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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_iqp_wp046, Report 1

Request ID: cder_iqp_wp046_tnx_v01

Request Description: In this report, we aimed to assess demographic and clinical characteristics of patients with allogeneic hematopoietic stem cell transplantation (HSCT) as well as of patients with confirmed thrombotic microangiopathy (TMA) associated with allogeneic hematopoietic stem cell transplantation (HSCT-TMA)[1] using the TriNetX Live™ platform. This is report 1 of 2, report 2 includes a study period from September 1, 2020 to August 31, 2024.

Data Source: We ran this query on September 26, 2024, using data from 60 health care organizations (HCOs), provided through the TriNetX Live™ platform in their USA Network with Minimal Shift from July 1, 2009 to August 31, 2020.

TriNetX aggregates electronic health record (EHR) systems data from its partner HCOs to create queryable datasets. TriNetX datasets primarily comprise clinical patient data such as demographics, diagnoses, procedures, labs, and medications. The USA Network with Minimal Shift contains HCOs that date shift their data by 14 or fewer days (including 0). For more information on the TriNetX Live™ platform and the TriNetX data visit their website here: https://trinetx.com/.

Study Design: In this retrospective cohort study, we identified adult (age 18 years or above on index date) and pediatric (age less than 18 years on index date) patients with their first code for allogeneic HSCT during the query period of July 1, 2009 to August 31, 2020. The index date for these two cohorts (cohorts 1 and 2) is the date of the allogeneic HSCT code in the query period. We also identified adult and pediatric patients with their first code for confirmed TMA (defined as presence of diagnosis codes for either TMA or hemolytic uremic syndrome (HUS)) as defined by Wang et al.,[1] within 12 months of any code for allogeneic HSCT during the query period. The index date for these two cohorts (cohorts 3 and 4) is the date of the code for TMA or HUS in the query period. We used the Query Builder module in the TriNetX Live™ platform to create the aforementioned patient cohorts (four in total).
We used the Advanced Explore Cohort analytics module available on the TriNetX Live™ platform with all four cohorts to list the prevalence of certain baseline characteristics in the period between 183 days prior to index date to the index date (i.e., inclusive of index date). We also used the Analyze Outcomes analytic module with all cohorts to determine the number of patients with codes for certain high-risk characteristics over a period of three, six and twelve months post-index date as well as on index date (only for cohorts 3 and 4).

Index Events/Exposures of Interest: We defined the events of interest, allogeneic HSCT and confirmed TMA using the following diagnosis and procedure codes in the Query Builder modules: International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) diagnosis codes, International Classification of Diseases, Tenth Revision, Procedural Coding System (ICD-10-PCS) and Current Procedural Terminology, Fourth Edition (CPT-4) procedure codes. The ICD-10-CM diagnosis and ICD-10-PCS procedure codes automatically map to corresponding ICD-9-CM diagnosis and ICD-9-PCS procedure codes within the TriNetX platform.
We defined allogeneic HSCT using evidence of a procedure code and we defined confirmed TMA as evidence of a diagnosis code for either TMA or HUS during the query period betwen July 1, 2009 and August 31, 2020. For further details of cohort eligibility, please see the next section on Cohort Eligibility Criteria.
Please see Appendix A for a list of diagnosis and procedure codes used to define the index events of interest.

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Outcomes of Interest: Our outcomes of interest in this request are listed below:

(1) Any of the following high-risk characteristics (presence of any code for the listed conditions)
- (a) acute graft versus host disease (GVHD),
- (b) serum Cb-9 (complement C5b-9) levels > upper limit of normal i.e., > 250 ng/mL,
- (c) random urine protein/creatinine ratio ≥ 1mg/mg,
- (d) serum lactate dehydrogenase level (LDH) ≥ 2 x upper limit of normal i.e., ≥ 500 U/L,
- (e) certain viral or bacterial infections, or
- (f) organ dysfunction (presence of any code for the listed conditions):
  - (i) pulmonary hypertension,
  - (ii) need for dialysis (code for dialysis, chronic kidney disease, stage 5 or end stage renal disease),
  - (iii) acute renal failure or kidney disease,
  - (iv) intubation or mechanical ventilation,
  - (v) seizures, convulsions, or altered mental status, or
  - (vi) creatinine levels ≥ 2 times the upper limit of normal i.e., ≥ 2.6 mg/dL)

(2) Death

(3) Results of the following laboratory tests (the latest in the assessment period):
- (a) serum Cb-9 (complement C5b-9) levels
- (b) serum LDH levels
- (c) creatinine levels
- (d) random urine protein/creatinine ratio

We defined the outcomes using diagnoses codes (ICD-10 CM), procedure codes (ICD-10-PCS, CPT-4, Current Procedural Terminology, Second Edition (CPT-2) and Healthcare Common Procedure Coding System (HCPCS)) and codes for laboratory tests (Logical Observation Identifiers Names and Codes (LOINC) or TriNetX aggregate lab terms (TNX:LAB) that group clinically relevant LOINC codes together for each test). We only considered each patient's most recent lab test value in the assessment period for defining outcomes. Please see Appendix B for a list of diagnosis, procedure and lab codes used to define the outcomes in this request.

Assessment periods:

For cohorts 1 and 2, we had three assessment periods for the outcomes, (1) index date to three months post-index, (2) index date to six months post-index and (3) index date to twelve months post-index.

For cohorts 3 and 4, we had four assessment periods for the outcomes, (1) index date, (2) index date to three months post-index, (3) index date to six months post-index and (4) index date to twelve months post-index.

Please see Appendix C for specifications of the analytic modules used in this request.

Cohort Eligibility Criteria: We created four cohorts using the Query builder module using the query period between July 1, 2009 and August 31, 2020.

Cohort 1: Adult (age 18 years or above on index date) patients with their first code for allogeneic HSCT during the query period.

Cohort 2: Pediatric (less than age 18 years on index date) patients with their first code for allogeneic HSCT during the query period.

The index date for cohorts 1 and 2 is the date of the code for allogeneic HSCT.

Cohort 3: Adult (age 18 years or above on index date) patients with their first code for confirmed TMA i.e., TMA or HUS diagnosis code within 12 months of any code for allogeneic HSCT during the query period.

Cohort 4: Pediatric (less than 18 years of age on index date) patients with their first code for confirmed TMA within 12 months of any code for allogeneic HSCT during the query period.

The index date for cohorts 3 and 4 is the date of the code for confirmed TMA.

Please see Appendix D for the specifications of the cohort parameters as included in the Query Builder.

Overview for Request: cder_iqp_wp046, Report 1

Baseline Characteristics:

For each of the four cohorts, we utilized the Advanced Explore Cohort module to assess the following characteristics in the six months prior to the index date i.e., from 183 days prior to index date to index date (-183, 0):

- Demographic characteristics: Age at index date, sex, race and ethnicity
- Potential indications for HSCT: Hodgkin's lymphoma, non-Hodgkin's lymphomas (follicular lymphoma, non-follicular lymphoma, mature T/NK-cell lymphomas, other specified and unspecified types of non-Hodgkin lymphoma and other specified types of T/NK-cell lymphoma), acute and chronic lymphocytic leukemia (ALL and CLL), acute and chronic myeloid leukemia (AML and CML), polycythemia vera, myelodysplastic syndrome (MDS), essential thrombocytosis, thalassemia, sickle cell disease, other aplastic anemias and other bone marrow failure syndromes, myelofibrosis and severe combined immune deficiency syndrome (SCID)
- Conditioning regimens: Total body irradiation, chemotherapeutic agents - fludarabine, busulfan, melphalan and anti-thymocyte globulin
- Comorbid conditions: Cardiovascular risk factors and comorbidities (primary hypertension, type 2 diabetes mellitus, ischemic heart diseases, congestive heart failure, peripheral vascular disease, cerebrovascular diseases), peptic ulcer disease, liver diseases (including portal hypertension), viral hepatitis, acute kidney failure, chronic kidney disease, hemiplegia and hemiparesis, and certain neoplasms (including malignant neoplasms of lymphoid, hematopoietic and related tissue)
- Prescription medications: defibrotide, ravulizumab and eculizumab
- Results of certain laboratory tests: serum C5b-9 (complement C5b-9) levels, serum LDH levels, creatinine levels and random urine protein/creatinine ratio.

We defined the baseline characteristics using diagnoses codes (ICD-10 CM), procedure codes (ICD-10-PCS, CPT-4 and HCPCS) and codes for laboratory tests (LOINC or TriNetX aggregate lab terms). We only considered patient's most recent lab test value in the assessment period i.e. the test closest temporally to the index date. Please see Appendix E for a list of diagnosis, procedure and lab codes used to define the baseline characteristics and Appendix C for specifications of the analytic modules used in this request.

Limitations: Algorithms used to define exposures, characteristics, and mapping of source data to the data model are imperfect and susceptible to misclassification. Additionally, EHR data in the United States lacks longitudinality. The information before or after patients' healthcare encounters could be missing, especially if patient care was administered across different HCOs that may or may not participate in the TriNetX USA network. We are unable to determine if absence of evidence of a condition implies a true absence of a condition or if the condition was not observed in the data. Furthermore, not all HCOs provide brand name or route information for RxNorm terms or laboratory data. Therefore, data should be interpreted with these limitations in mind.

The units for lab tests in TriNetX are harmonized across labs when bringing new data onto the network. However, TriNetX does not remove outlier values so as not to bias the data. Hence, certain unexpected or implausible lab values may be observed in the database.

Additionally, lab values of 0 units could be observed in the database, but the interpretation of such a value could be different based on organization-specific practices for rounding, errors, or indicating inconclusive results.

All counts provided through the TriNetX Live™ platform are rounded up to the nearest 10 to protect patient privacy. This rounding affects error, especially as sample sizes decrease. Error due to rounding can range from <0.09% when sample sizes are

>10,000 to nearly 20% as sample sizes drop. Thus, all estimates should be interpreted as ranges, and small sample sizes should be interpreted with caution. Additionally, percentages are calculated based on these rounded numerators and denominators. Thus, due to rounding, the sum of each value in a category may not total to 100%.

A subset of HCOs that contribute to the TriNetX USA Minimal Shift network may implement date shifting up to 14 days in either direction at the level of the patient record prior to data ingestion at TriNetX as a method to preserve patient privacy. When interpreting the results of an analysis, the impact of date shifting should be considered; readers should exercise caution when extrapolating information related to time.

Notes: We ran this query on September 26, 2024. A re-run of this query for the same query period in the future may not yield the same results owing to the dynamic nature of the TriNetX Live™ network.

Overview for Request: cder_iqp_wp046, Report 1
Please contact the Sentinel Operations Center (info@sentinelsystem.org) for questions and to provide comments/suggestions for future enhancements to this document. For more information on Sentinel's querying in the TriNetX platform, please refer to the Sentinel Website (https://www.sentinelinitiative.org/methods-data-tools/methods/trinetx-rapid-querying).

[1] Wang Y, Rava A, Smuzynski M, et al. Real-World Analysis of the Underdiagnosis, Clinical Outcomes and Associated Burden of Hematopoietic Stem Cell Transplantation-Associated Thrombotic Microangiopathy (HSCT-TMA) in the United States of America. Blood. 2023;142

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Glossary of Terms for Analyses Using TriNetX Live™ Platform*

Characteristic - A medical fact (e.g., diagnosis, procedure, lab result) that occurred on or before the cohort-defining index event.

Explore Cohort - A description module on the TriNetX platform that presents a clinical profile of patients in a given cohort. Patient counts are rounded up to the nearest 10 before percentages are calculated, so the sum each of the values in one category may not total to 100%.

Date Shifting - A data obfuscation technique that some HCOs use to preserve patient privacy. Date shifting entails assigning each patient a random number of days (e.g., -365 to +365 days) and consistently adjusting each of their dates by that number of days, thus maintaining temporal relationships between records within a single patient.

Fact - (Medical Fact) A unit of utilization that represents a medical observation on a patient (e.g., diagnosis, procedure, clinical observation).

Filter - A method of limiting terms included in queries to a specific subset of data. Filters include age at time of event, data source (electronic health record or natural language processing); brand name, route, and strength for medication terms; occurrence (first or most recent) for lab terms; and priority for diagnosis and procedure terms.

Group - A series of codes and terms defined with Boolean logic that are used to create a query cohort. For each group, users have the ability to specified time periods of interest, and the number of instances that the group must occur for cohort entry.

> **Subgroup -** Within a group, additional subgroups can be specified to define temporal relationships between the terms in the subgroup (e.g., terms in subgroup B must occur within 5 days after terms in subgroup A). Users can require that these temporal constraints be applied to the 1) first, 2) last, or 3) any instance of each subgroup.

Health Care Organization (HCO) - Organizations that contribute electronic healthcare record data to the TriNetX data networks. HCOs include academic institutions and community health provider systems and a single HCO may contain one or more individual sites or facilities.

Index - The first date when a patient meets all of the cohort-defining criteria. In Analytics modules, the index can be defined as the date when a patient meets all of the cohort criteria, or only one specific group's criteria.

Module - A subsection of the TriNetX platform that performs a distinct functionality. Cohorts are created using the Query Builder module. Descriptive modules include Healthcare Organizations, Explore Cohorts, Rate of Arrival, Summary Statistics, and Analyze Criteria. Advanced analytic modules include Analyze Outcomes, Compare Outcomes, Compare Cohorts, Treatment Pathways, and Incidence and Prevalence.

Network - An aggregation of HCOs contributing data to the platform. Multiple networks are available for querying on the platform; the different networks represent subsets of HCOs organized by date-shifting practices or availability of downloadable datasets.

Outcome - A medical fact (e.g., diagnosis, procedure, lab result) that occurred on or after the cohort-defining index event.

Query - In the TriNetX platform, a query is a distinct cohort with a unique set of terms and logic. Query cohorts are created using the Query Builder platform module.

Risk - In Advanced Analytics modules, risk refers to the percentage of patients in each cohort with the specified outcome of interest.

Priority - An indication whether the code was the condition that the provider spent the most time evaluating or treating during a visit. Possible values include primary, secondary, or unknown.

Term - The codes used to specify patient cohort criteria in a query. Code options include diagnoses, procedures, medications, labs, demographics, genomics, and visits. Terms can be linked together using and/or Boolean logic. TriNetX also creates terms that group together multiple medical codes into single clinical concepts.

> **Cannot Have Term -** A category of terms within a query group that patients must not have evidence of to be included in the cohort.
> **Must Have Term -** A category of terms within a query group that patients must have evidence of to be included in the cohort.

Glossary of Terms for Analyses Using TriNetX Live™ Platform*

Time Constraint - used to define time periods of interest for each group within a query. Time constraints can be defined relative to the date the query was run (e.g., any time before today), or defined based on specific dates (e.g., January 1, 2015 to September 30, 2020).

