Study information

Title	Administration of ELranaTamab In the Real-World: Treatment Patterns, Healthcare Resource Utilization, Costs, Effectiveness, anD SafEty (ALTITUDE-2)
Protocol number	C1071044
Protocol version identifier	V 2.0
Date	6 August 2025
EU Post Authorization Study (PAS) register number	EUPAS1000000293
Active substance	L01FX32. Elranatamab
Medicinal product	ELREXFIO™
Research question and objectives	The overall research question of this study is to describe the real-world usage of elranatamab. The specific objectives are as follows: **Primary** • **Objective 1:** To describe the demographics, clinical history, and treatment history of patients treated with elranatamab • **Objective 2:** To describe the administration and treatment management of elranatamab • **Objective 3:** To describe all-cause and MM-related healthcare resource utilization (HCRU) and associated costs among patients treated with elranatamab **Exploratory** • **Exploratory Objective 1:** To describe the tolerability and real-world safety of elranatamab • **Exploratory Objective 2:** To describe the overall effectiveness of elranatamab in terms of time to next treatment or death (TTNT/D) and overall survival (OS) **Exploratory Objective 3**: In a separate cohort, replicate all objectives for patients who initiated teclistamab
Country(ies) of study	United States

Author	Redacted Redacted

1. TABLE OF CONTENTS

2. LIST OF ABBREVIATIONS

Abbreviation	Definition
AE	Adverse Event
BCMA	B-Cell Maturation Antigen
BsAb	Bispecific Antibody
CAR-T	Chimeric Antigen Receptor T-Cell Therapy
CCI	Charlson Comorbidity Index
CI	Confidence Interval
CMS	Centers for Medicare and Medicaid Services
CPT	Current Procedural Terminology
CRS	Cytokine Release Syndrome
DoR	Duration of Response
EC	Ethics Committee
ED	Emergency Department
ESRD	End-Stage Renal Disease
FDA	Food and Drug Administration
FFS	Fee for Service
GPP	Good Pharmacoepidemiology Practices
HCPCS	Healthcare Common Procedure Coding System
HCRU	Healthcare Resource Utilization
ICANS	Immune Effector Cell-Associated Neurotoxicity Syndrome
ICD-10	International Classification of Diseases, 10th Edition
IMiDs	Immunomodulatory Drugs
IP	Inpatient
IQR	Interquartile Range
IRB	Institutional Review Board
mAbs	Monoclonal Antibodies
MG	Milligram
MM	Multiple Myeloma
NDC	National Drug Code

NCCN	National Comprehensive Cancer Network
OP	Outpatient
ORR	Objective Response Rate
OS	Overall Survival
PIs	Proteasome Inhibitors
PJP	Pneumocystis Jiroveci Pneumonia
PPPM	Per-Person-Per-Month
RAI	Relative Administration Intensity
RDI	Relative Dose Intensity
RRMM	Relapsed And Refractory Multiple Myeloma
SAP	Statistical Analysis Plan
SD	Standard Deviation
SDoH	Social Determinants of Health
TTD	Time to Discontinuation
TTNT/D	Time To Next Treatment/Death
US	United States
VRDC	Virtual Research Data Center

3. RESPONSIBLE PARTIES

Principal Investigator(s) of the Protocol

Name, Degree(s)	Job Title	Affiliation	Address
Redacted	Redacted	Pfizer, Inc	Redacted
Redacted	Redacted	Pfizer, Inc	Redacted
Redacted	Redacted	Pfizer, Inc	Redacted
Redacted	Redacted	Pfizer, Inc	Redacted
Redacted	Redacted	Pfizer, Inc	Redacted
Redacted	Redacted	Pfizer, Inc	Redacted
Redacted	Redacted	Pfizer, Inc	Redacted
Redacted	Redacted	Pfizer, Inc	Redacted
Redacted	Redacted	Pfizer, Inc	Redacted
Redacted	Redacted	Pfizer, Inc	Redacted
Redacted	Redacted	Redacted	Redacted
Redacted	Redacted	Redacted	Redacted
Redacted	Redacted	Redacted	Redacted

4. ABSTRACT

Title: Administration of ELranaTamab In the Real-World: Treatment Patterns, Healthcare Resource Utilization, Costs, Effectiveness, anD SafEty (ALTITUDE-2)

Version: v2.0

Date: 6 August 2025

Author: Redacted

Rationale and background: Multiple Myeloma (MM) is a hematological malignancy characterized by the proliferation of malignant plasma cells within the bone marrow. This cancerous growth disrupts the normal production of blood cells, leading to weakened immune function, anemia, bone pain, and increased susceptibility to infections. MM accounts for approximately 1% of all cancers and.

Elranatamab is a B-cell maturation antigen (BCMA) bispecific antibody (BsAb) that was approved in the United States (US) for patients with MM who have been treated with at least four lines of therapy, including a proteasome inhibitor (PIs), an immunomodulatory agent (IMiD), and an anti-CD38 monoclonal antibody (mAb). This study will describe the real-world usage, patient outcomes, and healthcare resource utilization (HCRU) associated with elranatamab in the US by leveraging up-to-date Medicare Fee for Service (FFS) data. An exploratory objective seeks to describe the real-world usage another approved BCMA BsAb, teclistamab.

Research question and objectives: This study aims to describe the real-world usage of elranatamab for the treatment of RRMM. To meet these objectives, the Clarify team will partner with Pfizer to create a curated dataset of Medicare FFS beneficiaries to serve as the foundation upon which to generate descriptive data.

The overall research question of this study is to describe the real-world usage of elranatamab. Specifically, the analysis will focus on the following primary research objectives:

Primary

- **Objective 1:** To describe the demographics, clinical history, and treatment history of patients treated with elranatamab
- **Objective 2:** To describe the administration and treatment management of elranatamab
- **Objective 3:** To describe all-cause and MM-related HCRU and associated costs among patients treated with elranatamab

Exploratory

- **Exploratory Objective 1:** To describe the tolerability and real-world safety of elranatamab
- **Exploratory Objective 2:** To describe the overall effectiveness of elranatamab in terms of time to next treatment or death (TTNT/D) and overall survival (OS)
- **Exploratory Objective 3**: In a separate cohort, replicate all objectives for patients who initiated teclistamab

Study Design: This will be a retrospective, non-interventional descriptive cohort study using de-identified patient data from US-based Medicare FFS beneficiaries. The study will utilize claims data from the Centers for Medicare and Medicaid Services (CMS), spanning from 2016 through December 2025.

Population: This study will include adult (≥18 years old) patients with an International Classification of Diseases, tenth revision (ICD-10) code for RRMM (defined as MM ICD-10 codes: C90.0x). The study cohort will include patients with RRMM who initiate elranatamab between August 14, 2023 (US approval date for elranatamab) and March 2025. The index date for patients will be defined as the date of the first prescription or medical claim for elranatamab. Patients will be required to have at least 180 days of continuous closed-claims enrollment before the index date and 30 days after the index date. Select exploratory analyses will also include a teclistamab-exposed cohort.

Variables: Based on the study cohorts of interest, patients may be characterized by the following attributes of interest:

- Demographic characteristics such as age, sex, race/ethnicity, state, and region
- Social determinants of health such as household income, education level, marital status, and homeownership
- Clinical characteristics such as comorbidities or past treatment status
- Healthcare resource utilization such as hospitalization and place of service distribution

Prior treatment history will be captured based on the use of National Comprehensive Cancer Network (NCCN) guideline-recommended treatments, which include chimeric antigen receptor T cell therapy (CAR-T), PIs, and IMiDs.

HCRU and costs will be described overall and by place of service, including inpatient (IP) visits, outpatient visits (OP, defined as non-IP/non-ED), emergency department (ED) visits, and pharmacy claims. Additionally, HCRU and associated costs will be reported as all-cause and MM-related.

Adverse events will include cytokine release syndrome (CRS), immune effector cell-associated neurotoxicity syndrome (ICANS), peripheral neuropathy, and infections. Effectiveness outcomes will include TTNT/D and OS.

Data Sources: This study will use 100% Medicare FFS claims data (including parts A, B and D) accessed through the Virtual Research Data Center (VRDC) from 2016 through December 2025.

Study Size: As of August 2024, the dataset included 133 patients with a claim for elranatamab. To further assess whether sufficient sample size is available to proceed with the study, a power analysis will be completed to assess estimates of precision for a one sample means.

Data Analysis: This study will be largely descriptive in nature, and no formal statistical comparisons will be performed. The number of patients who meet study eligibility criteria will be summarized in an attrition table. Inclusion and exclusion criteria will be listed hierarchically and the number of patients remaining at each step will be reported. Patient and treatment characteristics will be

summarized using descriptive statistics. Categorical variables will be summarized by the number of available observations, frequency, percentage, and 95% confidence limits. Continuous variables will be summarized by the number of available observations, mean, standard deviation, 95% confidence limits, median, quartiles, minimum, and maximum, where appropriate. The prevalence and incidence, as well as the associated 95% confidence intervals (CI) for each adverse event, will be estimated. Kaplan-Meier methods will be used to estimate the median time to event, including 95% CIs for TTNT/D and OS.

Milestones: Data analysis will begin 1 October 2024 and end 4 June 2025. An interim set of results will be delivered 18 December 2024 using data through September 2024. Additional interim results will be delivered in September 2025 (based on June 2025 data) and in December 2025 (based on September 2025 data) with a final analysis to be delivered in February 2026 (based on December 2025 data). A final report will be delivered in May 2026 based on this final analysis.

5. AMENDMENTS AND UPDATES

Version Identifier	Date	Amendment Type (substantial or administrative)	Protocol Section(s) Changed	Summary of Amendment(s)	Reason
V 2.0	06 August 2025	Substantial	Abstract	The study end date and corresponding data availability period were updated. Two additional interim analyses were added.	The study period was extended to increase sample size and follow-up time for analysis.
V 2.0	06 August 2025	Substantial	Milestones	The study end date and corresponding data availability period were updated. Two additional interim analyses were added.	Same as above
V 2.0	06 August 2025	Substantial	Study Design	The end date for data availability was changed from March 2025 to December 2025.	Same as above
V 2.0	06 August 2025	Substantial	Data Source	The study end date and corresponding data availability period were updated. Two additional interim analyses were added.	Same as above

V 2.0	06 August 2025	Substantial	ANNEX 2. ADDITIONAL INFORMATION	HCPC codes for IV antibiotics were added to the 'Antibiotics' section	Additional HCPC codes for IV Anti-Infectives were identified and added to the overall Antibiotics category
V 2.0	06 August 2025	Substantial	Data Analysis	Added mandatory template text about separate SAP.	Separate SAP was be developed.
V 2.0	06 August 2025	Substantial	Title page	Active substance and Medicinal product rows	Updated to match Pfizer template requirement.
V 2.0	06 August 2025	Substantial	9.6.1. Case Report Forms/Data Collection Tools/Electronic Data Record and 9.6.2. Record Retention	Sections 9.6.1 and 9.6.2 removed.	Per template instructions: Sections 9.6.1 and 9.6.2 should be deleted for studies with no human review of unstructured data; these are studies in which either of the following occurs: • All study data exist as structured data by the time of study start • The conversion of unstructured data to structured data during the implementation of the protocol is performed solely by a computer using automated/algorithmic methods, such as natural language processing.
V 2.0	06 August 2025	Substantial	List of Abbreviations	Abbreviations added	AE, EC, ESRD, CMS, SAP and VRDC were missing

V 2.0	06 August 2025	Substantial	Setting	Added the following blurb for Figure 1: "The data end date in Figure 1 will be updated at the time of the second, third, and final analyses, estimating data through June, September, and December 2025, respectively. All other dates shown in the figure will remain the same for the subsequent analyses"	This clarification was needed because of milestones change.
V 2.0	06 August 2025	Substantial	Annex 2	Code J9415 changed to J9145	while reviewing codes it was noticed a typo in the 'CD38 mAbs' and 'mAbs' codes under Annex 2. It looks like the code J9415 should actually be J9145 for Daratumumab.

6. MILESTONES

Milestone	Planned Date
Start of data collection	25 October 2024
Interim study report	18 December 2024
First interim analysis based on data through December 2024	25 June 2025
Second interim analysis based on data through June 2025	30 September 2025
Third interim analysis based on data through September 2025	19 December 2025
End of data collection	31 December 2025
Final analysis based on data through December 2025	27 February 2026
Final study report	8 May 2026

7. RATIONALE AND BACKGROUND

Multiple myeloma (MM) is a hematological malignancy originating in plasma cells in the bone marrow.[1,2] Healthy plasma cells secrete antibodies, also known as immunoglobulins, to fight infection and act as the humoral line of defense.[1,2] Plasma cells that have become cancerous (i.e., myeloma cells) proliferate and displace normal cell production in bone marrow, among other effects on the immune system. As a consequence, the general production of antibodies is impaired, decreasing the body's supply of antibodies.[3] MM is characterized by an increase in non-functional monoclonal proteins (M proteins), a decrease in blood count, renal failure, end-organ damage, susceptibility to infections, and bone weakness.[1–3] The incidence of MM was 7.4 per 100,000 people in the United States (US) from 2016-2020, while the 5-year relative survival from 2013 to 2019 was 59%.[4] MM is the second most prevalent hematological malignancy and accounted for approximately 1.8% of all new cancer cases in 2023.[5,6]

Many therapies for MM exist, and clinical advances continue to change the treatment landscape. The advent of therapies, such as proteasome inhibitors (PIs), immunomodulatory drugs (IMiDs), and monoclonal antibodies (mAbs), has increased the overall survival of MM patients.[7–9] Despite numerous advances in the available therapies for MM, most patients with MM will either relapse (fail to respond to treatment) or become refractory (have their treatment fail).[10] These patients are collectively referred to as having relapsed or refractory multiple myeloma (RRMM). Given relapse to later lines confers progressively worse outcomes including shorter survival time, there is a need to investigate alternative treatment options in this setting.[9,10]

Recent improvements in treatment for patients with RRMM included advances in B-based treatments targeting B-cell maturation antigen (BCMA), which is primarily present in malignant plasma cells. BCMA is expressed in B-cells and regulates their maturation into plasma cells.[11] BCMA bispecific antibodies (BsAb) target and bind BCMA-expressing plasma cells and the CD3 receptor on T-cells, activating cytotoxic activities of the T cell.[11] Elranatamab is approved in the US for patients who have received at least four lines of therapy, including a PI, an immunomodulatory agent, and an anti-CD38 mAbs.[12]

Teclistamab, another BCMA BsAb, was approved in October 2022, based on results from the MajesTEC-1 trials; the ORR was 63.0%, and common adverse events included infections (76.4%), cytokine release syndrome (72.1%), anemia (52.1%), and neutropenia (70.9%).[13] Elranatamab was approved in August of 2023, based on the results from the MagnetisMM-3 trial, a phase 2 trial aimed at assessing the efficacy of elranatamab monotherapy. The ORR was 61.0%, and common adverse events included infections (69.9%), cytokine release syndrome (57.7%), anemia (48.8%), and neutropenia (48.8%).[14] While some published studies have assessed the real-world utilization of other BCMA BsABs such as teclistamab, the real-world usage of elranatamab has not been characterized.[15,16] This study aims to describe the uptake and use of elranatamab subsequent to the August 2023 Food and Drug Administration (FDA) approval.

