

Baseline Characteristics

Characteristic Name	Characteristic Number	Combo Logic	Code Category	Care Setting	Principal Diagnosis Position	Characteristic Evaluation Period Start	Characteristic Evaluation Period End	Exclude Evidence of Days Supply if Event Washout Includes Dispensings	Number of Instances the Characteristic Should be Found in Evaluation Period	Output in Baseline Table (Y/N)
CKD Stage 1 Characteristics										
CKD 4/5: Diagnosis Code	43	38 and 1	Combo covariate	Any	n/a				1	No
CKD 4/5: Dialysis	44	38 and 2	Combo covariate	Any	n/a				1	No
CKD 3: Diagnosis Code	45	38 and 3	Combo covariate	Any	n/a				1	No
CKD 3: Any CKD x3	46	38 and 4	Combo covariate	Any	n/a				1	No
CKD 3: CKD and treatment	47	38 and 34	Combo covariate	Any	n/a				1	No
CKD 2: Renal failure	48	38 and 7	Combo covariate	Any	n/a				1	No
CKD 2: CKD Stage 1	49	38 and 8	Combo covariate	Any	n/a				1	No
CKD 2: CKD Stage 2	50	38 and 9	Combo covariate	Any	n/a				1	No
CKD 2: CKD Stage 3	51	38 and 10	Combo covariate	Any	n/a				1	No
CKD 2: CKD Stage 4	52	38 and 11	Combo covariate	Any	n/a				1	No
CKD 2: CKD Stage 5	53	38 and 12	Combo covariate	Any	n/a				1	No
CKD 2: Unspecified CKD	54	38 and 13	Combo covariate	Any	n/a				1	No
CKD 2: ESRD	55	38 and 14	Combo covariate	Any	n/a				1	No
History of DKA	56	38 and 15	Combo covariate	Any	n/a				1	No
At least 1 DKA event	57	38 and 16	Combo covariate	Any	n/a				1	No
Exactly 1 DKA event	58	38 and 39	Combo covariate	Any	n/a				1	No
Exactly 2 DKA events	59	38 and 40	Combo covariate	Any	n/a				1	No
Exactly 3 DKA events	60	38 and 41	Combo covariate	Any	n/a				1	No
Exactly 4 DKA events	61	38 and 42	Combo covariate	Any	n/a				1	No
At least 5 DKA events	62	38 and 20	Combo covariate	Any	n/a				1	No
Metformin	63	38 and 21	Combo covariate	Any	n/a				1	No
Sulfonylureas	64	38 and 22	Combo covariate	Any	n/a				1	No
Thiazolidinediones	65	38 and 23	Combo covariate	Any	n/a				1	No

Baseline Characteristics

Characteristic Name	Characteristic Number	Combo Logic	Code Category	Care Setting	Principal Diagnosis Position	Characteristic Evaluation Period Start	Characteristic Evaluation Period End	Exclude Evidence of Days Supply if Event Washout Includes Dispensings	Number of Instances the Characteristic Should be Found in Evaluation Period	Output in Baseline Table (Y/N)
CKD Stage 1 Characteristics										
Alpha-glucosidase inhibitors	66	38 and 24	Combo covariate	Any	n/a				1	No
Meglitinides	67	38 and 25	Combo covariate	Any	n/a				1	No
DPP-4 inhibitors	68	38 and 26	Combo covariate	Any	n/a				1	No
SGLT-2 inhibitors	69	38 and 27	Combo covariate	Any	n/a				1	No
GLP-1 RAs	70	38 and 28	Combo covariate	Any	n/a				1	No
Other oral diabetes drugs (bromocriptine and colesevelam)	71	38 and 29	Combo covariate	Any	n/a				1	No
Short/rapid acting insulin	72	38 and 30	Combo covariate	Any	n/a				1	No
Long/intermediate acting insulin	73	38 and 31	Combo covariate	Any	n/a				1	No
Combination insulin	74	38 and 32	Combo covariate	Any	n/a				1	No
Insulin pump	75	38 and 33	Combo covariate	Any	n/a				1	No

