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

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

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

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

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Overview for Request: cder_mpl1p_wp035, report 2 of 2, CMS only

Request ID: cder_mpl1p_wp035

Request Description: In this report, we evaluated patterns of initiation of tacrolimus, an immunosuppressant used to prevent allograft rejection subsequent to organ transplant. In particular, we assessed the number of patients in the Sentinel Distributed Database (SDD) receiving inpatient kidney or liver transplants, duration of SDD follow-up time for these transplant recipients, and how many of these patients initiated tacrolimus during their inpatient transplant stay, on the discharge date, and after hospital discharge.

Sentinel Routine Querying Module: Cohort Identification and Descriptive Analysis (CIDA) module, version 8.1.1.

Data Source: This request was distributed to the Duke Center for Medicare & Medicaid Services, a contributing Sentinel Distributed Database Data Partner, for execution on 100% Medicare fee-for-service data on January 12, 2021. The study period included data from August 10, 2009 through December 31, 2019. Please see Appendix A for a list of dates of available data for this Data Partner.

Study Design: We identified all liver and kidney transplant recipients with no history of prior transplant and no prior use of tacrolimus. Among these cohorts, we assessed use of tacrolimus products overall and from different manufacturers that occurred between the hospital admission date for transplant procedure and 60 days after discharge date. This is a Type 2 analysis in the Query Request Package (QRP) documentation, modified with ad hoc programming.

Exposure of Interest: Liver and kidney transplants were the exposures of interest. We identified individuals of all ages with an inpatient stay for liver or kidney transplant. We assessed follow-up time in the SDD following transplant discharge date, censoring at disenrollment, death, or Data Partner data end date.

We also evaluated use of tacrolimus products overall and from different manufacturers among identified liver and kidney transplant recipients, and assessed timing of tacrolimus initiation (during the hospital stay, on the discharge date, or within 60 days after the discharge date), duration of treatment, and reason for treatment episode censoring. Valid reasons for treatment episode censoring included disenrollment, death, Data Partner data end date, and switch to a tacrolimus product from a different manufacturer. Please see Appendix B for a list of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), International Classification of Diseases, Tenth Revision, Procedure Coding System (ICD-10-PCS), and Current Procedural Terminology, Fourth Edition (CPT-4) procedure codes used to define liver and kidney transplants in this request.

Cohort Eligibility Criteria: Cohort members were required to be enrolled in health plans with medical and drug coverage in the 365 days prior to and following their index transplant; a gap in coverage of up to 45 days was allowed and treated as continuous enrollment. We included the following age groups in our analysis: <18, 18-64, and 65+ years. We stratified results by tacrolimus product manufacturer, timing of first tacrolimus dispensing, race, and census bureau region. Zip code was used to assign census bureau region. In the Sentinel Common Data Model there is one zip code assigned per member and zip codes are updated and overwritten as the members' location changes over time. The location reflected in this report is the member's most recent zip code.

Incidence Criteria: We assessed incidence criteria for liver and kidney transplants with respect to the index hospital admission date (no transplant or tacrolimus exposure in entire patient history). Please see Appendix C for a list of 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, Procedure Coding System (ICD-10-PCS), Healthcare Common Procedure Coding System (HCPCS), and Current Procedural Terminology, Fourth Edition (CPT-4) diagnosis and procedure codes.

Overview for Request: cder_mpl1p_wp035, report 2 of 2, CMS only

Exclusion Criteria: In addition to the incidence requirement of no history of any transplant in an entire patient's history prior to the index event, we also excluded patients who had additional transplants during their hospitalization for liver or kidney transplant. We achieved this by excluding patients with any transplant other than the transplant of interest in their entire history with respect to hospital discharge date for liver or kidney transplant. We excluded inpatient encounters with missing discharge dates from all cohorts. Please see Appendix D for a list of 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, Procedure Coding System (ICD-10-PCS), and Current Procedural Terminology, Fourth Edition (CPT-4) diagnosis and procedure codes used to define exclusion criteria in this request.

Baseline Characteristics: We assessed baseline demographic characteristics for liver and kidney transplant recipients on discharge date. We identified tacrolimus dispensings and procedure codes that occurred between hospital admission date for the transplant surgery of interest through 60 days after hospital discharge date. Please see Appendices E and F for a list of Healthcare Common Procedure Coding System (HCPCS) procedure codes used to define tacrolimus use in this request and a list of generic and brands names and manufacturer group for tacrolimus used to define incidence criteria, use of tacrolimus, and covariates in this request.

Please see Appendices G and H for the specifications of parameters and baseline characteristics used in this request.

Limitations: Algorithms used to define exposures and inclusion criteria are imperfect; thus, it is possible that there may be misclassification. Therefore, data should be interpreted with this limitation in mind. Although we stratified some estimates by race/ethnicity, please keep in mind that this information is not well captured in many systems. In addition, our program assigned census bureau region of residence using enrollee's most recent zip code, which may not reflect residence or place of exposure at the time of transplant. Please see Appendix I for the study design diagram.

Notes: Please contact the Sentinel Operations Center (info@sentinel-system.org) for questions and to provide comments/suggestions for future enhancements to this document. For more information on Sentinel's routine querying modules, please refer to the documentation (<https://dev.sentinel-system.org/projects/SENTINEL/repos/sentinel-routine-querying-tool-documentation/browse>).

Table of Contents

<u>Glossary</u>	List of Terms Found in this Report and their Definitions
<u>Table 1a</u>	Baseline Characteristics of Patients at First Liver Transplant in the Sentinel Distributed Database (SDD) between January 1, 2009 and December 31, 2019
<u>Table 1b</u>	Baseline Characteristics at Discharge among Patients with Liver Transplant and Tacrolimus Dispensing in the Sentinel Distributed Databases (SDD) between January 1, 2009 and December 31, 2019
<u>Table 1c</u>	Baseline Characteristics at Discharge among Patients with Liver Transplant and First Tacrolimus Dispensing During Hospital Stay in the Sentinel Distributed Databases (SDD) between January 1, 2009 and December 31, 2019
<u>Table 1d</u>	Baseline Characteristics at Discharge among Patients with Liver Transplant and First Tacrolimus Dispensing on Discharge Date in the Sentinel Distributed Databases (SDD) between January 1, 2009 and December 31, 2019
<u>Table 1e</u>	Baseline Characteristics at Discharge among Patients with Liver Transplant and First Tacrolimus Dispensing within 60 Days After Discharge Date in the Sentinel Distributed Databases (SDD) between January 1, 2009 and December 31, 2019
<u>Table 1f</u>	Baseline Characteristics of Patients at First Kidney Transplant in the Sentinel Distributed Databases (SDD) between January 1, 2009 and December 31, 2019
<u>Table 1g</u>	Baseline Characteristics at Discharge among Patients with Kidney Transplant and Tacrolimus Dispensing in the Sentinel Distributed Databases (SDD) between January 1, 2009 and December 31, 2019
<u>Table 1h</u>	Baseline Characteristics at Discharge among Patients with Kidney Transplant and First Tacrolimus Dispensing During Hospital Stay in the Sentinel Distributed Databases (SDD) between January 1, 2009 and December 31, 2019
<u>Table 1i</u>	Baseline Characteristics at Discharge among Patients with Kidney Transplant and First Tacrolimus Dispensing on Discharge Date in the Sentinel Distributed Databases (SDD) between January 1, 2009 and December 31, 2019
<u>Table 1j</u>	Baseline Characteristics at Discharge among Patients with Kidney Transplant and First Tacrolimus Dispensing within 60 Days After Discharge Date in the Sentinel Distributed Databases (SDD) between January 1, 2009 and December 31, 2019
<u>Table 2a</u>	Time between First Dispensing for Tacrolimus and Hospital Discharge among Patients with First Dispensing During Hospital Stay in the Sentinel Distributed Databases (SDD) between January 1, 2009 and December 31, 2019, by Organ-Product Pair
<u>Table 2b</u>	Time between Hospital Discharge and First Dispensing for Tacrolimus among Patients with First Dispensing within 60 Days After Hospital Discharge in the Sentinel Distributed Databases (SDD) between January 1, 2009 and December 31, 2019, by Organ-Product Pair
<u>Table 2c</u>	Time between First Dispensing for Tacrolimus and Hospital Discharge among Patients with First Dispensing on Hospital Discharge Date in the Sentinel Distributed Databases (SDD) between January 1, 2009 and December 31, 2019, by Organ-Product Pair
<u>Table 3</u>	Total Enrolled Follow-up Time Following Organ Transplant in the Sentinel Distributed Databases (SDD) between January 1, 2009 and December 31, 2019

Table of Contents

<u>Appendix A</u>	Dates of Available Data for Each Data Partner (DP) as of Request Distribution Date (January 12, 2021)
<u>Appendix B</u>	List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), International Classification of Diseases, Tenth Revision, Procedure Coding System (ICD-10-PCS), and Current Procedural Terminology, Fourth Edition (CPT-4) Procedure Codes Used to Define Liver and Kidney Transplants in this Request
<u>Appendix C</u>	List of 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, Procedure Coding System (ICD-10-PCS), Healthcare Common Procedure Coding System (HCPCS), and Current Procedural Terminology, Fourth Edition (CPT-4) Diagnosis and Procedure Codes used to Define Incidence Criteria in this Request
<u>Appendix D</u>	List of 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, Procedure Coding System (ICD-10-PCS), and Current Procedural Terminology, Fourth Edition (CPT-4) Diagnosis and Procedure Codes Used to Define Exclusion Criteria in this Request
<u>Appendix E</u>	List of Healthcare Common Procedure Coding System (HCPCS) Used to Define Baseline Characteristics in this Request
<u>Appendix F</u>	List of Generic and Brand Names and Manufacturer Group for Tacrolimus Products Used to Define the Incidence Criteria and Covariates in this Request
<u>Appendix G</u>	Specifications Defining Parameters in this Request
<u>Appendix H</u>	Specifications Defining Baseline Characteristics in this Request
<u>Appendix I</u>	Design Diagram of Cohort Entry Requirements and Assessment Windows

**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. Baseline Characteristics of Patients at First Liver Transplant in the Sentinel Distributed Database (SDD) between January 1, 2009 and December 31, 2019

Characteristic¹	Number	Percent
Number of dispensings	3,713	
Number of unique patients	3,713	
Demographics	Mean	Standard Deviation
Mean Age (years)	62.4	8.9
Age (Years)	Number	Percent
00-17	*****	*****
18-64	*****	*****
65+	1,938	52.2%
Sex		
Female	1,411	38.0%
Male	2,302	62.0%
Year		
2009	0	0.0%
2010	0	0.0%
2011	288	7.8%
2012	300	8.1%
2013	373	10.0%
2014	417	11.2%
2015	392	10.6%
2016	475	12.8%
2017	494	13.3%
2018	481	13.0%
2019	493	13.3%
2020	0	0.0%
Race		
Black or African American	309	8.3%
White	2,925	78.8%
Other	141	3.8%
Unknown	338	9.1%
Census Bureau Region		
Mid West	880	23.7%
New England	618	16.6%
South	1,538	41.4%
West	668	18.0%
Other	*****	*****
Missing	*****	*****
Recorded History of:		
Charlson/Elixhauser Combined Comorbidity Score ²	8.0	3.4

Table 1a. Baseline Characteristics of Patients at First Liver Transplant in the Sentinel Distributed Database (SDD) between January 1, 2009 and December 31, 2019

Breakdown by Manufacturer		
Any oral tacrolimus ³	226	6.1%
Generic - Dr. Reddys	53	1.4%
Generic - Accord	93	2.5%
Generic - Sandoz	71	1.9%
Generic - Mylan	*****	*****
Brand - Astellas	*****	*****
Procedure code J7507	276	7.4%
Other tacrolimus	20	0.5%

¹All metrics are based on total number of episodes per group, except for sex, and census bureau region which are based on total number of unique patients

²The Charlson/Elixhauser Combined Comorbidity Score is calculated based on comorbidities observed during a requester-defined window around the exposure episode start date (index date).

³Any oral tacrolimus includes all products listed in Appendix F. It does not include the procedure code J7507.

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

Table 1b. Baseline Characteristics at Discharge among Patients with Liver Transplant and Tacrolimus Dispensing in the Sentinel Distributed Databases (SDD) between January 1, 2009 and December 31, 2019

Characteristic¹	Number	Percent
Number of dispensings	226	
Number of unique patients	226	
Demographics		
Mean Age (years)	62	10.0
Age (Years)	Number	Percent
00-17	*****	*****
18-64	*****	*****
65+	113	50.0%
Sex		
Female	71	31.4%
Male	155	68.6%
Year		
2009	0	0.0%
2010	0	0.0%
2011	*****	*****
2012	*****	*****
2013	*****	*****
2014	30	13.3%
2015	21	9.3%
2016	40	17.7%
2017	27	11.9%
2018	*****	*****
2019	83	36.7%
2020	0	0.0%
Race		
Black or African American	*****	*****
White	167	73.9%
Other	*****	*****
Unknown	28	12.4%
Census Bureau Region		
Mid West	53	23.5%
New England	*****	*****
South	84	37.2%
West	44	19.5%
Other	*****	*****
Missing	*****	*****
Recorded History of:		
Charlson/Elixhauser Combined Comorbidity Score ²	7.9	3.4

Table 1b. Baseline Characteristics at Discharge among Patients with Liver Transplant and Tacrolimus Dispensing in the Sentinel Distributed Databases (SDD) between January 1, 2009 and December 31, 2019

Breakdown by Manufacturer		
Any oral tacrolimus ³	226	100.0%
Generic - Dr. Reddys	53	23.5%
Generic - Accord	93	41.2%
Generic - Sandoz	71	31.4%
Generic - Mylan	*****	*****
Brand - Astellas	*****	*****
Procedure code J7507	23	10.2%
Other tacrolimus	20	8.8%

This table includes a subset of liver transplant recipients who also had a tacrolimus dispensing between their hospital admission date and 60 days following discharge.

¹All metrics are based on total number of episodes per group, except for sex, and census bureau region which are based on total number of unique patients

²The Charlson/Elixhauser Combined Comorbidity Score is calculated based on comorbidities observed during a requester-defined window around the exposure episode start date (index date).

³Any oral tacrolimus includes all products listed in Appendix F. It does not include the procedure code J7507.

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Table 1c. Baseline Characteristics at Discharge among Patients with Liver Transplant and First Tacrolimus Dispensing During Hospital Stay in the Sentinel Distributed Databases (SDD) between January 1, 2009 and December 31, 2019

Characteristic¹	Number	Percent
Number of dispensings	60	
Number of unique patients	60	
Demographics	Mean	Standard Deviation
Mean Age (years)	61	11.6
Age (Years)	Number	Percent
00-17	*****	*****
18-64	35	58.3%
65+	*****	*****
Sex		
Female	21	35.0%
Male	39	65.0%
Year		
2009	0	0.0%
2010	0	0.0%
2011	0	0.0%
2012	0	0.0%
2013	*****	*****
2014	11	18.3%
2015	*****	*****
2016	12	20.0%
2017	*****	*****
2018	*****	*****
2019	18	30.0%
2020	0	0.0%
Race		
Black or African American	11	18.3%
White	38	63.3%
Other	*****	*****
Unknown	*****	*****
Census Bureau Region		
Mid West	*****	*****
New England	13	21.7%
South	30	50.0%
West	*****	*****
Other	0	0.0%
Missing	0	0.0%
Recorded History of:		
Charlson/Elixhauser Combined Comorbidity Score ²	7.8	3.5

Table 1c. Baseline Characteristics at Discharge among Patients with Liver Transplant and First Tacrolimus Dispensing During Hospital Stay in the Sentinel Distributed Databases (SDD) between January 1, 2009 and December 31, 2019

Breakdown by Manufacturer		
Any oral tacrolimus ³	60	100.0%
Generic - Dr. Reddys	*****	*****
Generic - Accord	22	36.7%
Generic - Sandoz	*****	*****
Generic - Mylan	*****	*****
Brand - Astellas	*****	*****
Procedure code J7507	*****	*****
Other tacrolimus	*****	*****

This table includes a subset of liver transplant recipients who also had a tacrolimus dispensing during their hospital stay.

¹All metrics are based on total number of episodes per group, except for sex, and census bureau region which are based on total number of unique patients

²The Charlson/Elixhauser Combined Comorbidity Score is calculated based on comorbidities observed during a requester-defined window around the exposure episode start date (index date).

³Any oral tacrolimus includes all products listed in Appendix F. It does not include the procedure code J7507.