This noninterventional study is designated as a PASS and is conducted voluntarily by Pfizer.

8. RESEARCH QUESTION AND OBJECTIVES

The overall aim of the study is to understand the real-world usage of elranatamab for the treatment of MM. To meet these objectives, the Clarify team will partner with Pfizer to create a curated dataset of Medicare FFS beneficiaries and their treatments to serve as the foundation upon which to examine descriptive data.

Specifically, the analysis will focus on the following primary research objectives:

Primary

- **Objective 1:** To describe the demographics, clinical history, and treatment history of patients treated with elranatamab
- **Objective 2:** To describe the administration and treatment management of elranatamab
    - Assess administration and management details (place of service, dosage, timing, frequency, supportive MM medication usage)
    - Evaluate dose, duration, and reasons for administration interruption or discontinuation, as available
- **Objective 3:** To describe all-cause and MM-related healthcare resource utilization (HCRU) and associated costs among patients treated with elranatamab

Exploratory

- **Exploratory Objective 1:** To describe the tolerability and real-world safety of elranatamab
- **Exploratory Objective 2:** To describe the overall effectiveness of elranatamab in terms of
- time to next treatment or death (TTNT/D) and overall survival (OS)
- **Exploratory Objective 3**: In a separate cohort, replicate all objectives for patients who initiated teclistamab

9. RESEARCH METHODS

9.1. Study Design

This will be a retrospective, non-interventional descriptive cohort study using de-identified patient data from US-based Medicare Fee for Service (FFS) beneficiaries. The study will utilize claims data from the Centers for Medicare and Medicaid Services (CMS), spanning from 2016 through December 2025.

9.2. Setting

This study will evaluate adult patients with RRMM who initiate elranatamab or teclistamab. Patients will enter (i.e., index) on the first observed elranatamab or teclistamab claim between August 14, 2023 and March 2025. Limited eligibility criteria will be applied.

Study Period: Start of data (Jan 1, 2016) to the most current, available data.

MM diagnosis window: Start of data (Jan 1, 2016) to index date

Index date: First elranatamab or teclistamab claim after initial MM diagnosis

Observability: At least 180 days of continuous closed-claims medical and pharmacy enrollment prior to index (inclusive) and 30 days after the index date

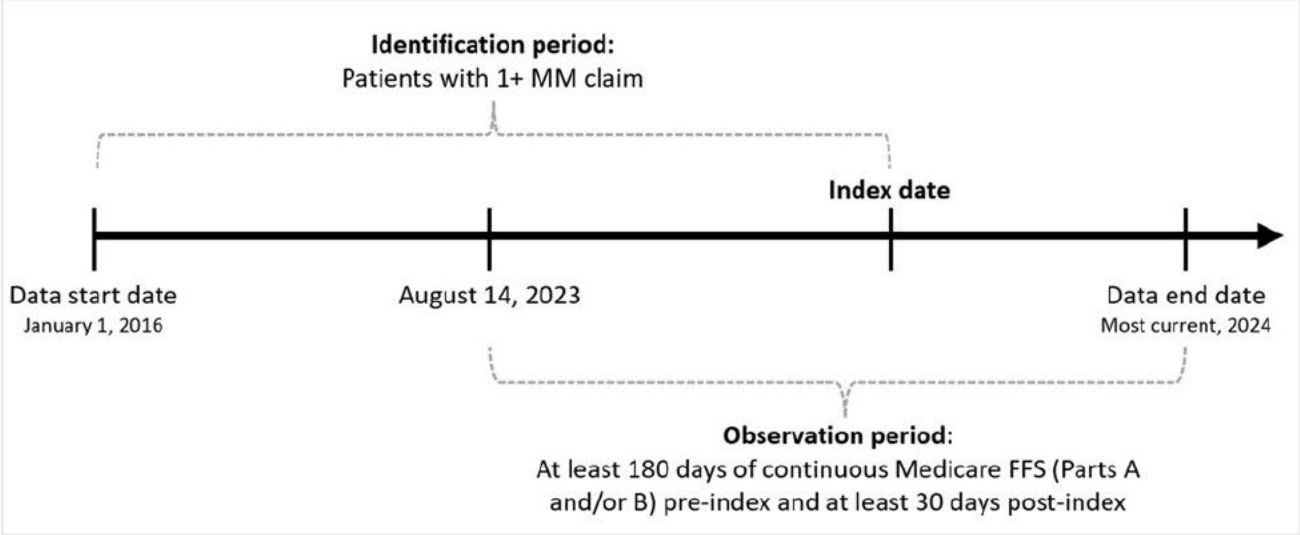
Baseline period for MM-related treatments and MM-related comorbidities: MM diagnosis to one day prior to index date

Charlson Comorbidity Index and baseline HCRU assessment window: 180 days prior to index date to index date

Follow-up: Index date until death, the earliest of end of study period, or end of continuous enrollment (unless otherwise noted). Alternative censoring criteria will be applied for certain outcomes (such as OS, TTD, and TTNT/D).

Figure 1 reflects the time periods of interest in the study cohort. The data end date in Figure 1 will be updated at the time of the second, third, and final analyses, estimating data through June, September, and December 2025, respectively. All other dates shown in the figure will remain the same for the subsequent analyses.

Figure 1. Study Schematic for Patients Receiving Elranatamab or Teclistamab



9.2.1. Inclusion Criteria

Patients must meet all of the following inclusion criteria to be eligible for inclusion in the study:

1. At least 1 observed prescription claim or medical claim for elranatamab or teclistamab in the dataset between August 14, 2023, and the most current date of data available. The index date will be the date of an individual's first claim. Patients who have received teclistamab before the August 14, 2023, date will require a period (i.e., 6 or 12 months) without a claim for teclistamab.

2. Age 18 or older on index date

3. Diagnosis of RRMM (defined as MM) any time prior to index date

4. At least 180 days of continuous closed-claims medical and pharmacy enrollment prior to index (inclusive) and 30 days post-index

9.2.2. Exclusion Criteria

Patients meeting any of the following criteria will not be included in the study:

1. Enrollment in Medicare Advantage at any point during the study period
2. Age above 115 years old on the index date
3. Any patient that is receiving/has received both elranatamab and teclistamab during the study period

9.3. Variables

Table 1 includes definitions and assessment periods for all study variables that will be used as eligibility criteria. The full code list can be found in ANNEX 2. ADDITIONAL INFORMATION.

Table 1. Variables Used to Determine Eligibility

Variable	Operational Definition	Assessment Period
Elranatamab	Prescription claim or medical claim with a National Drug Code (NDC), Healthcare Common Procedure Coding System (HCPCS), International Classification of Diseases, 10th Edition (ICD-10) code or generic name in the inpatient, non-inpatient or pharmacy setting for elranatamab	Index event
Teclistamab	Prescription claim or medical claim with an NDC, HCPCS, ICD-10 code or generic name in the inpatient, non-inpatient or pharmacy setting for teclistamab	Index event
Age	Age is greater than or equal to 18 years and is not missing	Index date
MM diagnosis	Medical claim in the inpatient or non-inpatient setting with an ICD-10 code for MM	All available data to index date
Observability	Closed-claims medical and pharmacy enrollment	180 days prior to index date to index date (inclusive) and 30 days post index
Medicare entitlement	Reason for Medicare entitlement	Index date

Table 2 includes definitions and assessment periods for all study variables that will be used as baseline and treatment characteristics. The full code list can be found in ANNEX 2. ADDITIONAL INFORMATION. If applicable, the frequency and percentage of patients with missing data for each variable will be described.

Table 2. Variables Used to Determine Baseline and Treatment Characteristics

Objective	Variable	Definition	Assessment Period(s)
1	Age	Age in years (continuous). Age will be calculated using the birth year variable from the beneficiary enrollment information.	Index date
1	Sex (assigned at birth)	Categorical sex • Male • Female • Unknown	Index date
1	Race/Ethnicity	Beneficiary enhanced race/ethnicity designation based on first and last name algorithms and the Social Security Administration race code (modified using the Research Triangle Institute algorithm). Categorical race and ethnicity • Caucasian • African American • Asian or Pacific Islander • Hispanic or Latino • Other • Unknown	Index date
1	US Census Region	Categorical region, assessed as the most recent value from index date • Northeast • Midwest • West • South • Unknown	Index date
1	State	State of residence	Index date
1	Care setting	Categorical care setting for elranatamab or teclistamab administration • Inpatient (IP) • Non-IP • Pharmacy	Index date, second treatment date, third treatment date, and overall

Objective	Variable	Definition	Assessment Period(s)
1	Time since MM diagnosis	Time (in months) from first MM diagnosis to index date (continuous)	MM diagnosis to index date
1	Income	Categorical household income	Index date
1	Education	Categorical level of highest education completed: • Some high school or less • High school • Bachelor • Graduate • Unknown	Index date
1	Marital Status	Categorical marital status: • Married • Single • Unknown	Index date
1	Home Ownership	Categorical home ownership status: • Renter • Owner • Unknown	Index date
1	Triple class exposed[17]	Medical claim in the IP, Non-IP or pharmacy setting with an NDC, HCPCS, Current Procedural Terminology (CPT), generic name, or ICD-10 procedure code for all the following therapies in the inpatient, non-IP, or pharmacy setting (dichotomous): • ≥ 1 claim for PIs (see generic names below) • ≥ 1 claim for IMiDs (see generic names below) • ≥ 1 claim for CD38 mAbs (generic names: daratumumab, isatuximab)	MM diagnosis to 1 day prior to index date
1	Penta-drug exposed[17]	Medical claims with an NDC, HCPCS, CPT, generic name, or ICD-10 procedure codes in the inpatient, non-IP or pharmacy setting for all of the following therapies(dichotomous): • ≥ 2 distinct claims for PIs (see generic names below) • ≥ 2 distinct claims for IMiDs (see generic names below) • ≥ 1 claim for CD38 mAbs (generic names: daratumumab, isatuximab)	MM diagnosis to 1 day prior to index date

Objective	Variable	Definition	Assessment Period(s)
1	Hematopoietic Stem Cell Transplantation	Medical claim with an HCPCS, CPT, or ICD-10 code for hematopoietic stem cell transplantation in the inpatient, non-IP setting (dichotomous)	MM diagnosis to 1 day prior to index date
1	BCMA-directed therapy	Medical claim with an NDC, HCPCS CPT, generic name or ICD-10 procedure code in the inpatient, non-IP, or pharmacy setting for idecabtagene vicleucel, ciltacabtagene autoleucel, or belantamab (dichotomous)	MM diagnosis to 1 day prior to indexhc date Index date to the end of follow-up
1	CAR-T	Medical claim with an NDC, HCPCS, generic name or CPT code in the inpatient, non-IP, or pharmacy setting for idecabtagene vicleucel or ciltacabtagene autoleucel (dichotomous)	MM diagnosis to 1 day prior to index date Index date to the end of follow-up
1	Talquetamab	Medical claim with an NDC, HCPCS, generic name or CPT code in the inpatient, non-IP, or pharmacy setting for talquetamab (dichotomous)	MM diagnosis to 1 day prior to index date Index date to the end of follow-up
1	PIs	Medical claim with an NDC, HCPCS, generic name or CPT code in the inpatient, non-IP, or pharmacy setting for bortezomib, carfilzomib, or ixazomib (dichotomous)	MM diagnosis to 1 day prior to index date Index date to the end of follow-up
1	IMiDs	Medical claim with an NDC code or generic name in the non-IP or pharmacy setting for lenalidomide, thalidomide, or pomalidomide (dichotomous)	MM diagnosis to 1 day prior to index date Index date to the end of follow-up
1	Steroids	Medical claim with an NDC, HCPCS, generic name or CPT code in the inpatient, non-IP, or pharmacy setting for dexamethasone, methylprednisolone, prednisone, or prednisolone (dichotomous)	MM diagnosis to 1 day prior to index date Index date to the end of follow-up

Objective	Variable	Definition	Assessment Period(s)
1	mAbs	Medical claim with an NDC, HCPCS, generic name or CPT code in the inpatient, non-IP, or pharmacy setting for daratumumab, isatuximab, or elotuzumab (dichotomous)	MM diagnosis to 1 day prior to index date Index date to the end of follow-up
1	Chemotherapies	Medical claim with an NDC, HCPCS, generic name or CPT code in the inpatient, non-IP, or pharmacy setting for doxorubicin hydrochloride, melphalan, bendamustine, cyclophosphamide, etoposide, or cisplatin (dichotomous)	MM diagnosis to 1 day prior to index date Index date to the end of follow-up
1	Small molecule inhibitors	Medical claim with an NDC, HCPCS, generic name or CPT code in the inpatient, non-IP, or pharmacy setting for venetoclax (dichotomous)	MM diagnosis to 1 day before index date Index date to the end of follow-up
1	Nuclear export inhibitors	Medical claim with an NDC, HCPCS, generic name or CPT code in the inpatient, non-IP, or pharmacy setting for selinexor (dichotomous)	MM diagnosis to 1 day before index date Index date to the end of follow-up
1	Antivirals	Medical claim with an NDC, HCPCS, generic name or CPT code in the inpatient, non-IP, or pharmacy setting for antiviral medications (dichotomous)	14 days prior to index date to 1 day prior to index date
1	Antibiotics	Medical claim with an NDC, HCPCS, generic name or CPT code in the inpatient, non-IP, or pharmacy setting for antibiotic medications (dichotomous)	14 days prior to index date to 1 day prior to index date
1	Antifungal Medication	Medical claim with an NDC, HCPCS, generic name or CPT code in the inpatient, non-IP, or pharmacy setting for antifungal medications (dichotomous)	14 days prior to index date to 1 day prior to index date
1	Intravenous immunoglobulin	Medical claim with an NDC, HCPCS, generic name, CPT, or ICD-10 procedure code in the inpatient, non-IP, or pharmacy setting for intravenous immunoglobulin administration (dichotomous)	MM diagnosis to 1 day prior to index date