Baseline Characteristics

Characteristic Name	Characteristic Number	Combo Logic	Code Category	Care Setting	Principal Diagnosis Position	Characteristic Evaluation Period Start	Characteristic Evaluation Period End	Exclude Evidence of Days Supply if Event Washout Includes Dispensings	Number of Instances the Characteristic Should be Found in Evaluation Period	Output in Baseline Table (Y/N)
CKD Stage 2 Characteristics										
CKD 4/5: Diagnosis Code	76	37 and 1	Combo covariate	Any	n/a				1	No
CKD 4/5: Dialysis	77	37 and 2	Combo covariate	Any	n/a				1	No
CKD 3: Diagnosis Code	78	37 and 3	Combo covariate	Any	n/a				1	No
CKD 3: Any CKD x3	79	37 and 4	Combo covariate	Any	n/a				1	No
CKD 3: CKD and treatment	80	37 and 34	Combo covariate	Any	n/a				1	No
CKD 2: Renal failure	81	37 and 7	Combo covariate	Any	n/a				1	No
CKD 2: CKD Stage 1	82	37 and 8	Combo covariate	Any	n/a				1	No
CKD 2: CKD Stage 2	83	37 and 9	Combo covariate	Any	n/a				1	No
CKD 2: CKD Stage 3	84	37 and 10	Combo covariate	Any	n/a				1	No
CKD 2: CKD Stage 4	85	37 and 11	Combo covariate	Any	n/a				1	No
CKD 2: CKD Stage 5	86	37 and 12	Combo covariate	Any	n/a				1	No
CKD 2: Unspecified CKD	87	37 and 13	Combo covariate	Any	n/a				1	No
CKD 2: ESRD	88	37 and 14	Combo covariate	Any	n/a				1	No
History of DKA	89	37 and 15	Combo covariate	Any	n/a				1	No
At least 1 DKA event	90	37 and 16	Combo covariate	Any	n/a				1	No
Exactly 1 DKA event	91	37 and 39	Combo covariate	Any	n/a				1	No
Exactly 2 DKA events	92	37 and 40	Combo covariate	Any	n/a				1	No
Exactly 3 DKA events	93	37 and 41	Combo covariate	Any	n/a				1	No
Exactly 4 DKA events	94	37 and 42	Combo covariate	Any	n/a				1	No
At least 5 DKA events	95	37 and 20	Combo covariate	Any	n/a				1	No
Metformin	96	37 and 21	Combo covariate	Any	n/a				1	No
Sulfonylureas	97	37 and 22	Combo covariate	Any	n/a				1	No
Thiazolidinediones	98	37 and 23	Combo covariate	Any	n/a				1	No

Appendix J. Specifications Used to Define Baseline Characteristic Parameters in this Request

								Exclude Evidence of Days Supply if Event Washout Includes	Number of Instances the Characteristic Should be Found	Output in
Characteristic Name	Characteristic Number	Combo Logic	Code Category	Care Setting	Principal Diagnosis Position	Characteristic Evaluation Period Start	Characteristic Evaluation Period End	Dispensings	in Evaluation Period	Baseline Table (Y/N)
CKD Stage 2 Characteristics										
Alpha-glucosidase inhibitors	99	37 and 24	Combo covariate	Any	n/a				1	No
Meglitinides	100	37 and 25	Combo covariate	Any	n/a				1	No
DPP-4 inhibitors	101	37 and 26	Combo covariate	Any	n/a				1	No
SGLT-2 inhibitors	102	37 and 27	Combo covariate	Any	n/a				1	No
GLP-1 RAs	103	37 and 28	Combo covariate	Any	n/a				1	No
Other oral diabetes drugs (bromocriptine and colesevelam)	104	37 and 29	Combo covariate	Any	n/a				1	No
Short/rapid acting insulin	105	37 and 30	Combo covariate	Any	n/a				1	No
Long/intermediate acting insulin	106	37 and 31	Combo covariate	Any	n/a				1	No
Combination insulin	107	37 and 32	Combo covariate	Any	n/a				1	No
Insulin pump	108	37 and 33	Combo covariate	Any	n/a				1	No