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

Table 1d. Baseline Characteristics at Discharge among Patients with Liver Transplant and First Tacrolimus Dispensing on Discharge Date in the Sentinel Distributed Databases (SDD) between January 1, 2009 and December 31, 2019

Characteristic¹	Number	Percent
Number of dispensings	22	
Number of unique patients	22	
Demographics	Mean	Standard Deviation
Mean Age (years)	64.3	5.8
Age (Years)	Number	Percent
00-17	0	0.0%
18-64	11	50.0%
65+	11	50.0%
Sex		
Female	*****	*****
Male	*****	*****
Year		
2009	0	0.0%
2010	0	0.0%
2011	0	0.0%
2012	0	0.0%
2013	0	0.0%
2014	*****	*****
2015	*****	*****
2016	*****	*****
2017	*****	*****
2018	0	0.0%
2019	*****	*****
2020	0	0.0%
Race		
Black or African American	*****	*****
White	17	77.3%
Other	*****	*****
Unknown	*****	*****
Census Bureau Region		
Mid West	*****	*****
New England	*****	*****
South	*****	*****
West	*****	*****
Other	0	0.0%
Missing	0	0.0%
Recorded History of:	Mean	Standard Deviation
Charlson/Elixhauser Combined Comorbidity Score ²	7.4	2.9

Table 1d. Baseline Characteristics at Discharge among Patients with Liver Transplant and First Tacrolimus Dispensing on Discharge Date in the Sentinel Distributed Databases (SDD) between January 1, 2009 and December 31, 2019

Breakdown by Manufacturer	Number	Percent
Any oral tacrolimus ³	22	100.0%
Generic - Dr. Reddys	*****	*****
Generic - Accord	12	54.5%
Generic - Sandoz	*****	*****
Generic - Mylan	*****	*****
Brand - Astellas	0	0.0%
Procedure code J7507	*****	*****
Other tacrolimus	*****	*****

This table includes a subset of liver transplant recipients who also had a tacrolimus dispensing on their hospital discharge date.

¹All metrics are based on total number of episodes per group, except for sex, and census bureau region which are based on total number of unique patients

²The Charlson/Elixhauser Combined Comorbidity Score is calculated based on comorbidities observed during a requester-defined window around the exposure episode start date (index date).

³Any oral tacrolimus includes all products listed in Appendix F. It does not include the procedure code J7507.

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

Table 1e. Baseline Characteristics at Discharge among Patients with Liver Transplant and First Tacrolimus Dispensing within 60 Days After Discharge Date in the Sentinel Distributed Databases (SDD) between January 1, 2009 and December 31, 2019

Characteristic¹	Number	Percent
Number of dispensings	144	
Number of unique patients	144	
Demographics	Mean	Percent
Mean Age (years)	62.1	9.9
Age (Years)	Number	Standard Deviation
00-17	0	0.0%
18-64	66	45.8%
65+	78	54.2%
Sex		
Female	44	30.6%
Male	100	69.4%
Year		
2009	0	0.0%
2010	0	0.0%
2011	*****	*****
2012	*****	*****
2013	*****	*****
2014	17	11.8%
2015	*****	*****
2016	20	13.9%
2017	18	12.5%
2018	*****	*****
2019	61	42.4%
2020	0	0.0%
Race		
Black or African American	*****	*****
White	112	77.8%
Other	*****	*****
Unknown	16	11.1%
Census Bureau Region		
Mid West	40	27.8%
New England	27	18.8%
South	46	31.9%
West	29	20.1%
Other	*****	*****
Missing	*****	*****
Recorded History of:	Mean	Standard Deviation
Charlson/Elixhauser Combined Comorbidity Score ²	8.1	3.4

Table 1e. Baseline Characteristics at Discharge among Patients with Liver Transplant and First Tacrolimus Dispensing within 60 Days After Discharge Date in the Sentinel Distributed Databases (SDD) between January 1, 2009 and December 31, 2019

Breakdown by Manufacturer	Number	Percent
Any oral tacrolimus ³	144	100.0%
Generic - Dr. Reddys	31	21.5%
Generic - Accord	59	41.0%
Generic - Sandoz	38	26.4%
Generic - Mylan	*****	*****
Brand - Astellas	*****	*****
Procedure code J7507	16	11.1%
Other tacrolimus	14	9.7%

This table includes a subset of liver transplant recipients who also had a tacrolimus dispensing after hospital discharge.

¹All metrics are based on total number of episodes per group, except for sex, and census bureau region which are based on total number of unique patients

²The Charlson/Elixhauser Combined Comorbidity Score is calculated based on comorbidities observed during a requester-defined window around the exposure episode start date (index date).

³Any oral tacrolimus includes all products listed in Appendix F. It does not include the procedure code J7507.

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

Table 1f. Baseline Characteristics of Patients at First Kidney Transplant in the Sentinel Distributed Databases (SDD) between January 1, 2009 and December 31, 2019

Characteristic¹	Number	Percent
Number of dispensings	34,370	
Number of unique patients	34,370	
Demographics	Mean	Standard Deviation
Mean Age (years)	53.4	14.3
Age (Years)	Number	Percent
00-17	259	0.8%
18-64	25,307	73.6%
65+	8,804	25.6%
Sex		
Female	13,529	39.4%
Male	20,841	60.6%
Year		
2009	0	0.0%
2010	0	0.0%
2011	3,588	10.4%
2012	3,585	10.4%
2013	3,584	10.4%
2014	3,727	10.8%
2015	3,881	11.3%
2016	3,828	11.1%
2017	3,859	11.2%
2018	3,951	11.5%
2019	4,367	12.7%
2020	0	0.0%
Race		
Black or African American	12,089	35.2%
White	14,039	40.8%
Other	2,251	6.5%
Unknown	5,991	17.4%
Census Bureau Region		
Mid West	6,922	20.1%
New England	6,207	18.1%
South	14,275	41.5%
West	6,925	20.1%
Other	26	0.1%
Missing	15	0.0%
Recorded History of:	Mean	Standard Deviation
Charlson/Elixhauser Combined Comorbidity Score ²	5.6	2.2

Table 1f. Baseline Characteristics of Patients at First Kidney Transplant in the Sentinel Distributed Databases (SDD) between January 1, 2009 and December 31, 2019

Breakdown by Manufacturer	Number	Percent
Any oral tacrolimus ³	1,936	5.6%
Generic - Dr. Reddys	360	1.0%
Generic - Accord	988	2.9%
Generic - Sandoz	586	1.7%
Generic - Mylan	166	0.5%
Brand - Astellas	38	0.1%
Procedure code J7507	2,742	8.0%
Other tacrolimus	103	0.3%

¹All metrics are based on total number of episodes per group, except for sex, and census bureau region which are based on total number of unique patients

²The Charlson/Elixhauser Combined Comorbidity Score is calculated based on comorbidities observed during a requester-defined window around the exposure episode start date (index date).

³Any oral tacrolimus includes all products listed in Appendix F. It does not include the procedure code J7507.

Table 1g. Baseline Characteristics at Discharge among Patients with Kidney Transplant and Tacrolimus Dispensing in the Sentinel Distributed Databases (SDD) between January 1, 2009 and December 31, 2019

Characteristic¹	Number	Percent
Number of dispensings	1,936	
Number of unique patients	1,936	
Demographics	Mean	Standard Deviation
Mean Age (years)	52.2	14.7
Age (Years)	Number	Percent
00-17	16	0.8%
18-64	1,465	75.7%
65+	455	23.5%
Sex		
Female	757	39.1%
Male	1,179	60.9%
Year		
2009	0	0.0%
2010	0	0.0%
2011	30	1.5%
2012	19	1.0%
2013	33	1.7%
2014	180	9.3%
2015	237	12.2%
2016	236	12.2%
2017	244	12.6%
2018	168	8.7%
2019	789	40.8%
2020	0	0.0%
Race		
Black or African American	611	31.6%
White	789	40.8%
Other	141	7.3%
Unknown	395	20.4%
Census Bureau Region		
Mid West	359	18.5%
New England	*****	*****
South	762	39.4%
West	474	24.5%
Other	*****	*****
Missing	0	0.0%
Recorded History of:	Mean	Standard Deviation
Charlson/Elixhauser Combined Comorbidity Score ²	5.7	2.2

Table 1g. Baseline Characteristics at Discharge among Patients with Kidney Transplant and Tacrolimus Dispensing in the Sentinel Distributed Databases (SDD) between January 1, 2009 and December 31, 2019

Breakdown by Manufacturer	Number	Percent
Any oral tacrolimus ³	1,936	100.0%
Generic - Dr. Reddys	360	18.6%
Generic - Accord	988	51.0%
Generic - Sandoz	586	30.3%
Generic - Mylan	166	8.6%
Brand - Astellas	38	2.0%
Procedure code J7507	182	9.4%
Other tacrolimus	103	5.3%

This table includes a subset of kidney transplant recipients who also had a tacrolimus dispensing between their hospital admission date and 60 days following discharge.

¹All metrics are based on total number of episodes per group, except for sex, and census bureau region which are based on total number of unique patients

²The Charlson/Elixhauser Combined Comorbidity Score is calculated based on comorbidities observed during a requester-defined window around the exposure episode start date (index date).

³Any oral tacrolimus includes all products listed in Appendix F. It does not include the procedure code J7507.

*****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 1h. Baseline Characteristics at Discharge among Patients with Kidney Transplant and First Tacrolimus Dispensing During Hospital Stay in the Sentinel Distributed Databases (SDD) between January 1, 2009 and December 31, 2019

Characteristic¹	Number	Percent
Number of dispensings	516	
Number of unique patients	516	
Demographics	Mean	Standard Deviaton
Mean Age (years)	52	14.0
Age (Years)	Number	Percent
00-17	*****	*****
18-64	417	80.8%
65+	*****	*****
Sex		
Female	195	37.8%
Male	321	62.2%
Year		
2009	0	0.0%
2010	0	0.0%
2011	*****	*****
2012	*****	*****
2013	*****	*****
2014	45	8.7%
2015	77	14.9%
2016	59	11.4%
2017	64	12.4%
2018	29	5.6%
2019	232	45.0%
2020	0	0.0%
Race		
Black or African American	178	34.5%
White	174	33.7%
Other	34	6.6%
Unknown	130	25.2%
Census Bureau Region		
Mid West	54	10.5%
New England	105	20.3%
South	242	46.9%
West	115	22.3%
Other	0	0.0%
Missing	0	0.0%
Recorded History of:	Mean	Standard Deviaton
Charlson/Elixhauser Combined Comorbidity Score ²	5.7	2.3

Table 1h. Baseline Characteristics at Discharge among Patients with Kidney Transplant and First Tacrolimus Dispensing During Hospital Stay in the Sentinel Distributed Databases (SDD) between January 1, 2009 and December 31, 2019

Breakdown by Manufacturer	Number	Percent
Any oral tacrolimus ³	516	100.0%
Generic - Dr. Reddys	103	20.0%
Generic - Accord	320	62.0%
Generic - Sandoz	145	28.1%
Generic - Mylan	*****	*****
Brand - Astellas	*****	*****
Procedure code J7507	45	8.7%
Other tacrolimus	*****	*****

This table includes a subset of kidney transplant recipients who also had a tacrolimus dispensing during their hospital stay.

¹All metrics are based on total number of episodes per group, except for sex, and census bureau region which are based on total number of unique patients

²The Charlson/Elixhauser Combined Comorbidity Score is calculated based on comorbidities observed during a requester-defined window around the exposure episode start date (index date).

³Any oral tacrolimus includes all products listed in Appendix F. It does not include the procedure code J7507.

*****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 1i. Baseline Characteristics at Discharge among Patients with Kidney Transplant and First Tacrolimus Dispensing on Discharge Date in the Sentinel Distributed Databases (SDD) between January 1, 2009 and December 31, 2019

Characteristic¹	Number	Percent
Number of dispensings	198	
Number of unique patients	198	
Demographics		
Mean Age (years)	49.6	14.4
Age (Years)		
00-17	*****	*****
18-64	165	83.3%
65+	*****	*****
Sex		
Female	81	40.9%
Male	117	59.1%
Year		
2009	0	0.0%
2010	0	0.0%
2011	*****	*****
2012	*****	*****
2013	*****	*****
2014	20	10.1%
2015	26	13.1%
2016	27	13.6%
2017	24	12.1%
2018	19	9.6%
2019	71	35.9%
2020	0	0.0%
Race		
Black or African American	61	30.8%
White	86	43.4%
Other	14	7.1%
Unknown	37	18.7%
Census Bureau Region		
Mid West	25	12.6%
New England	33	16.7%
South	81	40.9%
West	59	29.8%
Other	0	0.0%
Missing	0	0.0%
Recorded History of:		
Charlson/Elixhauser Combined Comorbidity Score ²	5.4	2.2

Table 1i. Baseline Characteristics at Discharge among Patients with Kidney Transplant and First Tacrolimus Dispensing on Discharge Date in the Sentinel Distributed Databases (SDD) between January 1, 2009 and December 31, 2019

Breakdown by Manufacturer	Number	Percent
Any oral tacrolimus ³	198	100.0%
Generic - Dr. Reddys	36	18.2%
Generic - Accord	103	52.0%
Generic - Sandoz	74	37.4%
Generic - Mylan	*****	*****
Brand - Astellas	*****	*****
Procedure code J7507	20	10.1%
Other tacrolimus	*****	*****

This table includes a subset of kidney transplant recipients who also had a tacrolimus dispensing on their hospital discharge date.

¹All metrics are based on total number of episodes per group, except for sex, and census bureau region which are based on total number of unique patients

²The Charlson/Elixhauser Combined Comorbidity Score is calculated based on comorbidities observed during a requester-defined window around the exposure episode start date (index date).

³Any oral tacrolimus includes all products listed in Appendix F. It does not include the procedure code J7507.

*****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 1j. Baseline Characteristics at Discharge among Patients with Kidney Transplant and First Tacrolimus Dispensing within 60 Days After Discharge Date in the Sentinel Distributed Databases (SDD) between January 1, 2009 and December 31, 2019

Characteristic¹	Number	Percent
Number of dispensings	1,222	
Number of unique patients	1,222	
Demographics	Mean	Standard Deviation
Mean Age (years)	52.8	15.0
Age (Years)	Number	Percent
00-17	*****	*****
18-64	883	72.3%
65+	*****	*****
Sex		
Female	481	39.4%
Male	741	60.6%
Year		
2009	0	0.0%
2010	0	0.0%
2011	*****	*****
2012	*****	*****
2013	*****	*****
2014	115	9.4%
2015	134	11.0%
2016	150	12.3%
2017	156	12.8%
2018	120	9.8%
2019	486	39.8%
2020	0	0.0%
Race		
Black or African American	372	30.4%
White	529	43.3%
Other	93	7.6%
Unknown	228	18.7%
Census Bureau Region		
Mid West	280	22.9%
New England	*****	*****
South	439	35.9%
West	300	24.5%
Other	*****	*****
Missing	0	0.0%
Recorded History of:	Mean	Standard Deviation
Charlson/Elixhauser Combined Comorbidity Score ²	5.8	2.2

Table 1j. Baseline Characteristics at Discharge among Patients with Kidney Transplant and First Tacrolimus Dispensing within 60 Days After Discharge Date in the Sentinel Distributed Databases (SDD) between January 1, 2009 and December 31, 2019

Breakdown by Manufacturer	Number	Percent
Any oral tacrolimus ³	1,222	100.0%
Generic - Dr. Reddys	221	18.1%
Generic - Accord	565	46.2%
Generic - Sandoz	367	30.0%
Generic - Mylan	87	7.1%
Brand - Astellas	23	1.9%
Procedure code J7507	117	9.6%
Other tacrolimus	77	6.3%

This table includes a subset of kidney transplant recipients who also had a tacrolimus dispensing after hospital discharge.

¹All metrics are based on total number of episodes per group, except for sex, and census bureau region which are based on total number of unique patients

²The Charlson/Elixhauser Combined Comorbidity Score is calculated based on comorbidities observed during a requester-defined window around the exposure episode start date (index date).

³Any oral tacrolimus includes all products listed in Appendix F. It does not include the procedure code J7507.