Objective	Variable	Definition	Assessment Period(s)
1	Other hematological malignancies	Medical claim with an ICD-10 code in the inpatient or non-IP setting for hematological malignancies other than MM (dichotomous)	MM diagnosis to 1 day prior to index date
1	Any non-hematological malignancy	Medical claim with an ICD-10 code in the inpatient or non-IP setting for non-hematological malignancies (dichotomous)	MM diagnosis to 1 day prior to index date
1	Plasma cell leukemia	Medical claim with an ICD-10 code in the inpatient or non-IP setting for plasma cell leukemia (dichotomous)	MM diagnosis to 1 day prior to index date
1	Bone lesions	Medical claim with an ICD-10 code in the inpatient or non-IP setting for bone lesions (dichotomous)	MM diagnosis to 1 day prior to index date
1	Peripheral neuropathy	Medical claim with an ICD-10 code in the inpatient or non-IP setting for peripheral neuropathy (dichotomous)	MM diagnosis to 1 day prior to index date
1	Any infection	Medical claim with an ICD-10 code in the inpatient or non-IP setting for any infection of the following types (dichotomous): ● COVID-19 ● Adenoviral pneumonia ● Cytomegaloviral pneumonitis ● COVID-19 pneumonia ● Other Pneumonia ● Upper respiratory tract infection ● Sepsis ● Cytomegaloviral infection ● Pneumocystis jiroveci pneumonia (PJP) ● Hepatitis C ● Hepatitis B ● Other infectious hepatitis ● Helicobacter pylori ● Candida esophagitis ● Urinary tract infection ● Sinusitis ● Bronchitis	MM diagnosis to 1 day prior to index date
1	Use of intravenous anti-infective	Medical claim with an NDC code generic name, CPT, or HCPCS code in the inpatient, non-IP, or pharmacy setting for anti-infective where the route	MM diagnosis to 1 day prior to index date

Objective	Variable	Definition	Assessment Period(s)
		of administration is intravenous for an intravenous anti-infective (dichotomous)	
1	Neutropenia	Medical claim with an ICD-10 code in the inpatient or non-IP setting for neutropenia (dichotomous)	MM diagnosis to 1 day prior to index date
1	Hypercalcemia	Medical claim with an ICD-10 code in the inpatient or non-IP setting for hypercalcemia (dichotomous)	MM diagnosis to 1 day prior to index date
1	Hepatotoxicity	Medical claim with an ICD-10 code in the inpatient or non-IP setting for hepatotoxicity (dichotomous)	MM diagnosis to 1 day prior to index date
1	Renal failure	Medical claim with an ICD-10 code in the inpatient or non-IP setting for renal failure (dichotomous)	MM diagnosis to 1 day prior to index date
1	Amyloidosis	Medical claim with an ICD-10 code in the inpatient or non-IP setting for amyloidosis (dichotomous)	MM diagnosis to 1 day prior to index date
1	Hypertension	Medical claim with an ICD-10 code in the inpatient or non-IP setting for hypertension (dichotomous)	MM diagnosis to 1 day prior to index date
1	Extramedullary disease	Medical claim with an ICD-10 code in the inpatient or non-IP setting for extramedullary disease (dichotomous)	MM diagnosis to 1 day prior to index date
1	Charlson Comorbidity Index (CCI) score	CCI[18] (continuous and categorical): ● 0 (no comorbidities) ● 1 to 2 (mild) ● 3 to 4 (moderate) ● ≥ 5 (severe)	180 days prior to index date to index date
1	Myocardial infarction	Medical claim with an ICD-10 code in the inpatient or non-IP setting for myocardial infarction (dichotomous)	180 days prior to index date to index date
1	Congestive heart failure	Medical claim with an ICD-10 code in the inpatient or non-IP setting for congestive heart failure (dichotomous)	180 days prior to index date to index date

Objective	Variable	Definition	Assessment Period(s)
1	Peripheral vascular disease	Medical claim with an ICD-10 code in the inpatient or non-IP setting for peripheral vascular disease (dichotomous)	180 days prior to index date to index date
1	Cerebrovascular disease	Medical claim with an ICD-10 code in the inpatient or non-IP setting for cerebrovascular disease (dichotomous)	180 days prior to index date to index date
1	Dementia	Medical claim with an ICD-10 code in the inpatient or non-IP setting for dementia (dichotomous)	180 days prior to index date to index date
1	Chronic pulmonary disease	Medical claim with an ICD-10 code in the inpatient or non-IP setting for chronic pulmonary disease (dichotomous)	180 days prior to index date to index date
1	Rheumatic disease	Medical claim with an ICD-10 code in the inpatient or non-IP setting for rheumatic disease (dichotomous)	180 days prior to index date to index date
1	Peptic ulcer disease	Medical claim with an ICD-10 code in the inpatient or non-IP setting for peptic ulcer disease (dichotomous)	180 days prior to index date to index date
1	Liver disease	Medical claim with an ICD-10 code in the inpatient or non-IP setting for liver disease (dichotomous)	180 days prior to index date to index date
1	Diabetes	Medical claim with an ICD-10 code in the inpatient or non-IP setting for diabetes (dichotomous)	180 days prior to index date to index date
1	Renal disease	Medical claim with an ICD-10 code in the inpatient or non-IP setting for renal disease (dichotomous)	180 days prior to index date to index date
1	Hemiplegia or paraplegia	Medical claim with an ICD-10 code in the inpatient or non-IP setting for hemiplegia or paraplegia (dichotomous)	180 days prior to index date to index date
1	Human immunodeficiency virus	Medical claim with an ICD-10 code in the inpatient or non-IP setting for human immunodeficiency virus (dichotomous)	180 days prior to index date to index date

Objective	Variable	Definition	Assessment Period(s)
1	Metastatic solid tumor	Medical claim with an ICD-10 code in the inpatient or non-IP setting for metastatic solid tumor (dichotomous)	180 days prior to index date to index date

Table 3 includes definitions and assessment periods for all study variables being used as outcomes. The full code list can be found in ANNEX 2. ADDITIONAL INFORMATION. If applicable, the frequency and percentage of patients with missing data for each variable will be described.

Table 3. Key Variables of Interest

Objective	Variable	Definition	Assessment Period(s)
Treatment exposure			
2	Use of supportive MM medications	Medical or pharmacy claim with evidence of an NDC, HCPCS, generic name or CPT code for the following medications (dichotomous): • Acetaminophen • Corticosteroids (including dexamethasone) • Diphenhydramine • Tocilizumab	Index date to the end of follow-up Index date Step-Up Dosing Period Maintenance Periods
2	Reported vial size	Reported vial size in the following categories (categorical): • Unknown vial – inpatient dose • 44mg/1.1mL • 76mg/1.9mL • Missing dose/unknown dose For the cohort of teclistamab patients the reported vial size (categorical): • Unknown vial – inpatient dose • 30mg/3mL • 153mg/7mL • Missing dose/unknown dose	Index date to the end of follow-up Index date Step-Up Dosing Period Maintenance Periods
2	Average time between elranatamab or teclistamab claims	Sum of the days between claims for the index drug (continuous) divided by the total number of administrations -1	Index date to the end of follow-up Step-Up Dosing Period

			Maintenance Periods
2	Frequency of elranatamab or teclistamab claims	Total number of inpatient, non-IP, and pharmacy claims of the index drug during the time period based on vial size (continuous)	Index date to the end of follow-up Step-Up Dosing Period Maintenance Periods
2	Relative Administration Intensity (RAI)	The ratio of the actual administrations received divided by the expected number of administrations according to the US label (continuous)	Index date to the end of follow-up Step-Up Dosing Period Maintenance Periods
2	Time to Discontinuation (TTD)	Time in months from first administration until last administration prior to treatment discontinuation (continuous). Treatment discontinuation is defined as an 8-week gap in elranatamab or teclistamab therapy, next treatment after index treatment (CAR-T, BsABs, bendamustine or belantamab), or death.	Index date to the end of follow-up
2	Reason for Discontinuation	Reason for treatment discontinuation used to estimate time to discontinuation, either an 8-week gap in elranatamab or teclistamab therapy, next treatment after index treatment (CAR-T, BsABs, bendamustine or belantamab), or death.	Index date to the end of follow-up
Health care resource utilization and costs			
3	All-cause IP visits	Medical claim for IP (non-emergency department [ED]) visit (dichotomous)	Start of data to 1 day before index date, index date until last recorded dose, and time from discontinuation through time of censoring
		Number of IP (non-ED) visits (continuous)	
3	All-cause OP visits	Medical claim for non-IP/non-ED visit (dichotomous)	Start of data to 1 day before index date, index date until last recorded dose, and time from discontinuation through time of censoring
		Number of non-IP/non-ED visits (continuous)	

3	All-cause ED visits	Medical claim for ED visit (dichotomous)	Start of data to 1 day before index date, index date until last recorded dose, and time from discontinuation through time of censoring
		Number of ED visits (continuous)	
3	All-cause pharmacy claims	Pharmacy claim (dichotomous)	Start of data to 1 day before index date, index date until last recorded dose, and time from discontinuation through time of censoring
		Number of pharmacy claims (continuous)	
3	Total duration of all-cause IP stays	The total time in days of IP stays among patients who have at least 1 IP stay (continuous).	Start of data to 1 day before index date, index date until last recorded dose, and time from discontinuation through time of censoring
3	Total all-cause HCRU	IP, OP, ED, or pharmacy claims (dichotomous)	Start of data to 1 day before index date, index date until last recorded dose, and time from discontinuation through time of censoring
		Number of IP, OP, ED, or pharmacy claims (continuous)	
3	MM-related IP visits	Medical claim for IP (non-ED) visit with an MM ICD-10 code or treatment for MM (dichotomous)	Start of data to 1 day before index date, index date until last recorded dose, and time from discontinuation through time of censoring
		Number of IP (non-ED) visits with an MM ICD-10 code or treatment for MM (continuous)	
3	MM-related OP visits	Medical claim for non-IP/non-ED visit with an MM ICD-10 code or treatment for MM (dichotomous)	Start of data to 1 day before index date, index date until last recorded dose, and time from discontinuation through time of censoring
		Non-IP/non-ED visits with an MM ICD-10 code or treatment for MM (continuous)	

3	MM-related pharmacy claims	Pharmacy claim with a treatment for MM (dichotomous)	Start of data to 1 day before index date, index date until last recorded dose, and time from discontinuation through time of censoring
		Number of pharmacy claims with a treatment for MM (continuous)	
3	Total duration of MM-related IP stays	The total time in days of IP stays with an MM ICD-10 code or treatment for MM, among patients who have at least 1 IP stay (continuous)	Start of data to 1 day before index date, index date until last recorded dose, and time from discontinuation through time of censoring
3	Total MM-related HCRU	IP, OP, ED, or pharmacy claims with an MM ICD-10 code or treatment for MM (dichotomous)	Start of data to 1 day before index date, index date until last recorded dose, and time from discontinuation through time of censoring
		IP, OP, ED, or pharmacy claims with an MM ICD-10 code or treatment for MM (continuous)	
3	Cost of all-cause IP visits	Cost of IP (non-ED) visits (continuous)	Start of data to 1 day before index date, index date until last recorded dose, and time from discontinuation through time of censoring
3	Cost of all-cause OP visits	Cost of non-IP/non-ED visits (continuous)	Start of data to 1 day before index date, index date until last recorded dose, and time from discontinuation through time of censoring
3	Costs of all-cause ED visits	Cost of ED visits (continuous)	Start of data to 1 day before index date, index date until last recorded dose, and time from discontinuation through time of censoring
3	Cost of all-cause pharmacy claims	Cost of pharmacy claims (continuous)	Start of data to 1 day before index date, index date until last recorded dose, and time from

			discontinuation through time of censoring
3	Total cost of all-cause HCRU	Cost of IP, OP, ED, or pharmacy claims (continuous)	Start of data to 1 day before index date, index date until last recorded dose, and time from discontinuation through time of censoring
3	Cost of MM-related IP visits	Cost of IP (non-ED) visits with an MM ICD-10 code or treatment for MM (continuous)	Start of data to 1 day before index date, index date until last recorded dose, and time from discontinuation through time of censoring
3	Cost of MM-related OP visits	Non-IP/non-ED visits with an MM ICD-10 code or treatment for MM (continuous)	Start of data to 1 day before index date, index date until last recorded dose, and time from discontinuation through time of censoring
3	Cost of MM-related ED visits	Cost of ED visits with an MM ICD-10 code or treatment for MM (continuous)	Start of data to 1 day before index date, index date until last recorded dose, and time from discontinuation through time of censoring
3	Cost of MM-related pharmacy claims	Cost of pharmacy claims with an MM ICD-10 code or treatment for MM (continuous)	Start of data to 1 day before index date, index date until last recorded dose, and time from discontinuation through time of censoring
3	Total cost of MM-related HCRU	Cost of MM-related IP, OP, ED, or pharmacy claim (continuous)	Start of data to 1 day before index date, index date until last recorded dose, and time from discontinuation through time of censoring
Adverse events			

Exploratory Obj 1	Cytokine release syndrome (CRS)[1]	Medical claim with an ICD-10 code in the inpatient, non-IP or pharmacy setting for CRS, categorized into the following grades (categorical): ● Any (all grades and unspecified grade) ● Grade 1 ● Grade 2 ● Grade 3 ● Grade 4 ● Grade 5 If patients have multiple, conflicting grades, then the highest recorded grade will be reported	Index date to end of follow-up, where follow-up will be based on last dose of elranatamab or teclistamab (e.g., 14 days after last recorded dose or 90 days after last recorded dose).
Exploratory Obj 1	Cytokine release syndrome (CRS)[1] symptoms	Medical claim with an ICD-10 code in the inpatient, non-IP or pharmacy setting for CRS symptoms, per a algorithmic type approach (e.g., Keating algorithm, identifying patients with fever, hypotension, fatigue, headaches, hypoxia)	Index date to end of follow-up, where follow-up will be based on last dose of elranatamab or teclistamab (e.g., 14 days after last recorded dose or 90 days after last recorded dose).
Exploratory Obj 1	Immune effector cell-associated neurotoxicity syndrome (ICANS) [1]	Medical claim with evidence of an ICD-10 code in the inpatient, non-IP or pharmacy setting for ICANS, categorized into the following grades (categorical): ● Any (all grades and unspecified grade) ● Grade 1 ● Grade 2 ● Grade 3 ● Grade 4 ● Grade 5 If patients have multiple, conflicting grades then the highest recorded grade will be reported	Index date to end of follow-up, where follow-up will be based on last dose of elranatamab or teclistamab (e.g., 14 days after last recorded dose or 90 days after last recorded dose).
Hematologic events			
Exploratory Obj 1	Anemia[1]	Medical claim with an ICD-10 code in the inpatient, non-IP, or pharmacy setting for anemia (dichotomous)	Index date to end of follow-up, where follow-up will be based on last dose of elranatamab or teclistamab (e.g., 14 days after last recorded dose or

