NON-INTERVENTIONAL (NI) STUDY PROTOCOL

Study Information

Title	Administration of Elranatamab In the Real-World: Treatment Patterns, Healthcare Resource Utilization, Costs, Effectiveness, and Safety (ALTITUDE).
Protocol number	C1071039
Protocol version identifier	V2.0
Date	31 July 2025
EU Post Authorization Study (PAS) register number	EUPAS1000000229
Active substance	L01FX32
Medicinal product	ELREXFIO™ (elranatamab)
Research question and objectives	**Research Question:** What are the patient characteristics, treatment characteristics, safety, effectiveness, healthcare resource utilization (HCRU), and costs of patients with relapsed/refractory multiple myeloma (RRMM) who initiate elranatamab using Komodo Health administrative claims data? The following objectives will be assessed among patients with RRMM receiving elranatamab: **Primary** ● **Objective 1:** Describe the demographics, clinical history, and treatment history of patients in the study ● **Objective 2:** Describe the administration and treatment management of elranatamab ● **Objective 3:** Describe all-cause and MM-related HCRU and costs by

	place of service of patients in the study **Exploratory** • **Exploratory Objective 1:** Describe the tolerability and real-world safety of elranatamab • **Exploratory Objective 2:** Describe the 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 with the same indication as elranatamab who initiated teclistamab
Country(ies) of study	United States (US)
Author	Redacted

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2. LIST OF ABBREVIATIONS

Abbreviation	Definition
AE	Adverse Event
ALT	Alanine Aminotransferase
ALTITUDE	Administration of Elranatamab In the Real-World: Treatment Patterns, Healthcare Resource Utilization, Costs, Effectiveness, and Safety
AST	Aspartate aminotransferase
BCMA	B-Cell Maturation Antigen
BsAb	Bispecific Antibody
CAR-T	Chimeric Antigen Receptor T-Cell Therapy
CCI	Charlson Comorbidity Index
CI	Confidence Interval
CPT	Current Procedural Terminology
CRS	Cytokine Release Syndrome
EC	Ethics Committee EMA
ED	Emergency Department
EMA	European Medicines Agency
FDA	Food and Drug Administration
GPP	Good Pharmacoepidemiology Practices
HCPCS	Healthcare Common Procedure Coding System
HCRU	Healthcare Resource Utilization
HMA	The Heads of Medicines Agencies
ICANS	Immune Effector Cell-Associated Neurotoxicity Syndrome

Abbreviation	Definition
ICD-10	International Classification of Diseases, 10th Edition
IgA	Immunoglobulin A
IgG	Immunoglobulin G
IgE	Immunoglobulin E
IgM	Immunoglobulin M
IMiDs	Immunomodulatory Agent
IP	Inpatient
IQR	Interquartile Range
IRB	Institutional Review Board
IV	Intravenous
mABs	Monoclonal Antibody
MG	Milligram
ML	Milliliter
MM	Multiple Myeloma
M protein	Monoclonal Protein
NDC	National Drug Code
NCCN	National Comprehensive Cancer Network
OP	Outpatient
ORR	Objective Response Rate
OS	Overall Survival
PASS	Post-Authorisation Safety Study

Abbreviation	Definition
PIs	Proteasome Inhibitors
PJP	Pneumocystis Jiroveci Pneumonia
PPPM	Per-Patient-Per-Month
RAI	Relative Administration Intensity
RRMM	Relapsed And Refractory Multiple Myeloma
RWD	Real World Data
SEER	Surveillance, Epidemiology, and End Results
TTD	Time to Discontinuation
TTNT/D	Time To Next Treatment/Death
SD	Standard Deviation
US	United States

3. RESPONSIBLE PARTIES

Principal Investigator(s) of the Protocol

Redacted			

4. ABSTRACT

Title: Administration of Elranatamab In the Real-World: Treatment Patterns, Healthcare Resource Utilization, Costs, Effectiveness, and Safety (ALTITUDE)

Version: v2.0

Date: 31 July 2025

Author: Redacted

Rationale and background: Elranatamab is a B-Cell Maturation Antigen (BCMA) bispecific antibody (BsAb) that was approved in the 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). A limited number of studies have been published assessing the real-world utilization of elranatamab due to its recent approval. This study will describe the real-world usage, patient outcomes, and HCRU associated with elranatamab in the US by leveraging an up-to-date healthcare claims dataset.

Research question and objectives: What are the descriptive characteristics, treatment patterns, all cause/MM-related, HCRU, safety and effectiveness of elranatamab therapy?

The study objectives are to:

Primary

- **Objective 1:** Describe the demographics, clinical history, and treatment history of patients in the study
- **Objective 2:** Describe the administration and treatment management of elranatamab
- **Objective 3:** Describe all-cause and MM-related HCRU and costs by place of service of patients in the study

Exploratory

- **Exploratory Objective 1:** Describe the tolerability and real-world safety of elranatamab
- **Exploratory Objective 2:** Describe the effectiveness of elranatamab in terms of TTNT/D and OS
- **Exploratory Objective 3:** In a separate cohort, replicate all objectives for patients with the same indication as elranatamab who initiated teclistamab

Study Design: This will be a retrospective descriptive cohort study using de-identified US claims data from Komodo Health.