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

Table 2a. Time between First Dispensing for Tacrolimus and Hospital Discharge among Patients with First Dispensing During Hospital Stay in the Sentinel Distributed Databases (SDD) between January 1, 2009 and December 31, 2019, by Organ-Product Pair

Summary Statistics (Days)								
Group by Organ-Product Pair	N	Mean	Standard Deviation	Minimum	Q1	Median	Q3	Maximum
Liver transplant								
Any oral tacrolimus*	60	-7.2	6.87	-40	-9	-6	-2	-1
Dr Reddy's tacrolimus	*****	-6.2	5.47	-14	-13	-4	-1	-1
Accord tacrolimus	21	-8.4	9.56	-40	-8	-6	-2	-1
Sandoz tacrolimus	24	-6.9	4.63	-20	-9	-6	-4	-1
Mylan tacrolimus	*****	*****	*****	*****	*****	*****	*****	*****
Astellas tacrolimus	*****	*****	*****	*****	*****	*****	*****	*****
Kidney transplant								
Any oral tacrolimus*	516	-3.7	4.03	-55	-4	-3	-2	-1
Dr Reddy's tacrolimus	79	-4.6	6.54	-55	-5	-3	-2	-1
Accord tacrolimus	272	-3.8	3.79	-45	-5	-3	-2	-1
Sandoz tacrolimus	115	-3.2	2.23	-12	-4	-3	-2	-1
Mylan tacrolimus	51	-3	2.28	-14	-4	-3	-1	-1
Astellas tacrolimus	12	-5.3	5.61	-21	-7	-4	-2	-1

*Any oral tacrolimus includes all products listed in Appendix F. It does not include the procedure code J7507

This table includes a subset of transplant recipients who also had a tacrolimus dispensing during their hospital stay

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

Table 2a. Time between First Dispensing for Tacrolimus and Hospital Discharge among Patients with First Dispensing During Hospital Stay in the Sentinel Distributed Databases (SDD) between January 1, 2009 and December 31, 2019, by Organ-Product Pair

Time of Tacrolimus Dispensing Prior to Discharge in Days

Group by Organ-Product Pair	≥21 days		11 - 20 days		6 - 10 days		3 - 5 days		1 - 2 days	
	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent
Liver transplant										
Any oral tacrolimus*	*****	*****	*****	*****	17	28.3%	14	23.3%	16	26.7%
Dr Reddy's tacrolimus	*****	*****	*****	*****	*****	*****	*****	*****	*****	*****
Accord tacrolimus	*****	*****	*****	*****	*****	*****	*****	*****	*****	*****
Sandoz tacrolimus	0	0.0%	*****	*****	*****	*****	*****	*****	*****	*****
Mylan tacrolimus	*****	*****	*****	*****	*****	*****	*****	*****	*****	*****
Astellas tacrolimus	*****	*****	*****	*****	*****	*****	*****	*****	*****	*****
Kidney transplant										
Any oral tacrolimus*	*****	*****	*****	*****	65	12.6%	231	44.8%	204	39.5%
Dr Reddy's tacrolimus	*****	*****	*****	*****	*****	*****	35	44.3%	27	34.2%
Accord tacrolimus	*****	*****	*****	*****	*****	*****	124	45.6%	101	37.1%
Sandoz tacrolimus	0	0.0%	*****	*****	*****	*****	51	44.3%	49	42.6%
Mylan tacrolimus	0	0.0%	*****	*****	*****	*****	*****	*****	24	47.1%
Astellas tacrolimus	*****	*****	0	0.0%	*****	*****	*****	*****	*****	*****

*Any oral tacrolimus includes all products listed in Appendix F. It does not include the procedure code J7507

This table includes a subset of transplant recipients who also had a tacrolimus dispensing during their hospital stay

*****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. Time between Hospital Discharge and First Dispensing for Tacrolimus among Patients with First Dispensing within 60 Days After Hospital Discharge in the Sentinel Distributed Databases (SDD) between January 1, 2009 and December 31, 2019, by Organ-Product Pair

Summary Statistics (Days)								
Group by Organ-Product Pair	Number	Mean	Standard Deviation	Minimum	Q1	Median	Q3	Maximum
Liver transplant								
Any oral tacrolimus*	144	26.6	16.13	1	13	24	37	60
Dr Reddy's tacrolimus	27	28.3	16.85	3	14	27	41	60
Accord tacrolimus	58	26.6	15.2	2	15	23	36	59
Sandoz tacrolimus	36	25.7	16.89	1	13	23	36	58
Mylan tacrolimus	*****	32.9	20.05	4	23	29	52	60
Astellas tacrolimus	*****	33.5	12.02	25	25	34	42	42
Kidney transplant								
Any oral tacrolimus*	1,222	27.1	16.52	1	14	25	40	60
Dr Reddy's tacrolimus	200	27.8	16.14	2	16	25	40	60
Accord tacrolimus	541	26.9	16.41	1	14	25	40	60
Sandoz tacrolimus	336	27.7	16.88	1	14	26	42	60
Mylan tacrolimus	78	24.5	16.39	1	12	24	31	59
Astellas tacrolimus	22	31.1	19.73	1	14	31	50	59

*Any oral tacrolimus includes all products listed in Appendix F. It does not include the procedure code J7507

This table includes a subset of transplant recipients who also had a tacrolimus dispensing after hospital discharge

NC = not calculated

*****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. Time between Hospital Discharge and First Dispensing for Tacrolimus among Patients with First Dispensing within 60 Days After Hospital Discharge in the Sentinel Distributed Databases (SDD) between January 1, 2009 and December 31, 2019, by Organ-Product Pair

Group by Organ-Product Pair	Time from Discharge to Tacrolimus Dispensing in Days									
	1-2 days		3-5 days		6-10 days		11-20 days		21-60 days	
	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent
Liver transplant										
Any oral tacrolimus*	*****	*****	*****	*****	17	11.8%	28	19.4%	88	61.1%
Dr Reddy's tacrolimus	0	0.0%	NC	NC	NC	NC	NC	NC	NC	NC
Accord tacrolimus	*****	*****	*****	*****	*****	*****	*****	*****	35	60.3%
Sandoz tacrolimus	*****	*****	*****	*****	*****	*****	*****	*****	22	61.1%
Mylan tacrolimus	*****	*****	*****	*****	*****	*****	*****	*****	*****	*****
Astellas tacrolimus	*****	*****	*****	*****	*****	*****	*****	*****	*****	*****
Kidney transplant										
Any oral tacrolimus*	61	5.0%	55	4.5%	117	9.6%	240	19.6%	749	61.3%
Dr Reddy's tacrolimus	*****	*****	12	6.0%	18	9.0%	38	19.0%	127	63.5%
Accord tacrolimus	28	5.2%	22	4.1%	51	9.4%	112	20.7%	328	60.6%
Sandoz tacrolimus	17	5.1%	12	3.6%	35	10.4%	62	18.5%	210	62.5%
Mylan tacrolimus	*****	*****	*****	*****	*****	*****	15	19.2%	45	57.7%
Astellas tacrolimus	*****	*****	*****	*****	*****	*****	*****	*****	*****	*****

*Any oral tacrolimus includes all products listed in Appendix F. It does not include the procedure code J7507

This table includes a subset of transplant recipients who also had a tacrolimus dispensing after hospital discharge

NC = not calculated

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

Table 2c. Time between First Dispensing for Tacrolimus and Hospital Discharge among Patients with First Dispensing on Hospital Discharge Date in the Sentinel Distributed Databases (SDD) between January 1, 2009 and December 31, 2019, by Organ-Product Pair

Group by Organ-Product Pair	Summary Statistics (Days)								Time from Discharge to Tacrolimus Dispensing in Days
	Number	Mean	Standard Deviation	Minimum	Q1	Median	Q3	Maximum	0 days
Liver transplant									
Any oral tacrolimus*	22	*****	*****	*****	*****	*****	*****	*****	22
Dr Reddy's tacrolimus	*****	*****	*****	*****	*****	*****	*****	*****	*****
Accord tacrolimus	*****	*****	*****	*****	*****	*****	*****	*****	*****
Sandoz tacrolimus	*****	*****	*****	*****	*****	*****	*****	*****	*****
Mylan tacrolimus	*****	*****	*****	*****	*****	*****	*****	*****	*****
Astellas tacrolimus	0	NC	NC	NC	NC	NC	NC	NC	0
Kidney transplant									
Any oral tacrolimus*	198	NC	NC	NC	NC	NC	NC	NC	198
Dr Reddy's tacrolimus	32	NC	NC	NC	NC	NC	NC	NC	32
Accord tacrolimus	92	NC	NC	NC	NC	NC	NC	NC	92
Sandoz tacrolimus	66	NC	NC	NC	NC	NC	NC	NC	66
Mylan tacrolimus	*****	*****	*****	*****	*****	*****	*****	*****	*****
Astellas tacrolimus	*****	*****	*****	*****	*****	*****	*****	*****	*****

*Any oral tacrolimus includes all products listed in Appendix F. It does not include the procedure code J7507

This table includes a subset of transplant recipients who also had a tacrolimus dispensing on their hospital discharge date

NC = not calculated

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

Table 3. Total Enrolled Follow-up Time Following Organ Transplant in the Sentinel Distributed Databases (SDD) between January 1, 2009 and December 31, 2019

Summary Statistics (Days)								
Group by Organ Transplant	Number	Mean	Standard Deviation	Minimum	Q1	Median	Q3	Maximum
Liver transplant	3,713	1,085.0	855.0	1	363	908	1,645	3,274
Kidney transplant	34,370	1,150.5	833.6	1	458	1,059	1,682	3,281

*Follow-up was truncated at disenrollment, death, or data partner end date

Appendix A. Dates of Available Data for Each Data Partner (DP) as of Request Distribution Date (January 12, 2021)

DP ID	Start Date¹	End Date¹
DP01	1/1/2010	12/31/2019

¹The start and end dates are based on the minimum and maximum dates within each DP. The month with the maximum date must have at least 80% of the number of records in the previous month.

Appendix B. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), International Classification of Diseases, Tenth Revision, Procedure Coding System (ICD-10-PCS), and Current Procedural Terminology, Fourth Edition (CPT-4) Procedure Codes Used to Define Liver and Kidney Transplants in this Request

Code	Description	Code	
		Category	Code Type
Liver Transplant			
50.5	Liver transplant	Procedure	ICD-9-CM
50.51	Auxiliary liver transplant	Procedure	ICD-9-CM
50.59	Other transplant of liver	Procedure	ICD-9-CM
47135	Liver allotransplantation; orthotopic, partial or whole, from cadaver or living donor, a	Procedure	CPT-4
0FY0	Transplantation / Liver	Procedure	ICD-10-PCS
0FY00Z0	Transplantation of Liver, Allogeneic, Open Approach	Procedure	ICD-10-PCS
Kidney Transplant			
50360	Renal allotransplantation, implantation of graft; without recipient nephrectomy	Procedure	CPT-4
50365	Renal allotransplantation, implantation of graft; with recipient nephrectomy	Procedure	CPT-4
55.69	Other kidney transplantation	Procedure	ICD-9-CM
55.6	Transplant of kidney	Procedure	ICD-9-CM
0TY1	Transplantation / Kidney, Left	Procedure	ICD-10-PCS
0TY0	Transplantation / Kidney, Right	Procedure	ICD-10-PCS
0TY10Z0	Transplantation of Left Kidney, Allogeneic, Open Approach	Procedure	ICD-10-PCS
0TY00Z0	Transplantation of Right Kidney, Allogeneic, Open Approach	Procedure	ICD-10-PCS

Appendix C. List of 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, Procedure Coding System (ICD-10-PCS), Healthcare Common Procedure Coding System (HCPCS), and Current Procedural Terminology, Fourth Edition (CPT-4) Diagnosis and Procedure Codes used to Define Incidence Criteria in this Request

Code	Description	Category	Code Type
Liver and Kidney Transplant Incidence			
J7507	Tacrolimus, immediate release, oral, 1 mg	Procedure	HCPCS
00.91	Transplant from live related donor	Procedure	ICD-9-CM
00.92	Transplant from live non-related donor	Procedure	ICD-9-CM
00.93	Transplant from cadaver	Procedure	ICD-9-CM
07.94	Transplantation of thymus	Procedure	ICD-9-CM
33.5	Lung transplant	Procedure	ICD-9-CM
33.50	Lung transplantation, NOS	Procedure	ICD-9-CM
33.51	Unilateral lung transplantation	Procedure	ICD-9-CM
33.52	Bilateral lung transplantation	Procedure	ICD-9-CM
33.6	Combined heart-lung transplantation	Procedure	ICD-9-CM
37.51	Heart transplantation	Procedure	ICD-9-CM
41.0	Bone marrow transplant	Procedure	ICD-9-CM
41.00	Bone marrow transplant, not otherwise specified	Procedure	ICD-9-CM
41.02	Allogeneic bone marrow transplant with purging	Procedure	ICD-9-CM
41.03	Allogeneic bone marrow transplant without purging	Procedure	ICD-9-CM
41.05	Allogeneic hematopoietic stem cell transplant without purging	Procedure	ICD-9-CM
41.06	Cord blood stem cell transplant	Procedure	ICD-9-CM
41.08	Allogeneic hematopoietic stem cell transplant with purging	Procedure	ICD-9-CM
41.94	Transplantation of spleen	Procedure	ICD-9-CM
46.97	Transplant of intestine	Procedure	ICD-9-CM
49.74	Gracilis muscle transplant for anal incontinence	Procedure	ICD-9-CM
50.5	Liver transplant	Procedure	ICD-9-CM
50.51	Auxiliary liver transplant	Procedure	ICD-9-CM
50.59	Other transplant of liver	Procedure	ICD-9-CM
52.8	Transplant of pancreas	Procedure	ICD-9-CM
52.80	Pancreatic transplant, not otherwise specified	Procedure	ICD-9-CM
52.82	Homotransplant of pancreas	Procedure	ICD-9-CM
52.83	Heterotransplant of pancreas	Procedure	ICD-9-CM
52.85	Allotransplantation of cells of islets of Langerhans	Procedure	ICD-9-CM
52.86	Transplantation of cells of islets of Langerhans, not otherwise specified	Procedure	ICD-9-CM
55.53	Removal of transplanted or rejected kidney	Procedure	ICD-9-CM
55.6	Transplant of kidney	Procedure	ICD-9-CM
55.69	Other kidney transplantation	Procedure	ICD-9-CM
63.53	Transplantation of spermatic cord	Procedure	ICD-9-CM
65.92	Transplantation of ovary	Procedure	ICD-9-CM
82.5	Transplantation of muscle and tendon of hand	Procedure	ICD-9-CM
82.56	Other hand tendon transfer or transplantation	Procedure	ICD-9-CM
82.58	Other hand muscle transfer or transplantation	Procedure	ICD-9-CM
83.75	Tendon transfer or transplantation	Procedure	ICD-9-CM
83.77	Muscle transfer or transplantation	Procedure	ICD-9-CM
199.2	Malignant neoplasm associated with transplanted organ	Diagnosis	ICD-9-CM
238.77	Post-transplant lymphoproliferative disorder [PTLD]	Diagnosis	ICD-9-CM
414.06	Coronary atherosclerosis, of native coronary artery of transplanted heart	Diagnosis	ICD-9-CM
414.07	Coronary atherosclerosis, of bypass graft (artery) (vein) of transplanted heart	Diagnosis	ICD-9-CM
996.80	Complications of transplanted organ, unspecified site	Diagnosis	ICD-9-CM
996.8	Complications of transplanted organ	Diagnosis	ICD-9-CM

Appendix C. List of 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, Procedure Coding System (ICD-10-PCS), Healthcare Common Procedure Coding System (HCPCS), and Current Procedural Terminology, Fourth Edition (CPT-4) Diagnosis and Procedure Codes used to Define Incidence Criteria in this Request

Code	Description	Category	Code Type
996.81	Complications of transplanted kidney	Diagnosis	ICD-9-CM
996.82	Complications of transplanted liver	Diagnosis	ICD-9-CM
996.83	Complications of transplanted heart	Diagnosis	ICD-9-CM
996.84	Complications of transplanted lung	Diagnosis	ICD-9-CM
996.85	Complications of bone marrow transplant	Diagnosis	ICD-9-CM
996.86	Complications of transplanted pancreas	Diagnosis	ICD-9-CM
996.87	Complications of transplanted organ, intestine	Diagnosis	ICD-9-CM
996.88	Complications of transplanted organ, stem cell	Diagnosis	ICD-9-CM
996.89	Complications of other transplanted organ	Diagnosis	ICD-9-CM
33935	Heart-lung transplant with recipient cardiectomy-pneumonectomy	Procedure	CPT-4
33945	Heart transplant, with or without recipient cardiectomy	Procedure	CPT-4
47135	Liver allotransplantation; orthotopic, partial or whole, from cadaver or living donor, any age	Procedure	CPT-4
50360	Renal allotransplantation, implantation of graft; without recipient nephrectomy	Procedure	CPT-4
50365	Renal allotransplantation, implantation of graft; with recipient nephrectomy	Procedure	CPT-4
50370	Removal of transplanted renal allograft	Procedure	CPT-4
50380	Renal autotransplantation, reimplantation of kidney	Procedure	CPT-4
02Y	Heart and Great Vessels, Transplantation	Procedure	ICD-10-PCS
02YA	Transplantation / Heart	Procedure	ICD-10-PCS
02YA0Z0	Transplantation of Heart, Allogeneic, Open Approach	Procedure	ICD-10-PCS
02YA0Z1	Transplantation of Heart, Syngeneic, Open Approach	Procedure	ICD-10-PCS
02YA0Z2	Transplantation of Heart, Zooplastic, Open Approach	Procedure	ICD-10-PCS
07YM0Z0	Transplantation of Thymus, Allogeneic, Open Approach	Procedure	ICD-10-PCS
07YM0Z1	Transplantation of Thymus, Syngeneic, Open Approach	Procedure	ICD-10-PCS
07YM0Z2	Transplantation of Thymus, Zooplastic, Open Approach	Procedure	ICD-10-PCS
07YP0Z0	Transplantation of Spleen, Allogeneic, Open Approach	Procedure	ICD-10-PCS
07YP0Z1	Transplantation of Spleen, Syngeneic, Open Approach	Procedure	ICD-10-PCS
07YP0Z2	Transplantation of Spleen, Zooplastic, Open Approach	Procedure	ICD-10-PCS
0BYC0Z0	Transplantation of Right Upper Lung Lobe, Allogeneic, Open Approach	Procedure	ICD-10-PCS
0BYC0Z1	Transplantation of Right Upper Lung Lobe, Syngeneic, Open Approach	Procedure	ICD-10-PCS
0BYC0Z2	Transplantation of Right Upper Lung Lobe, Zooplastic, Open Approach	Procedure	ICD-10-PCS
0BYD0Z0	Transplantation of Right Middle Lung Lobe, Allogeneic, Open Approach	Procedure	ICD-10-PCS
0BYD0Z1	Transplantation of Right Middle Lung Lobe, Syngeneic, Open Approach	Procedure	ICD-10-PCS
0BYD0Z2	Transplantation of Right Middle Lung Lobe, Zooplastic, Open Approach	Procedure	ICD-10-PCS
0BYF0Z0	Transplantation of Right Lower Lung Lobe, Allogeneic, Open Approach	Procedure	ICD-10-PCS
0BYF0Z1	Transplantation of Right Lower Lung Lobe, Syngeneic, Open Approach	Procedure	ICD-10-PCS
0BYF0Z2	Transplantation of Right Lower Lung Lobe, Zooplastic, Open Approach	Procedure	ICD-10-PCS
0BYG0Z0	Transplantation of Left Upper Lung Lobe, Allogeneic, Open Approach	Procedure	ICD-10-PCS
0BYG0Z1	Transplantation of Left Upper Lung Lobe, Syngeneic, Open Approach	Procedure	ICD-10-PCS
0BYG0Z2	Transplantation of Left Upper Lung Lobe, Zooplastic, Open Approach	Procedure	ICD-10-PCS
0BYH0Z0	Transplantation of Lung Lingula, Allogeneic, Open Approach	Procedure	ICD-10-PCS
0BYH0Z1	Transplantation of Lung Lingula, Syngeneic, Open Approach	Procedure	ICD-10-PCS
0BYH0Z2	Transplantation of Lung Lingula, Zooplastic, Open Approach	Procedure	ICD-10-PCS
0BYJ0Z0	Transplantation of Left Lower Lung Lobe, Allogeneic, Open Approach	Procedure	ICD-10-PCS
0BYJ0Z1	Transplantation of Left Lower Lung Lobe, Syngeneic, Open Approach	Procedure	ICD-10-PCS
0BYJ0Z2	Transplantation of Left Lower Lung Lobe, Zooplastic, Open Approach	Procedure	ICD-10-PCS
0BYK0Z0	Transplantation of Right Lung, Allogeneic, Open Approach	Procedure	ICD-10-PCS