			90 days after last recorded dose).
Exploratory Obj 1	Lymphopenia[1]	Medical claim with an ICD-10 code in the inpatient, non-IP, or pharmacy setting for lymphopenia (dichotomous)	Index date to end of follow-up, where follow-up will be based on last dose of elranatamab or teclistamab (e.g., 14 days after last recorded dose or 90 days after last recorded dose).
Non-hematologic events			
Exploratory Obj 1	Hypogammaglobulinemia[1]	Medical claim with an ICD-10 code in the inpatient, non-IP, or pharmacy setting for hypogammaglobulinemia (dichotomous)	Index date to end of follow-up, where follow-up will be based on last dose of elranatamab or teclistamab (e.g., 14 days after last recorded dose or 90 days after last recorded dose).
Exploratory Obj 1	Hypophosphataemia[1]	Medical claim with an ICD-10 code in the inpatient, non-IP, or pharmacy setting for hypophosphatemia (dichotomous)	Index date to end of follow-up, where follow-up will be based on last dose of elranatamab or teclistamab (e.g., 14 days after last recorded dose or 90 days after last recorded dose).
Exploratory Obj 1	Hypokalaemia[1]	Medical claim with an ICD-10 code in the inpatient, non-IP, or pharmacy setting for hypokalemia (dichotomous)	Index date to end of follow-up, where follow-up will be based on last dose of elranatamab or teclistamab (e.g., 14 days after last recorded dose or 90 days after last recorded dose).
Exploratory Obj 1	Hepatotoxicity[1]	Medical claim with an ICD-10 code in the inpatient, non-IP, or pharmacy setting for hepatotoxicity (dichotomous)	Index date to end of follow-up, where follow-up will be based on last dose of elranatamab or teclistamab (e.g., 14 days after last recorded dose or

			90 days after last recorded dose).
Exploratory Obj 1	Renal failure[2]	Medical claim with an ICD-10 code in the inpatient, non-IP, or pharmacy setting for renal failure (dichotomous)	Index date to end of follow-up, where follow-up will be based on last dose of elranatamab or teclistamab (e.g., 14 days after last recorded dose or 90 days after last recorded dose).
Exploratory Obj 1	Peripheral neuropathy[1]	Medical claim with an ICD-10 code in the inpatient, non-IP, or pharmacy setting for peripheral neuropathy (dichotomous)	Index date to end of follow-up, where follow-up will be based on last dose of elranatamab or teclistamab (e.g., 14 days after last recorded dose or 90 days after last recorded dose).
Exploratory Obj 1	Arthralgia[3]	Medical claim with an ICD-10 code in the inpatient, non-IP, or pharmacy setting for arthralgia (dichotomous)	Index date to end of follow-up, where follow-up will be based on last dose of elranatamab or teclistamab (e.g., 14 days after last recorded dose or 90 days after last recorded dose).
Exploratory Obj 1	Pyrexia[3]	Medical claim with an ICD-10 code in the inpatient, non-IP, or pharmacy setting for pyrexia (dichotomous)	Index date to end of follow-up, where follow-up will be based on last dose of elranatamab or teclistamab (e.g., 14 days after last recorded dose or 90 days after last recorded dose).
Exploratory Obj 1	Hypotension[3]	Medical claim with an ICD-10 code in the inpatient, non-IP, or pharmacy setting for hypotension (dichotomous)	Index date to end of follow-up, where follow-up will be based on last dose of elranatamab or teclistamab (e.g., 14 days after last recorded dose or 90 days after last recorded dose).

Exploratory Obj 1	Fatigue[3]	Medical claim with an ICD-10 code in the inpatient, non-IP, or pharmacy setting for fatigue (dichotomous)	Index date to end of follow-up, where follow-up will be based on last dose of elranatamab or teclistamab (e.g., 14 days after last recorded dose or 90 days after last recorded dose).
Exploratory Obj 1	Nausea or vomiting[3]	Medical claim with an ICD-10 code in the inpatient, non-IP, or pharmacy setting for nausea or vomiting (dichotomous)	Index date to end of follow-up, where follow-up will be based on last dose of elranatamab or teclistamab (e.g., 14 days after last recorded dose or 90 days after last recorded dose).
Exploratory Obj 1	Diarrhea[3]	Medical claim with an ICD-10 code in the inpatient, non-IP, or pharmacy setting for diarrhea (dichotomous)	Index date to end of follow-up, where follow-up will be based on last dose of elranatamab or teclistamab (e.g., 14 days after last recorded dose or 90 days after last recorded dose).
Exploratory Obj 1	Rash[3]	Medical claim with an ICD-10 code in the inpatient, non-IP, or pharmacy setting for rash (dichotomous)	Index date to end of follow-up, where follow-up will be based on last dose of elranatamab or teclistamab (e.g., 14 days after last recorded dose or 90 days after last recorded dose).
Exploratory Obj 1	Angioedema[3]	Medical claim with an ICD-10 code in the inpatient, non-IP, or pharmacy setting for angioedema (dichotomous)	Index date to end of follow-up, where follow-up will be based on last dose of elranatamab or teclistamab (e.g., 14 days after last recorded dose or 90 days after last recorded dose).
Exploratory Obj 1	Erythema[3]	Medical claim with an ICD-10 code in the inpatient, non-IP, or pharmacy setting for erythema (dichotomous)	Index date to end of follow-up, where follow-up will be based on last

			dose of elranatamab or teclistamab (e.g., 14 days after last recorded dose or 90 days after last recorded dose).
Exploratory Obj 1	Muscle spasms[3]	Medical claim with an ICD-10 code in the inpatient, non-IP, or pharmacy setting for muscle spasms (dichotomous)	Index date to end of follow-up, where follow-up will be based on last dose of elranatamab or teclistamab (e.g., 14 days after last recorded dose or 90 days after last recorded dose).
Exploratory Obj 1	Musculoskeletal pain[3]	Medical claim with an ICD-10 code in the inpatient, non-IP, or pharmacy setting for musculoskeletal pain (dichotomous)	Index date to end of follow-up, where follow-up will be based on last dose of elranatamab or teclistamab (e.g., 14 days after last recorded dose or 90 days after last recorded dose).
Infections			
Exploratory Obj 1	COVID-19[2]	Medical claim with an ICD-10 code in the inpatient, non-IP, or pharmacy setting for COVID-19 (dichotomous)	Index date to end of follow-up, where follow-up will be based on last dose of elranatamab or teclistamab (e.g., 14 days after last recorded dose or 90 days after last recorded dose).
Exploratory Obj 1	Adenoviral pneumonia[2]	Medical claim with an ICD-10 code in the inpatient, non-IP, or pharmacy setting for adenoviral pneumonia (dichotomous)	Index date to end of follow-up, where follow-up will be based on last dose of elranatamab or teclistamab (e.g., 14 days after last recorded dose or 90 days after last recorded dose).
Exploratory Obj 1	Cytomegaloviral pneumonitis[2]	Medical claim with an ICD-10 code in the inpatient, non-IP, or pharmacy setting for cytomegaloviral pneumonitis (dichotomous)	Index date to end of follow-up, where follow-up will be based on last dose of elranatamab or

			teclistamab (e.g., 14 days after last recorded dose or 90 days after last recorded dose).
Exploratory Obj 1	COVID-19 pneumonia[2]	Medical claim with an ICD-10 code in the inpatient, non-IP, or pharmacy setting for COVID-19 related pneumonia (dichotomous)	Index date to end of follow-up, where follow-up will be based on last dose of elranatamab or teclistamab (e.g., 14 days after last recorded dose or 90 days after last recorded dose).
Exploratory Obj 1	Other pneumonia[2]	Medical claim with an ICD-10 code in the inpatient, non-IP, or pharmacy setting for pneumonia other than adenoviral or cytomegaloviral pneumonia (dichotomous)	Index date to end of follow-up, where follow-up will be based on last dose of elranatamab or teclistamab (e.g., 14 days after last recorded dose or 90 days after last recorded dose).
Exploratory Obj 1	Upper respiratory tract Infection[2]	Medical claim with an ICD-10 code in the inpatient, non-IP, or pharmacy setting for upper respiratory tract infection (dichotomous)	Index date to end of follow-up, where follow-up will be based on last dose of elranatamab or teclistamab (e.g., 14 days after last recorded dose or 90 days after last recorded dose).
Exploratory Obj 1	Sepsis[2]	Medical claim with an ICD-10 code in the inpatient, non-IP, or pharmacy setting for sepsis (dichotomous)	Index date to end of follow-up, where follow-up will be based on last dose of elranatamab or teclistamab (e.g., 14 days after last recorded dose or 90 days after last recorded dose).
Exploratory Obj 1	Cytomegaloviral infection[2]	Medical claim with an ICD-10 code in the inpatient, non-IP, or pharmacy setting for cytomegaloviral infection (dichotomous)	Index date to end of follow-up, where follow-up will be based on last dose of elranatamab or teclistamab (e.g., 14 days after last recorded dose or

			90 days after last recorded dose).
Exploratory Obj 1	PJP[2]	Medical claim with an ICD-10 code for PJP (dichotomous)	Index date to end of follow-up, where follow-up will be based on last dose of elranatamab or teclistamab (e.g., 14 days after last recorded dose or 90 days after last recorded dose).
Exploratory Obj 1	Hepatitis C[2]	Medical claim with an ICD-10 code in the inpatient, non-IP or pharmacy setting for hepatitis C (dichotomous)	Index date to end of follow-up, where follow-up will be based on last dose of elranatamab or teclistamab (e.g., 14 days after last recorded dose or 90 days after last recorded dose).
Exploratory Obj 1	Hepatitis B[2]	Medical claim with an ICD-10 code in the inpatient, non-IP or pharmacy setting for hepatitis B (dichotomous)	Index date to end of follow-up, where follow-up will be based on last dose of elranatamab or teclistamab (e.g., 14 days after last recorded dose or 90 days after last recorded dose).
Exploratory Obj 1	Other infectious hepatitis[2]	Medical claim with an ICD-10 code in the inpatient, non-IP or pharmacy setting for infectious hepatitis (other than hepatitis B or C) (dichotomous)	Index date to end of follow-up, where follow-up will be based on last dose of elranatamab or teclistamab (e.g., 14 days after last recorded dose or 90 days after last recorded dose).
Exploratory Obj 1	Helicobacter pylori[2]	Medical claim with an ICD-10 code in the inpatient, non-IP or pharmacy setting for helicobacter pylori (dichotomous)	Index date to end of follow-up, where follow-up will be based on last dose of elranatamab or teclistamab (e.g., 14 days after last recorded dose or 90 days after last recorded dose).

Exploratory Obj 1	Candida esophagitis[2]	Medical claim with an ICD-10 code in the inpatient, non-IP or pharmacy setting for candida esophagitis (dichotomous)	Index date to end of follow-up, where follow-up will be based on last dose of elranatamab or teclistamab (e.g., 14 days after last recorded dose or 90 days after last recorded dose).
Exploratory Obj 1	Urinary tract infection[2]	Medical claim with an ICD-10 code in the inpatient, non-IP or pharmacy setting for a urinary tract infection (dichotomous)	Index date to end of follow-up, where follow-up will be based on last dose of elranatamab or teclistamab (e.g., 14 days after last recorded dose or 90 days after last recorded dose).
Exploratory Obj 1	Time to infection onset	Time in days from index date to first infection for the following infections: ∉ COVID-19 ● Adenoviral pneumonia ● Cytomegaloviral pneumonitis ● Other Pneumonia ● Upper respiratory tract infection ● Sepsis ● Cytomegaloviral infection ● PJP ● Hepatitis C ● Hepatitis B ● Other infectious hepatitis ● Helicobacter pylori ● Candida esophagitis ● Urinary tract infection	Index date until censor
Effectiveness			
Exploratory Obj 2	OS	Time (in months) from index date until date of death (continuous)	Index date until censor
Exploratory Obj 2	TTNT/D	Time (in months) from index date until the date of the next treatment (CAR-T, BsABs, bendamustine or belantamab) or death (continuous)	Index date until censor

1. Variable will be measured as incident and prevalent. Incident cases have 30-day washout period applied
2. Variable will be measured as incident and prevalent. Incident cases have 60-day washout period applied
3. Variable will be measured as incident and prevalent. Incident cases have 14-day washout period applied

9.4. Data Sources

This study will use Medicare FFS data from the VRDC, which represents 100% of the claims for all Medicare FFS beneficiaries in the US. The Medicare FFS data includes information on patient demographic and enrollment information, as well as inpatient, outpatient, and prescription drug claims. This source of insurance claims data encompasses comprehensive, longitudinal records detailing medical procedures, diagnoses, treatments, and associated costs within the healthcare system, as well as patient characteristics and outcomes such as race/ethnicity, zip code, and all-cause mortality records. The proposed data cut for this study spans from 2016 to December 2025. Data through September 2024, June 2025, and September 2025 will be used for interim analysis, with data through December 2025 to be used for the final analysis and for the final report.

The Medicare FFS data is subject to the CMS cell size suppression policy, which sets minimum thresholds for the display of CMS data. The policy stipulates that no cell (e.g., admissions, discharges, patients, services, etc.) containing a value of 1 to 10 can be reported directly. A value of zero does not violate the minimum cell size policy. The intent of this policy is to protect patient privacy and to protect any users of the data. The implication is that the analysis can extract data only in cases where the underlying cohort size is greater than ten patients. Distributions can still be reported, e.g., so long as a patient cohort volume is not displayed as less than 11. All insights derived from the CMS dataset are subject to export and approval processes administered and scheduled by CMS.

A strong advantage of the Medicare FFS database is its representation of all Medicare beneficiaries in the US and therefore is a comprehensive view of the population of patients over age 65. However, within the Medicare population there are unique dynamics such as dual eligible status, age less than 65 and Medicare Advantage plans. The Clarify Health team is skilled at minimizing the impact of these factors. Moreover, the Medicare population are likely to be more burdened by disease than a younger, commercially insured population. Therefore, controlling for comorbidities by using something like the Charlson Comorbidity Index, or matching patients, can allow for a more robust analysis.

In addition to the Medicare FFS data that Clarify has access to from the VRDC, we source and maintain a dataset of social determinants of health (SDoH) attributes which can be linked to the Medicare FFS data at the patient level. These attributes are not available for all beneficiaries but will be included where available. As an example, attributes that can be included in the analysis are household income, household education, among others. Clarify Health is the only analytics organization with approval to do so from CMS. These attributes are sourced from third party vendors such as credit agencies and advertising agencies and have undergone validation by Clarify Health prior to ensure they are suitable for analysis.