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 14 August 2023 (US approval date) and end of data (defined as the latest data available, at the time of the specified analysis). Exploratory analyses will also include a teclistamab-exposed cohort, which will include patients with RRMM who initiate teclistamab between 14 August 2023, and the end of data. The index date for patients in each cohort will be defined as the date of the first prescription or medical claim for elranatamab or teclistamab. Patients will be required to have at least 180 days of continuous closed-claims enrollment before the index date.

Variables: Variables used to define eligibility will include elranatamab, MM diagnosis, and observability.

Variables to define demographic and clinical characteristics will include, but are not limited to, age, sex, race/ethnicity, region, Charlson Comorbidity Index (CCI), and prior infections.

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 imputed costs will be reported as all-cause and MM-related.

Adverse events (AEs) 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.

Country of Study: US

Data Sources: This study will use Komodo Health data. The data source is a healthcare technology firm that owns, links, and integrates open and closed-claims databases from over 150 public and private payers/insurers and clearinghouses across the US. The database is closely aligned with the population of the National Health Interview Survey in terms of geography and demographics. 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 current cut of the data includes over 700,000 patients with MM. The results of this study may be updated as additional data become available for elranatamab.

Study Size: This is a retrospective descriptive cohort study; therefore, sample size calculations are not applicable. As of 24 April 2024, the dataset included 56 patients with a claim for elranatamab.

Data Analysis: Categorical and binary variables will be summarized by the number and percentage of patients in each category. Continuous variables will be described using mean, standard deviation (SD), median, interquartile range (IQR), minimum, and maximum. If applicable, the frequency and percentage of patients with missing data for each variable will be described. 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. 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 that occurred over the follow-up period and in the 180-day baseline period. Given the variable follow-up time available for each patient, HCRU and costs will be reported per-patient-per-month (PPPM). The prevalence and incidence, as well as the associated 95% confidence intervals (CI) for each AE, will be estimated. Kaplan-Meier methods will be used to estimate the median time to event, including 95% CIs for TTNT/D, TTD, and OS. All analyses will be repeated in an exploratory cohort of patients receiving teclistamab.

Milestones: Data analysis will begin after protocol finalization by 15 August 2024.There will be one initial set of results and four subsequent quarterly refreshes with updated data throughout 2025. At the end of implementation, a final report will be generated by 28 February 2026.

5. AMENDMENTS AND UPDATES

Version Identifier	Date	Amendment Type (substantial or administrative)	Protocol Section(s) Changed	Summary of Amendment(s)	Reason
2.0	31 July 2025	Administrative	2	Addition of abbreviations in the list of abbreviations	Updated to reflect new variables and some not previously defined.
2.0	31 July 2025	Administrative	3	Update of the study team roster	Updated to reflect departures or additions to the team.
2.0	31 July 2025	Substantial	4	Version and date were updated. Small wording updates were made to clarify the definition of "end of data" and to further describe the four prespecified study quarterly refreshes.	The set end date was removed and replaced with flexible language reflecting the amendment to conduct quarterly updates.
2.0	31 July 2025	Substantial	6	Update of the milestone dates and inclusion of the four study refreshes	Four quarterly refreshes have been added.
2.0	31 July 2025	Substantial	8	Minor updates to the objectives wording	This section was updated to improve clarity
2.0	31 July 2025	Substantial	9.2 (inclusive of subsections)	clarified the definition of the end of the study	The set end date was removed and

				period; formatting changes to reflect Pfizer's protocol template.	replaced with flexible language reflecting the amendment to conduct quarterly updates.
2.0	31 July 2025	Substantial	9.3: Table 2	Added baseline lab assessments, certain clinical characteristics defined by the results of specific laboratory tests and insurance type in Table 2. Minor update to assessment periods. Addition of a footnote to flag variables that are assessed during follow-up.	Data was received from the vendor containing information on laboratory test results and patterns. Minor changes were made to assessment periods and to further clarify assessment periods of baseline characteristics.
2.0	31 July 2025	Substantial	9.3: Table 3	Study variables added: the proportion of patients with two administrations, IP visit information from different Komodo tables, and HCRU during the step-up dosing period.	Better captures measures of interest based on data explorations.
2.0	31 July 2025	Substantial	9.5	Study end date replaced with flexible language	The set end date was removed and replaced with flexible

					language reflecting the amendment to conduct quarterly updates.
2.0	31 July 2025	Substantial	9.7.1	Additional lab variable subgroup in the baseline characteristics	This subgroup will help contextualize any difference with respect to lab availability
2.0	31 July 2025	Substantial	9.7.2: Figure 2	The study figure was updated The time period of assessment for duration on treatment and censoring reasons as clarified.	To clarify the exact end dates for each dosing period, reflecting ELREXFIO label. The set end date was removed and replaced with flexible language reflecting the amendment to conduct quarterly updates.
2.0	31 July 2025	Substantial	9.7.3	RAI assessment added. Censoring criteria for RAI was updated to include the last administration of the index treatment. Study end date replaced with flexible language	The addition of this analysis better help contextualize the “upper” bound of RAI. Last administration of the index treatment was included as a censoring criterion as many patients

					have long periods of no treatment from their last administration to the censor date. RAI estimates seemed to be underestimated due to this factor.
2.0	31 July 2025	Substantial	9.7.4	Removal of the phrase stating "If follow-up time is adequate" Study end date replaced with flexible language	Patients will be included in the TTD assessment regardless of duration of follow-up. The set end date was removed and replaced with flexible language reflecting the amendment to conduct quarterly updates.
2.0	31 July 2025	Substantial	9.7.5	A sentence to clarify pharmacy claim capture for HCRU was included. A sentence rationalizing the usages of PPPM estimates was included. An additional time period for HCRU	The additional sentences were for clarification. The new time of assessment was a request based on interest in measuring HCRU during the step-up period.