Appendix C. List of 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, Procedure Coding System (ICD-10-PCS), Healthcare Common Procedure Coding System (HCPCS), and Current Procedural Terminology, Fourth Edition (CPT-4) Diagnosis and Procedure Codes used to Define Incidence Criteria in this Request

Code	Description	Category	Code Type
OBYK0Z1	Transplantation of Right Lung, Syngeneic, Open Approach	Procedure	ICD-10-PCS
OBYK0Z2	Transplantation of Right Lung, Zooplastic, Open Approach	Procedure	ICD-10-PCS
OBYL0Z0	Transplantation of Left Lung, Allogeneic, Open Approach	Procedure	ICD-10-PCS
OBYL0Z1	Transplantation of Left Lung, Syngeneic, Open Approach	Procedure	ICD-10-PCS
OBYL0Z2	Transplantation of Left Lung, Zooplastic, Open Approach	Procedure	ICD-10-PCS
OBYM0Z0	Transplantation of Bilateral Lungs, Allogeneic, Open Approach	Procedure	ICD-10-PCS
OBYM0Z1	Transplantation of Bilateral Lungs, Syngeneic, Open Approach	Procedure	ICD-10-PCS
OBYM0Z2	Transplantation of Bilateral Lungs, Zooplastic, Open Approach	Procedure	ICD-10-PCS
ODY80Z0	Transplantation of Small Intestine, Allogeneic, Open Approach	Procedure	ICD-10-PCS
ODY80Z1	Transplantation of Small Intestine, Syngeneic, Open Approach	Procedure	ICD-10-PCS
ODY80Z2	Transplantation of Small Intestine, Zooplastic, Open Approach	Procedure	ICD-10-PCS
ODYE0Z0	Transplantation of Large Intestine, Allogeneic, Open Approach	Procedure	ICD-10-PCS
ODYE0Z1	Transplantation of Large Intestine, Syngeneic, Open Approach	Procedure	ICD-10-PCS
ODYE0Z2	Transplantation of Large Intestine, Zooplastic, Open Approach	Procedure	ICD-10-PCS
OFY0	Transplantation / Liver	Procedure	ICD-10-PCS
OFY00Z0	Transplantation of Liver, Allogeneic, Open Approach	Procedure	ICD-10-PCS
OFY00Z1	Transplantation of Liver, Syngeneic, Open Approach	Procedure	ICD-10-PCS
OFY00Z2	Transplantation of Liver, Zooplastic, Open Approach	Procedure	ICD-10-PCS
OFYG0Z0	Transplantation of Pancreas, Allogeneic, Open Approach	Procedure	ICD-10-PCS
OFYG0Z1	Transplantation of Pancreas, Syngeneic, Open Approach	Procedure	ICD-10-PCS
OFYG0Z2	Transplantation of Pancreas, Zooplastic, Open Approach	Procedure	ICD-10-PCS
OTY0	Transplantation / Kidney, Right	Procedure	ICD-10-PCS
OTY00Z0	Transplantation of Right Kidney, Allogeneic, Open Approach	Procedure	ICD-10-PCS
OTY00Z1	Transplantation of Right Kidney, Syngeneic, Open Approach	Procedure	ICD-10-PCS
OTY00Z2	Transplantation of Right Kidney, Zooplastic, Open Approach	Procedure	ICD-10-PCS
OTY1	Transplantation / Kidney, Left	Procedure	ICD-10-PCS
OTY10Z0	Transplantation of Left Kidney, Allogeneic, Open Approach	Procedure	ICD-10-PCS
OTY10Z1	Transplantation of Left Kidney, Syngeneic, Open Approach	Procedure	ICD-10-PCS
OTY10Z2	Transplantation of Left Kidney, Zooplastic, Open Approach	Procedure	ICD-10-PCS
OUY00Z0	Transplantation of Right Ovary, Allogeneic, Open Approach	Procedure	ICD-10-PCS
OUY00Z1	Transplantation of Right Ovary, Syngeneic, Open Approach	Procedure	ICD-10-PCS
OUY00Z2	Transplantation of Right Ovary, Zooplastic, Open Approach	Procedure	ICD-10-PCS
OUY10Z0	Transplantation of Left Ovary, Allogeneic, Open Approach	Procedure	ICD-10-PCS
OUY10Z1	Transplantation of Left Ovary, Syngeneic, Open Approach	Procedure	ICD-10-PCS
OUY10Z2	Transplantation of Left Ovary, Zooplastic, Open Approach	Procedure	ICD-10-PCS
30230G2	Transfusion of Allogeneic Related Bone Marrow into Peripheral Vein, Open Approach	Procedure	ICD-10-PCS
30230G3	Transfusion of Allogeneic Unrelated Bone Marrow into Peripheral Vein, Open Approach	Procedure	ICD-10-PCS
30230G4	Transfusion of Allogeneic Unspecified Bone Marrow into Peripheral Vein, Open Approach	Procedure	ICD-10-PCS
30233G2	Transfusion of Allogeneic Related Bone Marrow into Peripheral Vein, Percutaneous Approach	Procedure	ICD-10-PCS
30233G3	Transfusion of Allogeneic Unrelated Bone Marrow into Peripheral Vein, Percutaneous Approach	Procedure	ICD-10-PCS
30233G4	Transfusion of Allogeneic Unspecified Bone Marrow into Peripheral Vein, Percutaneous Approach	Procedure	ICD-10-PCS
30240G2	Transfusion of Allogeneic Related Bone Marrow into Central Vein, Open Approach	Procedure	ICD-10-PCS
30240G3	Transfusion of Allogeneic Unrelated Bone Marrow into Central Vein, Open Approach	Procedure	ICD-10-PCS

Appendix C. List of 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, Procedure Coding System (ICD-10-PCS), Healthcare Common Procedure Coding System (HCPCS), and Current Procedural Terminology, Fourth Edition (CPT-4) Diagnosis and Procedure Codes used to Define Incidence Criteria in this Request

Code	Description	Category	Code Type
30240G4	Transfusion of Allogeneic Unspecified Bone Marrow into Central Vein, Open Approach	Procedure	ICD-10-PCS
30243G2	Transfusion of Allogeneic Related Bone Marrow into Central Vein, Percutaneous Approach	Procedure	ICD-10-PCS
30243G3	Transfusion of Allogeneic Unrelated Bone Marrow into Central Vein, Percutaneous Approach	Procedure	ICD-10-PCS
30243G4	Transfusion of Allogeneic Unspecified Bone Marrow into Central Vein, Percutaneous Approach	Procedure	ICD-10-PCS
30250G1	Transfusion of Nonautologous Bone Marrow into Peripheral Artery, Open Approach	Procedure	ICD-10-PCS
30253G1	Transfusion of Nonautologous Bone Marrow into Peripheral Artery, Percutaneous Approach	Procedure	ICD-10-PCS
30260G1	Transfusion of Nonautologous Bone Marrow into Central Artery, Open Approach	Procedure	ICD-10-PCS
30263G1	Transfusion of Nonautologous Bone Marrow into Central Artery, Percutaneous Approach	Procedure	ICD-10-PCS
3E030U1	Introduction of Nonautologous Pancreatic Islet Cells into Peripheral Vein, Open Approach	Procedure	ICD-10-PCS
3E033O5	Introduction of Other Antineoplastic into Peripheral Vein, Percutaneous Approach	Procedure	ICD-10-PCS
3E033U1	Introduction of Nonautologous Pancreatic Islet Cells into Peripheral Vein, Percutaneous Approach	Procedure	ICD-10-PCS
3E0J3U1	Introduction of Nonautologous Pancreatic Islet Cells into Biliary and Pancreatic Tract, Percutaneous Approach	Procedure	ICD-10-PCS
3E0J7U1	Introduction of Nonautologous Pancreatic Islet Cells into Biliary and Pancreatic Tract, Via Natural or Artificial Opening	Procedure	ICD-10-PCS
3E0J8U1	Introduction of Nonautologous Pancreatic Islet Cells into Biliary and Pancreatic Tract, Via Natural or Artificial Opening Endoscopic	Procedure	ICD-10-PCS
BT29	Computerized Tomography (CT Scan) / Kidney Transplant	Procedure	ICD-10-PCS
BT2900Z	Computerized Tomography (CT Scan) of Kidney Transplant using High Osmolar Contrast, Unenhanced and Enhanced	Procedure	ICD-10-PCS
BT290ZZ	Computerized Tomography (CT Scan) of Kidney Transplant using High Osmolar Contrast	Procedure	ICD-10-PCS
BT2910Z	Computerized Tomography (CT Scan) of Kidney Transplant using Low Osmolar Contrast, Unenhanced and Enhanced	Procedure	ICD-10-PCS
BT291ZZ	Computerized Tomography (CT Scan) of Kidney Transplant using Low Osmolar Contrast	Procedure	ICD-10-PCS
BT29Y0Z	Computerized Tomography (CT Scan) of Kidney Transplant using Other Contrast, Unenhanced and Enhanced	Procedure	ICD-10-PCS
BT29YZZ	Computerized Tomography (CT Scan) of Kidney Transplant using Other Contrast	Procedure	ICD-10-PCS
BT29ZZZ	Computerized Tomography (CT Scan) of Kidney Transplant	Procedure	ICD-10-PCS
BT39	Magnetic Resonance Imaging (MRI) / Kidney Transplant	Procedure	ICD-10-PCS
BT39Y0Z	Magnetic Resonance Imaging (MRI) of Kidney Transplant using Other Contrast, Unenhanced and Enhanced	Procedure	ICD-10-PCS
BT39YZZ	Magnetic Resonance Imaging (MRI) of Kidney Transplant using Other Contrast	Procedure	ICD-10-PCS
BT39ZZZ	Magnetic Resonance Imaging (MRI) of Kidney Transplant	Procedure	ICD-10-PCS
BT49	Ultrasonography / Kidney Transplant	Procedure	ICD-10-PCS
BT49ZZZ	Ultrasonography of Kidney Transplant	Procedure	ICD-10-PCS
C80.2	Malignant neoplasm associated with transplanted organ	Diagnosis	ICD-10-CM
D47.Z1	Post-transplant lymphoproliferative disorder (PTLD)	Diagnosis	ICD-10-CM

Appendix C. List of 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, Procedure Coding System (ICD-10-PCS), Healthcare Common Procedure Coding System (HCPCS), and Current Procedural Terminology, Fourth Edition (CPT-4) Diagnosis and Procedure Codes used to Define Incidence Criteria in this Request

Code	Description	Category	Code Type
I25.7	Atherosclerosis of coronary artery bypass graft(s) and coronary artery of transplanted heart with angina pectoris	Diagnosis	ICD-10-CM
I25.75	Atherosclerosis of native coronary artery of transplanted heart with angina pectoris	Diagnosis	ICD-10-CM
I25.750	Atherosclerosis of native coronary artery of transplanted heart with unstable angina	Diagnosis	ICD-10-CM
I25.751	Atherosclerosis of native coronary artery of transplanted heart with angina pectoris with documented spasm	Diagnosis	ICD-10-CM
I25.758	Atherosclerosis of native coronary artery of transplanted heart with other forms of angina pectoris	Diagnosis	ICD-10-CM
I25.759	Atherosclerosis of native coronary artery of transplanted heart with unspecified angina pectoris	Diagnosis	ICD-10-CM
I25.76	Atherosclerosis of bypass graft of coronary artery of transplanted heart with angina pectoris	Diagnosis	ICD-10-CM
I25.760	Atherosclerosis of bypass graft of coronary artery of transplanted heart with unstable angina	Diagnosis	ICD-10-CM
I25.761	Atherosclerosis of bypass graft of coronary artery of transplanted heart with angina pectoris with documented spasm	Diagnosis	ICD-10-CM
I25.768	Atherosclerosis of bypass graft of coronary artery of transplanted heart with other forms of angina pectoris	Diagnosis	ICD-10-CM
I25.769	Atherosclerosis of bypass graft of coronary artery of transplanted heart with unspecified angina pectoris	Diagnosis	ICD-10-CM
I25.811	Atherosclerosis of native coronary artery of transplanted heart without angina pectoris	Diagnosis	ICD-10-CM
I25.812	Atherosclerosis of bypass graft of coronary artery of transplanted heart without angina pectoris	Diagnosis	ICD-10-CM
T86	Complications of transplanted organs and tissue	Diagnosis	ICD-10-CM
T86.0	Complications of bone marrow transplant	Diagnosis	ICD-10-CM
T86.00	Unspecified complication of bone marrow transplant	Diagnosis	ICD-10-CM
T86.01	Bone marrow transplant rejection	Diagnosis	ICD-10-CM
T86.02	Bone marrow transplant failure	Diagnosis	ICD-10-CM
T86.03	Bone marrow transplant infection	Diagnosis	ICD-10-CM
T86.09	Other complications of bone marrow transplant	Diagnosis	ICD-10-CM
T86.1	Complications of kidney transplant	Diagnosis	ICD-10-CM
T86.10	Unspecified complication of kidney transplant	Diagnosis	ICD-10-CM
T86.11	Kidney transplant rejection	Diagnosis	ICD-10-CM
T86.12	Kidney transplant failure	Diagnosis	ICD-10-CM
T86.13	Kidney transplant infection	Diagnosis	ICD-10-CM
T86.19	Other complication of kidney transplant	Diagnosis	ICD-10-CM
T86.2	Complications of heart transplant	Diagnosis	ICD-10-CM
T86.20	Unspecified complication of heart transplant	Diagnosis	ICD-10-CM
T86.21	Heart transplant rejection	Diagnosis	ICD-10-CM
T86.22	Heart transplant failure	Diagnosis	ICD-10-CM
T86.23	Heart transplant infection	Diagnosis	ICD-10-CM
T86.29	Other complications of heart transplant	Diagnosis	ICD-10-CM
T86.290	Cardiac allograft vasculopathy	Diagnosis	ICD-10-CM
T86.298	Other complications of heart transplant	Diagnosis	ICD-10-CM
T86.3	Complications of heart-lung transplant	Diagnosis	ICD-10-CM
T86.30	Unspecified complication of heart-lung transplant	Diagnosis	ICD-10-CM
T86.31	Heart-lung transplant rejection	Diagnosis	ICD-10-CM

Appendix C. List of 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, Procedure Coding System (ICD-10-PCS), Healthcare Common Procedure Coding System (HCPCS), and Current Procedural Terminology, Fourth Edition (CPT-4) Diagnosis and Procedure Codes used to Define Incidence Criteria in this Request