9.5. Study Size

As of August 2024, the dataset included 133 patients with a claim for elranatamab. To further assess whether sufficient sample size is available to proceed with the study, power analysis will be completed to assess estimates of precision for a one sample means considering either the elranatamab or teclistamab samples.

9.6. Data Management

This study will leverage Medicare FFS insurance claims data from the VRDC, representing 100% of the claims for all Medicare FFS beneficiaries in the United States. This system is securely managed by CMS and access is only provided to authorized users. An analytical dataset comprising all records required for planned analyses will be created from information contained exclusively within the Clarify Health database. The analytic file will include person-level data, and will include information on baseline characteristics, study measures, and health plan enrolment dates. Variables will be created based on information from healthcare claims and enrolment information, which will be linked at the person level. Data for this study will be processed and managed exclusively by Clarify Health.

9.7. Data Analysis

This study will be largely descriptive in nature, and no formal statistical comparisons will be performed between groups. All characteristics and outcomes will be reported separately for each cohort. The number of patients who meet study eligibility criteria will be summarized in an attrition table. Inclusion and exclusion criteria will be listed hierarchically and the number of patients remaining at each step will be reported. Patient and treatment characteristics will be summarized using descriptive statistics. Categorical variables will be summarized by the number of available observations, frequency, percentage, and 95% confidence limits. Continuous variables will be summarized by the number of available observations, mean, standard deviation, 95% confidence limits, median, quartiles, minimum, and maximum, where appropriate. The prevalence and incidence, as well as the associated 95% confidence intervals (CI) for each adverse event, will be estimated. Kaplan-Meier methods will be used to estimate the median time to event, including 95% CIs for TTNT/D and OS. All-cause HCRU and MM-related HCRU will be measured as the mean, SD, median, IQR, minimum, and maximum of the total number of IP, OP, ED, and pharmacy claims. Given the variable follow-up time available for each patient, HCRU and costs will be reported, for instance, on a per-patient-per-month (PPPM) basis. Relative Administration Intensity (RAI) will be calculated as the ratio of the actual number of administrations during each time period divided by the expected number of administrations based on the label for the treatment.

Based on the study cohorts of interest, patients may be characterized by the following attributes of interest:

- Demographic characteristics such as age, sex, race/ethnicity, state, and region
- Reason for Medicare enrollment
- Social determinants of health such as household income, education level, marital status, and home ownership

- Clinical characteristics such as comorbidity and past treatment status
- Healthcare resource utilization such as hospitalization and place of service distribution

Subgroup analysis will identify samples of patients based on reason for Medicare entitlement: disabled beneficiaries, beneficiaries with end-stage renal disease (ESRD), and beneficiaries aged 65 to 115 years qualifying by age.

Additional segmentations may be added if agreed upon by Pfizer and Clarify and documented appropriately in the study protocol. These attributes can be assessed during baseline, pre-index and/or post-index as deemed appropriate by the study team.

Detailed methodology for summary and statistical analyses of data collected in this study will be documented in a statistical analysis plan (SAP), which will be dated, filed, and maintained by the sponsor. The SAP may modify the plans outlined in the protocol; any major modifications of primary endpoint definitions or their analyses would be reflected in a protocol amendment.

9.7.1. Descriptive Analysis

Dichotomous and categorical variables will be summarized by the number and percentage of patients in each category. Continuous variables will be described using mean (SD), median (IQR), minimum, and maximum. If applicable, the frequency and percentage of patients with missing data for each variable will be described. Missing categorical data will be included as a separate "missing" category. Missing continuous data will not be included in the summaries and analyses (i.e., only non-missing data will be analyzed). No imputations will be performed.

9.7.2. Treatment Exposure Outcomes

Treatment exposure outcomes include RAI and time between administrations. The assessment periods shown in Table 4 are based on the elranatamab label instructions and will be used to measure treatment and dosing-related outcomes for patients receiving elranatamab.[19] The assessment periods shown in Table 5 are based on the teclistamab label instructions and will be used to measure treatment and dosing-related outcomes for patients receiving teclistamab.[20] These periods are also provided in Figure 2.

Table 4. Dosing Schedule and Expected Administrations and Vial Size of Elranatamab

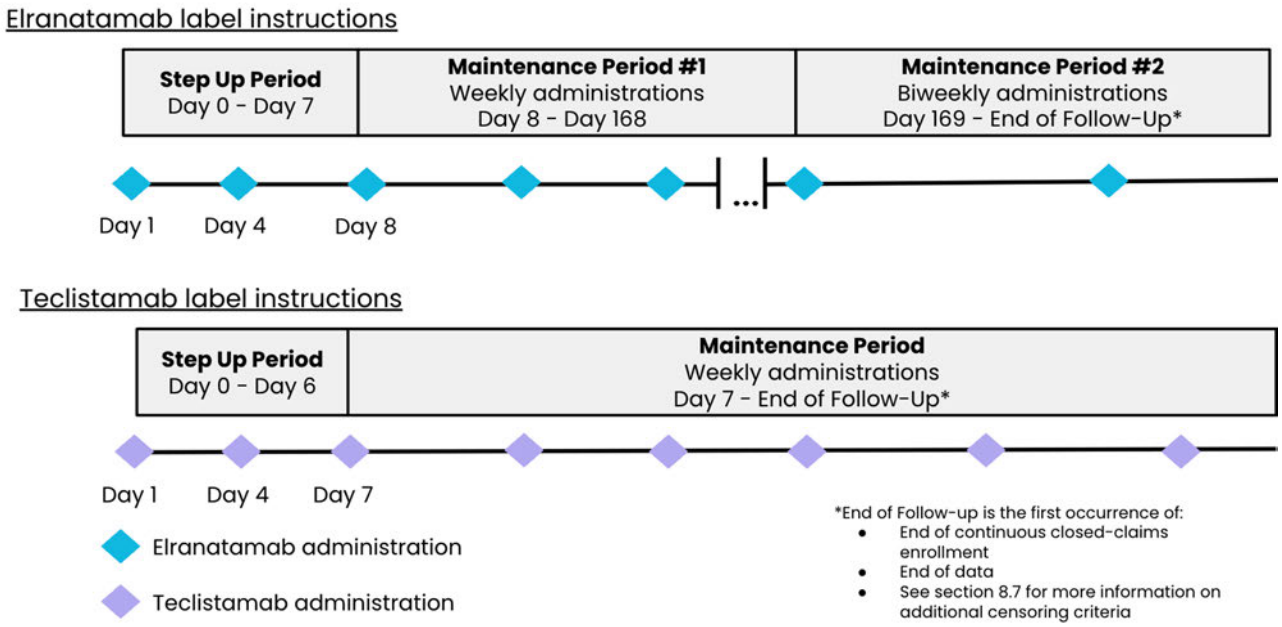
Dosing Schedule	Time Period	Expected Administrations	Vial Size
Step-Up	Index date - Day 8	3	44mg/1.1mL, 76mg/1.9mL
Maintenance Period 1	Day 9 - Day 168	1 per week	76mg/1.9mL

Maintenance Period 2	Day 169 - Censor	1 every two weeks	76mg/1.9mL

Table 5. Dosing Schedule and Expected Administrations and Vial Size of Teclistamab

Dosing Schedule	Time Period	Expected Administrations	Vial Size
Step-Up	Index date - Day 7	3	30 mg/3mL
Maintenance Period	Day 8 - Censor	1 per week	153 mg/1.7mL

Figure 2. Dosing Schedule for Elranatamab and Teclistamab



Dosing outcomes (reported vial size, average time between claims, and frequency of claims) will be assessed during the above time periods regardless of whether the number of administrations during the period matches the number indicated on the label instructions.

Patients will be censored at the earliest of death, next treatment (CAR-T, BsAbs, bendamustine or belantamab), the end of part A or B continuous closed-claim coverage, or the end of data.

9.7.3. Healthcare Resource Utilization and Cost

All-cause HCRU and MM-related HCRU (i.e., HCRU with a diagnosis code or treatment for MM) will be measured as the total number of per-patient-per-month (PPPM) IP, OP, ED, and pharmacy claims that occurred over the follow-up period. Medical claims will only be counted once per day to estimate visits. Additionally, the total length of IP stays will be reported among patients with at least one IP visit. Given the recency of the study period, costs will not be adjusted for inflation.

HCRU and costs will be measured across three different time periods: from the start of data to a day before the index date, from the index date until last recorded dose, and the time from discontinuation through the time of censoring. Patients will be censored at the earliest of death, next treatment (CAR-T, BsABs, bendamustine or belantamab), the end of part A or B continuous closed-claim coverage, or the end of data.

9.7.4. Relative Administration Intensity

RAI will be calculated as the cumulative frequency of administration received over the expected number of administrations (see Table 4 and Table 5).

$$RAI = \frac{No.\ of\ administrations\ received}{No.\ of\ expected\ administrations\ during\ the\ time\ period}$$

Treatment exposure outcomes will be assessed across the different maintenance and step-up period. Patients will be censored at the earliest of death, next treatment (CAR-T, BsABs, bendamustine or belantamab), the end of part A or B continuous closed-claim coverage, or the end of data.

9.7.5. Time to Discontinuation

Prior to the assessment of this outcome, the average follow-up time will be assessed; if the study team deems that the follow-up time is adequate, then TTD will be assessed. TTD is the total amount of time from the index date until the date of discontinuation; treatment discontinuation is defined as an 8-week gap in elranatamab or teclistamab, next treatment after index treatment (CAR-T, BsABs, bendamustine or belantamab), or death. TTD will be assessed as the time in months (1 month = 30.4375 days) using Kaplan-Meier methods. Median time-to-event will be reported along with the IQR. The 95% confidence intervals (CI) for the median time-to-event will be calculated using log-log transformation. Results will be depicted graphically by Kaplan-Meier curves. Patients who do not have a recorded discontinuation event or death will be censored on the earliest of the end of continuous closed-claim coverage or end of data. The percentage of patients who reached the outcome, as well as the percentage of censored patients, will be reported.

9.7.6. Tolerability

The prevalence and incidence for each adverse event (Table 3) will be estimated. All prevalence and incidence estimates will be reported as a percent with corresponding 95% CIs.

$$Prevalance = \left(\frac{No.\ of\ patients\ with\ an\ event}{Total\ number\ of\ patients\ in\ the\ cohort}\right) x\ 100$$

For the incidence analysis, only patients who did not have the event prior to their index date will be included. The length of the washout is dependent on the outcome (see Table 3).

$$Incidence = \left(\frac{No.\ of\ patients\ with\ an\ event\ that\ did\ not\ have\ an\ event\ in\ baseline}{Total\ number\ of\ patients\ in\ the\ cohort}\right) x\ 100$$

Patients will be assessed over two time periods: from the index date until 14 days or 90 days after their last administration of the index medication.

Additionally, the time to infection onset will be assessed using unadjusted Kaplan-Meier methods. The median time to event in days will be reported along with the IQR. The 95% CIs for the median time to event will be calculated using log-log transformation.

Patients will be censored at the earliest of death, next treatment (CAR-T, BsABs, bendamustine or belantamab), the end of part A or B continuous closed-claim coverage, or the end of data.

9.7.7. Overall Survival and Time to Next Treatment

OS and TTNT/D will be assessed using unadjusted Kaplan-Meier methods. The median time to event in months will be reported along with the IQR. The 95% CIs for the median time to event will be calculated using log-log transformation. Results will be depicted graphically by Kaplan-Meier curves, and the percentage of patients who reached the outcome and censored patients will also be reported.

OS will be assessed as the time in months from index date to date of death. TTNT/D will be assessed as the time in months from index date until switch a new treatment or death. Patients will be censored at the earliest of death, next treatment (CAR-T, BsAbs, bendamustine or belantamab), the end of continuous closed-claim coverage, or the end of data. Patients without an event will be censored at the earliest of the end of continuous closed-claim coverage or end of data.

9.8. Quality Control

Clarify Health will code measures for cohort identification, outcomes, and other variables of interest based on codes and algorithms described in this protocol. This protocol will be strictly followed when conducting the analysis of this study. All cohorts developed, statistical analyses implemented, and tables completed will undergo quality control review by at least one additional analyst or scientist under the supervision of the Study Lead. The Study Lead will review all results tables and other final deliverables to confirm accuracy, logical flow, and appropriate format.

9.9. Limitations of the Research Methods

While claims databases provide a wealth of comprehensive information to assess patients' demographic and clinical characteristics, a few limitations arise when using such databases. For instance, there may be misclassification of patient records due to provider coding practices (e.g., using a diagnosis code as a rule-out criterion) or incorrect coding (e.g., data entry errors). As such, the presence of a diagnosis code may not always accurately reflect the presence of disease for an individual patient. Such errors could affect patient eligibility and all variables used to assess treatment characteristics, HCRU, etc. Another potential issue that arises when using any database is generalizability. Oftentimes, the demographic makeup of the dataset is dependent on the providers

that supply the information; if a dataset is heavily receiving data from one region of the US, then that might affect overall generalizability.

The proposed analysis, consistent with claims analyses more generally, is subject to certain inherent limitations. The underlying Medicare data reflect a publicly-insured, elderly and/or disabled patient population and may not be representative of other payer populations. Although we plan to include individuals in the dataset aged younger than 65+ qualifying for Medicare due to a disability or ESRD status, the overall sample population will be older and have a higher disease burden than an overall US population would be.

Clinical events of interest defined by diagnosis codes may not capture the occurrence or intensity of the disease. Certain conditions, such as hematological toxicities, are often defined via specific cut-offs for certain lab values, which are not often provided in a claims data source. Therefore, ICD codes are used instead. Without lab values, the severity of the disease/grade cannot be determined. Therefore, patients whose adverse events were not as severe in grade may not be captured. Claims data do not contain variables used to assess standard oncology endpoints. Claims databases do not often detail clinical contexts, such as physician notes, imaging results, or laboratory findings. Common oncology endpoints such as real-world progression-free survival, real-world objective response rate, and reasons for discontinuation are typically defined using variables abstracted from patient charts that are not available in a claims dataset. Similarly, any treatments or drug utilization (such as over-the-counter purchasing of medications directly by patients) not directly reimbursed by the Medicare program will not be available for review.

The recency of elranatamab and teclistamab approval is important for interpreting results. The expected sample size is low, potentially resulting in uncertain estimates, as evidenced by wide confidence intervals. Very few eligibility criteria will be applied, which may allow patients with other malignancies or other conditions that are often excluded in a real-world study to enter. Additionally, the patients who have received elranatamab or teclistamab soon after approval may have more severe or advanced disease. Due to the recency of approval, the generalizability of outcomes may be limited to a brief period following initiation.