				assessment was included. Study end date replaced with flexible language	The set end date was removed and replaced with flexible language reflecting the amendment to conduct quarterly updates.
2.0	31 July 2025	Substantial	9.7.5	Study end date replaced with flexible language	The set end date was removed and replaced with flexible language reflecting the amendment to conduct quarterly updates.
2.0	31 July 2025	Substantial	9.7.6	Study end date replaced with flexible language	The set end date was removed and replaced with flexible language reflecting the amendment to conduct quarterly updates.
2.0	31 July 2025	Administrative	ANNEX	Inclusion of the most update to date ANNEX containing study variables. Multiple Myeloma codes were added into the Any Malignancy component for the CCI score.	Data was received from the vendor containing information on laboratory test results and patterns. MM codes were added into the CCI

					definition to accurately reflect the published definition of CCI.

6. MILESTONES

Milestone	Planned Date
Start of data collection	15 August 2024
Registration in The Heads of Medicines Agencies (HMA)-European Medical Agency (EMA) Catalogues of Real World Date (RWD) studies	26 July 2024
Interim results delivery	23 September 2024
Full results delivery	15 November 2024
Full result refresh 1	15 January 2025
Full result refresh 2	09 April 2025
Full result refresh 3	09 September 2025
End of data collection	20 November 2025
Full result refresh 4	20 December 2025
Final study report	28 February 2026

7. RATIONALE AND BACKGROUND

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 (ie, 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 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), IMiDs, and mAbs, has increased the OS 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 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 BCMA, which is primarily present in malignant plasma cells. BCMA is expressed in B-cells and regulates their maturation into plasma cells.[11] BCMA BsAbs target and bind BCMA-expressing plasma cells and the CD3 receptor on T-cells, activating cytotoxic activities of the T cell.[11] Elranatamab is a BCMA BsAb indicated for patients who have received at least four lines of therapy, including a PI, an IMiD, and an anti-CD38 mAbs.[12] 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 Objective Response Rate (ORR) was 61.0%, and common AEs included infections (69.9%) CRS (57.7%), anemia (48.8%), and neutropenia (48.8%).[13] 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.[14,15] This study aims to describe the uptake and use of elranatamab subsequent to the August 2023 Food and Drug Administration (FDA) approval using recent data reflecting real-world clinical practice.

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

8. RESEARCH QUESTION AND OBJECTIVES

Research Question: What are the descriptive characteristics, treatment patterns, all cause/ MM-related HCRU, safety and effectiveness of elranatamab therapy?

The study objectives are to:

Primary

- **Objective 1:** Describe the demographics, clinical history, and treatment history of patients in the study
- **Objective 2:** Describe the administration and treatment management of elranatamab
- **Objective 3:** Describe all-cause and MM-related HCRU and costs by place of service of patients in the study

Exploratory

- **Exploratory Objective 1:** Describe the tolerability and real-world safety of elranatamab
- **Exploratory Objective 2:** Describe the effectiveness of elranatamab in terms of TTNT/D and OS
- **Exploratory Objective 3:** In a separate cohort, replicate all objectives for patients with the same indication as elranatamab who initiated teclistamab

9. RESEARCH METHODS

9.1. Study Design

This retrospective descriptive cohort study will assess the demographic, clinical, treatment characteristics, HCRU, costs, effectiveness, and safety of MM patients with an elranatamab claim and will use de-identified data from Komodo Health.

9.2. Setting

This study will evaluate adult patients with RRMM who initiate elranatamab. Patients will enter (i.e., index) on the first observed elranatamab claim between 14 August 2023 and the end of data (defined as the latest data at the time of the specified analysis). Limited eligibility criteria will be applied.