Code	Description	Category	Code Type
T86.32	Heart-lung transplant failure	Diagnosis	ICD-10-CM
T86.33	Heart-lung transplant infection	Diagnosis	ICD-10-CM
T86.39	Other complications of heart-lung transplant	Diagnosis	ICD-10-CM
T86.4	Complications of liver transplant	Diagnosis	ICD-10-CM
T86.40	Unspecified complication of liver transplant	Diagnosis	ICD-10-CM
T86.41	Liver transplant rejection	Diagnosis	ICD-10-CM
T86.42	Liver transplant failure	Diagnosis	ICD-10-CM
T86.43	Liver transplant infection	Diagnosis	ICD-10-CM
T86.49	Other complications of liver transplant	Diagnosis	ICD-10-CM
T86.5	Complications of stem cell transplant	Diagnosis	ICD-10-CM
T86.8	Complications of other transplanted organs and tissues	Diagnosis	ICD-10-CM
T86.81	Complications of lung transplant	Diagnosis	ICD-10-CM
T86.810	Lung transplant rejection	Diagnosis	ICD-10-CM
T86.811	Lung transplant failure	Diagnosis	ICD-10-CM
T86.812	Lung transplant infection	Diagnosis	ICD-10-CM
T86.818	Other complications of lung transplant	Diagnosis	ICD-10-CM
T86.819	Unspecified complication of lung transplant	Diagnosis	ICD-10-CM
T86.830	Bone graft rejection	Diagnosis	ICD-10-CM
T86.831	Bone graft failure	Diagnosis	ICD-10-CM
T86.832	Bone graft infection	Diagnosis	ICD-10-CM
T86.838	Other complications of bone graft	Diagnosis	ICD-10-CM
T86.839	Unspecified complication of bone graft	Diagnosis	ICD-10-CM
T86.85	Complication of intestine transplant	Diagnosis	ICD-10-CM
T86.850	Intestine transplant rejection	Diagnosis	ICD-10-CM
T86.851	Intestine transplant failure	Diagnosis	ICD-10-CM
T86.852	Intestine transplant infection	Diagnosis	ICD-10-CM
T86.858	Other complications of intestine transplant	Diagnosis	ICD-10-CM
T86.859	Unspecified complication of intestine transplant	Diagnosis	ICD-10-CM
T86.89	Complications of other transplanted tissue	Diagnosis	ICD-10-CM
T86.890	Other transplanted tissue rejection	Diagnosis	ICD-10-CM
T86.891	Other transplanted tissue failure	Diagnosis	ICD-10-CM
T86.892	Other transplanted tissue infection	Diagnosis	ICD-10-CM
T86.898	Other complications of other transplanted tissue	Diagnosis	ICD-10-CM
T86.899	Unspecified complication of other transplanted tissue	Diagnosis	ICD-10-CM
T86.9	Complication of unspecified transplanted organ and tissue	Diagnosis	ICD-10-CM
T86.90	Unspecified complication of unspecified transplanted organ and tissue	Diagnosis	ICD-10-CM
T86.91	Unspecified transplanted organ and tissue rejection	Diagnosis	ICD-10-CM
T86.92	Unspecified transplanted organ and tissue failure	Diagnosis	ICD-10-CM
T86.93	Unspecified transplanted organ and tissue infection	Diagnosis	ICD-10-CM
T86.99	Other complications of unspecified transplanted organ and tissue	Diagnosis	ICD-10-CM
V42	Organ or tissue replaced by transplant	Diagnosis	ICD-9-CM
V42.0	Kidney replaced by transplant	Diagnosis	ICD-9-CM
V42.1	Heart replaced by transplant	Diagnosis	ICD-9-CM
V42.2	Heart valve replaced by transplant	Diagnosis	ICD-9-CM
V42.3	Skin replaced by transplant	Diagnosis	ICD-9-CM
V42.4	Bone replaced by transplant	Diagnosis	ICD-9-CM
V42.6	Lung replaced by transplant	Diagnosis	ICD-9-CM
V42.7	Liver replaced by transplant	Diagnosis	ICD-9-CM

Appendix C. List of 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, Procedure Coding System (ICD-10-PCS), Healthcare Common Procedure Coding System (HCPCS), and Current Procedural Terminology, Fourth Edition (CPT-4) Diagnosis and Procedure Codes used to Define Incidence Criteria in this Request

Code	Description	Category	Code Type
V42.8	Other specified organ or tissue replaced by transplant	Diagnosis	ICD-9-CM
V42.81	Bone marrow replaced by transplant	Diagnosis	ICD-9-CM
V42.82	Peripheral stem cells replaced by transplant	Diagnosis	ICD-9-CM
V42.83	Pancreas replaced by transplant	Diagnosis	ICD-9-CM
V42.84	Organ or tissue replaced by transplant, intestines	Diagnosis	ICD-9-CM
V42.89	Other organ or tissue replaced by transplant	Diagnosis	ICD-9-CM
V42.9	Unspecified organ or tissue replaced by transplant	Diagnosis	ICD-9-CM
V45.87	Transplanted organ removal status	Diagnosis	ICD-9-CM
V58.44	Aftercare following organ transplant	Diagnosis	ICD-9-CM
Y83.0	Surgical operation with transplant of whole organ 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
Z48.2	Encounter for aftercare following organ transplant	Diagnosis	ICD-10-CM
Z48.21	Encounter for aftercare following heart transplant	Diagnosis	ICD-10-CM
Z48.22	Encounter for aftercare following kidney transplant	Diagnosis	ICD-10-CM
Z48.23	Encounter for aftercare following liver transplant	Diagnosis	ICD-10-CM
Z48.24	Encounter for aftercare following lung transplant	Diagnosis	ICD-10-CM
Z48.28	Encounter for aftercare following multiple organ transplant	Diagnosis	ICD-10-CM
Z48.280	Encounter for aftercare following heart-lung transplant	Diagnosis	ICD-10-CM
Z48.288	Encounter for aftercare following multiple organ transplant	Diagnosis	ICD-10-CM
Z48.29	Encounter for aftercare following other organ transplant	Diagnosis	ICD-10-CM
Z48.290	Encounter for aftercare following bone marrow transplant	Diagnosis	ICD-10-CM
Z48.298	Encounter for aftercare following other organ transplant	Diagnosis	ICD-10-CM
Z94	Transplanted organ and tissue status	Diagnosis	ICD-10-CM
Z94.0	Kidney transplant status	Diagnosis	ICD-10-CM
Z94.1	Heart transplant status	Diagnosis	ICD-10-CM
Z94.2	Lung transplant status	Diagnosis	ICD-10-CM
Z94.3	Heart and lungs transplant status	Diagnosis	ICD-10-CM
Z94.4	Liver transplant status	Diagnosis	ICD-10-CM
Z94.5	Skin transplant status	Diagnosis	ICD-10-CM
Z94.6	Bone transplant status	Diagnosis	ICD-10-CM
Z94.8	Other transplanted organ and tissue status	Diagnosis	ICD-10-CM
Z94.81	Bone marrow transplant status	Diagnosis	ICD-10-CM
Z94.82	Intestine transplant status	Diagnosis	ICD-10-CM
Z94.83	Pancreas transplant status	Diagnosis	ICD-10-CM
Z94.84	Stem cells transplant status	Diagnosis	ICD-10-CM
Z94.89	Other transplanted organ and tissue status	Diagnosis	ICD-10-CM
Z94.9	Transplanted organ and tissue status, unspecified	Diagnosis	ICD-10-CM
Z95.3	Presence of xenogenic heart valve	Diagnosis	ICD-10-CM
Z95.4	Presence of other heart-valve replacement	Diagnosis	ICD-10-CM
Z98.85	Transplanted organ removal status	Diagnosis	ICD-10-CM

Appendix D. List of 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, Procedure Coding System (ICD-10-PCS), and Current Procedural Terminology, Fourth Edition (CPT-4) Diagnosis and Procedure Codes Used to Define Exclusion Criteria in this Request

Code	Description	Category	Code Type
Liver Transplant Exclusions			
07.94	Transplantation of thymus	Procedure	ICD-09-CM
33.5	Lung transplant	Procedure	ICD-09-CM
33.50	Lung transplantation, NOS	Procedure	ICD-09-CM
33.51	Unilateral lung transplantation	Procedure	ICD-09-CM
33.52	Bilateral lung transplantation	Procedure	ICD-09-CM
33.6	Combined heart-lung transplantation	Procedure	ICD-09-CM
37.51	Heart transplantation	Procedure	ICD-09-CM
41.0	Bone marrow transplant	Procedure	ICD-09-CM
41.00	Bone marrow transplant, not otherwise specified	Procedure	ICD-09-CM
41.02	Allogeneic bone marrow transplant with purging	Procedure	ICD-09-CM
41.03	Allogeneic bone marrow transplant without purging	Procedure	ICD-09-CM
41.05	Allogeneic hematopoietic stem cell transplant without purging	Procedure	ICD-09-CM
41.06	Cord blood stem cell transplant	Procedure	ICD-09-CM
41.08	Allogeneic hematopoietic stem cell transplant with purging	Procedure	ICD-09-CM
41.94	Transplantation of spleen	Procedure	ICD-09-CM
46.97	Transplant of intestine	Procedure	ICD-09-CM
49.74	Gracilis muscle transplant for anal incontinence	Procedure	ICD-09-CM
52.8	Transplant of pancreas	Procedure	ICD-09-CM
52.80	Pancreatic transplant, not otherwise specified	Procedure	ICD-09-CM
52.82	Homotransplant of pancreas	Procedure	ICD-09-CM
52.83	Heterotransplant of pancreas	Procedure	ICD-09-CM
52.85	Allotransplantation of cells of islets of Langerhans	Procedure	ICD-09-CM
52.86	Transplantation of cells of islets of Langerhans, not otherwise specified	Procedure	ICD-09-CM
55.53	Removal of transplanted or rejected kidney	Procedure	ICD-09-CM
55.6	Transplant of kidney	Procedure	ICD-09-CM
55.69	Other kidney transplantation	Procedure	ICD-09-CM
63.53	Transplantation of spermatic cord	Procedure	ICD-09-CM
65.92	Transplantation of ovary	Procedure	ICD-09-CM
82.5	Transplantation of muscle and tendon of hand	Procedure	ICD-09-CM
82.56	Other hand tendon transfer or transplantation	Procedure	ICD-09-CM
82.58	Other hand muscle transfer or transplantation	Procedure	ICD-09-CM
83.75	Tendon transfer or transplantation	Procedure	ICD-09-CM
83.77	Muscle transfer or transplantation	Procedure	ICD-09-CM
414.06	Coronary atherosclerosis, of native coronary artery of transplanted heart	Diagnosis	ICD-09-CM
414.07	Coronary atherosclerosis, of bypass graft (artery) (vein) of transplanted heart	Diagnosis	ICD-09-CM
996.81	Complications of transplanted kidney	Diagnosis	ICD-09-CM
996.83	Complications of transplanted heart	Diagnosis	ICD-09-CM
996.84	Complications of transplanted lung	Diagnosis	ICD-09-CM
996.85	Complications of bone marrow transplant	Diagnosis	ICD-09-CM
996.86	Complications of transplanted pancreas	Diagnosis	ICD-09-CM
996.87	Complications of transplanted organ, intestine	Diagnosis	ICD-09-CM
996.88	Complications of transplanted organ, stem cell	Diagnosis	ICD-09-CM
33935	Heart-lung transplant with recipient cardiectomy-pneumonectomy	Procedure	CPT-4
33945	Heart transplant, with or without recipient cardiectomy	Procedure	CPT-4
50360	Renal allotransplantation, implantation of graft; without recipient nephrectomy	Procedure	CPT-4
50365	Renal allotransplantation, implantation of graft; with recipient nephrectomy	Procedure	CPT-4

Appendix D. List of 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, Procedure Coding System (ICD-10-PCS), and Current Procedural Terminology, Fourth Edition (CPT-4) Diagnosis and Procedure Codes Used to Define Exclusion Criteria in this Request

Code	Description	Category	Code Type
50370	Removal of transplanted renal allograft	Procedure	CPT-4
50380	Renal autotransplantation, reimplantation of kidney	Procedure	CPT-4
02Y	Heart and Great Vessels, Transplantation	Procedure	ICD-10-PCS
02YA	Transplantation / Heart	Procedure	ICD-10-PCS
02YA0Z0	Transplantation of Heart, Allogeneic, Open Approach	Procedure	ICD-10-PCS
02YA0Z1	Transplantation of Heart, Syngeneic, Open Approach	Procedure	ICD-10-PCS
02YA0Z2	Transplantation of Heart, Zooplastic, Open Approach	Procedure	ICD-10-PCS
07YM0Z0	Transplantation of Thymus, Allogeneic, Open Approach	Procedure	ICD-10-PCS
07YM0Z1	Transplantation of Thymus, Syngeneic, Open Approach	Procedure	ICD-10-PCS
07YM0Z2	Transplantation of Thymus, Zooplastic, Open Approach	Procedure	ICD-10-PCS
07YPOZ0	Transplantation of Spleen, Allogeneic, Open Approach	Procedure	ICD-10-PCS
07YPOZ1	Transplantation of Spleen, Syngeneic, Open Approach	Procedure	ICD-10-PCS
07YPOZ2	Transplantation of Spleen, Zooplastic, Open Approach	Procedure	ICD-10-PCS
0BYC0Z0	Transplantation of Right Upper Lung Lobe, Allogeneic, Open Approach	Procedure	ICD-10-PCS
0BYC0Z1	Transplantation of Right Upper Lung Lobe, Syngeneic, Open Approach	Procedure	ICD-10-PCS
0BYC0Z2	Transplantation of Right Upper Lung Lobe, Zooplastic, Open Approach	Procedure	ICD-10-PCS
0BYD0Z0	Transplantation of Right Middle Lung Lobe, Allogeneic, Open Approach	Procedure	ICD-10-PCS
0BYD0Z1	Transplantation of Right Middle Lung Lobe, Syngeneic, Open Approach	Procedure	ICD-10-PCS
0BYD0Z2	Transplantation of Right Middle Lung Lobe, Zooplastic, Open Approach	Procedure	ICD-10-PCS
0BYF0Z0	Transplantation of Right Lower Lung Lobe, Allogeneic, Open Approach	Procedure	ICD-10-PCS
0BYF0Z1	Transplantation of Right Lower Lung Lobe, Syngeneic, Open Approach	Procedure	ICD-10-PCS
0BYF0Z2	Transplantation of Right Lower Lung Lobe, Zooplastic, Open Approach	Procedure	ICD-10-PCS
0BYG0Z0	Transplantation of Left Upper Lung Lobe, Allogeneic, Open Approach	Procedure	ICD-10-PCS
0BYG0Z1	Transplantation of Left Upper Lung Lobe, Syngeneic, Open Approach	Procedure	ICD-10-PCS
0BYG0Z2	Transplantation of Left Upper Lung Lobe, Zooplastic, Open Approach	Procedure	ICD-10-PCS
0BYH0Z0	Transplantation of Lung Lingula, Allogeneic, Open Approach	Procedure	ICD-10-PCS
0BYH0Z1	Transplantation of Lung Lingula, Syngeneic, Open Approach	Procedure	ICD-10-PCS
0BYH0Z2	Transplantation of Lung Lingula, Zooplastic, Open Approach	Procedure	ICD-10-PCS
0BYJ0Z0	Transplantation of Left Lower Lung Lobe, Allogeneic, Open Approach	Procedure	ICD-10-PCS
0BYJ0Z1	Transplantation of Left Lower Lung Lobe, Syngeneic, Open Approach	Procedure	ICD-10-PCS
0BYJ0Z2	Transplantation of Left Lower Lung Lobe, Zooplastic, Open Approach	Procedure	ICD-10-PCS
0BYK0Z0	Transplantation of Right Lung, Allogeneic, Open Approach	Procedure	ICD-10-PCS
0BYK0Z1	Transplantation of Right Lung, Syngeneic, Open Approach	Procedure	ICD-10-PCS
0BYK0Z2	Transplantation of Right Lung, Zooplastic, Open Approach	Procedure	ICD-10-PCS
0BYLOZ0	Transplantation of Left Lung, Allogeneic, Open Approach	Procedure	ICD-10-PCS
0BYLOZ1	Transplantation of Left Lung, Syngeneic, Open Approach	Procedure	ICD-10-PCS
0BYLOZ2	Transplantation of Left Lung, Zooplastic, Open Approach	Procedure	ICD-10-PCS
0BYM0Z0	Transplantation of Bilateral Lungs, Allogeneic, Open Approach	Procedure	ICD-10-PCS
0BYM0Z1	Transplantation of Bilateral Lungs, Syngeneic, Open Approach	Procedure	ICD-10-PCS
0BYM0Z2	Transplantation of Bilateral Lungs, Zooplastic, Open Approach	Procedure	ICD-10-PCS
0DY80Z0	Transplantation of Small Intestine, Allogeneic, Open Approach	Procedure	ICD-10-PCS
0DY80Z1	Transplantation of Small Intestine, Syngeneic, Open Approach	Procedure	ICD-10-PCS
0DY80Z2	Transplantation of Small Intestine, Zooplastic, Open Approach	Procedure	ICD-10-PCS
0DYE0Z0	Transplantation of Large Intestine, Allogeneic, Open Approach	Procedure	ICD-10-PCS
0DYE0Z1	Transplantation of Large Intestine, Syngeneic, Open Approach	Procedure	ICD-10-PCS
0DYE0Z2	Transplantation of Large Intestine, Zooplastic, Open Approach	Procedure	ICD-10-PCS
0FYG0Z0	Transplantation of Pancreas, Allogeneic, Open Approach	Procedure	ICD-10-PCS
0FYG0Z1	Transplantation of Pancreas, Syngeneic, Open Approach	Procedure	ICD-10-PCS

Appendix D. List of 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, Procedure Coding System (ICD-10-PCS), and Current Procedural Terminology, Fourth Edition (CPT-4) Diagnosis and Procedure Codes Used to Define Exclusion Criteria in this Request