Baseline Characteristics

Characteristic Name	Characteristic Number	Combo Logic	Code Category	Care Setting	Principal Diagnosis Position	Characteristic Evaluation Period Start	Characteristic Evaluation Period End	Exclude Evidence of Days Supply if Event Washout Includes Dispensings	Number of Instances the Characteristic Should be Found in Evaluation Period	Output in Baseline Table (Y/N)
CKD Stage 3 Characteristics										
CKD 4/5: Diagnosis Code	109	36 and 1	Combo covariate	Any	n/a				1	No
CKD 4/5: Dialysis	110	36 and 2	Combo covariate	Any	n/a				1	No
CKD 3: Diagnosis Code	111	36 and 3	Combo covariate	Any	n/a				1	No
CKD 3: Any CKD x3	112	36 and 4	Combo covariate	Any	n/a				1	No
CKD 3: CKD and treatment	113	36 and 34	Combo covariate	Any	n/a				1	No
CKD 2: Renal failure	114	36 and 7	Combo covariate	Any	n/a				1	No
CKD 2: CKD Stage 1	115	36 and 8	Combo covariate	Any	n/a				1	No
CKD 2: CKD Stage 2	116	36 and 9	Combo covariate	Any	n/a				1	No
CKD 2: CKD Stage 3	117	36 and 10	Combo covariate	Any	n/a				1	No
CKD 2: CKD Stage 4	118	36 and 11	Combo covariate	Any	n/a				1	No
CKD 2: CKD Stage 5	119	36 and 12	Combo covariate	Any	n/a				1	No
CKD 2: Unspecified CKD	120	36 and 13	Combo covariate	Any	n/a				1	No
CKD 2: ESRD	121	36 and 14	Combo covariate	Any	n/a				1	No
History of DKA	122	36 and 15	Combo covariate	Any	n/a				1	No
At least 1 DKA event	123	36 and 16	Combo covariate	Any	n/a				1	No
Exactly 1 DKA event	124	36 and 39	Combo covariate	Any	n/a				1	No
Exactly 2 DKA events	125	36 and 40	Combo covariate	Any	n/a				1	No
Exactly 3 DKA events	126	36 and 41	Combo covariate	Any	n/a				1	No
Exactly 4 DKA events	127	36 and 42	Combo covariate	Any	n/a				1	No
At least 5 DKA events	128	36 and 20	Combo covariate	Any	n/a				1	No
Metformin	129	36 and 21	Combo covariate	Any	n/a				1	No
Sulfonylureas	130	36 and 22	Combo covariate	Any	n/a				1	No
Thiazolidinediones	131	36 and 23	Combo covariate	Any	n/a				1	No

Appendix J. Specifications Used to Define Baseline Characteristic Parameters in this Request

Baseline Characteristics

Characteristic Name	Characteristic Number	Combo Logic	Code Category	Care Setting	Principal Diagnosis Position	Characteristic Evaluation Period Start	Characteristic Evaluation Period End	Exclude Evidence of Days Supply if Event Washout Includes Dispensings	Number of Instances the Characteristic Should be Found in Evaluation Period	Output in Baseline Table (Y/N)
CKD Stage 3 Characteristics										
Alpha-glucosidase inhibitors	132	36 and 24	Combo covariate	Any	n/a				1	No
Meglitinides	133	36 and 25	Combo covariate	Any	n/a				1	No
DPP-4 inhibitors	134	36 and 26	Combo covariate	Any	n/a				1	No
SGLT-2 inhibitors	135	36 and 27	Combo covariate	Any	n/a				1	No
GLP-1 RAs	136	36 and 28	Combo covariate	Any	n/a				1	No
Other oral diabetes drugs (bromocriptine and colesevelam)	137	36 and 29	Combo covariate	Any	n/a				1	No
Short/rapid acting insulin	138	36 and 30	Combo covariate	Any	n/a				1	No
Long/intermediate acting insulin	139	36 and 31	Combo covariate	Any	n/a				1	No
Combination insulin	140	36 and 32	Combo covariate	Any	n/a				1	No
Insulin pump	141	36 and 33	Combo covariate	Any	n/a				1	No

Appendix J. Specifications Used to Define Baseline Characteristic Parameters in this Request