Study Period: Start of data availability (01 January 2016) to the end of data

MM diagnosis window: Start of data availability (01 January 2016) to index date

Index date: First elranatamab claim after initial MM diagnosis

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

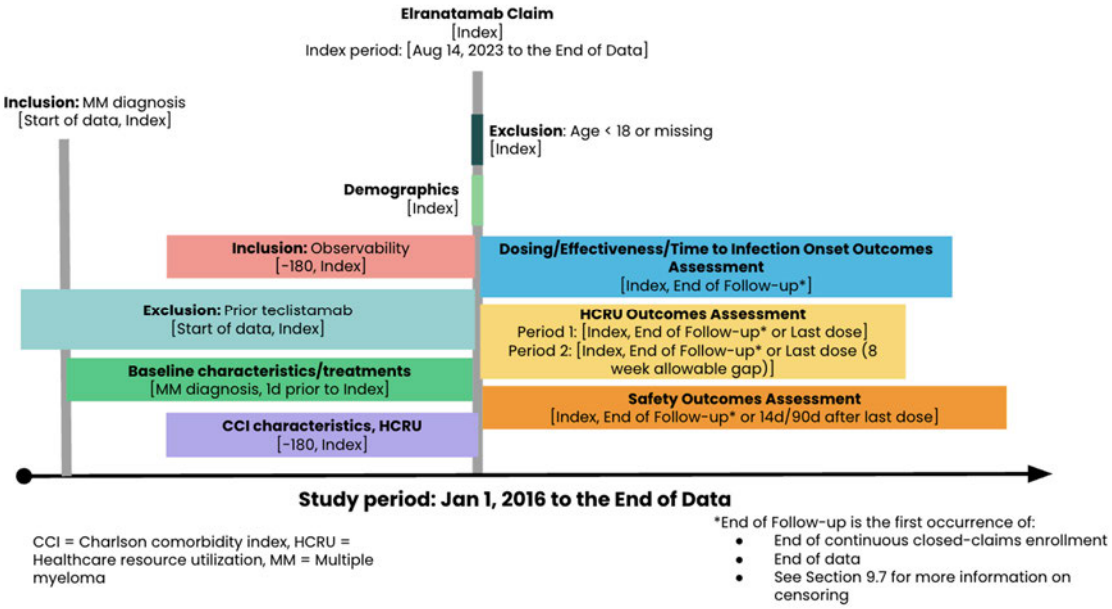
Baseline period for MM-related treatments and MM-related comorbidities: MM diagnosis to one day prior to index date (unless otherwise specified)

CCI and baseline HCRU assessment window: 180 days prior to index date to index date.

Follow-up: Index date until death, the earliest of the end of data, or end of continuous enrollment (unless otherwise noted). Alternative censoring criteria will be applied for certain outcomes (such as OS, TTD, and TTNT/D); see Section 9.7 for more details.

Figure 1 reflects the time periods of interest in the study cohort.

Figure 1. Study Schematic for Patients Receiving Elranatamab



9.2.1. Inclusion Criteria

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

1. Index date: First observed prescription claim or medical claim for elranatamab in the dataset (14 August 2023 to the end of data)

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)

For the exploratory cohort of patients receiving teclistamab, patients will be required to meet the same inclusion criteria as those receiving elranatamab. The only difference is that patients will index on their first teclistamab claim within the same time window (14 August 2023 to the end of data).

9.2.2. Exclusion Criteria

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

1. Treatment with teclistamab any time prior to index date

2. For the exploratory cohort of patients receiving teclistamab, patients will be excluded based on prior use of elranatamab.

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	Role	Assessment Period
Elranatamab	Prescription claim or medical claim with a National Drug Code (NDC), Healthcare Common Procedure Coding System (HCPCS), ICD-10 code or generic name in the IP, non-IP or pharmacy setting for elranatamab	Inclusion	Index event
Teclistamab	Prescription claim or medical claim with an NDC, HCPCS, ICD-10 code or generic name in the IP, non-IP or pharmacy setting for teclistamab	Exclusion	All available data to index date

Variable	Operational Definition	Role	Assessment Period
Age	Age is greater than or equal to 18 years and is not missing	Inclusion	Index date
MM diagnosis	Medical claim in the IP or non-IP setting with an ICD-10 code for MM	Inclusion	All available data to index date
Observability	Closed-claims medical and pharmacy enrollment	Inclusion	180 days prior to index date to index date (inclusive)

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)	Index date
1	Sex	Categorical sex Male Female	Index date
1	Race/Ethnicity	Categorical race and ethnicity Caucasian African American Asian or Pacific Islander Hispanic or Latino Other	Start of data availability to index date

Objective	Variable	Definition	Assessment Period(s)
		Unknown	
1	Region	Categorical region, assessed as the most recent value from index date Northeast Midwest West South	Start of data to index date
	Insurance type	Categorical insurance type, assessed as the most recent value to index date Commercial Medicaid Medicare Other Unknown	180 days prior to index date to index date
1	Location (Zip code)	Categorical zip code assessed as the most recent value from index date. The full categories will be reported during implementation.	Index date
1	Care setting	Categorical care setting for elranatamab or teclistamab administration IP Non-IP Pharmacy	Index date
1	Time since MM diagnosis	Time (in months) from first MM diagnosis to index date (continuous)	MM diagnosis to index date

Objective	Variable	Definition	Assessment Period(s)
1	Triple class exposed	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 IP, non-IP, or pharmacy setting (dichotomous)[16]: ● ≥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	Medical claims with an NDC, HCPCS, CPT, generic name, or ICD-10 procedure codes in the IP, non-IP or pharmacy setting for all of the following therapies (dichotomous)[16]: ● ≥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
1	Hematopoietic Stem Cell Transplantation[1]	Medical claim with an HCPCS, CPT, or ICD-10 code for hematopoietic stem cell transplantation in the IP, non-IP setting (dichotomous)	MM diagnosis to 1 day prior to index date Index date to the end of follow-up
1	BCMA-directed therapy[1]	Medical claim with an NDC, HCPCS CPT, generic name or ICD-10 procedure code in the IP, non-IP, or pharmacy setting for idecabtagene vicleucel, ciltacabtagene autoleucel, or belantamab (dichotomous)	MM diagnosis to 1 day prior to index date Index date to the end of follow-up
1	CAR-T[1]	Medical claim with an NDC, HCPCS, generic name or CPT code in the IP, non-IP, or pharmacy setting for idecabtagene vicleucel or	MM diagnosis to 1 day prior to index date