Treatment Pathway - In Advanced Analytics modules, the Treatment Pathways module returns the order in which patients received treatment and the prevalence of treatments, including combination of medications, following an index event.

TriNetX Codes - For commonly used laboratory terms, TriNetX aggregates Logical Observation Identifiers Names and Codes (LOINC) laboratory codes at a clinically significant level to new queryable TNX:LAB terms.

Visit - A type of term used to specify the type of medical encounter or facility where the encounter was recorded. Visit terms are derived by TriNetX from the source data. Visits are recorded separately from the codes or labs that occurred during the encounter; care settings are not attached to individual codes. Values for visit terms include: ambulatory, emergency, field, home health, inpatient encounter, inpatient acute, inpatient non-acute, laboratory, observation, pharmacy, pre-admission, short stay, virtual, and unknown.

*all terms may not be used in this report

Table 1a. Baseline Characteristics[a] of Patients with Allogeneic Hematopoietic Stem Cell Transplantation (HSCT) Between July 1, 2009 and August 31, 2020, Stratified by Age

	Adult patients (aged ≥ 18 years)	Pediatric patients (aged < 18 years)
Total Patients	**12,350**	**1,300**
Demographics		
Age at Index (years), mean (SD)	**48.1 (18.0)**	**3.6 (3.3)**
Sex, n (%)		
Female	5,290 (42.8)	520 (40.0)
Male	6,950 (56.3)	790 (60.8)
Unknown	120 (1.0)	0 (0)
Race, n (%)		
Asian	320 (2.6)	50 (3.8)
American Indian or Alaska Native	40 (0.3)	10 (0.8)
Black or African American	1,020 (8.3)	130 (10)
Native Hawaiian or Other Pacific Islander	30 (0.2)	10 (0.8)
Other	590 (4.8)	90 (6.9)
Unknown	1,060 (8.6)	220 (16.9)
White	9,320 (75.5)	820 (63.1)
Ethnicity, n (%)		
Hispanic or Latino	780 (6.3)	100 (7.7)
Not Hispanic or Latino	8,390 (67.9)	830 (63.8)
Unknown Ethnicity	3,190 (25.8)	380 (29.2)
Conditioning Regimens, n (%)		
Total Body Irradiation		
Special Treatment Procedure e.g., Total Body Irradiation, Hemibody Radiation, per Oral or Endocavitary Irradiation (CPT code 77470)	2,200 (17.8)	80 (6.2)
Whole Body Beam Radiation Therapy (ICD-10-PCS DW05XXX)	390 (3.2)	30 (2.3)
Total Body Irradiation (SNOMED 47479005)	10 (0.1)	0 (0)
Chemotherapeutic agents		
Fludarabine		
Fludarabine (RxNorm 24698)	6,960 (56.4)	480 (36.9)
Injection, Fludarabine Phosphate, 50 mg (HCPCS J9185)	1,420 (11.5)	320 (24.6)
Oral Fludarabine Phosphate, 10 mg (HCPCS J8562)	0 (0)	0 (0)

Table 1a. Baseline Characteristics[a] of Patients with Allogeneic Hematopoietic Stem Cell Transplantation (HSCT) Between July 1, 2009 and August 31, 2020, Stratified by Age

	Adult patients (aged ≥ 18 years)	Pediatric patients (aged < 18 years)
Busulfan		
Busulfan (RxNorm 1828)	3,870 (31.3)	400 (30.8)
Busulfan; Oral, 2 mg (HCPCS J8510)	10 (0.1)	0 (0)
Injection, Busulfan, 1 mg (HCPCS J0594)	750 (6.1)	280 (21.5)
Melphalan		
Melphalan (RxNorm 6718)	1,950 (15.8)	170 (13.1)
Injection, melphalan (evomela), 1 mg (HCPCS J9246)	0 (0)	0 (0)
Injection, melphalan hydrochloride, not otherwise specified, 50 mg (HCPCS J9245)	490 (4.0)	100 (7.7)
Introduction of Melphalan Hydrochloride Antineoplastic into Peripheral Artery, Percutaneous Approach, New Technology Group 9 (ICD-10-PCS XW053T9)	0 (0)	0 (0)
Anti-Thymocyte Globulin		
Lymphocyte immune globulin, antithymocyte globulin, rabbit, parenteral, 25 mg (HCPCS J7511)	570 (4.6)	100 (7.7)
Lymphocyte immune globulin, antithymocyte globulin, equine, parenteral, 250 mg (HCPCS J7504)	150 (1.2)	100 (7.7)
Lymphocyte immune globulin, anti-thymocyte globulin (RxNorm 1011)	1990 (16.1)	280 (21.5)
Indications for Allogeneic Hematopoietic Stem Cell Transplant[b], n (%)		
Hodgkin's Lymphoma (C81)	440 (3.6)	10 (0.8)
Non-Hodgkin's Lymphoma		
Follicular lymphoma (C82)	300 (2.4)	10 (0.8)
Non-follicular lymphoma (C83)	940 (7.6)	20 (1.5)
Mature T/NK-cell lymphomas (C84)	470 (3.8)	10 (0.8)
Other specified and unspecified types of non-Hodgkin lymphoma (C85)	1480 (12.0)	30 (2.3)
Other specified types of T/NK-cell lymphoma (C86)	130 (1.1)	10 (0.8)
Acute Lymphocytic Leukemia (ALL) (C91.0)	2360 (19.1)	230 (17.7)
Chronic Lymphocytic Leukemia (CLL) (C91.1)	510 (4.1)	10 (0.8)
Acute Myeloid Leukemia (AML) (C92.0)	5480 (44.4)	210 (16.2)
Chronic Myeloid Leukemia (CML)		
Chronic myeloid leukemia, BCR/ABL-positive- (C92.1)	810 (6.6)	20 (1.5)
Atypical chronic myeloid leukemia, BCR/ABL-negative (C92.2)	60 (0.5)	10 (0.8)
Polycythemia Vera (D45)	130 (1.1)	10 (0.8)

Table 1a. Baseline Characteristics[a] of Patients with Allogeneic Hematopoietic Stem Cell Transplantation (HSCT) Between July 1, 2009 and August 31, 2020, Stratified by Age

	Adult patients (aged ≥ 18 years)	Pediatric patients (aged < 18 years)
Myelodysplastic Syndrome (MDS) (D46)	2600 (21.1)	70 (5.4)
Essential Thrombocytosis (D47.3)	410 (3.3)	10 (0.8)
Thalassemia (D56)	60 (0.5)	90 (6.9)
Sickle Cell Disease (D57)	140 (1.1)	60 (4.6)
Other aplastic anemias and other bone marrow failure syndromes (D61)	7830 (63.4)	610 (46.9)
Myelofibrosis (D75.81)	600 (4.9)	10 (0.8)
Severe Combined Immune Deficiency Syndrome (SCID)		
Severe combined immunodeficiency with reticular dysgenesis (D81.0)	30 (0.2)	50 (3.8)
Severe combined immunodeficiency w low T- and B-cell numbers (D81.1)	30 (0.2)	70 (5.4)
Severe combined immunodef w low or normal B-cell numbers (D81.2)	30 (0.2)	50 (3.8)
Clinical Characteristics[b], n (%)		
Primary Hypertension (I10)	4800 (38.9)	380 (29.2)
Type 2 Diabetes Mellitus (E11)	1530 (12.4)	20 (1.5)
Ischemic Heart Diseases (I20 - I25)	1440 (11.7)	10 (0.8)
Acute Myocardial Infarction (I21)	280 (2.3)	10 (0.8)
Chronic Ischemic Heart Disease (I25)	1180 (9.6)	10 (0.8)
Congestive Heart Failure (I50)	980 (7.9)	30 (2.3)
Peripheral Vascular Disease (I73)	180 (1.4)	10 (0.8)
Cerebrovascular Diseases (I60 - I69)	700 (5.7)	50 (3.8)
Nontraumatic Subarachnoid Hemorrhage (I60)	70 (0.6)	0 (0)
Nontraumatic Intracerebral Hemorrhage (I61)	120 (1.0)	10 (0.8)
Other and Unspecified Nontraumatic Intracranial Hemorrhage (I62)	190 (1.5)	20 (1.5)
Cerebral Infarction (I63)	200 (1.6)	20 (1.5)
Peptic Ulcer Disease		
Gastric Ulcer (K25)	90 (0.7)	10 (0.8)
Duodenal Ulcer (K26)	40 (0.3)	10 (0.8)
Gastrojejunal Ulcer (K28)	20 (0.2)	10 (0.8)
Peptic Ulcer, Site Unspecified (K27)	70 (0.6)	0 (0)
Liver Disease (K70 - K77)	1490 (12.1)	190 (14.6)
Chronic Hepatitis, Not Elsewhere Classified (K73)	30 (0.2)	10 (0.8)

Table 1a. Baseline Characteristics[a] of Patients with Allogeneic Hematopoietic Stem Cell Transplantation (HSCT) Between July 1, 2009 and August 31, 2020, Stratified by Age

	Adult patients (aged ≥ 18 years)	Pediatric patients (aged < 18 years)
Fibrosis and Cirrhosis of Liver (K74)	130 (1.1)	10 (0.8)
Toxic Liver Disease (K71)	140 (1.1)	20 (1.5)
Hepatic Failure, Not Elsewhere Classified (K72)	200 (1.6)	40 (3.1)
Portal Hypertension (K76.6)	90 (0.7)	10 (0.8)
Viral Hepatitis (B15 - B19)	360 (2.9)	20 (1.5)
Acute Kidney Failure (N17)	2820 (22.8)	160 (12.3)
Chronic Kidney Disease (N18)	770 (6.2)	50 (3.8)
Hemiplegia and Hemiparesis (G81)	60 (0.5)	10 (0.8)
Neoplasms (C00 - D49)	10220 (82.8)	580 (44.6)
Malignant Neoplasms of Lip, Oral Cavity and Pharynx (C00 - C14)	50 (0.4)	10 (0.8)
Malignant Neoplasms of Digestive Organs (C15 - C26)	120 (1.0)	10 (0.8)
Malignant Neoplasms of Respiratory and Intrathoracic Organs (C30 - C39)	90 (0.7)	10 (0.8)
Melanoma and Other Malignant Neoplasms of Skin (C43 - C44)	190 (1.5)	10 (0.8)
Malignant Neoplasms of Breast (C50)	200 (1.6)	10 (0.8)
Malignant Neoplasms of Female Genital Organs (C51 - C58)	50 (0.4)	0 (0)
Malignant Neoplasms of Male Genital Organs (C60 - C63)	120 (1.0)	10 (0.8)
Malignant Neoplasms of Lymphoid, Hematopoietic and Related Tissue (C81 - C96)	9140 (74.0)	450 (34.6)
In Situ Neoplasms (D00 - D09)	70 (0.6)	0 (0)
Benign Neoplasms, Except Benign Neuroendocrine Tumors (D10 - D36)	650 (5.3)	60 (4.6)
Prescription medications, n (%)		
Defibrotide		
Defibrotide (RxNorm 1311089)	30 (0.2)	20 (1.5)
Introduction of Defibrotide Sodium Anticoagulant into Central Vein, Percutaneous Approach, New Technology Group 2 (deprecated 2022) (ICD-10-PCS XW04392)	10 (0.1)	0 (0)
Introduction of Defibrotide Sodium Anticoagulant into Peripheral Vein, Percutaneous Approach, New Technology Group 2 (deprecated 2022) (ICD-10-PCS XW03392)	10 (0.1)	0 (0)
Ravulizumab		
Ravulizumab (RxNorm 2107301)	10 (0.1)	0 (0)
Injection, ravulizumab-cwvz, 10 mg (HCPCS J1303)	0 (0)	0 (0)
Injection, ravulizumab-cwvz, 10 mg (deprecated 2019) (HCPCS C9052)	0 (0)	0 (0)

Table 1a. Baseline Characteristics[a] of Patients with Allogeneic Hematopoietic Stem Cell Transplantation (HSCT) Between July 1, 2009 and August 31, 2020, Stratified by Age

	Adult patients (aged ≥ 18 years)	Pediatric patients (aged < 18 years)
Eculizumab		
Eculizumab (RxNorm 591781)	20 (0.2)	10 (0.8)
Eculizumab injection (HCPCS J1300)	10 (0.1)	10 (0.8)
Introduction of Eculizumab into Central Vein, Percutaneous Approach, New Technology Group 6 (ICD-10-PCS XW043C6)	0 (0)	0 (0)
Introduction of Eculizumab into Peripheral Vein, Percutaneous Approach, New Technology Group 6 (ICD-10-PCS XW033C6)	0 (0)	0 (0)
Laboratory Tests		
Serum Cb-9 (complement C5b-9)[c] in ng/mL, n(%)	0 (0)	10 (0.8)
Mean (SD)	-	144
Range	-	144 - 144
Random Urine protein/creatinine ratio[d] in mg/g(creat), n(%)	120 (1.0)	20 (1.5)
Mean (SD)	548 (1,628)	38.2 (128)
Range	0 - 15,038	0.1 - 446
Blood Lactate dehydrogenase (LDH)[e] in U/L, n(%)	11370 (92.1)	1010 (77.7)
Mean (SD)	244 (264)	388 (483)
Range	0 - 15,539	69 - 11,145
Creatinine levels[f] in mg/dL, n(%)	11920 (96.5)	1220 (93.8)
Mean (SD)	0.752 (0.348)	0.218 (0.189)
Range	0 - 8.3	0 - 1.92

All counts provided through the TriNetX Live™ platform are rounded up to the nearest 10 to protect patient privacy.

[a]The index date for these two cohorts is the date of first observed allogeneic HSCT code during the query period. Baseline characteristics assessed in the six months before index (-183 days before index to index date).