9.10. Other Aspects

Not applicable

10. PROTECTION OF HUMAN PARTICIPANTS

10.1. Patient Information

This study involves secondary data that exist in deidentified/anonymized structured format and contain no patient personal information. Clarify has been granted an IRB exemption for observational, retrospective research using the 100% Medicare FFS data accessed through the VRDC by Advarra (Columbia, MD, USA).

10.2. Patient Consent

As this study involves deidentified/anonymized structured data, which according to applicable legal requirements do not contain data subject to privacy laws, obtaining informed consent from patients by Pfizer is not required.

10.3. Institutional Review Board (IRB)/Ethics Committee (EC)

This study does not require IRB/EC approval. An exemption was received.

10.4. Ethical Conduct of the Study

The study will be conducted in accordance with legal and regulatory requirements, as well as with scientific purpose, value, and rigor and follow generally accepted research practices described in Guidelines for Good Epidemiologic Practice practices laid out in 2005 FDA Good Pharmacoepidemiology Practices (GPP),[2] Best Practices for Conducting and Reporting Pharmacoepidemiologic Safety Studies Using Electronic Healthcare Data Sets,[22] and the 2015 International Society of Pharmacoepidemiology GPP.[23]

11. MANAGEMENT AND REPORTING OF ADVERSE EVENTS/ADVERSE REACTIONS

This study involves data that exist as structured data by the time of study start. In these data sources, individual patient data are not retrieved or validated, and it is not possible to link (i.e., identify a potential association between) a particular product and medical event for any individual. Thus, the minimum criteria for reporting an adverse event (AE) (i.e., identifiable patient, identifiable reporter, a suspect product, and event) cannot be met.

12. PLANS FOR DISSEMINATING AND COMMUNICATING STUDY RESULTS

In the event of any prohibition or restriction imposed (e.g., clinical hold) by an applicable competent authority in any area of the world, or if the party responsible for collecting data from the participant is aware of any new information which might influence the evaluation of the benefits and risks of a Pfizer product, Pfizer should be informed immediately.

13. REFERENCES

1. What Is Multiple Myeloma? | Plasma Cell Cancer. Accessed April 5, 2024. https://www.cancer.org/cancer/types/multiple-myeloma/about/what-is-multiple-myeloma.html
2. Kumar SK, Callander NS, Adekola K, et al. Multiple Myeloma, Version 2.2024, NCCN Clinical Practice Guidelines in Oncology. *J Natl Compr Canc Netw*. 2023;21(12):1281-1301. doi:10.6004/jnccn.2023.0061

3. Multiple myeloma - Symptoms and causes. Mayo Clinic. Accessed April 5, 2024. https://www.mayoclinic.org/diseases-conditions/multiple-myeloma/symptoms-causes/syc-20353378
4. Cancer Statistics Center. American Cancer Society. Accessed April 5, 2024. https://cancerstatisticscenter.cancer.org/
5. Myeloma - Cancer Stat Facts. SEER. Accessed January 9, 2024. https://seer.cancer.gov/statfacts/html/mulmy.html
6. Dima D, Jiang D, Singh DJ, et al. Multiple Myeloma Therapy: Emerging Trends and Challenges. *Cancers*. 2022;14(17):4082. doi:10.3390/cancers14174082
7. Kumar SK, Rajkumar SV, Dispenzieri A, et al. Improved survival in multiple myeloma and the impact of novel therapies. *Blood*. 2008;111(5):2516-2520. doi:10.1182/blood-2007-10-116129
8. Thorsteinsdottir S, Dickman PW, Landgren O, et al. Dramatically improved survival in multiple myeloma patients in the recent decade: results from a Swedish population-based study. *Haematologica*. 2018;103(9):e412-e415. doi:10.3324/haematol.2017.183475
9. Pinto V, Bergantim R, Caires HR, Seca H, Guimarães JE, Vasconcelos MH. Multiple Myeloma: Available Therapies and Causes of Drug Resistance. *Cancers*. 2020;12(2):407. doi:10.3390/cancers12020407
10. Usmani S, Ahmadi T, Ng Y, et al. Analysis of Real-World Data on Overall Survival in Multiple Myeloma Patients With ≥3 Prior Lines of Therapy Including a Proteasome Inhibitor (PI) and an Immunomodulatory Drug (IMiD), or Double Refractory to a PI and an IMiD. *The Oncologist*. 2016;21(11):1355-1361. doi:10.1634/theoncologist.2016-0104
11. Yu B, Jiang T, Liu D. BCMA-targeted immunotherapy for multiple myeloma. *J Hematol OncolJ Hematol Oncol*. 2020;13(1):125. doi:10.1186/s13045-020-00962-7
12. Research C for DE and. FDA grants accelerated approval to elranatamab-bcmm for multiple myeloma. *FDA*. Published online August 14, 2023. Accessed April 5, 2024. https://www.fda.gov/drugs/resources-information-approved-drugs/fda-grants-accelerated-approval-elranatamab-bcmm-multiple-myeloma
13. Moreau P, Garfall AL, van de Donk NW, et al. Teclistamab in relapsed or refractory multiple myeloma. *New England Journal of Medicine.* 2022;387(6), 495-505.
14. Lesokhin, AM., Tomasson, M.H., Arnulf, B. et al. Elranatamab in relapsed or refractory multiple myeloma: phase 2 MagnetisMM-3 trial results. Nat Med 29, 2259–2267 (2023). https://doi.org/10.1038/s41591-023-02528-9
15. Riedhammer C, Bassermann F, Besemer B, et al. Real-world analysis of teclistamab in 123 RRMM patients from Germany. *Leukemia*. 2024;38(2):365-371. doi:10.1038/s41375-024-02154-5
16. Real-World Evaluation of Teclistamab for the Treatment of Relapsed/Refractory Multiple Myeloma (RRMM) | Blood | American Society of Hematology. Accessed April 9, 2024. https://ashpublications.org/blood/article/142/Supplement%201/3347/499934/Real-World-Evaluation-of-Teclistamab-for-the
17. Bal S, Malek E, Kansagra A, et al. Treatment outcomes of triple class refractory multiple myeloma: a benchmark for new therapies. *Leukemia*. 2022;36(3):877-880. doi:10.1038/s41375-021-01471-3
18. Glasheen WP, Cordier T, Gumpina R, Haugh G, Davis J, Renda A. Charlson Comorbidity Index: ICD-9 Update and ICD-10 Translation. *Am Health Drug Benefits*. 2019;12(4):188-197.
19. FDA. *ELREXFIO™ (Elranatamab-Bcmm) Injection, for Subcutaneous Use Initial U.S. Approval: 2023*.; 2023. Accessed April 5, 2024. https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/761345s000lbl.pdf
20. FDA. *TECVAYLI™ (Teclistamab-Cqyv) Injection, for Subcutaneous Use Initial U.S. Approval: 2022*.; 2022. Accessed April 5, 2024. https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/761291s000lbl.pdf

2. FDA. Guidance for Industry Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment. Published online 2005. https://www.fda.gov/files/drugs/published/Good-Pharmacovigilance-Practices-and-Pharmacoepidemiologic-Assessment-March-2005.pdf
22. Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research. Best Practices for Conducting and Reporting Pharmacoepidemiologic Safety Studies Using Electronic Healthcare Data Sets. U.S. Food and Drug Administration. Published May 2013. Accessed October 17, 2022. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/best-practices-conducting-and-reporting-pharmacoepidemiologic-safety-studies-using-electronic
23. International Society for PharmacoEpidemiology (ISPE). Guidelines for Good Pharmacoepidemiology Practices (GPP) [Issued 1996, revised August 2004, April 2007, & June 2015]. Accessed April 28, 2020. https://www.pharmacoepi.org/resources/policies/guidelines-08027/

14. LIST OF TABLES

15. LIST OF FIGURES

ANNEX 1. LIST OF STANDALONE DOCUMENTS

None.

ANNEX 2. ADDITIONAL INFORMATION

Variable	Role	Data Source(s)	Codes
Elranatamab	Inclusion criteria	Claims data	HCPCS: C9165, J1323 NDC: 00069449401, 00069449402, 00069252201, 00069252202 ICD-10 Procedure code: XW013L9 Generic name: Elranatamab
Teclistamab	Inclusion criteria	Claims data	HCPCS: J9380, C9148 NDC: 57894044901, 57894045001 ICD-10 Procedure code: XW013487Generic name: Teclistamab
Multiple Myeloma	Inclusion criteria, Outcome - HCRU	Claims data	C90.0x
Age	Inclusion criteria, Baseline characteristic - Demographic	Claims data	N/A
Sex	Baseline characteristic - Demographic	Claims data	N/A

Race/Ethnicity	Baseline characteristic - Demographic	Claims data	N/A
US Census Region	Baseline characteristic - Demographic	Claims data	N/A
State	Baseline characteristic - Demographic	Claims data	– N/A
BCMA-directed therapy	Baseline characteristic - Treatments, Outcome - HCRU	Claims data	CPT: 0537T, 0538T, 0539T, 0540T HCPCS: C9081, C9098, Q2055, Q2056, J9037, C9069 NDC: 57894011101, 57894011102, 59572051501, 59572051502, 59572051503, 00173089601 Generic names: Idecabtagene Vicleucel, Ciltacabtagene Autoleucel, Belantamab ICD10PCS: XW033K7, XW043K7, XW043A7, XW033A7
CAR-T	Baseline characteristic - Treatments, Outcome - HCRU	Claims data	CPT: 0537T, 0538T, 0539T, 0540T HCPCS: C9081, C9098, Q2055, Q2056 NDC: 57894011101, 57894011102, 59572051501, 59572051502, 59572051503 Revenue codes: 0871, 0872, 0873, 0874, 0891 ICD10PCS: XW033C7 XW033G7 XW033J7 XW033K7 XW043C7 XW043G7 XW043K7 Generic names: Idecabtagene Vicleucel, Ciltacabtagene Autoleucel
Hematopoietic stem cell transplantation	Baseline characteristic - Treatments	Claims data	CPT: 38240, 38241, 38242, 38243 HCPCS: A52879, S2150 ICD-10 Diagnosis: T86.0, T86.00, T86.01, T86.02, T86.03, T86.09, T86.5, Z48.290, Z94.81, Z94.84 ICD-10 Procedure: 30240Y0, 30243Y0, 30250Y0, 30253Y0, 30260Y0, 30263Y0, 30230Y1, 30233Y1, 30240Y1, 30243Y1, 30230Y2, 30233Y2, 30240Y2, 30243Y2, 30230Y3, 30233Y3, 30240Y3, 30243Y3, 30230Y4, 30233Y4, 30240Y4, 30243Y4, 30253Y1, 30260Y1, 30263Y1, 30233X0,

			30233G0, 30233G1, 30233G2, 30233G3, 30233X1, 30233X2, 30233X3, 30233X4, 30233Y0, 30243X0, 30243G0, 30243G1, 30243G2, 30243G3, 30243X1, 30243X2, 30243X3, 30243X4, 0243Y4, 30283X0, 30283G0, 30283G1, 30283G2, 30283G3, 30283X1, 30283X2, 30283X3, 30283X4, 30283Y1, 30283Y2, 30283Y3, 30283Y4
Talquetamab	Baseline characteristic - Treatments, Outcome - HCRU	Claims data	HCPCS: C9163 NDC: 57894046901, 57894047001 Generic name: Talquetamab
Proteasome inhibitors	Baseline characteristic - Treatments, Outcome - HCRU	Claims data	HCPCS: C9295, J9041, J9044, J9046, J9047, J9048, J9049, S0115 NDC: 00143909801, 00409170001, 00409170301, 00409170401, 00781325870, 10019099101, 25021024410, 43598042660, 43598086560, 50742048401, 51817058601, 55150033701, 60505605004, 63020004901, 63020007801, 63020007802, 63020007901, 63020007902, 63020008001, 63020008002, 63323082110, 68001053436, 68001054036, 68001054136, 70511016105, 70511016202, 70710141101, 70771170801, 70860022510, 71288011810, 72205018301, 72266024301, 72266024401, 76075010101, 76075010201, 76075010301, 83090000801 Generic names: Bortezomib, Carfilzomib, Ixazomib
Immunomodulatory drugs	Baseline characteristic - Treatments, Outcome - HCRU	Claims data	NDC: 00378193501, 00378193528, 00378193601, 00378193628, 00378193701, 00378193728, 378194001, 00378194021,00 00378194101, 00378194121, 00378194201, 00378194221, 00480124128, 00480124228, 00480124328, 00480124421, 00480124521, 00480124621, 31722025701, 31722025728, 31722025801, 31722025828, 31722025901, 31722025928, 31722026001, 31722026021, 31722026101, 31722026121, 31722026201, 31722026221, 43598051101, 43598051163, 43598051201, 43598051263, 43598051301, 43598051321, 43598051401, 43598051421, 43598051501, 43598051521, 43598051601, 43598051663, 47781048301, 47781048328, 47781048401, 47781048428, 47781048501, 47781048528, 47781048601, 47781048677, 47781048701, 47781048777, 47781048801, 47781048877, 59572020514, 59572020517, 59572020594, 59572020597, 59572021015, 59572021095, 59572021513, 59572021593,

			59572022016, 59572022096, 59572040200, 59572040228, 59572040500, 59572040528, 59572041000, 59572041028, 59572041500, 59572041521, 59572042000, 59572042021, 59572042500, 59572042521, 59572050100, 59572050121, 59572050200, 59572050221, 59572050300, 59572050321, 59572050400, 59572050421, 59651034201, 59651034207, 59651034228, 59651034301, 59651034307, 59651034328, 59651034401, 59651034407, 59651034428, 59651034501, 59651034507, 59651034521, 59651034601, 59651034607, 59651034621, 59651034701, 59651034707, 59651034721, 60505453202, 60505453301, 60505453302, 60505453401, 60505453402, 60505453501, 60505453502, 60505453602, 60505453701, 60505453702, 63304004101, 63304004127, 63304004201, 63304004227, 63304004301, 63304004327, 63304004401, 63304004422, 63304004501, 63304004522, 63304004601, 63304004622, 69097038173, 69097038273, 69097038381, 69097038481, 69097038581, 69097060473, 70710103001, 70710103007, 70710103101, 70710103107, 70710103201, 70710103207, 70710103301, 70710103308, 70710103401, 70710103408, 70710103501, 70710103508, 70771167601, 70771167607, 70771167701, 70771167707, 70771167801, 70771167807, 70771167901, 70771167908, 70771168001, 70771168008, 70771168101, 70771168108, 76282069748, 76282069848, 76282069947, 76282070148 Generic names: Lenalidomide, Thalidomide, Pomalidomide
Steroids	Baseline characteristic - Treatments, Outcome - HCRU	Claims data	HCPCS: C9034, C9256, J1020, J1030, J1040, J1094, J1095, J1096, J1100, J2920, J2930, J7312, J7509, J7637, J7638, J8540, K0512, K0513, S0173, J7506, J7512 Generic names (and associated NDCs): Dexamethasone, Methylprednisolone, Prednisone, Prednisolone
CD38 mAbs	Baseline characteristic - Treatments, Outcome - HCRU	Claims data	HCPCS: C9062, C9476, J9144, J9227, J9145 NDC: 00024065401, 00024065601, 57894050205, 57894050220, 57894050301, 57894050505, 57894050520 Generic names: Daratumumab, Isatuximab
mAbs	Baseline characteristic - Treatments,	Claims data	HCPCS: C9062, C9476, J9144, J9227, J9145, C9477, J9176