Objective	Variable	Definition	Assessment Period(s)
		ciltacabtagene autoleucel (dichotomous)	Index date to the end of follow-up
1	Talquetamab[1]	Medical claim with an NDC, HCPCS, generic name or CPT code in the IP, 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[1]	Medical claim with an NDC, HCPCS, generic name or CPT code in the IP, 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[1]	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[1]	Medical claim with an NDC, HCPCS, generic name or CPT code in the IP, 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
1	MAbs[1]	Medical claim with an NDC, HCPCS, generic name or CPT code in the IP, 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[1]	Medical claim with an NDC, HCPCS, generic name or CPT code in the IP, non-IP, or pharmacy setting for	MM diagnosis to 1 day prior to index date

Objective	Variable	Definition	Assessment Period(s)
		doxorubicin hydrochloride, melphalan, bendamustine, cyclophosphamide, etoposide, or cisplatin (dichotomous)	Index date to the end of follow-up
1	Small molecule inhibitors[1]	Medical claim with an NDC, HCPCS, generic name or CPT code in the IP, 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[1]	Medical claim with an NDC, HCPCS, generic name or CPT code in the IP, 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[1]	Medical claim with an NDC, HCPCS, generic name or CPT code in the IP, non-IP, or pharmacy setting for antiviral medications (dichotomous)	14 days prior to index date to 1 day prior to index date Index date to the end of follow-up
1	Antibiotics[1]	Medical claim with an NDC, HCPCS, generic name or CPT code in the IP, non-IP, or pharmacy setting for antibiotic medications (dichotomous)	14 days prior to index date to 1 day prior to index date Index date to the end of follow-up
1	Antifungal Medication[1]	Medical claim with an NDC, HCPCS, generic name or CPT code in the IP, non-IP, or pharmacy setting for antifungal medications (dichotomous)	14 days prior to index date to 1 day prior to index date Index date to the end of follow-up
1	Intravenous immunoglobulin [1]	Medical claim with an NDC, HCPCS, generic name, CPT, or ICD-10 procedure code in the IP, non-IP, or pharmacy setting for intravenous	14 days prior index date to 1 day prior to index date

Objective	Variable	Definition	Assessment Period(s)
		immunoglobulin administration (dichotomous)	Index date to the end of follow-up
1	Other hematological malignancies	Medical claim with an ICD-10 code in the IP 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 IP 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 IP 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 IP 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 IP 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 IP or non-IP setting for any infection of the following types (dichotomous): COVID-19 Sinusitis Bronchitis Adenoviral pneumonia Cytomegaloviral pneumonitis Other Pneumonia Upper respiratory tract infection	MM diagnosis to 1 day prior to index date

Objective	Variable	Definition	Assessment Period(s)
		Sepsis Cytomegaloviral infection Pneumocystis jiroveci pneumonia (PJP) Hepatitis C Hepatitis B Other infectious hepatitis Helicobacter pylori Candida esophagitis Urinary tract infection	
1	Use of intravenous anti-infective	Medical claim with an NDC code generic name, CPT, or HCPCS code in the IP, non-IP, or pharmacy setting for anti-infective where the route of administration is intravenous for an intravenous anti-infective (dichotomous)	MM diagnosis to 1 day prior to index date
1	Neutropenia	Medical claim with an ICD-10 code in the IP or non-IP setting for neutropenia (dichotomous) or event in the lab table where absolute neutrophil count is < 1,500 cells per µL	MM diagnosis to 1 day prior to index date
1	Hypercalcemia	Medical claim with an ICD-10 code in the IP or non-IP setting for hypercalcemia (dichotomous) or an event in the lab table where corrected serum calcium is > 11.5 mg/dL	MM diagnosis to 1 day prior to index date
1	Hepatotoxicity	Medical claim with an ICD-10 code in the IP or non-IP setting for hepatotoxicity (dichotomous)	MM diagnosis to 1 day prior to index date

Objective	Variable	Definition	Assessment Period(s)
1	Renal failure	Medical claim with an ICD-10 code in the IP 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 IP 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 IP 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 IP or non-IP setting for extramedullary disease (dichotomous)	MM diagnosis to 1 day prior to index date
1	CCI score	CCI[17] (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 IP 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 IP or non-IP setting for congestive heart failure (dichotomous)	180 days prior to index date to index date
1	Peripheral vascular disease	Medical claim with an ICD-10 code in the IP 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 IP or non-IP setting for cerebrovascular disease (dichotomous)	180 days prior to index date to index date