[b]The codes in parentheses are International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) diagnosis codes

[c] The Logical Observation Identifiers Names and Codes (LOINC) codes for Serum Cb-9 complement levels are: 13117.7 and 93244-2

[d] The curated TNX:Lab code LG34791-0 for Urine Protein/Creatinine Ratio includes the following LOINC codes: 2890-2, 60678-0, 13801-6

[e] The curated TNX:Lab code 9052 for Serum Lactate Dehyrogenase includes the following LOINC codes: 2532-0, 14805-6, 14804-9

[f] The curated TNX:Lab code 9024 for Creatinine levels includes the following LOINC codes: 38483-4, 2160-0 , 20624-3, 30004-6, 57344-4, 57346-9, 35674-1, 2161-8

Table 1b. Baseline Characteristics[a] of Patients with Confirmed Thrombotic Microangiopathy (TMA) within 12 Months of Allogeneic Hematopoietic Stem Cell Transplantation (HSCT) Between July 1, 2009 and August 31, 2020, Stratified by Age

	Adult patients (aged ≥ 18 years)	Pediatric patients (aged < 18 years)
Total Patients	**290**	**60**
Demographics		
Age at Index (years), mean (SD)	**39.2 (21.1)**	**3.1 (2.67)**
Sex, n (%)		
Female	140 (48.3)	30 (50.0)
Male	160 (55.2)	40 (66.7)
Unknown	0 (0)	0 (0)
Race, n (%)		
Asian	10 (3.4)	10 (16.7)
American Indian or Alaska Native	0 (0)	10 (16.7)
Black or African American	40 (13.8)	10 (16.7)
Native Hawaiian or Other Pacific Islander	0 (0)	0 (0)
Other	20 (6.9)	10 (16.7)
Unknown	20 (6.9)	10 (16.7)
White	210 (72.4)	40 (66.7)
Ethnicity, n (%)		
Hispanic or Latino	30 (10.3)	10 (16.7)
Not Hispanic or Latino	230 (79.3)	50 (83.3)
Unknown Ethnicity	40 (13.8)	10 (16.7)
Conditioning Regimens, n (%)		
Total Body Irradiation		
Special Treatment Procedure e.g., Total Body Irradiation, Hemibody Radiation, per Oral or Endocavitary Irradiation (CPT code 77470)	20 (6.9)	10 (16.7)
Whole Body Beam Radiation Therapy (ICD-10-PCS DW05XXX)	0 (0)	0 (0)
Total Body Irradiation (SNOMED 47479005)	0 (0)	0 (0)
Chemotherapeutic agents		
Fludarabine		
Fludarabine (RxNorm 24698)	160 (55.2)	20 (33.3)
Injection, Fludarabine Phosphate, 50 mg (HCPCS J9185)	80 (27.6)	20 (33.3)
Oral Fludarabine Phosphate, 10 mg (HCPCS J8562)	0 (0)	0 (0)

Table 1b. Baseline Characteristics[a] of Patients with Confirmed Thrombotic Microangiopathy (TMA) within 12 Months of Allogeneic Hematopoietic Stem Cell Transplantation (HSCT) Between July 1, 2009 and August 31, 2020, Stratified by Age

	Adult patients (aged ≥ 18 years)	Pediatric patients (aged < 18 years)
Busulfan		
Busulfan (RxNorm 1828)	70 (24.1)	30 (50.0)
Busulfan; Oral, 2 mg (HCPCS J8510)	0 (0)	0 (0)
Injection, Busulfan, 1 mg (HCPCS J0594)	30 (10.3)	20 (33.3)
Melphalan		
Melphalan (RxNorm 6718)	80 (27.6)	10 (16.7)
Injection, melphalan (evomela), 1 mg (HCPCS J9246)	0 (0)	0 (0)
Injection, melphalan hydrochloride, not otherwise specified, 50 mg (HCPCS J9245)	50 (17.2)	10 (16.7)
Introduction of Melphalan Hydrochloride Antineoplastic into Peripheral Artery, Percutaneous Approach, New Technology Group 9 (ICD-10-PCS XW053T9)	0 (0)	0 (0)
Anti-Thymocyte Globulin		
Lymphocyte immune globulin, antithymocyte globulin, rabbit, parenteral, 25 mg (HCPCS J7511)	30 (10.3)	10 (16.7)
Lymphocyte immune globulin, antithymocyte globulin, equine, parenteral, 250 mg (HCPCS J7504)	20 (6.9)	10 (16.7)
Lymphocyte immune globulin, anti-thymocyte globulin (RxNorm 1011)	70 (24.1)	10 (16.7)
Indications for Allogeneic Hematopoietic Stem Cell Transplant[b], n (%)		
Hodgkin's Lymphoma (C81)	10 (3.4)	0 (0)
Non-Hodgkin's Lymphoma		
Follicular lymphoma (C82)	10 (3.4)	0 (0)
Non-follicular lymphoma (C83)	20 (6.9)	10 (16.7)
Mature T/NK-cell lymphomas (C84)	20 (6.9)	10 (16.7)
Other specified and unspecified types of non-Hodgkin lymphoma (C85)	50 (17.2)	10 (16.7)
Other specified types of T/NK-cell lymphoma (C86)	10 (3.4)	0 (0)
Acute Lymphocytic Leukemia (ALL) (C91.0)	80 (27.6)	10 (16.7)
Chronic Lymphocytic Leukemia (CLL) (C91.1)	20 (6.9)	0 (0)
Acute Myeloid Leukemia (AML) (C92.0)	130 (44.8)	10 (16.7)
Chronic Myeloid Leukemia (CML)		
Chronic myeloid leukemia, BCR/ABL-positive- (C92.1)	20 (6.9)	0 (0)
Atypical chronic myeloid leukemia, BCR/ABL-negative (C92.2)	10 (3.4)	0 (0)
Polycythemia Vera (D45)	10 (3.4)	0 (0)

Table 1b. Baseline Characteristics[a] of Patients with Confirmed Thrombotic Microangiopathy (TMA) within 12 Months of Allogeneic Hematopoietic Stem Cell Transplantation (HSCT) Between July 1, 2009 and August 31, 2020, Stratified by Age

	Adult patients (aged ≥ 18 years)	Pediatric patients (aged < 18 years)
Myelodysplastic Syndrome (MDS) (D46)	50 (17.2)	10 (16.7)
Essential Thrombocytosis (D47.3)	20 (6.9)	10 (16.7)
Thalassemia (D56)	10 (3.4)	10 (16.7)
Sickle Cell Disease (D57)	10 (3.4)	10 (16.7)
Other aplastic anemias and other bone marrow failure syndromes (D61)	230 (79.3)	30 (50.0)
Myelofibrosis (D75.81)	20 (6.9)	0 (0)
Severe Combined Immune Deficiency Syndrome (SCID)		
Severe combined immunodeficiency with reticular dysgenesis (D81.0)	0 (0)	0 (0)
Severe combined immunodeficiency w low T- and B-cell numbers (D81.1)	10 (3.4)	0 (0)
Severe combined immunodef w low or normal B-cell numbers (D81.2)	10 (3.4)	0 (0)
Clinical Characteristics[b], n (%)		
Primary Hypertension (I10)	210 (72.4)	50 (83.3)
Type 2 Diabetes Mellitus (E11)	60 (20.7)	10 (16.7)
Ischemic Heart Diseases (I20 - I25)	50 (17.2)	10 (16.7)
Acute Myocardial Infarction (I21)	20 (6.9)	10 (16.7)
Chronic Ischemic Heart Disease (I25)	30 (10.3)	0 (0)
Congestive Heart Failure (I50)	60 (20.7)	10 (16.7)
Peripheral Vascular Disease (I73)	20 (6.9)	10 (16.7)
Cerebrovascular Diseases (I60 - I69)	60 (20.7)	10 (16.7)
Nontraumatic Subarachnoid Hemorrhage (I60)	10 (3.4)	0 (0)
Nontraumatic Intracerebral Hemorrhage (I61)	10 (3.4)	10 (16.7)
Other and Unspecified Nontraumatic Intracranial Hemorrhage (I62)	20 (6.9)	10 (16.7)
Cerebral Infarction (I63)	20 (6.9)	10 (16.7)
Peptic Ulcer Disease		
Gastric Ulcer (K25)	10 (3.4)	10 (16.7)
Duodenal Ulcer (K26)	10 (3.4)	10 (16.7)
Gastrojejunal Ulcer (K28)	10 (3.4)	0 (0)
Peptic Ulcer, Site Unspecified (K27)	10 (3.4)	0 (0)
Liver Disease (K70 - K77)	110 (37.9)	20 (33.3)
Chronic Hepatitis, Not Elsewhere Classified (K73)	10 (3.4)	0 (0)

Table 1b. Baseline Characteristics[a] of Patients with Confirmed Thrombotic Microangiopathy (TMA) within 12 Months of Allogeneic Hematopoietic Stem Cell Transplantation (HSCT) Between July 1, 2009 and August 31, 2020, Stratified by Age

	Adult patients (aged ≥ 18 years)	Pediatric patients (aged < 18 years)
Fibrosis and Cirrhosis of Liver (K74)	10 (3.4)	0 (0)
Toxic Liver Disease (K71)	10 (3.4)	0 (0)
Hepatic Failure, Not Elsewhere Classified (K72)	30 (10.3)	10 (16.7)
Portal Hypertension (K76.6)	20 (6.9)	10 (16.7)
Viral Hepatitis (B15 - B19)	30 (10.3)	10 (16.7)
Acute Kidney Failure (N17)	200 (69.0)	30 (50.0)
Chronic Kidney Disease (N18)	70 (24.1)	10 (16.7)
Hemiplegia and Hemiparesis (G81)	10 (3.4)	0 (0)
Neoplasms (C00 - D49)	250 (86.2)	30 (50.0)
Malignant Neoplasms of Lip, Oral Cavity and Pharynx (C00 - C14)	10 (3.4)	0 (0)
Malignant Neoplasms of Digestive Organs (C15 - C26)	10 (3.4)	0 (0)
Malignant Neoplasms of Respiratory and Intrathoracic Organs (C30 - C39)	10 (3.4)	0 (0)
Melanoma and Other Malignant Neoplasms of Skin (C43 - C44)	10 (3.4)	0 (0)
Malignant Neoplasms of Breast (C50)	10 (3.4)	0 (0)
Malignant Neoplasms of Female Genital Organs (C51 - C58)	10 (3.4)	0 (0)
Malignant Neoplasms of Male Genital Organs (C60 - C63)	10 (3.4)	0 (0)
Malignant Neoplasms of Lymphoid, Hematopoietic and Related Tissue (C81 - C96)	230 (79.3)	20 (33.3)
In Situ Neoplasms (D00 - D09)	10 (3.4)	0 (0)
Benign Neoplasms, Except Benign Neuroendocrine Tumors (D10 - D36)	40 (13.8)	10 (16.7)
Prescription medications, n (%)		
Defibrotide		
Defibrotide (RxNorm 1311089)	10 (3.4)	10 (16.7)
Introduction of Defibrotide Sodium Anticoagulant into Central Vein, Percutaneous Approach, New Technology Group 2 (deprecated 2022) (ICD-10-PCS XW04392)	0 (0)	0 (0)
Introduction of Defibrotide Sodium Anticoagulant into Peripheral Vein, Percutaneous Approach, New Technology Group 2 (deprecated 2022) (ICD-10-PCS XW03392)	0 (0)	0 (0)
Ravulizumab		
Ravulizumab (RxNorm 2107301)	0 (0)	0 (0)
Injection, ravulizumab-cwvz, 10 mg (HCPCS J1303)	0 (0)	0 (0)
Injection, ravulizumab-cwvz, 10 mg (deprecated 2019) (HCPCS C9052)	0 (0)	0 (0)

Table 1b. Baseline Characteristics[a] of Patients with Confirmed Thrombotic Microangiopathy (TMA) within 12 Months of Allogeneic Hematopoietic Stem Cell Transplantation (HSCT) Between July 1, 2009 and August 31, 2020, Stratified by Age

	Adult patients (aged ≥ 18 years)	Pediatric patients (aged < 18 years)
Eculizumab		
Eculizumab (RxNorm 591781)	20 (6.9)	10 (16.7)
Eculizumab injection (HCPCS J1300)	10 (3.4)	10 (16.7)
Introduction of Eculizumab into Central Vein, Percutaneous Approach, New Technology Group 6 (ICD-10-PCS XW043C6)	0 (0)	0 (0)
Introduction of Eculizumab into Peripheral Vein, Percutaneous Approach, New Technology Group 6 (ICD-10-PCS XW033C6)	0 (0)	0 (0)
Laboratory Tests		
Serum Cb-9 (complement C5b-9)[c] in ng/mL, n(%)	0 (0)	0 (0)
Mean (SD)	-	-
Range	-	-
Random Urine protein/creatinine ratio[d], n(%)	20 (6.9)	10 (16.7)
Mean (SD)	1,113 (1,259)	0.19
Range	0.35 - 4,200	0.19 - 0.19
Blood Lactate dehydrogenase (LDH)[e], n(%)	260 (89.7)	50 (83.3)
Mean (SD)	479 (353)	605 (446)
Range	0 - 2,887	179 - 1,827
Creatinine levels[f] in mg/dL, n(%)	280 (96.6)	60 (100.0)
Mean (SD)	1.32 (1.08)	0.358 (0.277)
Range	0 - 6.7	0 - 1.11

All counts provided through the TriNetX Live™ platform are rounded up to the nearest 10 to protect patient privacy.

[a] The index date for these two cohorts is the date of first observed code for Thrombotic Microangiopathy within 12 months of allogeneic HSCT code during the query period. Baseline characteristics assessed in the six months before index (-183 days before index to index date).