	Outcome - HCRU		NDC: 00024065401, 00024065601, 57894050205, 57894050220, 57894050301, 57894050505, 57894050520, 00003229111, 00003452211 Generic names: Daratumumab, Isatuximab, Elotuzumab
Chemotherapies	Baseline characteristic - Treatments, Outcome - HCRU	Claims data	HCPCS: C9080, C9087, C9243, C9420, C9421, J8530, J8600, J9033, J9034, J9036, J9056, J9058, J9059, J9070, J9071, J9080, J9090, J9091, J9092, J9093, J9094, J9095, J9096, J9097, J9245, J9246, J9247, J9000, C9415, J9002, Q2048, Q2049, Q2050, J9001, J9181, J9182, C9425, J8560, C9414, C9418, J9060, J9062 Generic names (and associated NDC codes): Melphalan, Bendamustine, Cyclophosphamide, Doxorubicin, Etoposide, Cisplatin
Small molecule inhibitors	Baseline characteristic - Treatments, Outcome - HCRU	Claims data	NDC: 00074056111, 00074056114, 00074056607, 00074056611, 00074057611, 00074057622, 00074057630, 00074057634, 00074057928 Generic name: Venetoclax
Nuclear export inhibitors	Baseline characteristic - Treatments, Outcome - HCRU	Claims data	NDC: 72237010401, 72237010101, 72237010102, 72237010103, 72237010104, 72237010105, 72237010106, 72237010107, 72237010202, 72237010206, 72237010207, 72237010305 Generic name: Selinexor
Antivirals	Baseline characteristic - Treatments	Claims data	HCPCS/CPT: J0133, Q4075, S0071, G9017, G9033, S0137, J1324, J1452, J1455, 67027, C9412, J1570, J1574, J7310, J1746, G9019, G9035, J2547, J0248, J0741, G9020, G9036, S0140, 0025U, G9018, G9034, J3485, S0104 Generic names (and associated NDC codes): Abacavir, Acyclovir, Amantadine, Atazanavir, Baloxavir Marboxil, Bictegravir, Brivudin, Cobicistat, Daclatasvir, Darunavir, Delavirdine, Didanosine, Dolutegravir, Doravirine, Efavirenz, Elvitegravi, Emtricitabine, Enfuvirtide, Entecavir, Etravirine, Famciclovir, Fomivirsen, Fosamprenavir, Foscarnet, Fostemsavir, Ganciclovir, Ibalizumab, Indinavir, Lamivudine, Ledipasvir, Lenacapavir, Letermovir, Lopinavir, Maraviroc, Maribavir, Molnupiravir, Nelfinavir,

			Nevirapine, Nevirapine, Nirmatrelvir/Ritonavir, Oseltamivir, Pemivibart, Penciclovir, Peramivir, Raltegravir, Remdesivir, Rilpivirine, Rimantadine, Ritonavir, Saquinavir, Simeprevir, Sofosbuvir, Stavudine, Tecovirimat, Tenofovir, Tenofovir, Tipranavi, Valaciclovir, Valacyclovir, Valganciclovir, Vilobelimab, Zanamivir, Zidovudine
Antibiotics	Baseline characteristic - Treatments	Claims data	HCPCS/CPT : 4041F, 4047F, 4048F, C9001, C9039, C9054, C9116, C9124, C9228, C9241, C9258, C9282, C9443, C9444, C9446, C9462, G8152, G8191, G8192, G8195, G8197, G8198, G8199, G8503, G8504, G8527, G8629, G8630, G9315, J0120, J0121, J0122, J0200, J0278, J0290, J0291, J0295, J0456, J0530, J0540, J0550, J0558, J0559, J0560, J0561, J0580, J0689, J0690, J0691, J0692, J0694, J0695, J0696, J0697, J0698, J0699, J0701, J0703, J0710, J0712, J0713, J0714, J0715, J0720, J0742, J0743, J0744, J0770, J0875, J0877, J0878, J1267, J1335, J1362, J1364, J1580, J1590, J1840, J1850, J1890, J1956, J2010, J2020, J2021, J2184, J2185, J2186, J2265, J2280, J2281, J2406, J2407, J2460, J2510, J2540, J2543, J2700, J2770, J2970, J3000, J3090, J3095, J3243, J3244, J3260, J3320, J3370, J3371, J3372, J7342, J7682, J7685, Q0144, S0016, S0021, S0024, S0030, S0032, S0034, S0039, S0040, S0072, S0073, S0074, S0077, S0081, S0085, S0142, S0143, J0457, J0688, J0687, J0736, J0737, J0872, J0873, J0874, J1271, J1836, J2290, J3374, J3375, J2183 Generic names (and associated NDC codes): Penicillin, Tobramycin, Cycloserine, Vancomycin, Capreomycin, Cefazolin, Streptomycin, Neomycin, Bacitracin, Sulfadiazine, Isoniazid, Cefaclor, Loracarbef, Cefuroxime, Cephalothin, Cefamandole, Ceftazidime, Drotrecogin Alfa, Amoxicillin, Cephradine, Ampicillin, Sulfamethoxazole, Erythromycin, Dicloxacillin, Cloxacillin, Metronidazole, Tetracycline, Doxycycline, Cephalexin, Nitrofurantoin, Aztreonam, Oxacillin, Nafcillin, Cefepime, Sulfisoxazole, Trimethoprim, Sulfisoxazole Acetyl, Ceftriaxone, Erythromycin Ethylsuccinate, Cefixime, Sulfasalazine, Ethambutol, Pyrazinamide, Minocycline, Demeclocycline, Norfloxacin, Cefoxitin, Imipenem, Ertapenem, Ceftizoxime, Cefonicid, Ethionamide,

			Tigecycline, Clindamycin, Lincomycin, Spectinomycin, Gentamicin, Cefpodoxime, Linezolid, Rifabutin, Gatifloxacin, Amikacin, Kanamycin, Cefadroxil, Cephapirin, Sulfanilamide, Sulfacetamide, Chloramphenicol, Dapsone, Polymyxin, Nalidixic Acid, Mafenide, Lomefloxacin, Mezlocillin, Ciprofloxacin, Ciprofloxacin Lactate, Moxifloxacin, Clofazimine, Mupirocin, Ticarcillin, Cefotetan, Cefotaxime, Silver Sulfadiazine, Levofloxacin, Oxytetracycline, Cefoperazone, Trovafloxacin Mesylate, Clarithromycin, Tinidazole, Ofloxacin, Doripenem, Sulfathiazole, Rifampin, Chloramphenicol Sod Succinate, Meropenem, Azithromycin, Cefdinir, Paromomycin, Colistin, Enoxacin, Sparfloxacin, Quinupristin, Netilmicin, Ceftibuten, Cefprozil, Rifapentine, Telithromycin, Daptomycin, Furazolidone, Bismuth Subsalicylate, Grepafloxacin, Piperacillin, Cefditoren, Ceftaroline Fosamil, Fosfomycin Tromethamine, Telavancin, Polymyxin B Sulfate, Gemifloxacin, Rifaximin, Sarecycline, Bacitracin,, Chloramphenicol Palmitate, Chlortetracycline, Trimethoprim,, Aminosalicylic, Pretomanid, Bacitracin Zinc, Fidaxomicin, Colloidal Bismuth Subcitrate, Omeprazole, Rifamycin, Dalbavancin, Cefiderocol, Bedaquiline, Oritavancin, Ceftolozane, Tedizolid, Plazomicin, Ozenoxacin, Delafloxacin Meglumine, Triamcinolone, Omadacycline, Eravacycline, Lefamulin, Ivermectin, Salicylic Acid
Antifungals	Baseline characteristic - Treatments	Claims data	HCPCS: J0285, J0286, J0287, J0288, J0289, 80285, J3465, J1450, J2248, J1835, J0637, J0348 Generic name (and associated NDC codes): Amphotericin B, Voriconazole, Natamycin, Fluconazole, Micafungin, Posaconazole, Itraconazole, Caspofungin, Anidulafungin, Isavuconazole, Nystatin
Intravenous immunoglobulin	Baseline characteristic - Treatments	Claims data	CPT: 90283 HCPCS: C9072, C9130, C9270, G0332, J1459, J1554, J1556, J1557, J1566, J1568, J1572, J1576, J1599, Q4087, Q4088, Q4091, Q4092, Q4097, Q9941, Q9942, Q9943, Q9944 ICD-10 Procedure: 30233S1, 30243S1, 30253S1, 30263S1 NDC: 00026064012, 00026064020, 00026064071, 00026064512, 00026064515,

			00026064520, 00026064524, 00026064571, 00026064612, 00026064620, 00026064624, 00026064625, 00026064671, 00026064812, 00026064815, 00026064820, 00026064871, 00026064912, 00026064920, 00026064924, 00026064971, 00069101101, 00069101102, 00069110901, 00069110902, 00069122401, 00069122402, 00069131201, 00069131202, 00069141501, 00069141502, 00069155801, 00069155802, 00078012058, 00078012094, 00078012219, 00078012259, 00078012295, 00078012419, 00078012460, 00078012496, 00078024419, 00078024493, 00192064012, 00192064020, 00192064025, 00192064071, 00192064912, 00192064920, 00192064924, 00192064971, 00944047169, 00944047172, 00944047175, 00944047180, 00944262001, 00944262002, 00944262003, 00944262004, 00944262005, 00944262006, 00944262007, 00944262008, 00944262302, 00944262406, 00944262503, 00944262607, 00944262704, 00944262808, 00944265503, 00944265504, 00944265603, 00944265707, 00944265804, 00944265908, 00944280704, 05276947180, 13533064512, 13533064515, 13533064520, 13533064524, 13533064571, 13533064612, 13533064620, 13533064624, 13533064625, 13533064671, 13533064812, 13533064815, 13533064820, 13533064824, 13533064871, 44206012058, 44206012259, 44206012460, 44206022600, 44206022601, 44206026661, 44206026763, 44206026866, 44206026972, 44206041501, 44206041603, 44206041690, 44206041706, 44206041791, 44206041812, 44206041892, 44206043605, 44206043690, 44206043710, 44206043791, 44206043820, 44206043892, 44206043940, 44206043992, 44206043993, 44206050551, 44206050653, 44206050756, 44206050806, 49669161201, 49669161301, 49669161401, 49669162201, 49669162301, 49669162401, 52769026866, 52769026972, 52769027071, 52769027073, 52769027076, 52769027082, 52769041501, 52769041603, 52769041706, 52769041812, 52769047172, 52769047175, 52769047180, 54129023310, 54129023350, 54238023305, 59730650201, 59730650301, 61953000301, 61953000302, 61953000303, 61953000304, 61953000400, 61953000401, 61953000402, 61953000403, 61953000404, 61953000405, 61953000406, 61953000407, 61953000408, 61953000409, 61953000501, 61953000502, 61953000503, 61953000504, 61953000505, 61953000506, 64193025050, 64208194801, 64208823401, 64208823402, 64208823403,

			64208823404, 64208823405, 64208823406, 64208823407, 64208823408, 64208823501, 64208823502, 64208823503, 64208823505, 64208823506, 64208823507, 67467084301, 67467084302, 67467084303, 67467084304, 67467084305, 68209084301, 68209084302, 68209084303, 68209084304, 68209084305, 68516162301, 68982082001, 68982082002, 68982082003, 68982082004, 68982082005, 68982082006, 68982082081, 68982082082, 68982082083, 68982082084, 68982082085, 68982082086, 68982082201, 68982082202, 68982082203, 68982082204, 68982082205, 68982082206, 68982082281, 68982082282, 68982082283, 68982082284, 68982082285, 68982082286, 68982084001, 68982084002, 68982084003, 68982084004, 68982084005, 68982085001, 68982085002, 68982085003, 68982085004, 68982085005, 69800025001, 69800025002, 69800650201, 69800650202, 69800650301, 69800650302, 76125091804, 76125091805, 76125091809, 76125091810
Other hematological malignancies	Baseline characteristic - Clinical	Claims data	ICD-10 Diagnosis: Non–Hodgkin's lymphoma: C82x, C83x, C84x, C85x Hodgkin’s lymphoma: C81x Lymphoid leukemia: C91x Leukemia: C92x-C95x
Any non-hematological malignancy	Baseline characteristic - Clinical	Claims data	ICD-10 Diagnosis: C0x.x, C1x.x, C2x.x, C30.x, C31.x, C32.x, C33.x, C34.x, C37.x, C38.x, C39.x, C40.x, C41.x, C43.x, C45.x, C46.x, C47.x, C48.x, C49.x, C50, C51-58.x, C60-63.x, C76.x, C80.1
Plasma cell leukemia	Baseline characteristic - Clinical	Claims data	ICD-10 Diagnosis: C90.1x
Acute graft vs host disease	Baseline characteristic - Clinical	Claims data	ICD-10 Diagnosis: D89.810
Bone lesions	Baseline characteristic - Clinical	Claims data	ICD-10 Diagnosis: D16.0-D16.9, M85.0, M85.4-M85.6, D48.0
Peripheral neuropathy	Baseline characteristic -	Claims data	ICD-10 Diagnosis: G90.50, G90.513, G90.511, G90.512, G90.519, G90.521, G90.529, G90.522, G90.523, G90.59, G54.0, G55., G54.2, G54.4, E08.41, E09.41, E10.41, E11.41,