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

Objective	Variable	Definition	Assessment Period(s)
1	Albumin serum	Lab event with albumin serum as the test name and g/dL as the result units (dichotomous)	180 days prior to index date to index date
		Most recent numeric value to index date of a lab event with albumin serum as the test name and g/dL as the result units (continuous)	
1	Alanine aminotransferase (ALT)	Lab event with ALT as the test name and IU/L as the result units (dichotomous)	180 days prior to index date to index date
		Most recent numeric value to index date of a lab event with ALT as the test name and IU/L as the result units (continuous)	
1	Aspartate aminotransferase (AST)	Lab event with AST as the test name and IU/L as the result units (dichotomous)	180 days prior to index date to index date
		Most recent numeric value to index date of a lab event with AST as the test name and IU/L as the result units (continuous)	
1	Neutrophil count	Lab event with neutrophil as the test name and thousands/µL as the result units (dichotomous)	180 days prior to index date to index date
		Most recent numeric value to index date of a lab event with neutrophil count as the test name and thousands/µL result units (continuous)	
1	Creatinine	Lab event with creatinine as the test name and mg/dL as the result units (dichotomous)	180 days prior to index date to index date

Objective	Variable	Definition	Assessment Period(s)
		Most recent numeric value of a lab event to index date with creatinine as the test name and mg/dL as the result units (continuous)	
1	Hemoglobin	Lab event with hemoglobin as the test name and g/dL as the result units (dichotomous)	180 days prior to index date to index date
		Most recent numeric value of a lab event with hemoglobin as the test name and g/dL as the result units (continuous)	
1	Lymphocyte count	Lab event with lymphocyte count as the test name and thousand/µL as the result units (dichotomous)	180 days prior to index date to index date
		Most recent numeric value of a lab event with lymphocyte count as the test name and thousand/µL as the result units (continuous)	
1	Monocyte count	Lab event with monocyte count as the test name and thousand/µL as the result units (dichotomous)	180 days prior to index date to index date
		Most recent numeric value of a lab event with monocyte count as the test name and thousand/µL as the result units (continuous)	
1	Platelet Count	Lab event with platelet count as the test name and thousand/µL as the result units (dichotomous)	180 days prior to index date to index date
		Most recent numeric value of a lab event with platelet count as the test name and thousand/µL as the result units (continuous)	

Objective	Variable	Definition	Assessment Period(s)
1	Serum immunoglobulin A (IgA)	Lab event with IGA as the test name and mg/dL as the result units (dichotomous)	180 days prior to index date to index date
		Most recent numeric value of a lab event with IGA as the test name and mg/dL as the result units (continuous)	
1	Serum immunoglobulin G (IgG)	Lab event with IGG as the test name and mg/dL as the result units (dichotomous)	180 days prior to index date to index date
		Most recent numeric value of a lab event with IGG as the test name and mg/dL as the result units (continuous)	
1	Serum immunoglobulin E (IgE)	Lab event with IGE as the test name and IU/mL as the result units (dichotomous)	180 days prior to index date to index date
		Most recent numeric value of a lab event with IGE as the test name and IU/mL as the result units (continuous)	
1	Serum immunoglobulin M (IgM)	Lab event with IGM as the test name and mg/dL as the result units (dichotomous)	180 days prior to index date to index date
		Most recent numeric value of a lab event with IGM as the test name and mg/dL as the result units (continuous)	
1	Bone marrow plasma cell percent	Lab event with bone marrow plasma cell percent as the test name and percent as the result units (dichotomous)	Most recent value recorded in the 180 days prior to index date to index date
		Most recent numeric value of a lab event with bone marrow plasma cell	

Objective	Variable	Definition	Assessment Period(s)
		percent as the test name and percent as the result units (continuous)	
1	M-Protein	Lab event with M-Spike as the test name and as the g/dL as the result units (dichotomous)	180 days prior to index date to index date
		Most recent numeric value of a lab event with M-Spike as the test name and g/dL as the result units (continuous)	

1. Variable assessed both at baseline and in follow-up

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 premedication	Medical or pharmacy claim with evidence of an NDC, HCPCS, generic name or CPT code for the following premedications (dichotomous): Acetaminophen Dexamethasone Diphenhydramine	Step-Up Dosing Period See Section 9.7.2 for censoring criteria
2	Reported vial size	Reported vial size in the following categories (categorical): ● Unknown vial – IP dose ● 44 milligram (mg)/1.1 milliliter (mL) ● 76mg/1.9mL ● Missing dose/unknown dose For the exploratory cohort of teclistamab patients the reported vial size (categorical): ● Unknown vial – IP 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 See Section 9.7.2 for more information on the assessment periods and censoring criteria
2	Patients with 2 or more administrations	Proportion of patients with 2 or more administrations of elranatamab during the assessment period	Index date to the end of follow-up Step-Up Dosing Period Maintenance Periods See Section 9.7.2 for more information on the assessment periods and censoring criteria

2	Average time between elranatamab claims	Sum of the days between claims for the index drug (continuous) divided by the total number of administrations -1 reported among patients with 2 or more administrations	Index date to the end of follow-up Step-Up Dosing Period Maintenance Periods See Section 9.7.2 for more information on the assessment periods and censoring criteria
2	Number of of elranatamab claims	Total number of IP, 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 See Section 9.7.2 for more information on the assessment periods and censoring criteria
3	RAI	The ratio of the actual administrations received divided by the expected number of administrations (continuous) See Section 9.7.3 for more details.	Index date to the last administration of the index drug Step-Up Dosing Period Maintenance Periods See Section 9.7.2 for more information on the assessment periods and Section 9.7.3 for censoring criteria
3	Duration on treatment	Time in days between first and last treatment administration for the index treatment (continuous)	Index date to the end of follow-up See Section 9.7.2 for censoring criteria