[b]The codes in parentheses are International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) diagnosis codes

[c] The Logical Observation Identifiers Names and Codes (LOINC) codes for Serum Cb-9 complement levels are: 13117.7 and 93244-2

[d] The curated TNX:Lab code LG34791-0 for Urine Protein/Creatinine Ratio includes the following LOINC codes: 2890-2, 60678-0, 13801-6

[e] The curated TNX:Lab code 9052 for Serum Lactate Dehyrogenase includes the following LOINC codes: 2532-0, 14805-6, 14804-9

[f] The curated TNX:Lab code 9024 for Creatinine levels includes the following LOINC codes: 38483-4, 2160-0 , 20624-3, 30004-6, 57344-4, 57346-9, 35674-1, 2161-8

Table 2a. Clinical Characteristics Associated with High-Risk of Adverse Outcomes Among Patients with Allogeneic Hematopoietic Stem Cell Transplantation (HSCT) Over Periods of 3-Months, 6-Months and 12-Months from Index Date*, Stratified by Age

	Index Date* to 3-Months Post-Index Date	Index Date* to 6-Months Post-Index Date	Index Date* to 12-Months Post-Index Date
High-Risk Clinical Characteristics and Outcome of Death			
Adult Patients (Aged ≥ 18 Years)	**12,350**	**12,350**	**12,350**
Presence of Any High-Risk Condition, n (%)	8,900 (72.1)	9,740 (78.9)	10,280 (83.2)
Serum Cb-9 (complement C5b-9) levels > upper limit of normal[a]	10 (0.1)	10 (0.1)	10 (0.1)
Random Urine protein/creatinine ratio ≥1mg/g	210 (1.7)	300 (2.4)	450 (3.6)
Blood levels of Lactate dehydrogenase (LDH) ≥ 2 x upper limit of normal[b]	3,010 (24.4)	3,850 (31.2)	4,500 (36.4)
Acute graft versus host disease (GVHD)	2,370 (19.2)	3,120 (25.3)	3,570 (28.9)
Concurrent viral or bacterial infection	5,810 (47.0)	6,760 (54.7)	7,400 (59.9)
Organ dysfunction (presence of any of the following)	4,750 (38.5)	5,710 (46.2)	6,540 (53.0)
Pulmonary Hypertension	170 (1.4)	280 (2.3)	400 (3.2)
Need for Diaylsis	770 (6.2)	1,010 (8.2)	1,240 (10.0)
Acute Renal Failure/Acute Kidney Injury	3,250 (26.3)	3,950 (31.9)	4,540 (36.8)
Creatinine level ≥ 2 x upper limit of normal[c]	1,290 (10.4)	1,650 (13.4)	1,990 (16.1)
Intubation or Mechanical Ventilation	1,250 (10.1)	1,780 (14.4)	2,330 (18.9)
Mental Status Change or Seizures	1,000 (8.1)	1,380 (11.2)	1,760 (14.3)
Death, n (%)	950 (7.7)	1,940 (15.7)	3,160 (25.6)
Laboratory Tests			
Serum Cb-9 (complement C5b-9)d in ng/mL, n (%)	10 (0.1)	10 (0.1)	10 (0.1)
Mean (SD)	296 (97.086)	293.571 (88.859)	293.571 (88.859)
Random Urine protein/creatinine ratioe in mg/g(creat), n (%)	260 (2.1)	370 (3.0)	550 (4.5)
Mean (SD)	891.294 (1,903.777)	810.655 (1,803.732)	833.396 (1,900.599)
Blood Lactate dehydrogenase (LDH)f in U/L, n (%)	10,850 (87.9)	11,060 (89.6)	11,240 (91.0)
Mean (SD)	356.548 (840.572)	385.276 (896.633)	412.275 (952.710)
Creatinine levelsg in mg/dL, n (%)	11,820 (95.7)	11,840 (95.9)	11,870 (96.1)
Mean (SD)	1.062 (0.575)	1.054 (0.621)	1.090 (0.693)
Pediatric Patients (Aged < 18 Years)	**1,300**	**1,300**	**1,300**
Presence of Any High-Risk Condition, n (%)	1,050 (80.8)	1,120 (86.2)	1,140 (87.7)
Serum Cb-9 (complement C5b-9) levels > upper limit of normal[a]	10 (0.8)	10 (0.8)	10 (0.8)
Random Urine protein/creatinine ratio ≥1mg/g	20 (1.5)	20 (1.5)	30 (2.3)
Blood levels of Lactate dehydrogenase (LDH) ≥ 2 x upper limit of normal[b]	600 (46.2)	640 (49.2)	680 (52.3)
Acute graft versus host disease (GVHD)	170 (13.1)	240 (18.4)	280 (21.5)

Table 2a. Clinical Characteristics Associated with High-Risk of Adverse Outcomes Among Patients with Allogeneic Hematopoietic Stem Cell Transplantation (HSCT) Over Periods of 3-Months, 6-Months and 12-Months from Index Date*, Stratified by Age

	Index Date* to 3-Months Post-Index Date	Index Date* to 6-Months Post-Index Date	Index Date* to 12-Months Post-Index Date
Concurrent viral or bacterial infection	690 (53.1)	830 (63.8)	890 (68.5)
Organ dysfunction (presence of any of the following)	400 (30.8)	480 (36.9)	530 (40.8)
Pulmonary Hypertension	20 (1.5)	20 (1.5)	30 (2.3)
Need for Diaylsis	130 (10.0)	170 (13.1)	190 (14.6)
Acute Renal Failure/Acute Kidney Injury	150 (11.5)	200 (15.4)	240 (18.5)
Creatinine levels ≥ 2 x upper limit of normal[c]	10 (0.8)	20 (1.5)	20 (1.5)
Intubation or Mechanical Ventilation	180 (13.8)	220 (16.9)	260 (20.0)
Mental Status Change or Seizures	100 (7.7)	130 (10.0)	160 (12.3)
Death, n (%)	60 (4.6)	120 (9.2)	180 (13.8)
Laboratory Tests			
Serum Cb-9 (complement C5b-9)d in ng/mL, n (%)	10 (0.8)	10 (0.8)	10 (0.8)
Mean (SD)	253 (1.414)	342.667 (233.960)	277.250 (231.536)
Random Urine protein/creatinine ratioe in mg/g(creat), n (%)	20 (1.5)	30 (2.3)	30 (2.3)
Mean (SD)	18.168 (62.256)	16.672 (56.882)	90.605 (412.518)
Blood Lactate dehydrogenase (LDH)f in U/L, n (%)	1,060 (81.5)	1,080 (83.1)	1,090 (83.8)
Mean (SD)	445.418 (470.815)	551.151 (1,872.012)	623.782 (2,671.316)
Creatinine levelsg in mg/dL, n (%)	1,220 (93.8)	1,220 (93.8)	1,230 (94.6)
Mean (SD)	0.331 (0.299)	0.332 (0.303)	0.327 (.0321)

All counts provided through the TriNetX Live™ platform are rounded up to the nearest 10 to protect patient privacy.

*The index date for these two cohorts is the date of first observed allogeneic HSCT code during the query period.

[a] Upper limit of normal for serum Cb-9 test is 250 ng/mL

[b] Upper limit of normal for blood levels of lactate dehydrogenase is 250 U/L

[c] Upper limit of normal for creatinine levels is 1.3 mg/dL

[d] The Logical Observation Identifiers Names and Codes (LOINC) codes for Serum Cb-9 complement levels are: 13117.7 and 93244-2

[e] The curated TNX:Lab code LG34791-0 for Urine Protein/Creatinine Ratio includes the following LOINC codes: 2890-2, 60678-0, 13801-6

[f] The curated TNX:Lab code 9052 for Serum Lactate Dehyrogenase includes the following LOINC codes: 2532-0, 14805-6, 14804-9

[g] The curated TNX:Lab code 9024 for Creatinine levels includes the following LOINC codes: 38483-4, 2160-0 , 20624-3, 30004-6, 57344-4, 57346-9, 35674-1, 2161-8

Table 2b. Clinical Characteristics Associated with High-Risk of Adverse Outcomes Among Patients with Confirmed Thrombotic Microangiopathy (TMA) within 12 Months of Allogeneic Hematopoietic Stem Cell Transplantation (HSCT) on Index Date* and Over Periods of 3-Months, 6-Months and 12-Months from Index Date, Stratified by Age

	On Index Date*	Index Date* to 3-Months Post-Index Date	Index Date* to 6-Months Post-Index Date	Index Date* to 12-Months Post-Index Date
High-Risk Clinical Characteristics and Outcome of Death				
Adult Patients (Aged ≥ 18 Years)	**290**	**290**	**290**	**290**
Presence of Any High-Risk Condition, n (%)	240 (82.8)	260 (89.7)	270 (93.1)	270 (93.1)
Serum Cb-9 (complement C5b-9) levels > upper limit of normal[a]	0 (0)	0 (0)	0 (0)	0 (0)
Random Urine protein/creatinine ratio ≥1mg/g	10 (3.4)	20 (6.9)	30 (10.3)	30 (10.3)
Blood levels of Lactate dehydrogenase (LDH) ≥ 2 x upper limit of normal[b]	50 (17.2)	160 (55.2)	170 (58.6)	170 (58.6)
Acute graft versus host disease (GVHD)	70 (24.1)	100 (34.5)	120 (41.4)	130 (44.8)
Concurrent viral or bacterial infection	180 (62.1)	180 (62.1)	200 (69.0)	220 (75.9)
Organ dysfunction (presence of any of the following)	170 (58.6)	190 (65.5)	200 (69.0)	220 (75.9)
Pulmonary Hypertension	10 (3.4)	20 (6.9)	20 (6.9)	30 (10.3)
Need for Diaylsis	20 (6.9)	70 (24.1)	80 (27.6)	90 (31.0)
Acute Renal Failure/Acute Kidney Injury	140 (48.3)	130 (44.8)	150 (51.7)	160 (55.2)
Creatinine level ≥ 2 x upper limit of normal[c]	30 (10.3)	80 (27.6)	100 (34.5)	100 (34.5)
Intubation or Mechanical Ventilation	50 (17.2)	80 (27.6)	90 (31.0)	100 (34.5)
Mental Status Change or Seizures	50 (17.2)	60 (20.7)	70 (24.1)	80 (27.6)
Death, n (%)	10 (3.4)	70 (24.1)	100 (34.5)	130 (44.8)
Laboratory Tests				
Serum Cb-9 (complement C5b-9)d in ng/mL, n (%)	0 (0)	0 (0)	0 (0)	0 (0)
Mean (SD)	-	-	-	-
Random Urine protein/creatinine ratioe in mg/g(creat), n (%)	10 (3.4)	20 (6.9)	30 (10.3)	30 (10.3)
Mean (SD)	2,200 (1,272.792)	503.189 (813.712)	507.368 (792.870)	417.289 (727.873)
Blood Lactate dehydrogenase (LDH)f in U/L, n (%)	120 (41.4)	250 (86.2)	250 (86.2)	250 (86.2)
Mean (SD)	528.923 (394.438)	597.971 (1,276.602)	592.434 (1,272.718)	576.572 (1,273.613)
Creatinine levelsg in mg/dL, n (%)	230 (79.3)	270 (93.1)	270 (93.1)	270 (93.1)
Mean (SD)	1.370 (1.135)	1.245 (1.016)	1.303 (1.110)	1.397 (1.416)
Pediatric Patients (Aged < 18 Years)	**60**	**60**	**60**	**60**
Presence of Any High-Risk Condition, n (%)	50 (83.3)	50 (83.3)	60 (100)	60 (100)
Serum Cb-9 (complement C5b-9) levels > upper limit of normal[a]	0 (0)	10 (16.7)	10 (16.7)	10 (16.7)
Random Urine protein/creatinine ratio ≥1mg/g	0 (0)	10 (16.7)	10 (16.7)	10 (16.7)

Table 2b. Clinical Characteristics Associated with High-Risk of Adverse Outcomes Among Patients with Confirmed Thrombotic Microangiopathy (TMA) within 12 Months of Allogeneic Hematopoietic Stem Cell Transplantation (HSCT) on Index Date* and Over Periods of 3-Months, 6-Months and 12-Months from Index Date, Stratified by Age

	On Index Date*	Index Date* to 3-Months Post-Index Date	Index Date* to 6-Months Post-Index Date	Index Date* to 12-Months Post-Index Date
Blood levels of Lactate dehydrogenase (LDH) ≥ 2 x upper limit of normal [b]	20 (33.3)	40 (66.7)	40 (66.7)	40 (66.7)
Acute graft versus host disease (GVHD)	20 (33.3)	20 (33.3)	30 (50)	30 (50)
Concurrent viral or bacterial infection	40 (66.7)	40 (66.7)	50 (83.3)	50 (83.3)
Organ dysfunction (presence of any of the following)	30 (50)	40 (66.7)	40 (66.7)	40 (66.7)
Pulmonary Hypertension	10 (16.7)	10 (16.7)	10 (16.7)	10 (16.7)
Need for Diaylsis	10 (16.7)	20 (33.3)	20 (33.3)	20 (33.3)
Acute Renal Failure/Acute Kidney Injury	20 (33.3)	30 (50)	30 (50)	30 (50)
Creatinine levels ≥ 2 x upper limit of normal [c]	0 (0)	10 (16.7)	10 (16.7)	10 (16.7)
Intubation or Mechanical Ventilation	10 (16.7)	20 (33.3)	20 (33.3)	20 (33.3)
Mental Status Change or Seizures	10 (16.7)	20 (33.3)	20 (33.3)	20 (33.3)
Death, n (%)	0 (0)	10 (16.7)	20 (33.3)	20 (33.3)
Laboratory Tests				
Serum Cb-9 (complement C5b-9)d in ng/mL, n (%)	0 (0)	10 (16.7)	10 (16.7)	10 (16.7)
Mean (SD)	-	387 (312.541)	387 (312.541)	387 (312.541)
Random Urine protein/creatinine ratioe in mg/g(creat), n (%)	0 (0)	10 (16.7)	10 (16.7)	10 (16.7)
Mean (SD)	-	30.220 (12.473)	30.220 (12.473)	30.220 (12.473)
Blood Lactate dehydrogenase (LDH)f in U/L, n (%)	30 (50)	50 (83.3)	50 (83.3)	50 (83.3)
Mean (SD)	645.957 (463.052)	620.204 (745.682)	785.020 (986.996)	738.102 (999.486)
Creatinine levelsg in mg/dL, n (%)	50 (83.3)	60 (100)	60 (100)	60 (100)
Mean (SD)	0.384 (0.303)	0.424 (0.471)	0.479 (0.596)	0.534 (0.709)

All counts provided through the TriNetX Live™ platform are rounded up to the nearest 10 to protect patient privacy.

*The index date for these cohorts is the date of first observed code for TMA within 12 months of allogeneic HSCT code during the query period.