Baseline Characteristics

Characteristic Name	Characteristic Number	Combo Logic	Code Category	Care Setting	Principal Diagnosis Position	Characteristic Evaluation Period Start	Characteristic Evaluation Period End	Exclude Evidence of Days Supply if Event Washout Includes Dispensings	Number of Instances the Characteristic Should be Found in Evaluation Period	Output in Baseline Table (Y/N)
CKD Stage 4/5 Characteristics										
CKD 4/5: Diagnosis Code	142	35 and 1	Combo covariate	Any	n/a				1	No
CKD 4/5: Dialysis	143	35 and 2	Combo covariate	Any	n/a				1	No
CKD 3: Diagnosis Code	144	35 and 3	Combo covariate	Any	n/a				1	No
CKD 3: Any CKD x3	145	35 and 4	Combo covariate	Any	n/a				1	No
CKD 3: CKD and treatment	146	35 and 34	Combo covariate	Any	n/a				1	No
CKD 2: Renal failure	147	35 and 7	Combo covariate	Any	n/a				1	No
CKD 2: CKD Stage 1	148	35 and 8	Combo covariate	Any	n/a				1	No
CKD 2: CKD Stage 2	149	35 and 9	Combo covariate	Any	n/a				1	No
CKD 2: CKD Stage 3	150	35 and 10	Combo covariate	Any	n/a				1	No
CKD 2: CKD Stage 4	151	35 and 11	Combo covariate	Any	n/a				1	No
CKD 2: CKD Stage 5	152	35 and 12	Combo covariate	Any	n/a				1	No
CKD 2: Unspecified CKD	153	35 and 13	Combo covariate	Any	n/a				1	No
CKD 2: ESRD	154	35 and 14	Combo covariate	Any	n/a				1	No
History of DKA	155	35 and 15	Combo covariate	Any	n/a				1	No
At least 1 DKA event	156	35 and 16	Combo covariate	Any	n/a				1	No
Exactly 1 DKA event	157	35 and 39	Combo covariate	Any	n/a				1	No
Exactly 2 DKA events	158	35 and 40	Combo covariate	Any	n/a				1	No
Exactly 3 DKA events	159	35 and 41	Combo covariate	Any	n/a				1	No
Exactly 4 DKA events	160	35 and 42	Combo covariate	Any	n/a				1	No
At least 5 DKA events	161	35 and 20	Combo covariate	Any	n/a				1	No
Metformin	162	35 and 21	Combo covariate	Any	n/a				1	No
Sulfonylureas	163	35 and 22	Combo covariate	Any	n/a				1	No
Thiazolidinediones	164	35 and 23	Combo covariate	Any	n/a				1	No

Baseline Characteristics

Characteristic Name	Characteristic Number	Combo Logic	Code Category	Care Setting	Principal Diagnosis Position	Characteristic Evaluation Period Start	Characteristic Evaluation Period End	Exclude Evidence of Days Supply if Event Washout Includes Dispensings	Number of Instances the Characteristic Should be Found in Evaluation Period	Output in Baseline Table (Y/N)
CKD Stage 4/5 Characteristics										
Alpha-glucosidase inhibitors	165	35 and 24	Combo covariate	Any	n/a				1	No
Meglitinides	166	35 and 25	Combo covariate	Any	n/a				1	No
DPP-4 inhibitors	167	35 and 26	Combo covariate	Any	n/a				1	No
SGLT-2 inhibitors	168	35 and 27	Combo covariate	Any	n/a				1	No
GLP-1 RAs	169	35 and 28	Combo covariate	Any	n/a				1	No
Other oral diabetes drugs (bromocriptine and colesevelam)	170	35 and 29	Combo covariate	Any	n/a				1	No
Short/rapid acting insulin	171	35 and 30	Combo covariate	Any	n/a				1	No
Long/intermediate acting insulin	172	35 and 31	Combo covariate	Any	n/a				1	No
Combination insulin	173	35 and 32	Combo covariate	Any	n/a				1	No
Insulin pump	174	35 and 33	Combo covariate	Any	n/a				1	No

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

**Type 2 design diagram:
Cohort Def 1**

Query start date

Cohort entry date
Short/Rapid -Acting Insulin
Day 0

Query end date

Enrollment requirement
Medical and drug coverage

Pre-index: [-365, 0]

Allowed coverage gap

45 days

Inclusion criteria
>50% Type 1 Diabetes

[-365 -5]

Exclusion Criteria
Non-insulin antidiabetic (not metformin)

[-365, -1]

Blackout period

[0]

Episode length/
Outcome Evaluation

Capture evidence of
diabetic ketoacidosis (DKA)
Max 365 days

Episode gap

10 days

Episode extension

10 days

Baseline Characteristics*

I: [-365, 0]

II: [-365, -1]

III: [1, 365]

*Baseline Characteristics

Window I: Chronic kidney disease stages + definition components

Window II: History of DKA, Anti -diabetic treatments

Window III: Post-exposure DKA events