3	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 for the exploratory analysis, teclistamab therapy), next treatment after index treatment (CAR-T, BsABs, bendamustine or belantamab), or death.	Index date to the end of follow-up. Follow-up will defined based on the censoring criteria described in Section 9.7.4
Health care resource utilization and costs			
4	All-cause IP visits	Medical claim for IP (non-ED) visit (dichotomous) Number of IP (non-ED) visits (continuous)	180 days prior to index date to 1 day prior to index date Step-Up Dosing Period Index date to end of follow-up. Follow-up will be defined two ways to account for gaps in elranatamab use. See Section 9.7.5 for censoring criteria
4	IP visits from the IP table	Medical claim for IP (non-ED) visit sourced from the IP table (dichotomous) Number of IP (non-ED) visits sourced from the IP table (continuous)	180 days prior to index date to 1 day prior to index date Step-Up Dosing Period Index date to end of follow-up. Follow-up will be defined two ways to account for gaps in elranatamab use. See Section 9.7.5 for censoring criteria
4	IP visits from the Non-IP table	Medical claim for IP (non-ED) visit sourced from the Non-IP table where place of service indicates an IP setting (dichotomous)	180 days prior to index date to 1 day prior to index date

		Number of IP (non-ED) visits sourced from the IP table place of service indicates an IP setting (continuous)	Step-Up Dosing Period Index date to end of follow-up. Follow-up will be defined two ways to account for gaps in elranatamab use. See Section 9.7.5 for censoring criteria
4	All-cause OP visits	Medical claim for non-IP/non-ED visit (dichotomous)	180 days prior to index date to 1 day prior to index date Step-Up Dosing Period Index date to end of follow-up. Follow-up will be defined two ways to account for gaps in elranatamab use. See Section 9.7.5 for censoring criteria
		Number of non-IP/non-ED visits (continuous)	
4	All-cause ED visits	Medical claim for ED visit (dichotomous)	180 days prior to index date to 1 day prior to index date Step-Up Dosing Period Index date to end of follow-up. Follow-up will be defined two ways to account for gaps in elranatamab use. See Section 9.7.5 for censoring criteria
		Number of ED visits (continuous)	
4	All-cause pharmacy claims	Pharmacy claim (dichotomous)	

		Number of pharmacy claims (continuous)	180 days prior to index date to 1 day prior to index date Step-Up Dosing Period Index date to end of follow-up. Follow-up will be defined two ways to account for gaps in elranatamab use. See Section 9.7.5 for censoring criteria
4	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).	180 days prior to index date to 1 day prior to index date Step-Up Dosing Period Index date to end of follow-up. Follow-up will be defined two ways to account for gaps in elranatamab use. See Section 9.7.5 for censoring criteria
4	Total all-cause HCRU	IP, OP, ED, or pharmacy claims (dichotomous)	180 days prior to index date to 1 day prior to index date Step-Up Dosing Period Index date to end of follow-up. Follow-up will be defined two ways to account for gaps in elranatamab use. See Section 9.7.5 for censoring criteria
2	Reported vial size	Number of IP, OP, ED, or pharmacy claims (continuous)	Index date to the end of follow-up Index date

			Step-Up Dosing Period Maintenance Periods See Section 9.7.2 for more information on the assessment periods and censoring criteria
4	MM-related IP visits	Medical claim for IP (non-ED) visit with an MM ICD-10 code or treatment for MM (dichotomous)	180 days prior to index date to 1 day prior to index date Step-Up Dosing Period Index date to end of follow-up. Follow-up will be defined two ways to account for gaps in elranatamab use. See Section 9.7.5 for censoring criteria
		Number of IP (non-ED) visits with an MM ICD-10 code or treatment for MM (continuous)	
4	MM-related OP visits	Medical claim for non-IP/non-ED visit with an MM ICD-10 code or treatment for MM (dichotomous)	180 days prior to index date to 1 day prior to index date Step-Up Dosing Period Index date to end of follow-up. Follow-up will be defined two ways to account for gaps in elranatamab use. See Section 9.7.5 for censoring criteria
		Non-IP/non-ED visits with an MM ICD-10 code or treatment for MM (continuous)	
4	MM-related pharmacy claims	Pharmacy claim with a treatment for MM (dichotomous)	180 days prior to index date to 1 day prior to index date Step-Up Dosing Period Index date to end of follow-up. Follow-up will be defined two ways
		Number of pharmacy claims with a treatment for MM (continuous)	

			to account for gaps in elranatamab use. See Section 9.7.5 for censoring criteria
4	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)	180 days prior to index date to 1 day prior to index date Step-Up Dosing Period Index date to end of follow-up. Follow-up will be defined two ways to account for gaps in elranatamab use. See Section 9.7.5 for censoring criteria
4	Total MM-related HCRU	IP, OP, ED, or pharmacy claims with an MM ICD-10 code or treatment for MM (dichotomous) IP, OP, ED, or pharmacy claims with an MM ICD-10 code or treatment for MM (continuous)	180 days prior to index date to 1 day prior to index date Step-Up Dosing Period Index date to end of follow-up. Follow-up will be defined two ways to account for gaps in elranatamab use. See Section 9.7.5 for censoring criteria