[a] Upper limit of normal for serum Cb-9 test is 250 ng/mL

[b] Upper limit of normal for blood levels of lactate dehydrogenase is 250 U/L

[c] Upper limit of normal for creatinine levels is 1.3 mg/dL

[d] The Logical Observation Identifiers Names and Codes (LOINC) codes for Serum Cb-9 complement levels are: 13117.7 and 93244-2

[e] The curated TNX:Lab code LG34791-0 for Urine Protein/Creatinine Ratio includes the following LOINC codes: 2890-2, 60678-0, 13801-6

[f] The curated TNX:Lab code 9052 for Serum Lactate Dehyrogenase includes the following LOINC codes: 2532-0, 14805-6, 14804-9

[g] The curated TNX:Lab code 9024 for Creatinine levels includes the following LOINC codes: 38483-4, 2160-0 , 20624-3, 30004-6, 57344-4, 57346-9, 35674-1, 2161-8

Appendix A. List of Codes Used to Define Index Events in this Request

Code Type	Code	Description
		Allogeneic Hematopoietic Stem Cell Transplant (HSCT)
CPT	38240	Hematopoietic progenitor cell (HPC); allogeneic transplantation per donor
ICD-10-PCS	30230Y4	Transfusion of Allogeneic Unspecified Hematopoietic Stem Cells into Peripheral Vein, Open Approach
ICD-10-PCS	30233Y4	Transfusion of Allogeneic Unspecified Hematopoietic Stem Cells into Peripheral Vein, Percutaneous Approach
ICD-10-PCS	30240Y4	Transfusion of Allogeneic Unspecified Hematopoietic Stem Cells into Central Vein, Open Approach
ICD-10-PCS	30243Y4	Transfusion of Allogeneic Unspecified Hematopoietic Stem Cells into Central Vein, Percutaneous Approach
ICD-10-PCS	30250Y1	Transfusion of Nonautologous Hematopoietic Stem Cells into Peripheral Artery, Open Approach
ICD-10-PCS	30253Y1	Transfusion of Nonautologous Hematopoietic Stem Cells into Peripheral Artery, Percutaneous Approach
ICD-10-PCS	30260Y1	Transfusion of Nonautologous Hematopoietic Stem Cells into Central Artery, Open Approach
ICD-10-PCS	30263Y1	Transfusion of Nonautologous Hematopoietic Stem Cells into Central Artery, Percutaneous Approach
ICD-10-PCS	30230Y3	Transfusion of Allogeneic Unrelated Hematopoietic Stem Cells into Peripheral Vein, Open Approach
ICD-10-PCS	30233Y3	Transfusion of Allogeneic Unrelated Hematopoietic Stem Cells into Peripheral Vein, Percutaneous Approach
ICD-10-PCS	30240Y3	Transfusion of Allogeneic Unrelated Hematopoietic Stem Cells into Central Vein, Open Approach
ICD-10-PCS	30243Y3	Transfusion of Allogeneic Unrelated Hematopoietic Stem Cells into Central Vein, Percutaneous Approach
ICD-10-PCS	30230Y2	Transfusion of Allogeneic Related Hematopoietic Stem Cells into Peripheral Vein, Open Approach
ICD-10-PCS	30233Y2	Transfusion of Allogeneic Related Hematopoietic Stem Cells into Peripheral Vein, Percutaneous Approach
ICD-10-PCS	30240U2	Transfusion of Allogeneic Related T-cell Depleted Hematopoietic Stem Cells into Central Vein, Open Approach
ICD-10-PCS	30243U2	Transfusion of Allogeneic Related T-cell Depleted Hematopoietic Stem Cells into Central Vein, Percutaneous Approach
ICD-10-PCS	30230U2	Transfusion of Allogeneic Related T-cell Depleted Hematopoietic Stem Cells into Peripheral Vein, Open Approach
ICD-10-PCS	30233U2	Transfusion of Allogeneic Related T-cell Depleted Hematopoietic Stem Cells into Peripheral Vein, Percutaneous Approach
ICD-10-PCS	30240U3	Transfusion of Allogeneic Unrelated T-cell Depleted Hematopoietic Stem Cells into Central Vein, Open Approach
ICD-10-PCS	30243U3	Transfusion of Allogeneic Unrelated T-cell Depleted Hematopoietic Stem Cells into Central Vein, Percutaneous Approach
ICD-10-PCS	30230U3	Transfusion of Allogeneic Unrelated T-cell Depleted Hematopoietic Stem Cells into Peripheral Vein, Open Approach
ICD-10-PCS	30233U3	Transfusion of Allogeneic Unrelated T-cell Depleted Hematopoietic Stem Cells into Peripheral Vein, Percutaneous Approach
ICD-10-PCS	30240U4	Transfusion of Allogeneic Unspecified T-cell Depleted Hematopoietic Stem Cells into Central Vein, Open Approach
ICD-10-PCS	30243U4	Transfusion of Allogeneic Unspecified T-cell Depleted Hematopoietic Stem Cells into Central Vein, Percutaneous Approach
ICD-10-PCS	30230U4	Transfusion of Allogeneic Unspecified T-cell Depleted Hematopoietic Stem Cells into Peripheral Vein, Open Approach

Appendix A. List of Codes Used to Define Index Events in this Request

Code Type	Code	Description
ICD-10-PCS	30233U4	Transfusion of Allogeneic Unspecified T-cell Depleted Hematopoietic Stem Cells into Peripheral Vein, Percutaneous Approach
ICD-10-PCS	30243Y1	Transfusion of Nonautologous Hematopoietic Stem Cells into Central Vein, Percutaneous Approach
ICD-10-PCS	30230Y1	Transfusion of Nonautologous Hematopoietic Stem Cells into Peripheral Vein, Open Approach
ICD-10-PCS	30233Y1	Transfusion of Nonautologous Hematopoietic Stem Cells into Peripheral Vein, Percutaneous Approach
ICD-10-PCS	30240Y1	Transfusion of Nonautologous Hematopoietic Stem Cells into Central Vein, Open Approach
ICD-10-PCS	30243Y2	Transfusion of Allogeneic Related Hematopoietic Stem Cells into Central Vein, Percutaneous Approach
ICD-10-PCS	30240Y2	Transfusion of Allogeneic Related Hematopoietic Stem Cells into Central Vein, Open Approach
ICD-10-PCS	30230G2	Transfusion of Allogeneic Related Bone Marrow into Peripheral Vein, Open Approach
ICD-10-PCS	30230G3	Transfusion of Allogeneic Unrelated Bone Marrow into Peripheral Vein, Open Approach
ICD-10-PCS	30230G4	Transfusion of Allogeneic Unspecified Bone Marrow into Peripheral Vein, Open Approach
ICD-10-PCS	30230X2	Transfusion of Allogeneic Related Cord Blood Stem Cells into Peripheral Vein, Open Approach
ICD-10-PCS	30230X3	Transfusion of Allogeneic Unrelated Cord Blood Stem Cells into Peripheral Vein, Open Approach
ICD-10-PCS	30230X4	Transfusion of Allogeneic Unspecified Cord Blood Stem Cells into Peripheral Vein, Open Approach
ICD-10-PCS	30233G2	Transfusion of Allogeneic Related Bone Marrow into Peripheral Vein, Percutaneous Approach
ICD-10-PCS	30233G3	Transfusion of Allogeneic Unrelated Bone Marrow into Peripheral Vein, Percutaneous Approach
ICD-10-PCS	30233G4	Transfusion of Allogeneic Unspecified Bone Marrow into Peripheral Vein, Percutaneous Approach
ICD-10-PCS	30233X2	Transfusion of Allogeneic Related Cord Blood Stem Cells into Peripheral Vein, Percutaneous Approach
ICD-10-PCS	30233X3	Transfusion of Allogeneic Unrelated Cord Blood Stem Cells into Peripheral Vein, Percutaneous Approach
ICD-10-PCS	30233X4	Transfusion of Allogeneic Unspecified Cord Blood Stem Cells into Peripheral Vein, Percutaneous Approac
ICD-10-PCS	30240G2	Transfusion of Allogeneic Related Bone Marrow into Central Vein, Open Approach
ICD-10-PCS	30240G3	Transfusion of Allogeneic Unrelated Bone Marrow into Central Vein, Open Approach
ICD-10-PCS	30240G4	Transfusion of Allogeneic Unspecified Bone Marrow into Central Vein, Open Approach
ICD-10-PCS	30240X2	Transfusion of Allogeneic Related Cord Blood Stem Cells into Central Vein, Open Approach
ICD-10-PCS	30240X3	Transfusion of Allogeneic Unrelated Cord Blood Stem Cells into Central Vein, Open Approach
ICD-10-PCS	30240X4	Transfusion of Allogeneic Unspecified Cord Blood Stem Cells into Central Vein, Open Approach
ICD-10-PCS	30243G2	Transfusion of Allogeneic Related Bone Marrow into Central Vein, Percutaneous Approach
ICD-10-PCS	30243G3	Transfusion of Allogeneic Unrelated Bone Marrow into Central Vein, Percutaneous Approach
ICD-10-PCS	30243G4	Transfusion of Allogeneic Unspecified Bone Marrow into Central Vein, Percutaneous Approach
ICD-10-PCS	30243X2	Transfusion of Allogeneic Related Cord Blood Stem Cells into Central Vein, Percutaneous Approach
ICD-10-PCS	30243X3	Transfusion of Allogeneic Unrelated Cord Blood Stem Cells into Central Vein, Percutaneous Approach
ICD-10-PCS	30243X4	Transfusion of Allogeneic Unspecified Cord Blood Stem Cells into Central Vein, Percutaneous Approach
ICD-10-PCS	30250G1	Transfusion of Nonautologous Bone Marrow into Peripheral Artery, Open Approach
ICD-10-PCS	30250X1	Transfusion of Nonautologous Cord Blood Stem Cells into Peripheral Artery, Open Approach
ICD-10-PCS	30260G1	Transfusion of Nonautologous Bone Marrow into Central Artery, Open Approach

Appendix A. List of Codes Used to Define Index Events in this Request

Code Type	Code	Description
ICD-10-PCS	30260X1	Transfusion of Nonautologous Cord Blood Stem Cells into Central Artery, Open Approach
ICD-10-PCS	30253G1	Transfusion of Nonautologous Bone Marrow into Peripheral Artery, Percutaneous Approach
ICD-10-PCS	30253X1	Transfusion of Nonautologous Cord Blood Stem Cells into Peripheral Artery, Percutaneous Approach
ICD-10-PCS	30263G1	Transfusion of Nonautologous Bone Marrow into Central Artery, Percutaneous Approach
ICD-10-PCS	30263X1	Transfusion of Nonautologous Cord Blood Stem Cells into Central Artery, Percutaneous Approach
Thrombotic Microangiopathy (TMA)		
ICD-10-CM	M31.1	Thrombotic microangiopathy
ICD-10-CM	M31.10	Thrombotic microangiopathy, unspecified
ICD-10-CM	M31.19	Other thrombotic microangiopathy
ICD-10-CM	M31.11	Hematopoietic stem cell transplantation-associated thrombotic microangiopathy [HSCT-TMA]
Hemolytic-Uremic Syndrome (HUS)		
ICD-10-CM	D59.30	Hemolytic-uremic syndrome, unspecified
ICD-10-CM	D59.31	Infection-associated hemolytic-uremic syndrome
ICD-10-CM	D59.39	Other hemolytic-uremic syndrome

Appendix B. List of Codes Used to Define Outcomes in this Request

Code Type	Code	Description
Acute Graft-Versus-Host Disease (GVHD)		
ICD-10-CM	D89.810	Acute graft-versus-host disease
Viral or Bacterial Infection		
ICD-10-CM	A04	Other bacterial intestinal infections
ICD-10-CM	A08	Viral and other specified intestinal infections
ICD-10-CM	A09	Infectious gastroenteritis and colitis, unspecified
ICD-10-CM	A39	Meningococcal infection
ICD-10-CM	A40	Streptococcal sepsis
ICD-10-CM	A41	Other sepsis
ICD-10-CM	A49	Bacterial infection of unspecified site
ICD-10-CM	A81	Atypical virus infections of central nervous system
ICD-10-CM	A85	Other viral encephalitis, not elsewhere classified
ICD-10-CM	A86	Unspecified viral encephalitis
ICD-10-CM	A87	Viral meningitis
ICD-10-CM	A88	Other viral infections of central nervous system, not elsewhere classified
ICD-10-CM	A89	Unspecified viral infection of central nervous system
ICD-10-CM	B25-B34	Other viral diseases
ICD-10-CM	B95	Streptococcus, Staphylococcus, and Enterococcus as the cause of diseases classified elsewhere
ICD-10-CM	B96	Other bacterial agents as the cause of diseases classified elsewhere
ICD-10-CM	U07.1	COVID-19 infection
Pulmonary Hypertension		
ICD-10-CM	I27.0	Primary pulmonary hypertension
ICD-10-CM	I27.20	Pulmonary hypertension, unspecified
Need for Dialysis		
ICD-10-PCS	3E1M39Z	Irrigation of Peritoneal Cavity using Dialysate, Percutaneous Approach
ICD-10-PCS	B50W0ZZ	Plain Radiography of Dialysis Shunt/Fistula using High Osmolar Contrast
ICD-10-PCS	B50W1ZZ	Plain Radiography of Dialysis Shunt/Fistula using Low Osmolar Contrast
ICD-10-PCS	B50WYZZ	Plain Radiography of Dialysis Shunt/Fistula using Other Contrast
ICD-10-PCS	B51W0ZA	Fluoroscopy of Dialysis Shunt/Fistula using High Osmolar Contrast, Guidance
ICD-10-PCS	B51W0ZZ	Fluoroscopy of Dialysis Shunt/Fistula using High Osmolar Contrast
ICD-10-PCS	B51W1ZA	Fluoroscopy of Dialysis Shunt/Fistula using Low Osmolar Contrast, Guidance
ICD-10-PCS	B51W1ZZ	Fluoroscopy of Dialysis Shunt/Fistula using Low Osmolar Contrast
ICD-10-PCS	B51WYZA	Fluoroscopy of Dialysis Shunt/Fistula using Other Contrast, Guidance
ICD-10-PCS	B51WYZZ	Fluoroscopy of Dialysis Shunt/Fistula using Other Contrast
ICD-10-PCS	B51WZZA	Fluoroscopy of Dialysis Shunt/Fistula, Guidance
ICD-10-PCS	B51WZZZ	Fluoroscopy of Dialysis Shunt/Fistula
ICD-10-CM	N18.5	Chronic kidney disease, stage 5
ICD-10-CM	N18.6	End stage renal disease
ICD-10-CM	I95.3	Hypotension of hemodialysis
ICD-10-CM	R88.0	Cloudy (hemodialysis) (peritoneal) dialysis effluent
ICD-10-CM	T81.502	Unspecified complication of foreign body accidentally left in body following kidney dialysis
ICD-10-CM	T81.502A	Unspecified complication of foreign body accidentally left in body following kidney dialysis, initial encounter