Code	Description	Category	Code Type
0FYG0Z2	Transplantation of Pancreas, Zooplastic, Open Approach	Procedure	ICD-10-PCS
0TY0	Transplantation / Kidney, Right	Procedure	ICD-10-PCS
0TY00Z0	Transplantation of Right Kidney, Allogeneic, Open Approach	Procedure	ICD-10-PCS
0TY00Z1	Transplantation of Right Kidney, Syngeneic, Open Approach	Procedure	ICD-10-PCS
0TY00Z2	Transplantation of Right Kidney, Zooplastic, Open Approach	Procedure	ICD-10-PCS
0TY1	Transplantation / Kidney, Left	Procedure	ICD-10-PCS
0TY10Z0	Transplantation of Left Kidney, Allogeneic, Open Approach	Procedure	ICD-10-PCS
0TY10Z1	Transplantation of Left Kidney, Syngeneic, Open Approach	Procedure	ICD-10-PCS
0TY10Z2	Transplantation of Left Kidney, Zooplastic, Open Approach	Procedure	ICD-10-PCS
0UY00Z0	Transplantation of Right Ovary, Allogeneic, Open Approach	Procedure	ICD-10-PCS
0UY00Z1	Transplantation of Right Ovary, Syngeneic, Open Approach	Procedure	ICD-10-PCS
0UY00Z2	Transplantation of Right Ovary, Zooplastic, Open Approach	Procedure	ICD-10-PCS
0UY10Z0	Transplantation of Left Ovary, Allogeneic, Open Approach	Procedure	ICD-10-PCS
0UY10Z1	Transplantation of Left Ovary, Syngeneic, Open Approach	Procedure	ICD-10-PCS
0UY10Z2	Transplantation of Left Ovary, Zooplastic, Open Approach	Procedure	ICD-10-PCS
30230G2	Transfusion of Allogeneic Related Bone Marrow into Peripheral Vein, Open Approach	Procedure	ICD-10-PCS
30230G3	Transfusion of Allogeneic Unrelated Bone Marrow into Peripheral Vein, Open Approach	Procedure	ICD-10-PCS
30230G4	Transfusion of Allogeneic Unspecified Bone Marrow into Peripheral Vein, Open Approach	Procedure	ICD-10-PCS
30233G2	Transfusion of Allogeneic Related Bone Marrow into Peripheral Vein, Percutaneous Approach	Procedure	ICD-10-PCS
30233G3	Transfusion of Allogeneic Unrelated Bone Marrow into Peripheral Vein, Percutaneous Approach	Procedure	ICD-10-PCS
30233G4	Transfusion of Allogeneic Unspecified Bone Marrow into Peripheral Vein, Percutaneous Approach	Procedure	ICD-10-PCS
30240G2	Transfusion of Allogeneic Related Bone Marrow into Central Vein, Open Approach	Procedure	ICD-10-PCS
30240G3	Transfusion of Allogeneic Unrelated Bone Marrow into Central Vein, Open Approach	Procedure	ICD-10-PCS
30240G4	Transfusion of Allogeneic Unspecified Bone Marrow into Central Vein, Open Approach	Procedure	ICD-10-PCS
30243G2	Transfusion of Allogeneic Related Bone Marrow into Central Vein, Percutaneous Approach	Procedure	ICD-10-PCS
30243G3	Transfusion of Allogeneic Unrelated Bone Marrow into Central Vein, Percutaneous Approach	Procedure	ICD-10-PCS
30243G4	Transfusion of Allogeneic Unspecified Bone Marrow into Central Vein, Percutaneous Approach	Procedure	ICD-10-PCS
30250G1	Transfusion of Nonautologous Bone Marrow into Peripheral Artery, Open Approach	Procedure	ICD-10-PCS
30253G1	Transfusion of Nonautologous Bone Marrow into Peripheral Artery, Percutaneous Approach	Procedure	ICD-10-PCS
30260G1	Transfusion of Nonautologous Bone Marrow into Central Artery, Open Approach	Procedure	ICD-10-PCS
30263G1	Transfusion of Nonautologous Bone Marrow into Central Artery, Percutaneous Approach	Procedure	ICD-10-PCS
3E030U1	Introduction of Nonautologous Pancreatic Islet Cells into Peripheral Vein, Open Approach	Procedure	ICD-10-PCS
3E033U1	Introduction of Nonautologous Pancreatic Islet Cells into Peripheral Vein, Percutaneous Approach	Procedure	ICD-10-PCS

Appendix D. List of 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, Procedure Coding System (ICD-10-PCS), and Current Procedural Terminology, Fourth Edition (CPT-4) Diagnosis and Procedure Codes Used to Define Exclusion Criteria in this Request

Code	Description	Category	Code Type
3E0J3U1	Introduction of Nonautologous Pancreatic Islet Cells into Biliary and Pancreatic Tract, Percutaneous Approach	Procedure	ICD-10-PCS
3E0J7U1	Introduction of Nonautologous Pancreatic Islet Cells into Biliary and Pancreatic Tract, Via Natural or Artificial Opening	Procedure	ICD-10-PCS
3E0J8U1	Introduction of Nonautologous Pancreatic Islet Cells into Biliary and Pancreatic Tract, Via Natural or Artificial Opening Endoscopic	Procedure	ICD-10-PCS
BT29	Computerized Tomography (CT Scan) / Kidney Transplant	Procedure	ICD-10-PCS
BT2900Z	Computerized Tomography (CT Scan) of Kidney Transplant using High Osmolar Contrast, Unenhanced and Enhanced	Procedure	ICD-10-PCS
BT290ZZ	Computerized Tomography (CT Scan) of Kidney Transplant using High Osmolar Contrast	Procedure	ICD-10-PCS
BT2910Z	Computerized Tomography (CT Scan) of Kidney Transplant using Low Osmolar Contrast, Unenhanced and Enhanced	Procedure	ICD-10-PCS
BT291ZZ	Computerized Tomography (CT Scan) of Kidney Transplant using Low Osmolar Contrast	Procedure	ICD-10-PCS
BT29Y0Z	Computerized Tomography (CT Scan) of Kidney Transplant using Other Contrast, Unenhanced and Enhanced	Procedure	ICD-10-PCS
BT29YZZ	Computerized Tomography (CT Scan) of Kidney Transplant using Other Contrast	Procedure	ICD-10-PCS
BT29ZZZ	Computerized Tomography (CT Scan) of Kidney Transplant	Procedure	ICD-10-PCS
BT39	Magnetic Resonance Imaging (MRI) / Kidney Transplant	Procedure	ICD-10-PCS
BT39Y0Z	Magnetic Resonance Imaging (MRI) of Kidney Transplant using Other Contrast, Unenhanced and Enhanced	Procedure	ICD-10-PCS
BT39YZZ	Magnetic Resonance Imaging (MRI) of Kidney Transplant using Other Contrast	Procedure	ICD-10-PCS
BT39ZZZ	Magnetic Resonance Imaging (MRI) of Kidney Transplant	Procedure	ICD-10-PCS
BT49	Ultrasonography / Kidney Transplant	Procedure	ICD-10-PCS
BT49ZZZ	Ultrasonography of Kidney Transplant	Procedure	ICD-10-PCS
I25.7	Atherosclerosis of coronary artery bypass graft(s) and coronary artery of transplanted heart with angina pectoris	Diagnosis	ICD-10-CM
I25.75	Atherosclerosis of native coronary artery of transplanted heart with angina pectoris	Diagnosis	ICD-10-CM
I25.750	Atherosclerosis of native coronary artery of transplanted heart with unstable angina	Diagnosis	ICD-10-CM
I25.751	Atherosclerosis of native coronary artery of transplanted heart with angina pectoris with documented spasm	Diagnosis	ICD-10-CM
I25.758	Atherosclerosis of native coronary artery of transplanted heart with other forms of angina pectoris	Diagnosis	ICD-10-CM
I25.759	Atherosclerosis of native coronary artery of transplanted heart with unspecified angina pectoris	Diagnosis	ICD-10-CM
I25.76	Atherosclerosis of bypass graft of coronary artery of transplanted heart with angina pectoris	Diagnosis	ICD-10-CM
I25.760	Atherosclerosis of bypass graft of coronary artery of transplanted heart with unstable angina	Diagnosis	ICD-10-CM
I25.761	Atherosclerosis of bypass graft of coronary artery of transplanted heart with angina pectoris with documented spasm	Diagnosis	ICD-10-CM
I25.768	Atherosclerosis of bypass graft of coronary artery of transplanted heart with other forms of angina pectoris	Diagnosis	ICD-10-CM
I25.769	Atherosclerosis of bypass graft of coronary artery of transplanted heart with unspecified angina pectoris	Diagnosis	ICD-10-CM
I25.811	Atherosclerosis of native coronary artery of transplanted heart without angina pectoris	Diagnosis	ICD-10-CM

Appendix D. List of 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, Procedure Coding System (ICD-10-PCS), and Current Procedural Terminology, Fourth Edition (CPT-4) Diagnosis and Procedure Codes Used to Define Exclusion Criteria in this Request

Code	Description	Category	Code Type
I25.812	Atherosclerosis of bypass graft of coronary artery of transplanted heart without angina pectoris	Diagnosis	ICD-10-CM
T86.0	Complications of bone marrow transplant	Diagnosis	ICD-10-CM
T86.00	Unspecified complication of bone marrow transplant	Diagnosis	ICD-10-CM
T86.01	Bone marrow transplant rejection	Diagnosis	ICD-10-CM
T86.02	Bone marrow transplant failure	Diagnosis	ICD-10-CM
T86.03	Bone marrow transplant infection	Diagnosis	ICD-10-CM
T86.09	Other complications of bone marrow transplant	Diagnosis	ICD-10-CM
T86.1	Complications of kidney transplant	Diagnosis	ICD-10-CM
T86.10	Unspecified complication of kidney transplant	Diagnosis	ICD-10-CM
T86.11	Kidney transplant rejection	Diagnosis	ICD-10-CM
T86.12	Kidney transplant failure	Diagnosis	ICD-10-CM
T86.13	Kidney transplant infection	Diagnosis	ICD-10-CM
T86.19	Other complication of kidney transplant	Diagnosis	ICD-10-CM
T86.2	Complications of heart transplant	Diagnosis	ICD-10-CM
T86.20	Unspecified complication of heart transplant	Diagnosis	ICD-10-CM
T86.21	Heart transplant rejection	Diagnosis	ICD-10-CM
T86.22	Heart transplant failure	Diagnosis	ICD-10-CM
T86.23	Heart transplant infection	Diagnosis	ICD-10-CM
T86.29	Other complications of heart transplant	Diagnosis	ICD-10-CM
T86.290	Cardiac allograft vasculopathy	Diagnosis	ICD-10-CM
T86.298	Other complications of heart transplant	Diagnosis	ICD-10-CM
T86.3	Complications of heart-lung transplant	Diagnosis	ICD-10-CM
T86.30	Unspecified complication of heart-lung transplant	Diagnosis	ICD-10-CM
T86.31	Heart-lung transplant rejection	Diagnosis	ICD-10-CM
T86.32	Heart-lung transplant failure	Diagnosis	ICD-10-CM
T86.33	Heart-lung transplant infection	Diagnosis	ICD-10-CM
T86.39	Other complications of heart-lung transplant	Diagnosis	ICD-10-CM
T86.5	Complications of stem cell transplant	Diagnosis	ICD-10-CM
T86.81	Complications of lung transplant	Diagnosis	ICD-10-CM
T86.810	Lung transplant rejection	Diagnosis	ICD-10-CM
T86.811	Lung transplant failure	Diagnosis	ICD-10-CM
T86.812	Lung transplant infection	Diagnosis	ICD-10-CM
T86.818	Other complications of lung transplant	Diagnosis	ICD-10-CM
T86.819	Unspecified complication of lung transplant	Diagnosis	ICD-10-CM
T86.830	Bone graft rejection	Diagnosis	ICD-10-CM
T86.831	Bone graft failure	Diagnosis	ICD-10-CM
T86.832	Bone graft infection	Diagnosis	ICD-10-CM
T86.838	Other complications of bone graft	Diagnosis	ICD-10-CM
T86.839	Unspecified complication of bone graft	Diagnosis	ICD-10-CM
T86.85	Complication of intestine transplant	Diagnosis	ICD-10-CM
T86.850	Intestine transplant rejection	Diagnosis	ICD-10-CM
T86.851	Intestine transplant failure	Diagnosis	ICD-10-CM
T86.852	Intestine transplant infection	Diagnosis	ICD-10-CM
T86.858	Other complications of intestine transplant	Diagnosis	ICD-10-CM
T86.859	Unspecified complication of intestine transplant	Diagnosis	ICD-10-CM
V42.0	Kidney replaced by transplant	Diagnosis	ICD-09-CM
V42.1	Heart replaced by transplant	Diagnosis	ICD-09-CM

Appendix D. List of 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, Procedure Coding System (ICD-10-PCS), and Current Procedural Terminology, Fourth Edition (CPT-4) Diagnosis and Procedure Codes Used to Define Exclusion Criteria in this Request

Code	Description	Category	Code Type
V42.2	Heart valve replaced by transplant	Diagnosis	ICD-09-CM
V42.3	Skin replaced by transplant	Diagnosis	ICD-09-CM
V42.4	Bone replaced by transplant	Diagnosis	ICD-09-CM
V42.6	Lung replaced by transplant	Diagnosis	ICD-09-CM
V42.8	Other specified organ or tissue replaced by transplant	Diagnosis	ICD-09-CM
V42.81	Bone marrow replaced by transplant	Diagnosis	ICD-09-CM
V42.82	Peripheral stem cells replaced by transplant	Diagnosis	ICD-09-CM
V42.83	Pancreas replaced by transplant	Diagnosis	ICD-09-CM
V42.84	Organ or tissue replaced by transplant, intestines	Diagnosis	ICD-09-CM
Z48.21	Encounter for aftercare following heart transplant	Diagnosis	ICD-10-CM
Z48.22	Encounter for aftercare following kidney transplant	Diagnosis	ICD-10-CM
Z48.24	Encounter for aftercare following lung transplant	Diagnosis	ICD-10-CM
Z48.28	Encounter for aftercare following multiple organ transplant	Diagnosis	ICD-10-CM
Z48.280	Encounter for aftercare following heart-lung transplant	Diagnosis	ICD-10-CM
Z48.288	Encounter for aftercare following multiple organ transplant	Diagnosis	ICD-10-CM
Z48.29	Encounter for aftercare following other organ transplant	Diagnosis	ICD-10-CM
Z48.290	Encounter for aftercare following bone marrow transplant	Diagnosis	ICD-10-CM
Z94.0	Kidney transplant status	Diagnosis	ICD-10-CM
Z94.1	Heart transplant status	Diagnosis	ICD-10-CM
Z94.2	Lung transplant status	Diagnosis	ICD-10-CM
Z94.3	Heart and lungs transplant status	Diagnosis	ICD-10-CM
Z94.5	Skin transplant status	Diagnosis	ICD-10-CM
Z94.6	Bone transplant status	Diagnosis	ICD-10-CM
Z94.8	Other transplanted organ and tissue status	Diagnosis	ICD-10-CM
Z94.81	Bone marrow transplant status	Diagnosis	ICD-10-CM
Z94.82	Intestine transplant status	Diagnosis	ICD-10-CM
Z94.83	Pancreas transplant status	Diagnosis	ICD-10-CM
Z94.84	Stem cells transplant status	Diagnosis	ICD-10-CM
Z94.89	Other transplanted organ and tissue status	Diagnosis	ICD-10-CM
Z95.3	Presence of xenogenic heart valve	Diagnosis	ICD-10-CM
Z95.4	Presence of other heart-valve replacement	Diagnosis	ICD-10-CM
Kidney Transplant Exclusions			
07.94	Transplantation of thymus	Procedure	ICD-09-CM
33.5	Lung transplant	Procedure	ICD-09-CM
33.50	Lung transplantation, NOS	Procedure	ICD-09-CM
33.51	Unilateral lung transplantation	Procedure	ICD-09-CM
33.52	Bilateral lung transplantation	Procedure	ICD-09-CM
33.6	Combined heart-lung transplantation	Procedure	ICD-09-CM
37.51	Heart transplantation	Procedure	ICD-09-CM
41.0	Bone marrow transplant	Procedure	ICD-09-CM
41.00	Bone marrow transplant, not otherwise specified	Procedure	ICD-09-CM
41.02	Allogeneic bone marrow transplant with purging	Procedure	ICD-09-CM
41.03	Allogeneic bone marrow transplant without purging	Procedure	ICD-09-CM
41.05	Allogeneic hematopoietic stem cell transplant without purging	Procedure	ICD-09-CM
41.06	Cord blood stem cell transplant	Procedure	ICD-09-CM
41.08	Allogeneic hematopoietic stem cell transplant with purging	Procedure	ICD-09-CM
41.94	Transplantation of spleen	Procedure	ICD-09-CM
46.97	Transplant of intestine	Procedure	ICD-09-CM