	Clinical, Adverse event		E13.41, G57.70, G57.71, G57.72, G57.73, G59, G57.80, G57.81, G57.82, G57.83, G58.8, G58.9, G64., G61.0, M05.50, M05.511, M05.512, M05.519, M05.521, M05.522, M05.529, M05.531, M05.532, M05.539, M05.541, M05.542, M05.549, M05.551, M05.552, M05.559, M05.561, M05.562, M05.569, M05.571, M05.572, M05.579, M05.59, E08.40, E08.42, E09.40, E09.42, E10.40, E10.42, E11.40, E11.42, E13.40, E13.42, G13.0, G13.1, A36.83, A52.15, G63, M34.83, G62.1, G61.1, G62.0, G62.2, G62.82, G61.81, G62.81, G61.89, G62.89, G61.9, G62.9, H46.3, M54.10, M54.18, M79.2, R20.0, R20.1, R20.2, R20.3, R20.8, R20.9
Any infection	Baseline characteristic - Clinical	Claims data	An ICD-10 Diagnosis Code for any of the following types of infections. See the rows below for codes for each infection type. COVID-19, Adenoviral pneumonia, Cytomegaloviral pneumonitis, Other Pneumonia, Upper respiratory tract infection, Sepsis, Cytomegaloviral infection, Pneumocystis jiroveci pneumonia (PJP), Hepatitis C, Hepatitis B, Other infectious hepatitis, Helicobacter pylori, Candida esophagitis, Urinary tract infection
Use of intravenous anti-infective	Baseline characteristic - Clinical	Claims data	See “Antivirals” and “Antibiotics” above
Neutropenia	Baseline characteristic - Clinical, Adverse event	Claims data	ICD-10 Diagnosis: D70x
Hypercalcemia	Baseline characteristic - Clinical	Claims data	ICD-10 Diagnosis: E83.52
Hypoxia	Baseline characteristic - Clinical, Adverse event	Claims data	ICD-10 Diagnosis: J96.20, J96.11, J96.90, J96.01, J96.00, J96.10, J96.21, J96.91, I27.23, R09.02
Hepatotoxicity	Baseline characteristic - Clinical, Adverse event	Claims data	ICD-10 Diagnosis: K71.x
Renal failure	Baseline characteristic -	Claims data	ICD-10 Diagnosis: N17x, N18x, N19x, R34x, T82.4, Z49.02, Z99.2

	Clinical, Adverse event		
Amyloidosis	Baseline characteristic - Clinical	Claims data	ICD-10 Diagnosis: E85.4x, E85.8x, E85.9x
Hypertension	Baseline characteristic - Clinical	Claims data	ICD-10 Diagnosis: I10x-I15x, I16x
Extramedullary disease	Baseline characteristic - Clinical	Claims data	ICD-10 Diagnosis: C90.2x
CCI score	Baseline characteristic - Clinical	Claims data	See components below
Myocardial infarction	Baseline characteristic - Clinical	Claims data	ICD-10 Diagnosis: I21.x, I22.x, I25.2
Congestive heart failure	Baseline characteristic - Clinical	Claims data	ICD-10 Diagnosis: I11.0, I13.0, I13.2, I25.5, I42.0, I42.5, I42.6, I42.7, I42.8, I42.9, I43.x, I50.x, P29.0
Peripheral vascular disease	Baseline characteristic - Clinical	Claims data	ICD-10 Diagnosis: I70.x, I71.x, I73.1, I73.8, I73.9, I77.1, I79.0, I79.1, I79.8, K55.1, K55.8, K55.9, Z95.8, Z95.9
Cerebrovascular disease	Baseline characteristic - Clinical	Claims data	ICD-10 Diagnosis: G45.x, G46.x, H34.0x, H34.1x, H34.2x, I60.x, I61.x, I62.x, I63.x, I64.x, I65.x, I66.x, I67.x, I68.x
Dementia	Baseline characteristic - Clinical	Claims data	ICD-10 Diagnosis: F01.x, F02.x, F03.x, F04, F05, F06.1, F06.8, G13.2, G13.8, G30.x, G31.0x, G31.1, G31.2, G91.4, G94, R41.81, R54
Chronic pulmonary disease	Baseline characteristic - Clinical	Claims data	ICD-10 Diagnosis: J40.x, J41.x, J42.x, J43.x, J44.x, J45.x, J46.x, J47.x, J60.x, J61.x, J62.x, J63.x, J64.x, J65.x, J66.x, J67.x, J68.4, J70.1, J70.3
Rheumatic disease	Baseline characteristic - Clinical	Claims data	ICD-10 Diagnosis: M05.x, M06.x, M31.5, M32.x, M33.x, M34.x, M35.1, M35.3, M36.0
Peptic ulcer disease	Baseline characteristic - Clinical	Claims data	ICD-10 Diagnosis: K25.x, K26.x, K27.x, K28.x

Liver disease	Baseline characteristic - Clinical	Claims data	ICD-10 Diagnosis: B18.x, K70.0, K70.1, K70.2, K70.3, K70.9, K71.3, K71.4, K71.5, K71.7, K73.x, K74.x, K76.0, K76.2, K76.3, K76.4, K76.8, K76.9, Z94.4, I85.0x, I86.4, K70.4x, K71.1x, K72.1x, K72.9x, K76.5, K76.6, K76.7
Diabetes	Baseline characteristic - Clinical	Claims data	ICD-10 Diagnosis: E08.0x, E08.1x, E08.6x, E08.8x, E08.9x, E09.0x, E09.1x, E09.6x, E09.8x, E09.9x, E10.0x, E10.1x, E10.6x, E10.8x, E10.9x, E11.0x, E11.1x, E11.6x, E11.8x, E11.9x, E13.0x, E13.1x, E13.6x, E13.8x, E13.9x, E08.2x, E08.3x, E08.4x, E08.5x, E09.2x, E09.3x, E09.4x, E09.5x, E10.2x, E10.3x, E10.4x, E10.5x, E11.2x, E11.3x, E11.4x, E11.5x, E13.2x, E13.3x, E13.4x, E13.5x
Renal disease	Baseline characteristic - Clinical	Claims data	ICD-10 Diagnosis: I12.9, I13.0, I13.10, N03.x, N05.x, N18.1, N18.2, N18.3, N18.4, N18.9, Z94.0, I12.0, I13.11, I13.2, N18.5, N18.6, N19.x, N25.0, Z49.x, Z99.2
Hemiplegia or paraplegia	Baseline characteristic - Clinical	Claims data	ICD-10 Diagnosis: G04.1, G11.4, G80.0, G80.1, G80.2, G81.x, G82.x, G83.x
Human immunodeficiency virus	Baseline characteristic - Clinical	Claims data	ICD-10 Diagnosis: B20.x
Metastatic solid tumor	Baseline characteristic - Clinical	Claims data	ICD-10 Diagnosis: C77.x, C78.x, C79.x, C80.0, C80.2
Use of premedication	Outcome - Dosing and Administration Patterns	Claims data	HCPCS: J1094, J1096, J8540, J1100, J0131, J7637, J7638, J7312, J1200, Q0163 Generic names (and associated NDCs): Acetaminophen, Dexamethasone, Diphenhydramine
Inpatient	Baseline characteristic, Outcome - HCRU	Claims data	Any event in the inpatient table or an event in the non-inpatient table where acute_subacute is “acute inpatient” or where utilization type is “professional services”, and service subcategory contains the term “hospital/IP encounter”
Outpatient	Baseline characteristic, Outcome - HCRU	Claims data	Any event in the non-inpatient table where utilization type is outpatient and service subcategory is not “emergency dept encounter”

Emergency department	Baseline characteristic, Outcome - HCRU	Claims data	Any event in the non-inpatient table where utilization type is “outpatient” and service subcategory is “emergency dept encounter”
Cytokine release syndrome (CRS)	Safety events	Claims data	ICD-10 Diagnosis: D89.83x
Immune effector cell-associated neurotoxicity Syndrome (ICANS)	Adverse events	Claims data	ICD-10 Diagnosis: G92.0x
Anemia	Adverse events	Claims data	ICD-10 Diagnosis: D46.0, D46.1, D46.20, D46.21, D46.22, D46.4, D46.9, D46.A, D46.B, D46.C, D46.Z, D47.4, D50.0, D50.1, D50.8, D50.9, D51.0, D51.1, D51.2, D51.3, D51.8, D51.9, D52.0, D52.1, D52.8, D52.9, D53.0, D53.1, D53.2, D53.8, D53.9, D55.0, D55.1, D55.2, D55.21, D55.29, D55.3, D55.8, D55.9, D59.0, D59.1, D59.10, D59.11, D59.12, D59.13, D59.19, D59.2, D59.3, D59.30, D59.31, D59.39, D59.4, D59.5, D59.6, D59.8, D59.9, D60.0, D60.1, D60.8, D60.9, D61.01, D61.09, D61.1, D61.2, D61.3, D61.810, D61.811, D61.818, D61.82, D61.89, D61.9, D63.0, D63.1, D63.8, D64.1, D64.2, D64.3, D64.81, D64.89, D64.9, D75.81
Lymphopenia	Adverse events	Claims data	ICD-10 Diagnosis: D72.810
Hypogammaglobulinemia	Adverse events	Claims data	ICD-10 Diagnosis: D80.1, D80.3, D80.9
Hypophosphataemia	Adverse events	Claims data	ICD-10 Diagnosis: E83.39
Hypokalaemia	Adverse events	Claims data	ICD-10 Diagnosis: E87.6
Arthralgia	Adverse events	Claims data	ICD-10 Diagnosis: M25.5x
Pyrexia	Adverse events	Claims data	ICD-10 Diagnosis: R50.x
Hypotension	Adverse events	Claims data	ICD-10 Diagnosis: I95.0, I95.81, I95.89, I95.9, I95.2
Fatigue	Adverse events	Claims data	ICD-10 Diagnosis: R53.x, G93.3x

Nausea or vomiting	Adverse events	Claims data	ICD-10 Diagnosis: R11.x
Diarrhea	Adverse events	Claims data	ICD-10 Diagnosis: R19.7, K59.1
Rash	Adverse events	Claims data	ICD-10 Diagnosis: R21, D72.12
Angioedema	Adverse events	Claims data	ICD-10 Diagnosis: T78.3X, D72.118
Erythema	Adverse events	Claims data	ICD-10 Diagnosis: L53.0, L53.1, L53.2, L51, L52, L71.0, L71.1, L71.8, L93.0, L93.2, L49.0, L49.1, L49.2, L49.3, L49.4, L49.5, L49.6, L49.7, L49.8, L49.9, L00, L26, L30.4, L53.8, L92.0, L95.1, L98.2, L53.9
Muscle spasms	Adverse events	Claims data	ICD-10 Diagnosis: M62.83X
Musculoskeletal pain	Adverse events	Claims data	ICD-10 Diagnosis: M25.50, M25.522, M25.551, M25.552, M25.561, M25.562, M25.572, M25.579, M25.59, M25.612, M25.621, M25.629, M25.631, M25.641, M25.642, M25.652, M25.661, M25.662, M25.669, M25.671, M25.673, M25.674, M25.675, M25.676, M54.6, M54.81, M79.1, M79.12, M79.18, M79.621, M79.622, M79.631, M79.639, M79.641, M79.644, M79.646, M79.652, M79.659, M79.661, M79.662, M79.669, M79.671, M79.673, M79.675, M25.511, M25.512, M25.519, M25.521, M25.529, M25.531, M25.532, M25.539, M25.541, M25.542, M25.549, M25.559, M25.569, M25.571, M25.60, M25.611, M25.619, M25.622, M25.632, M25.639, M25.649, M25.651, M25.659, M25.672, M25.69, M54.89, M54.9, M79.10, M79.11, M79.601, M79.602, M79.603, M79.604, M79.605, M79.606, M79.609, M79.629, M79.632, M79.642, M79.643, M79.645, M79.651, M79.672, M79.674, M79.676
COVID-19	Adverse event - infection	Claims data	ICD-10 Diagnosis: U07. 1

COVID-19 pneumonia	Adverse event - infection	Claims data	ICD-10: J12.82
Adenoviral pneumonia	Adverse event - infection	Claims data	ICD-10 Diagnosis: J12.0
Cytomegaloviral pneumonitis	Adverse event - infection	Claims data	ICD-10 Diagnosis: B25.0
Other pneumonia	Adverse event - infection	Claims data	ICD-10 Diagnosis: A01.03, A02.22, A20.2, A21.2, A31.0, A37.01, A37.11, A37.81, A37.91, A43.0, A48.1, B01.2, B05.2, B06.81, B37.1, B38.0, B38.2, B39.0, B39.2, B58.3, B59, B77.81, J10.00, J10.08, J11.00, J11.08, J12.1, J12.2, J12.3, J12.81, J12.89, J12.9, J13, J14, J15.0, J15.1, J15.20, J15.211, J15.212, J15.29, J15.3, J15.4, J15.5, J15.6, J15.7, J15.8, J15.9, J16.0, J16.8, J17, J18.0, J18.1, J18.8, J18.9, J85.1
Upper respiratory tract infection	Adverse event - infection	Claims data	ICD-10 Diagnosis: J20.9, J00.0, J04.0, J06.0, J06.9, J02.9
Sepsis	Adverse event - infection	Claims data	ICD-10 Diagnosis: A02.1, A32.1, A40.7, A40.0, A40.1, A40.3, A40.8, A41.9, A41.01, A41.02, A41.1, A41.2, A41.3, A41.4, A41.50, A41.51, A41.52, A41.53, A41.59, A41.81, A41.89, A42.9, A54.7, B37.86, R65.7, R65.20, A22.21, A26.7, A41.7, A41., A41.0, A41.5, P36.8, P36.0, P36.10, P36.19, P36.2, P36.30, P36.39, P36.4, P36.5, P36.8
Cytomegaloviral infection	Adverse event - infection	Claims data	ICD-10 Diagnosis: B25.0, B25.1, B25.2, B25.8, B25.9, B27.0, B27.1, B27.2, B27.9
PJP	Adverse event - infection	Claims data	ICD-10 Diagnosis: B59
Hepatitis C	Adverse event - infection	Claims data	ICD-10 Diagnosis: B17.1x, B18.2, B19.2x
Hepatitis B	Adverse event - infection	Claims data	ICD-10 Diagnosis: B16.x, B17.0, B18.0, B18.1, B19.1x
Other infectious hepatitis	Adverse event - infection	Claims data	ICD-10 Diagnosis: B17.2, B17.8, B17.9, B18.8, B18.9, B19.0, B19.9
Helicobacter pylori	Adverse event - infection	Claims data	ICD-10 Diagnosis: B96.81
Candida esophagitis	Adverse event - infection	Claims data	ICD-10 Diagnosis: B37.81
Urinary tract infection	Adverse event - infection	Claims data	ICD-10 Diagnosis: N39.0

Document Approval Record

Document Name:	C1071044_NON-INTERVENTIONAL STUDY PROTOCOL_V2_06AUG2025
Document Title:	C1071044_NON-INTERVENTIONAL STUDY PROTOCOL_V2_06AUG2025

Signed By:	Date(GMT)	Signing Capacity
Redacted	02-Sep-2025 15:50:58	Final Approval
Redacted	03-Sep-2025 15:07:21	Manager Approval