Appendix B. List of Codes Used to Define Outcomes in this Request

Code Type	Code	Description
ICD-10-CM	T81.502D	Unspecified complication of foreign body accidentally left in body following kidney dialysis, subsequent encounter
ICD-10-CM	T81.502S	Unspecified complication of foreign body accidentally left in body following kidney dialysis, sequela
ICD-10-CM	T81.512	Adhesions due to foreign body accidentally left in body following kidney dialysis
ICD-10-CM	T81.512A	Adhesions due to foreign body accidentally left in body following kidney dialysis, initial encounter
ICD-10-CM	T81.512D	Adhesions due to foreign body accidentally left in body following kidney dialysis, subsequent encounter
ICD-10-CM	T81.512S	Adhesions due to foreign body accidentally left in body following kidney dialysis, sequela
ICD-10-CM	T81.522	Obstruction due to foreign body accidentally left in body following kidney dialysis
ICD-10-CM	T81.522A	Obstruction due to foreign body accidentally left in body following kidney dialysis, initial encounter
ICD-10-CM	T81.522D	Obstruction due to foreign body accidentally left in body following kidney dialysis, subsequent encounter
ICD-10-CM	T81.522S	Obstruction due to foreign body accidentally left in body following kidney dialysis, sequela
ICD-10-CM	T81.532	Perforation due to foreign body accidentally left in body following kidney dialysis
ICD-10-CM	T81.532A	Perforation due to foreign body accidentally left in body following kidney dialysis, initial encounter
ICD-10-CM	T81.532D	Perforation due to foreign body accidentally left in body following kidney dialysis, subsequent encounter
ICD-10-CM	T81.532S	Perforation due to foreign body accidentally left in body following kidney dialysis, sequela
ICD-10-CM	T81.592	Other complications of foreign body accidentally left in body following kidney dialysis
ICD-10-CM	T81.592A	Other complications of foreign body accidentally left in body following kidney dialysis, initial encounter
ICD-10-CM	T81.592D	Other complications of foreign body accidentally left in body following kidney dialysis, subsequent encounter
ICD-10-CM	T81.592S	Other complications of foreign body accidentally left in body following kidney dialysis, sequela
ICD-10-CM	T82.41XA	Breakdown (mechanical) of vascular dialysis catheter, initial encounter
ICD-10-CM	T82.41XD	Breakdown (mechanical) of vascular dialysis catheter, subsequent encounter
ICD-10-CM	T82.41XS	Breakdown (mechanical) of vascular dialysis catheter, sequela
ICD-10-CM	T82.42XA	Displacement of vascular dialysis catheter, initial encounter
ICD-10-CM	T82.42XD	Displacement of vascular dialysis catheter, subsequent encounter
ICD-10-CM	T82.42XS	Displacement of vascular dialysis catheter, sequela
ICD-10-CM	T82.43XA	Leakage of vascular dialysis catheter, initial encounter
ICD-10-CM	T82.43XD	Leakage of vascular dialysis catheter, subsequent encounter
ICD-10-CM	T82.43XS	Leakage of vascular dialysis catheter, sequela
ICD-10-CM	T82.49XA	Other complication of vascular dialysis catheter, initial encounter
ICD-10-CM	T82.49XD	Other complication of vascular dialysis catheter, subsequent encounter
ICD-10-CM	T82.49XS	Other complication of vascular dialysis catheter, sequela
ICD-10-CM	T85.611	Breakdown (mechanical) of intraperitoneal dialysis catheter
ICD-10-CM	T85.611A	Breakdown (mechanical) of intraperitoneal dialysis catheter, initial encounter
ICD-10-CM	T85.611D	Breakdown (mechanical) of intraperitoneal dialysis catheter, subsequent encounter
ICD-10-CM	T85.611S	Breakdown (mechanical) of intraperitoneal dialysis catheter, sequela
ICD-10-CM	T85.621	Displacement of intraperitoneal dialysis catheter
ICD-10-CM	T85.621A	Displacement of intraperitoneal dialysis catheter, initial encounter

Appendix B. List of Codes Used to Define Outcomes in this Request

Code Type	Code	Description
ICD-10-CM	T85.621D	Displacement of intraperitoneal dialysis catheter, subsequent encounter
ICD-10-CM	T85.621S	Displacement of intraperitoneal dialysis catheter, sequela
ICD-10-CM	T85.631	Leakage of intraperitoneal dialysis catheter
ICD-10-CM	T85.631A	Leakage of intraperitoneal dialysis catheter, initial encounter
ICD-10-CM	T85.631D	Leakage of intraperitoneal dialysis catheter, subsequent encounter
ICD-10-CM	T85.631S	Leakage of intraperitoneal dialysis catheter, sequela
ICD-10-CM	T85.691	Other mechanical complication of intraperitoneal dialysis catheter
ICD-10-CM	T85.691A	Other mechanical complication of intraperitoneal dialysis catheter, initial encounter
ICD-10-CM	T85.691D	Other mechanical complication of intraperitoneal dialysis catheter, subsequent encounter
ICD-10-CM	T85.691S	Other mechanical complication of intraperitoneal dialysis catheter, sequela
ICD-10-CM	T85.71XA	Infection and inflammatory reaction due to peritoneal dialysis catheter, initial encounter
ICD-10-CM	T85.71XD	Infection and inflammatory reaction due to peritoneal dialysis catheter, subsequent encounter
ICD-10-CM	T85.71XS	Infection and inflammatory reaction due to peritoneal dialysis catheter, sequela
ICD-10-CM	Y62.2	Failure of sterile precautions during kidney dialysis and other perfusion
ICD-10-CM	Y84.1	Kidney dialysis as the cause of abnormal reaction of the patient, or of later complication, without mention of misadventure at the time of the procedure
ICD-10-CM	Z49.01	Encounter for fitting and adjustment of extracorporeal dialysis catheter
ICD-10-CM	Z49.02	Encounter for fitting and adjustment of peritoneal dialysis catheter
ICD-10-CM	Z49.31	Encounter for adequacy testing for hemodialysis
ICD-10-CM	Z49.32	Encounter for adequacy testing for peritoneal dialysis
ICD-10-CM	Z91.15	Patient's noncompliance with renal dialysis
ICD-10-CM	Z94.0	Kidney transplant status
ICD-10-CM	Z99.2	Dependence on renal dialysis
CPT	0505F	Hemodialysis plan of care documented (ESRD, P-ESRD)
CPT	0507F	Peritoneal dialysis plan of care documented (ESRD)
CPT	4052F	Hemodialysis via functioning arteriovenous (AV) fistula (ESRD)
CPT	4053F	Hemodialysis via functioning arteriovenous (AV) graft (ESRD)
CPT	4054F	Hemodialysis via catheter (ESRD)
CPT	4055F	Patient receiving peritoneal dialysis (ESRD)
CPT	75791	Angiography, arteriovenous shunt (eg, dialysis patient fistula/graft), complete evaluation of dialysis access, including fluoroscopy, image documentation and report (includes injections of contrast and all necessary imaging from the arterial anastomosis and adjacent artery through entire venous outflow including the inferior or superior vena cava), radiological supervision and interpretation
CPT	90935	Hemodialysis procedure with single evaluation by a physician or other qualified health care professional
CPT	90937	Hemodialysis procedure requiring repeated evaluation(s) with or without substantial revision of dialysis prescription
CPT	90939	Hemodialysis access flow study to determine blood flow in grafts and arteriovenous fistulae by an indicator dilution method, hook-up; transcutaneous measurement and disconnection
CPT	90940	Hemodialysis access flow study to determine blood flow in grafts and arteriovenous fistulae by an indicator method
CPT	90941	Hemodialysis, For Acute Renal Failure And Or Intoxication,
CPT	90942	Hemodialysis, For Acute Renal Failure And Or Intoxication,
CPT	90943	Hemodialysis, For Acute Renal Failure And Or Intoxication,

Appendix B. List of Codes Used to Define Outcomes in this Request

Code Type	Code	Description
CPT	90944	Hemodialysis, For Acute Renal Failure And Or Intoxication,
CPT	90945	Dialysis procedure other than hemodialysis (eg, peritoneal dialysis, hemofiltration, or other continuous renal replacement therapies), with single evaluation by a physician or other qualified health care professional
CPT	90947	Dialysis procedure other than hemodialysis (eg, peritoneal dialysis, hemofiltration, or other continuous renal replacement therapies) requiring repeated evaluations by a physician or other qualified health care professional, with or without substantial revision of dialysis prescription
CPT	90951	End-stage renal disease (ESRD) related services monthly, for patients younger than 2 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents; with 4 or more face-to-face visits by a physician or other qualified health care professional per month
CPT	90952	End-stage renal disease (ESRD) related services monthly, for patients younger than 2 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents; with 2-3 face-to-face visits by a physician or other qualified health care professional per month
CPT	90953	End-stage renal disease (ESRD) related services monthly, for patients younger than 2 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents; with 1 face-to-face visit by a physician or other qualified health care professional per month
CPT	90954	End-stage renal disease (ESRD) related services monthly, for patients 2-11 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents; with 4 or more face-to-face visits by a physician or other qualified health care professional per month
CPT	90955	End-stage renal disease (ESRD) related services monthly, for patients 2-11 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents; with 2-3 face-to-face visits by a physician or other qualified health care professional per month
CPT	90956	End-stage renal disease (ESRD) related services monthly, for patients 2-11 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents; with 1 face-to-face visit by a physician or other qualified health care professional per month
CPT	90957	End-stage renal disease (ESRD) related services monthly, for patients 12-19 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents; with 4 or more face-to-face visits by a physician or other qualified health care professional per month
CPT	90958	End-stage renal disease (ESRD) related services monthly, for patients 12-19 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents; with 2-3 face-to-face visits by a physician or other qualified health care professional per month
CPT	90959	End-stage renal disease (ESRD) related services monthly, for patients 12-19 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents; with 1 face-to-face visit by a physician or other qualified health care professional per month

Appendix B. List of Codes Used to Define Outcomes in this Request

Code Type	Code	Description
CPT	90960	End-stage renal disease (ESRD) related services monthly, for patients 20 years of age and older; with 4 or more face-to-face visits by a physician or other qualified health care professional per month
CPT	90961	End-stage renal disease (ESRD) related services monthly, for patients 20 years of age and older; with 2-3 face-to-face visits by a physician or other qualified health care professional per month
CPT	90962	End-stage renal disease (ESRD) related services monthly, for patients 20 years of age and older; with 1 face-to-face visit by a physician or other qualified health care professional per month
CPT	90963	End-stage renal disease (ESRD) related services for home dialysis per full month, for patients younger than 2 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents
CPT	90964	End-stage renal disease (ESRD) related services for home dialysis per full month, for patients 2-11 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents
CPT	90965	End-stage renal disease (ESRD) related services for home dialysis per full month, for patients 12-19 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents
CPT	90966	End-stage renal disease (ESRD) related services for home dialysis per full month, for patients 20 years of age and older
CPT	90967	End-stage renal disease (ESRD) related services for dialysis less than a full month of service, per day; for patients younger than 2 years of age
CPT	90968	End-stage renal disease (ESRD) related services for dialysis less than a full month of service, per day; for patients 2-11 years of age
CPT	90969	End-stage renal disease (ESRD) related services for dialysis less than a full month of service, per day; for patients 12-19 years of age
CPT	90970	End-stage renal disease (ESRD) related services for dialysis less than a full month of service, per day; for patients 20 years of age and older
CPT	90976	Peritoneal Dialysis For End-stage Renal Disease (esrd),
CPT	90977	Peritoneal Dialysis For End-stage Renal Disease (esrd),
CPT	90978	Peritoneal Dialysis For End-stage Renal Disease (esrd),
CPT	90979	Peritoneal Dialysis For End-stage Renal Disease (esrd),
CPT	90982	Peritoneal Dialysis For End-stage Renal Disease (esrd),
CPT	90983	Peritoneal Dialysis For End-stage Renal Disease (esrd),
CPT	90984	Peritoneal Dialysis For End-stage Renal Disease (esrd),
CPT	90985	Peritoneal Dialysis For End-stage Renal Disease (esrd),
CPT	90988	Supervision Of Hemodialysis In Hospital Or Other Facility (excluding Home Dialysis), On Monthly Basis
CPT	90989	Dialysis training, patient, including helper where applicable, any mode, completed course
CPT	90990	Hemodialysis Training And/or Counseling
CPT	90991	Home Hemodialysis Care, Outpatient, For Those Services Either Provided By The Physician Primarily Responsible
CPT	90992	Peritoneal Dialysis Training And/or Counseling
CPT	90993	Dialysis training, patient, including helper where applicable, any mode, course not completed, per training session

Appendix B. List of Codes Used to Define Outcomes in this Request

Code Type	Code	Description
CPT	90994	Supervision Of Chronic Ambulatory Peritoneal Dialysis (capd), Home Or Out-patient (monthly)
CPT	90995	End Stage Renal Disease (esrd) Related Services, Per Full Month
CPT	90996	Continuous Arteriovenous Hemofiltration (cavh) (per Day)
CPT	90998	End Stage Renal Disease (esrd) Related Services (less Than Full Month), Per Day
CPT	90999	Unlisted dialysis procedure, inpatient or outpatient
CPT	99512	Home visit for hemodialysis
CPT	99559	Home infusion of peritoneal dialysis, per visit
HCPCS	A4655	Needles and syringes for dialysis
HCPCS	A4663	Blood pressure cuff only
HCPCS	A4672	Drainage extension line, sterile, for dialysis, each
HCPCS	A4690	Dialyzer (artificial kidneys), all types, all sizes, for hemodialysis, each
HCPCS	A4700	Standard dialysate solution, each
HCPCS	A4705	Bicarbonate dialysate solution, each
HCPCS	A4720	Dialysate solution, any concentration of dextrose, fluid volume greater than 249 cc, but less than or equal to 999 cc, for peritoneal dialysis
HCPCS	A4721	Dialysate solution, any concentration of dextrose, fluid volume greater than 999 cc but less than or equal to 1999 cc, for peritoneal dialysis
HCPCS	A4722	Dialysate solution, any concentration of dextrose, fluid volume greater than 1999 cc but less than or equal to 2999 cc, for peritoneal dialysis
HCPCS	A4723	Dialysate solution, any concentration of dextrose, fluid volume greater than 2999 cc but less than or equal to 3999 cc, for peritoneal dialysis
HCPCS	A4724	Dialysate solution, any concentration of dextrose, fluid volume greater than 3999 cc but less than or equal to 4999 cc, for peritoneal dialysis
HCPCS	A4725	Dialysate solution, any concentration of dextrose, fluid volume greater than 4999 cc but less than or equal to 5999 cc, for peritoneal dialysis
HCPCS	A4726	Dialysate solution, any concentration of dextrose, fluid volume greater than 5999 cc, for peritoneal dialysis
HCPCS	A4728	Dialysate solution, nondextrose containing, 500 ml
HCPCS	A4760	Dialysate solution test kit, for peritoneal dialysis, any type, each
HCPCS	A4765	Dialysate concentrate, powder, additive for peritoneal dialysis, per packet
HCPCS	A4766	Dialysate concentrate, solution, additive for peritoneal dialysis, per 10 ml
HCPCS	A4780	Sterilizing agent for dialysis equipment, per gallon
HCPCS	A4790	Cleansing agents for equipment for dialysis only
HCPCS	A4800	Heparin for dialysis and antidote, any strength, porcine or beef, up to 1000 units, 10-30 ml (for parenteral use see b4216)
HCPCS	A4820	Hemodialysis kit supplies
HCPCS	A4910	Non-medical supplies for dialysis, (i.e., scale, scissors, stopwatch, etc.)
HCPCS	A4913	Miscellaneous dialysis supplies, not otherwise specified
HCPCS	A4919	Dialyzer holder, each
HCPCS	A4929	Tourniquet for dialysis, each
HCPCS	C1037	Catheter, vaxcel chronic dialysis catheter, medcomp bio flex tesio catheter, medcomp silicone tesio catheter, medcomp hemo-cath long term silicone catheter, bard niagara dual lumen catheter, bard opti-flow dual lumen catheter, medcomp ash split catheter
HCPCS	C1750	Catheter, hemodialysis/peritoneal, long-term