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Code	Description	Category	Code Type
49.74	Gracilis muscle transplant for anal incontinence	Procedure	ICD-09-CM
50.5	Liver transplant	Procedure	ICD-09-CM
50.51	Auxiliary liver transplant	Procedure	ICD-09-CM
50.59	Other transplant of liver	Procedure	ICD-09-CM
52.8	Transplant of pancreas	Procedure	ICD-09-CM
52.80	Pancreatic transplant, not otherwise specified	Procedure	ICD-09-CM
52.82	Homotransplant of pancreas	Procedure	ICD-09-CM
52.83	Heterotransplant of pancreas	Procedure	ICD-09-CM
52.85	Allotransplantation of cells of islets of Langerhans	Procedure	ICD-09-CM
52.86	Transplantation of cells of islets of Langerhans, not otherwise specified	Procedure	ICD-09-CM
63.53	Transplantation of spermatic cord	Procedure	ICD-09-CM
65.92	Transplantation of ovary	Procedure	ICD-09-CM
82.5	Transplantation of muscle and tendon of hand	Procedure	ICD-09-CM
82.56	Other hand tendon transfer or transplantation	Procedure	ICD-09-CM
82.58	Other hand muscle transfer or transplantation	Procedure	ICD-09-CM
83.75	Tendon transfer or transplantation	Procedure	ICD-09-CM
83.77	Muscle transfer or transplantation	Procedure	ICD-09-CM
414.06	Coronary atherosclerosis, of native coronary artery of transplanted heart	Diagnosis	ICD-09-CM
414.07	Coronary atherosclerosis, of bypass graft (artery) (vein) of transplanted heart	Diagnosis	ICD-09-CM
996.82	Complications of transplanted liver	Diagnosis	ICD-09-CM
996.83	Complications of transplanted heart	Diagnosis	ICD-09-CM
996.84	Complications of transplanted lung	Diagnosis	ICD-09-CM
996.85	Complications of bone marrow transplant	Diagnosis	ICD-09-CM
996.86	Complications of transplanted pancreas	Diagnosis	ICD-09-CM
996.87	Complications of transplanted organ, intestine	Diagnosis	ICD-09-CM
996.88	Complications of transplanted organ, stem cell	Diagnosis	ICD-09-CM
33935	Heart-lung transplant with recipient cardiectomy-pneumonectomy	Procedure	CPT-4
33945	Heart transplant, with or without recipient cardiectomy	Procedure	CPT-4
47135	Liver allotransplantation; orthotopic, partial or whole, from cadaver or living donor, any age	Procedure	CPT-4
02Y	Heart and Great Vessels, Transplantation	Procedure	ICD-10-PCS
02YA	Transplantation / Heart	Procedure	ICD-10-PCS
02YA0Z0	Transplantation of Heart, Allogeneic, Open Approach	Procedure	ICD-10-PCS
02YA0Z1	Transplantation of Heart, Syngeneic, Open Approach	Procedure	ICD-10-PCS
02YA0Z2	Transplantation of Heart, Zooplasic, Open Approach	Procedure	ICD-10-PCS
07YM0Z0	Transplantation of Thymus, Allogeneic, Open Approach	Procedure	ICD-10-PCS
07YM0Z1	Transplantation of Thymus, Syngeneic, Open Approach	Procedure	ICD-10-PCS
07YM0Z2	Transplantation of Thymus, Zooplasic, Open Approach	Procedure	ICD-10-PCS
07YP0Z0	Transplantation of Spleen, Allogeneic, Open Approach	Procedure	ICD-10-PCS
07YP0Z1	Transplantation of Spleen, Syngeneic, Open Approach	Procedure	ICD-10-PCS
07YP0Z2	Transplantation of Spleen, Zooplasic, Open Approach	Procedure	ICD-10-PCS
0BYC0Z0	Transplantation of Right Upper Lung Lobe, Allogeneic, Open Approach	Procedure	ICD-10-PCS
0BYC0Z1	Transplantation of Right Upper Lung Lobe, Syngeneic, Open Approach	Procedure	ICD-10-PCS
0BYC0Z2	Transplantation of Right Upper Lung Lobe, Zooplasic, Open Approach	Procedure	ICD-10-PCS
0BYD0Z0	Transplantation of Right Middle Lung Lobe, Allogeneic, Open Approach	Procedure	ICD-10-PCS
0BYD0Z1	Transplantation of Right Middle Lung Lobe, Syngeneic, Open Approach	Procedure	ICD-10-PCS
0BYD0Z2	Transplantation of Right Middle Lung Lobe, Zooplasic, Open Approach	Procedure	ICD-10-PCS

Appendix D. List of 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, Procedure Coding System (ICD-10-PCS), and Current Procedural Terminology, Fourth Edition (CPT-4) Diagnosis and Procedure Codes Used to Define Exclusion Criteria in this Request

Code	Description	Category	Code Type
0BYF0Z0	Transplantation of Right Lower Lung Lobe, Allogeneic, Open Approach	Procedure	ICD-10-PCS
0BYF0Z1	Transplantation of Right Lower Lung Lobe, Syngeneic, Open Approach	Procedure	ICD-10-PCS
0BYF0Z2	Transplantation of Right Lower Lung Lobe, Zooplastic, Open Approach	Procedure	ICD-10-PCS
0BYG0Z0	Transplantation of Left Upper Lung Lobe, Allogeneic, Open Approach	Procedure	ICD-10-PCS
0BYG0Z1	Transplantation of Left Upper Lung Lobe, Syngeneic, Open Approach	Procedure	ICD-10-PCS
0BYG0Z2	Transplantation of Left Upper Lung Lobe, Zooplastic, Open Approach	Procedure	ICD-10-PCS
0BYH0Z0	Transplantation of Lung Lingula, Allogeneic, Open Approach	Procedure	ICD-10-PCS
0BYH0Z1	Transplantation of Lung Lingula, Syngeneic, Open Approach	Procedure	ICD-10-PCS
0BYH0Z2	Transplantation of Lung Lingula, Zooplastic, Open Approach	Procedure	ICD-10-PCS
0BYJ0Z0	Transplantation of Left Lower Lung Lobe, Allogeneic, Open Approach	Procedure	ICD-10-PCS
0BYJ0Z1	Transplantation of Left Lower Lung Lobe, Syngeneic, Open Approach	Procedure	ICD-10-PCS
0BYJ0Z2	Transplantation of Left Lower Lung Lobe, Zooplastic, Open Approach	Procedure	ICD-10-PCS
0BYK0Z0	Transplantation of Right Lung, Allogeneic, Open Approach	Procedure	ICD-10-PCS
0BYK0Z1	Transplantation of Right Lung, Syngeneic, Open Approach	Procedure	ICD-10-PCS
0BYK0Z2	Transplantation of Right Lung, Zooplastic, Open Approach	Procedure	ICD-10-PCS
0BYL0Z0	Transplantation of Left Lung, Allogeneic, Open Approach	Procedure	ICD-10-PCS
0BYL0Z1	Transplantation of Left Lung, Syngeneic, Open Approach	Procedure	ICD-10-PCS
0BYL0Z2	Transplantation of Left Lung, Zooplastic, Open Approach	Procedure	ICD-10-PCS
0BYM0Z0	Transplantation of Bilateral Lungs, Allogeneic, Open Approach	Procedure	ICD-10-PCS
0BYM0Z1	Transplantation of Bilateral Lungs, Syngeneic, Open Approach	Procedure	ICD-10-PCS
0BYM0Z2	Transplantation of Bilateral Lungs, Zooplastic, Open Approach	Procedure	ICD-10-PCS
0DY80Z0	Transplantation of Small Intestine, Allogeneic, Open Approach	Procedure	ICD-10-PCS
0DY80Z1	Transplantation of Small Intestine, Syngeneic, Open Approach	Procedure	ICD-10-PCS
0DY80Z2	Transplantation of Small Intestine, Zooplastic, Open Approach	Procedure	ICD-10-PCS
0DYE0Z0	Transplantation of Large Intestine, Allogeneic, Open Approach	Procedure	ICD-10-PCS
0DYE0Z1	Transplantation of Large Intestine, Syngeneic, Open Approach	Procedure	ICD-10-PCS
0DYE0Z2	Transplantation of Large Intestine, Zooplastic, Open Approach	Procedure	ICD-10-PCS
0FY0	Transplantation / Liver	Procedure	ICD-10-PCS
0FY00Z0	Transplantation of Liver, Allogeneic, Open Approach	Procedure	ICD-10-PCS
0FY00Z1	Transplantation of Liver, Syngeneic, Open Approach	Procedure	ICD-10-PCS
0FY00Z2	Transplantation of Liver, Zooplastic, Open Approach	Procedure	ICD-10-PCS
0FYG0Z0	Transplantation of Pancreas, Allogeneic, Open Approach	Procedure	ICD-10-PCS
0FYG0Z1	Transplantation of Pancreas, Syngeneic, Open Approach	Procedure	ICD-10-PCS
0FYG0Z2	Transplantation of Pancreas, Zooplastic, Open Approach	Procedure	ICD-10-PCS
0UY00Z0	Transplantation of Right Ovary, Allogeneic, Open Approach	Procedure	ICD-10-PCS
0UY00Z1	Transplantation of Right Ovary, Syngeneic, Open Approach	Procedure	ICD-10-PCS
0UY00Z2	Transplantation of Right Ovary, Zooplastic, Open Approach	Procedure	ICD-10-PCS
0UY10Z0	Transplantation of Left Ovary, Allogeneic, Open Approach	Procedure	ICD-10-PCS
0UY10Z1	Transplantation of Left Ovary, Syngeneic, Open Approach	Procedure	ICD-10-PCS
0UY10Z2	Transplantation of Left Ovary, Zooplastic, Open Approach	Procedure	ICD-10-PCS
30230G2	Transfusion of Allogeneic Related Bone Marrow into Peripheral Vein, Open Approach	Procedure	ICD-10-PCS
30230G3	Transfusion of Allogeneic Unrelated Bone Marrow into Peripheral Vein, Open Approach	Procedure	ICD-10-PCS
30230G4	Transfusion of Allogeneic Unspecified Bone Marrow into Peripheral Vein, Open Approach	Procedure	ICD-10-PCS
30233G2	Transfusion of Allogeneic Related Bone Marrow into Peripheral Vein, Percutaneous Approach	Procedure	ICD-10-PCS

Appendix D. List of 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, Procedure Coding System (ICD-10-PCS), and Current Procedural Terminology, Fourth Edition (CPT-4) Diagnosis and Procedure Codes Used to Define Exclusion Criteria in this Request

Code	Description	Category	Code Type
30233G3	Transfusion of Allogeneic Unrelated Bone Marrow into Peripheral Vein, Percutaneous Approach	Procedure	ICD-10-PCS
30233G4	Transfusion of Allogeneic Unspecified Bone Marrow into Peripheral Vein, Percutaneous Approach	Procedure	ICD-10-PCS
30240G2	Transfusion of Allogeneic Related Bone Marrow into Central Vein, Open Approach	Procedure	ICD-10-PCS
30240G3	Transfusion of Allogeneic Unrelated Bone Marrow into Central Vein, Open Approach	Procedure	ICD-10-PCS
30240G4	Transfusion of Allogeneic Unspecified Bone Marrow into Central Vein, Open Approach	Procedure	ICD-10-PCS
30243G2	Transfusion of Allogeneic Related Bone Marrow into Central Vein, Percutaneous Approach	Procedure	ICD-10-PCS
30243G3	Transfusion of Allogeneic Unrelated Bone Marrow into Central Vein, Percutaneous Approach	Procedure	ICD-10-PCS
30243G4	Transfusion of Allogeneic Unspecified Bone Marrow into Central Vein, Percutaneous Approach	Procedure	ICD-10-PCS
30250G1	Transfusion of Nonautologous Bone Marrow into Peripheral Artery, Open Approach	Procedure	ICD-10-PCS
30253G1	Transfusion of Nonautologous Bone Marrow into Peripheral Artery, Percutaneous Approach	Procedure	ICD-10-PCS
30260G1	Transfusion of Nonautologous Bone Marrow into Central Artery, Open Approach	Procedure	ICD-10-PCS
30263G1	Transfusion of Nonautologous Bone Marrow into Central Artery, Percutaneous Approach	Procedure	ICD-10-PCS
3E030U1	Introduction of Nonautologous Pancreatic Islet Cells into Peripheral Vein, Open Approach	Procedure	ICD-10-PCS
3E033U1	Introduction of Nonautologous Pancreatic Islet Cells into Peripheral Vein, Percutaneous Approach	Procedure	ICD-10-PCS
3E0J3U1	Introduction of Nonautologous Pancreatic Islet Cells into Biliary and Pancreatic Tract, Percutaneous Approach	Procedure	ICD-10-PCS
3E0J7U1	Introduction of Nonautologous Pancreatic Islet Cells into Biliary and Pancreatic Tract, Via Natural or Artificial Opening	Procedure	ICD-10-PCS
3E0J8U1	Introduction of Nonautologous Pancreatic Islet Cells into Biliary and Pancreatic Tract, Via Natural or Artificial Opening Endoscopic	Procedure	ICD-10-PCS
I25.7	Atherosclerosis of coronary artery bypass graft(s) and coronary artery of transplanted heart with angina pectoris	Diagnosis	ICD-10-CM
I25.75	Atherosclerosis of native coronary artery of transplanted heart with angina pectoris	Diagnosis	ICD-10-CM
I25.750	Atherosclerosis of native coronary artery of transplanted heart with unstable angina	Diagnosis	ICD-10-CM
I25.751	Atherosclerosis of native coronary artery of transplanted heart with angina pectoris with documented spasm	Diagnosis	ICD-10-CM
I25.758	Atherosclerosis of native coronary artery of transplanted heart with other forms of angina pectoris	Diagnosis	ICD-10-CM
I25.759	Atherosclerosis of native coronary artery of transplanted heart with unspecified angina pectoris	Diagnosis	ICD-10-CM
I25.76	Atherosclerosis of bypass graft of coronary artery of transplanted heart with angina pectoris	Diagnosis	ICD-10-CM
I25.760	Atherosclerosis of bypass graft of coronary artery of transplanted heart with unstable angina	Diagnosis	ICD-10-CM

Appendix D. List of 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, Procedure Coding System (ICD-10-PCS), and Current Procedural Terminology, Fourth Edition (CPT-4) Diagnosis and Procedure Codes Used to Define Exclusion Criteria in this Request

Code	Description	Category	Code Type
I25.761	Atherosclerosis of bypass graft of coronary artery of transplanted heart with angina pectoris with documented spasm	Diagnosis	ICD-10-CM
I25.768	Atherosclerosis of bypass graft of coronary artery of transplanted heart with other forms of angina pectoris	Diagnosis	ICD-10-CM
I25.769	Atherosclerosis of bypass graft of coronary artery of transplanted heart with unspecified angina pectoris	Diagnosis	ICD-10-CM
I25.811	Atherosclerosis of native coronary artery of transplanted heart without angina pectoris	Diagnosis	ICD-10-CM
I25.812	Atherosclerosis of bypass graft of coronary artery of transplanted heart without angir	Diagnosis	ICD-10-CM
T86.0	Complications of bone marrow transplant	Diagnosis	ICD-10-CM
T86.00	Unspecified complication of bone marrow transplant	Diagnosis	ICD-10-CM
T86.01	Bone marrow transplant rejection	Diagnosis	ICD-10-CM
T86.02	Bone marrow transplant failure	Diagnosis	ICD-10-CM
T86.03	Bone marrow transplant infection	Diagnosis	ICD-10-CM
T86.09	Other complications of bone marrow transplant	Diagnosis	ICD-10-CM
T86.2	Complications of heart transplant	Diagnosis	ICD-10-CM
T86.20	Unspecified complication of heart transplant	Diagnosis	ICD-10-CM
T86.21	Heart transplant rejection	Diagnosis	ICD-10-CM
T86.22	Heart transplant failure	Diagnosis	ICD-10-CM
T86.23	Heart transplant infection	Diagnosis	ICD-10-CM
T86.29	Other complications of heart transplant	Diagnosis	ICD-10-CM
T86.290	Cardiac allograft vasculopathy	Diagnosis	ICD-10-CM
T86.298	Other complications of heart transplant	Diagnosis	ICD-10-CM
T86.3	Complications of heart-lung transplant	Diagnosis	ICD-10-CM
T86.30	Unspecified complication of heart-lung transplant	Diagnosis	ICD-10-CM
T86.31	Heart-lung transplant rejection	Diagnosis	ICD-10-CM
T86.32	Heart-lung transplant failure	Diagnosis	ICD-10-CM
T86.33	Heart-lung transplant infection	Diagnosis	ICD-10-CM
T86.39	Other complications of heart-lung transplant	Diagnosis	ICD-10-CM
T86.4	Complications of liver transplant	Diagnosis	ICD-10-CM
T86.40	Unspecified complication of liver transplant	Diagnosis	ICD-10-CM
T86.41	Liver transplant rejection	Diagnosis	ICD-10-CM
T86.42	Liver transplant failure	Diagnosis	ICD-10-CM
T86.43	Liver transplant infection	Diagnosis	ICD-10-CM
T86.49	Other complications of liver transplant	Diagnosis	ICD-10-CM
T86.5	Complications of stem cell transplant	Diagnosis	ICD-10-CM
T86.81	Complications of lung transplant	Diagnosis	ICD-10-CM
T86.810	Lung transplant rejection	Diagnosis	ICD-10-CM
T86.811	Lung transplant failure	Diagnosis	ICD-10-CM
T86.812	Lung transplant infection	Diagnosis	ICD-10-CM
T86.818	Other complications of lung transplant	Diagnosis	ICD-10-CM
T86.819	Unspecified complication of lung transplant	Diagnosis	ICD-10-CM
T86.830	Bone graft rejection	Diagnosis	ICD-10-CM
T86.831	Bone graft failure	Diagnosis	ICD-10-CM
T86.832	Bone graft infection	Diagnosis	ICD-10-CM
T86.838	Other complications of bone graft	Diagnosis	ICD-10-CM
T86.839	Unspecified complication of bone graft	Diagnosis	ICD-10-CM
T86.85	Complication of intestine transplant	Diagnosis	ICD-10-CM

Appendix D. List of 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, Procedure Coding System (ICD-10-PCS), and Current Procedural Terminology, Fourth Edition (CPT-4) Diagnosis and Procedure Codes Used to Define Exclusion Criteria in this Request