Appendix B. List of Codes Used to Define Outcomes in this Request

Code Type	Code	Description
HCPCS	C1752	Catheter, hemodialysis/peritoneal, short-term
HCPCS	C1881	Dialysis access system (implantable)
HCPCS	E1510	Kidney, dialysate delivery system kidney machine, pump recirculating, air removal system, flowrate meter, power off, heater and temperature control with alarm, IV poles, pressure gauge, concentrate container
HCPCS	E1570	Adjustable chair, for ESRD patients
HCPCS	E1590	Hemodialysis machine
HCPCS	E1592	Automatic intermittent peritoneal dialysis system
HCPCS	E1594	Cycler dialysis machine for peritoneal dialysis
HCPCS	E1632	Wearable artificial kidney, each
HCPCS	E1634	Peritoneal dialysis clamps, each
HCPCS	E1635	Compact (portable) travel hemodialyzer system
HCPCS	E1638	Heating pad, for peritoneal dialysis, any size, each
HCPCS	E1699	Dialysis equipment, not otherwise specified
HCPCS	G0257	Unscheduled or emergency dialysis treatment for an ESRD patient in a hospital outpatient department that is not certified as an ESRD facility
HCPCS	G0321	ESRD related services for home dialysis patients per full month; for patients 2 to 11 years of age to include monitoring for adequacy of nutrition, assessment of growth and development, and counseling of parents
HCPCS	G0322	End Stage Renal disease (ESRD) related services for home dialysis patients per full month; for patients 12 to 19 years of age to include monitoring for adequacy of nutrition, assessment of growth and development, and counseling of parents
HCPCS	G0323	End Stage Renal disease (ESRD) related services for home dialysis patients per full month; for patients 20 years of age and older
HCPCS	G0324	ESRD related services for home dialysis (less than full month), per day; for patients under 2 years of age
HCPCS	G0325	ESRD related services for home dialysis (less than full month), per day; for patients between 2 and 11 years of age
HCPCS	G0326	ESRD related services for home dialysis (less than full month), per day; for patients between twelve and nineteen years of age
HCPCS	G0327	ESRD related services for home dialysis (less than full month), per day; for patients twenty years of age and over
HCPCS	G8075	ESRD patient with documented dialysis dose of URR greater than or equal to 65% (or Kt/ V greater than or equal to 1.2)
HCPCS	G8076	ESRD patient with documented dialysis dose of URR less than 65% (or Kt/V less than 1.2)
HCPCS	G8081	ESRD patient requiring hemodialysis vascular access documented to have received autogenous AV fistula
HCPCS	G8082	ESRD patient requiring hemodialysis documented to have received vascular access other than autogenous AV fistula
HCPCS	G8085	ESRD patient requiring hemodialysis vascular access was not an eligible candidate for autogenous AV fistula
HCPCS	G8714	Hemodialysis treatment performed exactly 3 times per week > 90 days
HCPCS	G8715	Hemodialysis treatment performed less than 3 times per week or greater than 3 times per week
HCPCS	G8727	Patient receiving hemodialysis, peritoneal dialysis or kidney transplantation
HCPCS	G9231	Documentation of end stage renal disease (ESRD), dialysis, renal transplant before or during the measurement period or pregnancy during the measurement period

Appendix B. List of Codes Used to Define Outcomes in this Request

Code Type	Code	Description
HCPCS	J0882	Injection, darbepoetin alfa, 1 mcg (for ESRD on dialysis)
HCPCS	J0886	Injection, epoetin alfa, 1000 units (for ESRD on dialysis)
HCPCS	J0887	Injection, epoetin beta, 1 mcg, (for ESRD on dialysis)
HCPCS	K0610	Peritoneal dialysis clamp, each
HCPCS	K0612	Drainage extension line, sterile, for dialysis, each
HCPCS	Q0139	Injection, ferumoxytol, for treatment of iron deficiency anemia, 1 mg (for ESRD on dialysis)
HCPCS	Q4054	Injection, darbepoetin alfa, 1 mcg (for ESRD on dialysis)
HCPCS	Q4055	Injection, epoetin alfa, 1000 units (for ESRD on dialysis)
HCPCS	Q4081	Injection, epoetin alfa, 100 units (for ESRD on dialysis)
HCPCS	Q9972	Injection, epoetin beta, 1 microgram, (for ESRD on dialysis)
		Acute Kidney Injury
ICD-10-CM	N17	Acute kidney failure
ICD-10-CM	N17.0	Acute kidney failure with tubular necrosis
ICD-10-CM	N17.1	Acute kidney failure with acute cortical necrosis
ICD-10-CM	N17.2	Acute kidney failure with medullary necrosis
ICD-10-CM	N17.8	Other acute kidney failure
ICD-10-CM	N17.9	Acute kidney failure, unspecified
		Intubation or Mechanical Ventilation
CPT	31500	Intubation, endotracheal, emergency procedure
CPT	31719	Transtracheal (percutaneous) Introduction Of Indwelling Tube For Therapy (eg, Tickle Tube, Catheter For Oxygen Administration)
CPT	31730	Transtracheal (percutaneous) introduction of needle wire dilator/stent or indwelling tube for oxygen therapy
CPT	33946	Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; initiation, veno-venous
CPT	33947	Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; initiation, veno-arterial
CPT	33948	Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; daily management, each day, veno-venous
CPT	33949	Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; daily management, each day, veno-arterial
CPT	33952	Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; insertion of peripheral (arterial and/or venous) cannula(e), percutaneous, 6 years and older (includes fluoroscopic guidance, when performed)
CPT	33954	Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; insertion of peripheral (arterial and/or venous) cannula(e), open, 6 years and older
CPT	33956	Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; insertion of central cannula(e) by sternotomy or thoracotomy, 6 years and older
CPT	33958	Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; reposition peripheral (arterial and/or venous) cannula(e), percutaneous, 6 years and older (includes fluoroscopic guidance, when performed)
CPT	33962	Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; reposition peripheral (arterial and/or venous) cannula(e), open, 6 years and older (includes fluoroscopic guidance, when performed)

Appendix B. List of Codes Used to Define Outcomes in this Request

Code Type	Code	Description
CPT	33964	Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; reposition central cannula(e) by sternotomy or thoracotomy, 6 years and older (includes fluoroscopic guidance, when performed)
CPT	33966	Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; removal of peripheral (arterial and/or venous) cannula(e), percutaneous, 6 years and older
CPT	33984	Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; removal of peripheral (arterial and/or venous) cannula(e), open, 6 years and older
CPT	33986	Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; removal of central cannula(e) by sternotomy or thoracotomy, 6 years and older
CPT	33987	Arterial exposure with creation of graft conduit (eg, chimney graft) to facilitate arterial perfusion for ECMO/ECLS (List separately in addition to code for primary procedure)
CPT	33988	Insertion of left heart vent by thoracic incision (eg, sternotomy, thoracotomy) for ECMO/ECLS
CPT	33989	Removal of left heart vent by thoracic incision (eg, sternotomy, thoracotomy) for ECMO/ECLS
CPT	4168F	Patient receiving care in the intensive care unit (ICU) and receiving mechanical ventilation, 24 hours or less (CRIT)
CPT	94002	Ventilation assist and management, initiation of pressure or volume preset ventilators for assisted or controlled breathing; hospital inpatient/observation, initial day
CPT	94003	Ventilation assist and management, initiation of pressure or volume preset ventilators for assisted or controlled breathing; hospital inpatient/observation, each subsequent day
CPT	94004	Ventilation assist and management, initiation of pressure or volume preset ventilators for assisted or controlled breathing; nursing facility, per day
CPT	94656	Ventilation assist and management, initiation of pressure or volume preset ventilators for assisted or controlled breathing; first day
CPT	94657	Ventilation assist and management, initiation of pressure or volume preset ventilators for assisted or controlled breathing; subsequent days
HCPCS	A0396	ALS specialized service disposable supplies; esophageal intubation
HCPCS	A4483	Moisture exchanger, disposable, for use with invasive mechanical ventilation
HCPCS	A4608	Transtracheal oxygen catheter, each
HCPCS	A4623	Tracheostomy, inner cannula
HCPCS	A4624	Tracheal suction catheter, any type other than closed system, each
ICD-10-PCS	0BH13EZ	Insertion of Endotracheal Airway into Trachea, Percutaneous Approach
ICD-10-PCS	0BH17EZ	Insertion of Endotracheal Airway into Trachea, Via Natural or Artificial Opening
ICD-10-PCS	0BH18EZ	Insertion of Endotracheal Airway into Trachea, Via Natural or Artificial Opening Endoscopic
ICD-10-PCS	0CHY7BZ	Insertion of Airway into Mouth and Throat, Via Natural or Artificial Opening
ICD-10-PCS	0CHY8BZ	Insertion of Airway into Mouth and Throat, Via Natural or Artificial Opening Endoscopic
ICD-10-PCS	0DH57BZ	Insertion of Airway into Esophagus, Via Natural or Artificial Opening
ICD-10-PCS	0DH58BZ	Insertion of Airway into Esophagus, Via Natural or Artificial Opening Endoscopic
ICD-10-PCS	0DL57DZ	Occlusion of Esophagus with Intraluminal Device, Via Natural or Artificial Opening
ICD-10-PCS	0DL58DZ	Occlusion of Esophagus with Intraluminal Device, Via Natural or Artificial Opening Endoscopic
ICD-10-PCS	0WHQ73Z	Insertion of Infusion Device into Respiratory Tract, Via Natural or Artificial Opening
ICD-10-PCS	0WHQ7YZ	Insertion of Other Device into Respiratory Tract, Via Natural or Artificial Opening
ICD-10-PCS	5A09	Assistance / Respiratory
ICD-10-PCS	5A0920Z	Assistance with Respiratory Filtration, Continuous
ICD-10-PCS	5A09357	Assistance with Respiratory Ventilation, Less than 24 Consecutive Hours, Continuous Positive Airway Pressure

Appendix B. List of Codes Used to Define Outcomes in this Request

Code Type	Code	Description
ICD-10-PCS	5A09358	Assistance with Respiratory Ventilation, Less than 24 Consecutive Hours, Intermittent Positive Airway Pressure
ICD-10-PCS	5A09359	Assistance with Respiratory Ventilation, Less than 24 Consecutive Hours, Continuous Negative Airway Pressure
ICD-10-PCS	5A0935A	Assistance with Respiratory Ventilation, Less than 24 Consecutive Hours, High Nasal Flow/Velocity
ICD-10-PCS	5A0935B	Assistance with Respiratory Ventilation, Less than 24 Consecutive Hours, Intermittent Negative Airway Pressure
ICD-10-PCS	5A0935Z	Assistance with Respiratory Ventilation, Less than 24 Consecutive Hours
ICD-10-PCS	5A09457	Assistance with Respiratory Ventilation, 24-96 Consecutive Hours, Continuous Positive Airway Pressure
ICD-10-PCS	5A09458	Assistance with Respiratory Ventilation, 24-96 Consecutive Hours, Intermittent Positive Airway Pressure
ICD-10-PCS	5A09459	Assistance with Respiratory Ventilation, 24-96 Consecutive Hours, Continuous Negative Airway Pressure
ICD-10-PCS	5A0945A	Assistance with Respiratory Ventilation, 24-96 Consecutive Hours, High Nasal Flow/Velocity
ICD-10-PCS	5A0945B	Assistance with Respiratory Ventilation, 24-96 Consecutive Hours, Intermittent Negative Airway Pressure
ICD-10-PCS	5A0945Z	Assistance with Respiratory Ventilation, 24-96 Consecutive Hours
ICD-10-PCS	5A09557	Assistance with Respiratory Ventilation, Greater than 96 Consecutive Hours, Continuous Positive Airway Pressure
ICD-10-PCS	5A09558	Assistance with Respiratory Ventilation, Greater than 96 Consecutive Hours, Intermittent Positive Airway Pressure
ICD-10-PCS	5A09559	Assistance with Respiratory Ventilation, Greater than 96 Consecutive Hours, Continuous Negative Airway Pressure
ICD-10-PCS	5A0955A	Assistance with Respiratory Ventilation, Greater than 96 Consecutive Hours, High Nasal Flow/Velocity
ICD-10-PCS	5A0955B	Assistance with Respiratory Ventilation, Greater than 96 Consecutive Hours, Intermittent Negative Airway Pressure
ICD-10-PCS	5A0955Z	Assistance with Respiratory Ventilation, Greater than 96 Consecutive Hours
ICD-10-PCS	5A1935Z	Respiratory Ventilation, Less than 24 Consecutive Hours
ICD-10-PCS	5A1945Z	Respiratory Ventilation, 24-96 Consecutive Hours
ICD-10-PCS	5A1955Z	Respiratory Ventilation, Greater than 96 Consecutive Hours
ICD-10-CM	Z99.1	Dependence on respirator
ICD-10-CM	Z99.11	Dependence on respirator [ventilator] status
ICD-10-CM	Z99.12	Encounter for respirator [ventilator] dependence during power failure
		Seizure or Mental Status Change
ICD-10-CM	G40.89	Other seizures
ICD-10-CM	R56.9	Unspecified convulsions
ICD-10-CM	R41.82	Altered mental status, unspecified
		Random Urine Protein/Creatinine Ratio
LOINC	2890-2	Protein/Creatinine [mg/g] in Urine
LOINC	60678-0	Protein/Creatinine [mg/g] in 12 hour Urine
LOINC	13801-6	Protein/Creatinine [mg/g] in 24 hour Urine
		Serum Lactate Dehydrogenase (LDH)
LOINC	2532-0	Lactate dehydrogenase [U/L] in Serum or Plasma
LOINC	14805-6	Lactate dehydrogenase [U/L] in Serum or Plasma by Pyruvate to lactate reaction

Appendix B. List of Codes Used to Define Outcomes in this Request

Code Type	Code	Description
LOINC	14804-9	Lactate dehydrogenase [U/L] in Serum or Plasma by Lactate to pyruvate reaction
		Creatinine levels
LOINC	38483-4	Creatinine [mg/dL] in Blood
LOINC	2160-0	Creatinine [mg/dL] in Serum or Plasma
LOINC	20624-3	Creatinine [mg/dL] in 24 hour Urine
LOINC	30004-6	Creatinine [mg/dL] in Urine by Test strip
LOINC	57344-4	Creatinine [mg/dL] in 2 hour Urine
LOINC	57346-9	Creatinine [mg/dL] in 12 hour Urine
LOINC	35674-1	Creatinine [mg/dL] in Urine collected for unspecified duration
LOINC	2161-8	Creatinine [mg/dL] in Urine
		Serum Cb-9 (complement C5b-9)
LOINC	13117-7	Complement sc5b-9 ab [arb'U/mL] in serum or plasma
LOINC	93244-2	Complement sc5b-9 [ng/mL] in serum or plasma by immunoassay

Appendix C. Specifications Defining Analytic Modules in this Request

#	Module	Analysis Type	Cohort(s)	Window	Index Event(s)	Characteristics or Outcomes
1	Advanced Explore Cohort		1, 2	-183, 0 days	First allogeneic HSCT during query period	(1) Age at index, (2) race, (3) ethnicity, (4) sex, (5) conditioning regimens, (6) indications for HSCT, (7) common clinical comorbidities, (8) prescription medications, (9) certain laboratory tests
2	Analyze Outcomes	Risk	1, 2	1, 92 days 1, 183 days 1, 365 days	First allogeneic HSCT during query period	(1) Any of the following high risk conditions, (a) acute GVHD, (b) organ dysfunction (any one of the following: pulmonary hypertension, dialysis, acute renal failure or kidney disease, creatinine levels ≥ 2 x upper limit of normal, intubation, mechanical ventilation, mental status change, seizures), (c) serum c5b-9 levels > upper limit of normal, (d) random urine protein/creatinine ratio >= 1mg/mg, (e) lactate dehydrogenase level ≥ 2 x upper limit of normal, (f) viral or bacterial infection; (2) death; (3) Lab test values for creatinine levels, serum c5b-9, random urine protein/creatinine ratio and serum lactate dehydrogenase level
3	Advanced Explore Cohort		3, 4	-183, 0 days	First TMA/HUS within 12 months of allogeneic HSCT during the query period	(1) Age at index, (2) race, (3) ethnicity, (4) sex, (5) conditioning regimens, (6) indications for HSCT, (7) common clinical comorbidities, (8) prescription medications, (9) certain laboratory tests
4	Analyze Outcomes	Risk	3, 4	0 (index date) 1, 92 days 1, 183 days 1, 365 days	First TMA/HUS within 12 months of allogeneic HSCT during the query period	(1) Any of the following high risk conditions, (a) acute GVHD, (b) organ dysfunction (any one of the following: pulmonary hypertension, dialysis, acute renal failure or kidney disease, creatinine levels ≥ 2 x upper limit of normal, intubation, mechanical ventilation, mental status change, seizures), (c) serum c5b-9 levels > upper limit of normal, (d) random urine protein/creatinine ratio >= 1mg/mg, (e) lactate dehydrogenase level ≥ 2 x upper limit of normal, (f) viral or bacterial infection; (2) death; (3) Lab test values for creatinine levels, serum c5b-9, random urine protein/creatinine ratio and serum lactate dehydrogenase level

Appendix D. Specifications Defining Query Builder Modules in this Request

Network:	
USA Minimal Shift	
Cohort 1: Adult (Age 18+) Patients with Allogeneic HSCT	
Group 1:	**Time Restrictions**
Subgroup 1A	
Must Have:	
Allogeneic Hematopoietic Stem Cell Transplant	July 1, 2009 - Aug 31, 2020
Restriction: Age 18+	
Cannot Have:	
Cohort 2: Pediatric (Age <18) Patients with Allogeneic HSCT	
Group 1:	**Time Restrictions**
Subgroup 2A	
Must Have:	
Allogeneic Hematopoietic Stem Cell Transplant	July 1, 2009 - Aug 31, 2020
Restriction: Age 0-17	
Cannot Have:	
Cohort 3: Adult (Age 18+) Patients with TMA/HUS Diagnosis Within 12 Months of Allogeneic HSCT	
Group 1:	**Time Restrictions**
Subgroup 3A	
Must Have:	
Thrombotic Microangiopathy OR Hemolytic Uremic Syndrome	July 1, 2009 - Aug 31, 2020 for both groups
Restriction: Age 18+	
Cannot Have:	
Subgroup 3B:	
Must Have:	
Allogeneic Hematopoietic Stem Cell Transplant	Any instance of Group 1B occurred within 1 year on or before the first instance of TMA
Cannot Have:	

Appendix D. Specifications Defining Query Builder Modules in this Request

Cohort 4: Pediatric (Age <18) Patients with TMA/HUS Diagnosis Within 12 Months of Allogeneic HSCT	
Group 1:	**Time Restrictions**
Subgroup 4A	
Must Have:	
Thrombotic Microangiopathy OR Hemolytic Uremic Syndrome	July 1, 2009 - Aug 31, 2020 for both groups
Restriction: Age 0-17	
Cannot Have:	
Subgroup 4B:	
Must Have:	
Allogeneic Hematopoietic Stem Cell Transplant	Any instance of Group 1B occurred within 1 year on or before the first instance of TMA
Cannot Have:	

Appendix E. List of Codes Used to Define Baseline Characteristics in this Request

Code Type	Code	Description
Total Body Irradiation		
CPT	77470	Special Treatment Procedure e.g., Total Body Irradiation, Hemibody Radiation, per Oral or Endocavitary Irradiation
ICD-10-PCS	DW05*	Whole Body Beam Radiation Therapy
SNOMED	47479005	Total Body Irradiation
Chemotherapeutic Agents		
Fludarabine		
RxNorm	24698	Fludarabine
HCPCS	J9185	Injection, Fludarabine Phosphate, 50 mg
HCPCS	J8562	Oral Fludarabine Phosphate, 10 mg
Busulfan		
RxNorm	1828	Busulfan
HCPCS	J8510	Busulfan; Oral, 2 mg
HCPCS	J0594	Injection, Busulfan, 1 mg
Melphalan		
RxNorm	6718	Melphalan
HCPCS	J9246	Injection, melphalan (evomela), 1 mg
HCPCS	J9245	Injection, melphalan hydrochloride, not otherwise specified, 50 mg
ICD-10-PCS	XW053T9	Introduction of Melphalan Hydrochloride Antineoplastic into Peripheral Artery, Percutaneous Approach, New Technology Group 9
Anti-Thymocyte Globulin		
HCPCS	J7511	Lymphocyte immune globulin, antithymocyte globulin, rabbit, parenteral, 25 mg
HCPCS	J7504	Lymphocyte immune globulin, antithymocyte globulin, equine, parenteral, 250 mg
RxNorm	1011	Lymphocyte immune globulin, anti-thymocyte globulin
Indications for Allogeneic Hematopoietic Stem Cell Transplant		
Hodgkin's Lymphoma		
ICD-10-CM	C81	Hodgkin's Lymphoma
Non-Hodgkin's Lymphoma		
ICD-10-CM	C82	Follicular lymphoma
ICD-10-CM	C83	Non-follicular lymphoma
ICD-10-CM	C84	Mature T/NK-cell lymphomas
ICD-10-CM	C85	Other specified and unspecified types of non-Hodgkin lymphoma
ICD-10-CM	C86	Other specified types of T/NK-cell lymphoma
Acute Lymphocytic Leukemia (ALL)		
ICD-10-CM	C91.0	Acute Lymphocytic Leukemia (ALL)
Chronic Lymphocytic Leukemia (CLL)		
ICD-10-CM	C91.1	Chronic Lymphocytic Leukemia (CLL)
Acute Myeloid Leukemia (AML)		
ICD-10-CM	C92.0	Acute Myeloid Leukemia (AML)
Chronic Myeloid Leukemia (CML)		
ICD-10-CM	C92.1	Chronic myeloid leukemia, BCR/ABL-positive
ICD-10-CM	C92.2	Atypical chronic myeloid leukemia, BCR/ABL-negative
Polycythemia Vera		
ICD-10-CM	D45	Polycythemia Vera

Appendix E. List of Codes Used to Define Baseline Characteristics in this Request

Code Type	Code	Description
		Myelodysplastic Syndrome (MDS)
ICD-10-CM	D46	Myelodysplastic Syndrome (MDS)
		Essential Thrombocytosis
ICD-10-CM	D47.3	Essential Thrombocytosis
		Thalassemia
ICD-10-CM	D56	Thalassemia
		Sickle Cell Disease
ICD-10-CM	D57	Sickle Cell Disease
		Other Aplastic Anemias and Other Bone Marrow Failure Syndromes
ICD-10-CM	D61	Other aplastic anemias and other bone marrow failure syndromes
		Myelofibrosis
ICD-10-CM	D75.81	Myelofibrosis
		Severe Combined Immune Deficiency Syndrome (SCID)
ICD-10-CM	D81.0	Severe combined immunodeficiency with reticular dysgenesis
ICD-10-CM	D81.1	Severe combined immunodeficiency w low T- and B-cell numbers
ICD-10-CM	D81.2	Severe combined immunodef w low or normal B-cell numbers
		Clinical Characteristics
		Primary Hypertension
ICD-10-CM	I10	Primary Hypertension
		Type 2 Diabetes Mellitus
ICD-10-CM	E11	Type 2 Diabetes Mellitus
		Ischemic Heart Diseases
ICD-10-CM	I20-I25	Ischemic Heart Diseases
ICD-10-CM	I21	Acute Myocardial Infarction
ICD-10-CM	I25	Chronic Ischemic Heart Disease
		Congestive Heart Failure
ICD-10-CM	I50	Congestive Heart Failure
		Peripheral Vascular Disease
ICD-10-CM	I73	Peripheral Vascular Disease
		Cerebrovascular Diseases
ICD-10-CM	I60-I69	Cerebrovascular Diseases
ICD-10-CM	I60	Nontraumatic Subarachnoid Hemorrhage
ICD-10-CM	I61	Nontraumatic Intracerebral Hemorrhage
ICD-10-CM	I62	Other and Unspecified Nontraumatic Intracranial Hemorrhage
ICD-10-CM	I63	Cerebral Infarction
		Peptic Ulcer Disease
ICD-10-CM	K25	Gastric Ulcer
ICD-10-CM	K26	Duodenal Ulcer
ICD-10-CM	K28	Gastrojejunal Ulcer
ICD-10-CM	K27	Peptic Ulcer, Site Unspecified
		Liver Disease
ICD-10-CM	K70-K77	Liver Disease
ICD-10-CM	K73	Chronic Hepatitis, Not Elsewhere Classified

Appendix E. List of Codes Used to Define Baseline Characteristics in this Request

Code Type	Code	Description
ICD-10-CM	K74	Fibrosis and Cirrhosis of Liver
ICD-10-CM	K71	Toxic Liver Disease
ICD-10-CM	K72	Hepatic Failure, Not Elsewhere Classified
ICD-10-CM	K76.6	Portal Hypertension
		Viral Hepatitis
ICD-10-CM	B15-B19	Viral Hepatitis
		Acute Kidney Failure
ICD-10-CM	N17	Acute Kidney Failure
		Chronic Kidney Disease
ICD-10-CM	N18	Chronic Kidney Disease
		Hemiplegia and Hemiparesis
ICD-10-CM	G81	Hemiplegia and Hemiparesis
		Neoplasms
ICD-10-CM	C00-D49	Neoplasms
ICD-10-CM	C00 - C14	Malignant Neoplasms of Lip, Oral Cavity and Pharynx
ICD-10-CM	C15 - C26	Malignant Neoplasms of Digestive Organs
ICD-10-CM	C30 - C39	Malignant Neoplasms of Respiratory and Intrathoracic Organs
ICD-10-CM	C43 - C44	Melanoma and Other Malignant Neoplasms of Skin
ICD-10-CM	C50	Malignant Neoplasms of Breast
ICD-10-CM	C51 - C58	Malignant Neoplasms of Female Genital Organs
ICD-10-CM	C60 - C63	Malignant Neoplasms of Male Genital Organs
ICD-10-CM	C81 - C96	Malignant Neoplasms of Lymphoid, Hematopoietic and Related Tissue
ICD-10-CM	D00 - D09	In Situ Neoplasms
ICD-10-CM	D10 - D36	Benign Neoplasms, Except Benign Neuroendocrine Tumors
		Prescription Medications
		Defibrotide
RxNorm	1311089	Defibrotide
ICD-10-PCS	XW04392	Introduction of Defibrotide Sodium Anticoagulant into Central Vein, Percutaneous Approach, New Technology Group 2 (deprecated 2022)
ICD-10-PCS	XW03392	Introduction of Defibrotide Sodium Anticoagulant into Peripheral Vein, Percutaneous Approach, New Technology Group 2 (deprecated 2022)
		Ravulizumab
RxNorm	2107301	Ravulizumab
HCPCS	J1303	Injection, ravulizumab-cwvz, 10 mg
HCPCS	C9052	Injection, ravulizumab-cwvz, 10 mg (deprecated 2019)
		Eculizumab
RxNorm	591781	Eculizumab
HCPCS	J1300	Eculizumab injection
ICD-10-PCS	XW043C6	Introduction of Eculizumab into Central Vein, Percutaneous Approach, New Technology Group 6
ICD-10-PCS	XW033C6	Introduction of Eculizumab into Peripheral Vein, Percutaneous Approach, New Technology Group 6
		Random Urine Protein/Creatinine Ratio
LOINC	2890-2	Protein/Creatinine [mg/g] in Urine
LOINC	60678-0	Protein/Creatinine [mg/g] in 12 hour Urine

Appendix E. List of Codes Used to Define Baseline Characteristics in this Request

Code Type	Code	Description
LOINC	13801-6	Protein/Creatinine [mg/g] in 24 hour Urine
Serum Lactate Dehydrogenase (LDH)		
LOINC	2532-0	Lactate dehydrogenase [U/L] in Serum or Plasma
LOINC	14805-6	Lactate dehydrogenase [U/L] in Serum or Plasma by Pyruvate to lactate reaction
LOINC	14804-9	Lactate dehydrogenase [U/L] in Serum or Plasma by Lactate to pyruvate reaction
Creatinine levels		
LOINC	38483-4	Creatinine [mg/dL] in Blood
LOINC	2160-0	Creatinine [mg/dL] in Serum or Plasma
LOINC	20624-3	Creatinine [mg/dL] in 24 hour Urine
LOINC	30004-6	Creatinine [mg/dL] in Urine by Test strip
LOINC	57344-4	Creatinine [mg/dL] in 2 hour Urine
LOINC	57346-9	Creatinine [mg/dL] in 12 hour Urine
LOINC	35674-1	Creatinine [mg/dL] in Urine collected for unspecified duration
LOINC	2161-8	Creatinine [mg/dL] in Urine
Serum Cb-9 (complement C5b-9)		
LOINC	13117-7	Complement sc5b-9 ab [arb'U/mL] in serum or plasma
LOINC	93244-2	Complement sc5b-9 [ng/mL] in serum or plasma by immunoassay