Code	Description	Category	Code Type
T86.850	Intestine transplant rejection	Diagnosis	ICD-10-CM
T86.851	Intestine transplant failure	Diagnosis	ICD-10-CM
T86.852	Intestine transplant infection	Diagnosis	ICD-10-CM
T86.858	Other complications of intestine transplant	Diagnosis	ICD-10-CM
T86.859	Unspecified complication of intestine transplant	Diagnosis	ICD-10-CM
V42.1	Heart replaced by transplant	Diagnosis	ICD-09-CM
V42.2	Heart valve replaced by transplant	Diagnosis	ICD-09-CM
V42.3	Skin replaced by transplant	Diagnosis	ICD-09-CM
V42.4	Bone replaced by transplant	Diagnosis	ICD-09-CM
V42.6	Lung replaced by transplant	Diagnosis	ICD-09-CM
V42.7	Liver replaced by transplant	Diagnosis	ICD-09-CM
V42.8	Other specified organ or tissue replaced by transplant	Diagnosis	ICD-09-CM
V42.81	Bone marrow replaced by transplant	Diagnosis	ICD-09-CM
V42.82	Peripheral stem cells replaced by transplant	Diagnosis	ICD-09-CM
V42.83	Pancreas replaced by transplant	Diagnosis	ICD-09-CM
V42.84	Organ or tissue replaced by transplant, intestines	Diagnosis	ICD-09-CM
Z48.21	Encounter for aftercare following heart transplant	Diagnosis	ICD-10-CM
Z48.23	Encounter for aftercare following liver transplant	Diagnosis	ICD-10-CM
Z48.24	Encounter for aftercare following lung transplant	Diagnosis	ICD-10-CM
Z48.28	Encounter for aftercare following multiple organ transplant	Diagnosis	ICD-10-CM
Z48.280	Encounter for aftercare following heart-lung transplant	Diagnosis	ICD-10-CM
Z48.288	Encounter for aftercare following multiple organ transplant	Diagnosis	ICD-10-CM
Z48.29	Encounter for aftercare following other organ transplant	Diagnosis	ICD-10-CM
Z48.290	Encounter for aftercare following bone marrow transplant	Diagnosis	ICD-10-CM
Z94.1	Heart transplant status	Diagnosis	ICD-10-CM
Z94.2	Lung transplant status	Diagnosis	ICD-10-CM
Z94.3	Heart and lungs transplant status	Diagnosis	ICD-10-CM
Z94.4	Liver transplant status	Diagnosis	ICD-10-CM
Z94.5	Skin transplant status	Diagnosis	ICD-10-CM
Z94.6	Bone transplant status	Diagnosis	ICD-10-CM
Z94.8	Other transplanted organ and tissue status	Diagnosis	ICD-10-CM
Z94.81	Bone marrow transplant status	Diagnosis	ICD-10-CM
Z94.82	Intestine transplant status	Diagnosis	ICD-10-CM
Z94.83	Pancreas transplant status	Diagnosis	ICD-10-CM
Z94.84	Stem cells transplant status	Diagnosis	ICD-10-CM
Z94.89	Other transplanted organ and tissue status	Diagnosis	ICD-10-CM
Z95.3	Presence of xenogenic heart valve	Diagnosis	ICD-10-CM
Z95.4	Presence of other heart-valve replacement	Diagnosis	ICD-10-CM

Appendix E. List of Healthcare Common Procedure Coding System (HCPCS) Used to Define Baseline Characteristics in this Request

Code	Description	Code Category	Code Type	Covariate
J7507	Tacrolimus, immediate release, oral, 1 mg	Procedure	HCPCS	Procedure code J7507

Appendix F. List of Generic and Brand Names and Manufacturer Group for Tacrolimus Products Used to Define the Incidence Criteria and Covariates in this Request

Generic Name	Brand Name	Manufacturer Group
tacrolimus	Prograf (capsules)	Brand - Astellas
tacrolimus	tacrolimus	Brand - Astellas
tacrolimus	tacrolimus	Generic - Accord
tacrolimus	tacrolimus	Generic - Dr. Reddys
tacrolimus	tacrolimus	Generic - Mylan
tacrolimus	Hecoria	Generic - Sandoz
tacrolimus	tacrolimus	Generic - Sandoz
tacrolimus	Prograf (granules)	Other tacrolimus (other)
tacrolimus	tacrolimus	Other tacrolimus (Panacea)
tacrolimus	tacrolimus	Other tacrolimus (Strides)
tacrolimus	tacrolimus	Other tacrolimus (Watson)

Appendix G. Specifications Defining Parameters in this Request

This request utilized the Cohort Identification and Descriptive Analysis (CIDA) tool to evaluate the feasibility of using Sentinel data to compare clinical outcomes of brand vs. individual generic products of tacrolimus oral capsule. This request will identify the kidney and liver transplant population, and their follow-up time in Sentinel. Two reports will be presented: one for CMS only and the other for all non-CMS Data Partners aggregated. This request uses QRP 8.1.1 with plus programming.

Query Period: August 10, 2009 to most current available data
Coverage Requirement: Medical and Drug
Enrollment Requirement: 365 days
Enrollment Gap: 45 days
Age Groups: <18, 18-64, 65+
Data Partners: All Data Partners
Stratify by: age group, sex, year, 6 census bureau regions, 4 race categories
Envelope macro: do not reclassify on inpatient admit date (1)

Purpose	Scenario	Exposure						
		Exposure ¹	Care Setting	Incident with Respect to ²	Incidence Care Setting	Washout	Censor at Death	Cohort Definition
Counts of liver transplant patients with baseline demographic information (Table 1a) Total follow-up time (Table 3)	1	Liver transplant	Inpatient	Any transplant, any tacrolimus	Any	Entire patient history before admit date	Yes	First valid incident exposure
Time from liver transplant until any oral tacrolimus initiation (Tables 1b-1e; 2a-2c)	2	Liver transplant	Inpatient	Any transplant, any tacrolimus	Any	Entire patient history before admit date	Yes	First valid incident exposure
Time from liver transplant until Dr Reddy's oral tacrolimus initiation (Tables 2a-2c)	3	Liver transplant	Inpatient	Any transplant, any tacrolimus	Any	Entire patient history before admit date	Yes	First valid incident exposure
Time from liver transplant until Accord oral tacrolimus initiation (Tables 2a-2c)	4	Liver transplant	Inpatient	Any transplant, any tacrolimus	Any	Entire patient history before admit date	Yes	First valid incident exposure

Appendix G. Specifications Defining Parameters in this Request

Scenario	Inclusions/Exclusions				Baseline Characteristics	Outcome (assessed with the baseline table)		
	Conditions	Inclusion/Exclusion	Evaluation Start	Evaluation End	Conditions	Outcome	Care setting	Washout
1	Any transplant except index transplant (and index-associated codes)	Exclusion	Entire patient history	Day before discharge date	See Appendix H	Dummy	N/A	N/A
2	Any transplant except index transplant (and index-associated codes)	Exclusion	Entire patient history	Day before discharge date	See Appendix H	Any Oral Tacrolimus	Any	Entire patient history before admit date
3	Any transplant except index transplant (and index-associated codes)	Exclusion	Entire patient history	Day before discharge date	None	Dr Reddy's Oral Tacrolimus	Any	Entire patient history before admit date
4	Any transplant except index transplant (and index-associated codes)	Exclusion	Entire patient history	Day before discharge date	None	Accord Oral Tacrolimus	Any	Entire patient history before admit date

Appendix G. Specifications Defining Parameters in this Request

Purpose	Scenario	Exposure							Cohort Definition
		Exposure ¹	Care Setting	Incident with Respect to ²	Incidence Care Setting	Washout	Censor at Death		
Time from liver transplant until Sandoz oral tacrolimus initiation (Tables 2a-2c)	5	Liver transplant	Inpatient	Any transplant, any tacrolimus	Any	Entire patient history before admit date	Yes	First valid incident exposure	
Time from liver transplant until Mylan oral tacrolimus initiation (Tables 2a-2c)	6	Liver transplant	Inpatient	Any transplant, any tacrolimus	Any	Entire patient history before admit date	Yes	First valid incident exposure	
Time from liver transplant until Astellas oral tacrolimus initiation (Tables 2a-2c)	7	Liver transplant	Inpatient	Any transplant, any tacrolimus	Any	Entire patient history before admit date	Yes	First valid incident exposure	
Counts of kidney transplant patients with baseline demographic information (Table 1f) Total follow-up time (Table 3)	8	Kidney transplant	Inpatient	Any transplant, any tacrolimus	Any	Entire patient history from admit date	Yes	First valid incident exposure	
Time from kidney transplant until any oral tacrolimus initiation (Tables 1g-1j; 2a-2c)	9	Kidney transplant	Inpatient	Any transplant, any tacrolimus	Any	Entire patient history before admit date	Yes	First valid incident exposure	
Time from kidney transplant until Dr Reddy's oral tacrolimus initiation (Tables 2a-2c)	10	Kidney transplant	Inpatient	Any transplant, any tacrolimus	Any	Entire patient history before admit date	Yes	First valid incident exposure	
Time from kidney transplant until Accord oral tacrolimus initiation (Tables 2a-2c)	11	Kidney transplant	Inpatient	Any transplant, any tacrolimus	Any	Entire patient history before admit date	Yes	First valid incident exposure	

Appendix G. Specifications Defining Parameters in this Request

	Inclusions/Exclusions				Baseline Characteristic	Outcome (assessed with the baseline table)		
	Conditions	Inclusion/Exclusion	Evaluation Start	Evaluation End	Conditions	Outcome	Care setting	Washout
5	Any transplant except index transplant (and index-associated codes)	Exclusion	Entire patient history	Day before discharge date	None	Sandoz Oral Tacrolimus	Any	Entire patient history before admit date
6	Any transplant except index transplant (and index-associated codes)	Exclusion	Entire patient history	Day before discharge date	None	Mylan Oral Tacrolimus	Any	Entire patient history before admit date
7	Any transplant except index transplant (and index-associated codes)	Exclusion	Entire patient history	Day before discharge date	None	Astellas Oral Tacrolimus	Any	Entire patient history before admit date
8	Any transplant except index transplant (and index-associated codes)	Exclusion	Entire patient history	Day before discharge date	See Appendix H	Dummy	N/A	N/A
9	Any transplant except index transplant (and index-associated codes)	Exclusion	Entire patient history	Day before discharge date	See Appendix H	Any Oral Tacrolimus	Any	Entire patient history before admit date
10	Any transplant except index transplant (and index-associated codes)	Exclusion	Entire patient history	Day before discharge date	None	Dr Reddy's Oral Tacrolimus	Any	Entire patient history before admit date
11	Any transplant except index transplant (and index-associated codes)	Exclusion	Entire patient history	Day before discharge date	None	Accord Oral Tacrolimus	Any	Entire patient history before admit date

Appendix G. Specifications Defining Parameters in this Request

Purpose	Scenario	Exposure						
		Exposure ¹	Care Setting	Incident with Respect to ²	Incidence Care Setting	Washout	Censor at Death	Cohort Definition
Time from kidney transplant until Sandoz oral tacrolimus initiation (Tables 2a-2c)	12	Kidney transplant	Inpatient	Any transplant, any tacrolimus	Any	Entire patient history before admit date	Yes	First valid incident exposure
Time from kidney transplant until Mylan oral tacrolimus initiation (Tables 2a-2c)	13	Kidney transplant	Inpatient	Any transplant, any tacrolimus	Any	Entire patient history before admit date	Yes	First valid incident exposure
Time from kidney transplant until Astellas oral tacrolimus initiation (Tables 2a-2c)	14	Kidney transplant	Inpatient	Any transplant, any tacrolimus	Any	Entire patient history before admit date	Yes	First valid incident exposure

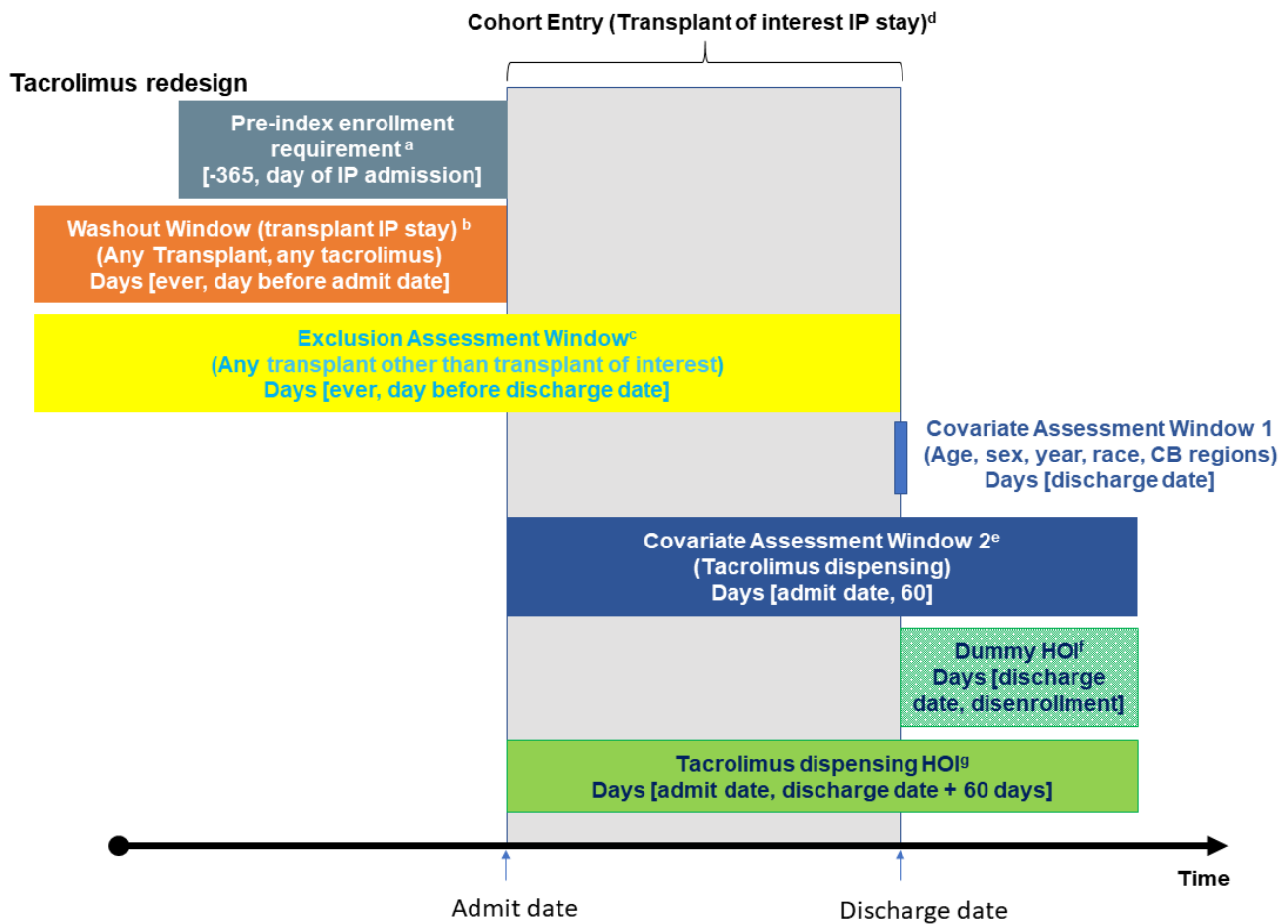
Appendix G. Specifications Defining Parameters in this Request

	Inclusions/Exclusions				Baseline Characteristic	Outcome (assessed with the baseline table)		
	Conditions	Inclusion/ Exclusion	Evaluation Start	Evaluation End	Conditions	Outcome	Care setting	Washout
12	Any transplant except index transplant (and index-associated codes)	Exclusion	Entire patient history	Day before discharge date	None	Sandoz Oral Tacrolimus	Any	Entire patient history before admit date
13	Any transplant except index transplant (and index-associated codes)	Exclusion	Entire patient history	Day before discharge date	None	Mylan Oral Tacrolimus	Any	Entire patient history before admit date
14	Any transplant except index transplant (and index-associated codes)	Exclusion	Entire patient history	Day before discharge date	None	Astellas Oral Tacrolimus	Any	Entire patient history before admit date

Appendix H. Specifications Defining Baseline Characteristics in this Request

Covariate	Care Setting	Look Start	Look End
First any oral tacrolimus	N/A	admit date	60 days post-discharge
Generic - Dr Reddy's	N/A	admit date	60 days post-discharge
Generic - Accord	N/A	admit date	60 days post-discharge
Generic - Sandoz	N/A	admit date	60 days post-discharge
Generic - Mylan	N/A	admit date	60 days post-discharge
Brand - Astellas	N/A	admit date	60 days post-discharge
HCPCS code J7507	N/A	admit date	60 days post-discharge
Other	N/A	admit date	60 days post-discharge

Appendix I. Design Diagram of Cohort Entry Requirements and Assessment Windows



- a. Up to 45 day gaps in medical or pharmacy enrollment allowed
- b. Washout window is prior to admission date
- c. Exclusion window is prior to discharge date
- d. 2 transplants of interest as separate cohorts: liver and kidney
- e. 6 tacrolimus exposure groups: any tacro, Dr Reddys, Accord, Sandoz, Mylan, Astellas
- f. Dummy outcome (HOI) for transplant cohorts characteristics (tables 1a/b), and follow-up time (table 3)
- g. Tacrolimus outcome for tables 2,4,5,6