4	Cost of all-cause IP visits	Cost of IP (non-ED) visits (continuous)	180 days prior to index date to 1 day prior to index date Step-Up Dosing Period Index date to end of follow-up. Follow-up will be defined two ways to account for gaps in elranatamab use. See Section 9.7.5 for censoring criteria
4	Cost of all-cause OP visits	Cost of non-IP/non-ED visits (continuous)	180 days prior to index date to 1 day prior to index date Step-Up Dosing Period Index date to end of follow-up. Follow-up will be defined two ways to account for gaps in elranatamab use. See Section 9.7.5 for censoring criteria

4	Costs of all-cause ED visits	Cost of ED visits (continuous)	180 days prior to index date to 1 day prior to index date Step-Up Dosing Period Index date to end of follow-up. Follow-up will be defined two ways to account for gaps in elranatamab use. See Section 9.7.5 for censoring criteria
4	Cost of all-cause pharmacy claims	Cost of pharmacy claims (continuous)	180 days prior to index date to 1 day prior to index date Step-Up Dosing Period Index date to end of follow-up. Follow-up will be defined two ways to account for gaps in elranatamab use. See Section 9.7.5 for censoring criteria
4	Total cost of all-cause HCRU	Cost of IP, OP, ED, or pharmacy claims (continuous)	180 days prior to index date to 1 day prior to index date Step-Up Dosing Period Index date to end of follow-up. Follow-up will be defined two ways to account for gaps in elranatamab use.

4	Cost of MM-related IP visits	Cost of IP (non-ED) visits with an MM ICD-10 code or treatment for MM (continuous) Non-IP/non-ED visits with an MM ICD-10 code or treatment for MM (continuous)	180 days prior to index date to 1 day prior to index date Step-Up Dosing Period Index date to end of follow-up. Follow-up will be defined two ways to account for gaps in elranatamab use. See Section 9.7.5 for censoring criteria
4	Cost of MM-related OP visits	Cost of ED visits with an MM ICD-10 code or treatment for MM (continuous)	180 days prior to index date to 1 day prior to index date Step-Up Dosing Period Index date to end of follow-up. Follow-up will be defined two ways to account for gaps in elranatamab use. See Section 9.7.4 for censoring criteria
4	Cost of MM-related ED visits	Cost of pharmacy claims with an MM ICD-10 code or treatment for MM (continuous)	180 days prior to index date to 1 day prior to index date Step-Up Dosing Period Index date to end of follow-up. Follow-up will be defined two ways to account for gaps in elranatamab use. See Section 9.7.5 for censoring criteria

4	Cost of MM-related pharmacy claims	Cost of MM-related IP, OP, ED, or pharmacy claim (continuous)	180 days prior to index date to 1 day prior to index date Step-Up Dosing Period Index date to end of follow-up. Follow-up will be defined two ways to account for gaps in elranatamab use. See Section 9.7.5 for censoring criteria
4	Total cost of MM-related HCRU	Cost of MM-related IP, OP, ED, or pharmacy claim (continuous)	180 days prior to index date to 1 day prior to index date Step-Up Dosing Period Index date to end of follow-up. Follow-up will be defined two ways to account for gaps in elranatamab use. See Section 9.7.5 for censoring criteria
Adverse events			
Exploratory Obj 1	CRS[1]	Medical claim with an ICD-10 code in the IP, 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	Index date to end of follow-up, where follow-up will be based on last dose of elranatamab (eg, 14 days after last recorded dose or 90 days after last recorded dose). See Section 9.7.6 for censoring criteria

		Grade 4 Grade 5 If patients have multiple, conflicting grades, then the highest recorded grade will be reported	
Exploratory Obj 1	ICANS[1]	Medical claim with an ICD-10 code in the IP, 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 (eg, 14 days after last recorded dose or 90 days after last recorded dose). See Section 9.7.6 for censoring criteria
Hematologic events			
Exploratory Obj 1	Anemia[1]	Medical claim with an ICD-10 code in the IP, non-IP, or pharmacy setting for anemia or event in the lab table where hemoglobin is <10g/dL (dichotomous)	Index date to end of follow-up, where follow-up will be based on last dose of elranatamab (eg, 14 days after last recorded dose or 90 days after last recorded dose). See Section 9.7.6 for censoring criteria

Exploratory Obj 1	Neutropenia[1]	Medical claim with an ICD-10 code in the IP, non-IP, or pharmacy setting for lymphopenia or event in the lab table where lymphocyte count is < 1,000 per uL (dichotomous)	Index date to end of follow-up, where follow-up will be based on last dose of elranatamab (eg, 14 days after last recorded dose or 90 days after last recorded dose). See Section 9.7.6 for censoring criteria
Exploratory Obj 1	Lymphopenia[1]	Medical claim with an ICD-10 code in the IP, non-IP, or pharmacy setting for lymphopenia or event in the lab table where lymphocyte count is < 1,000 per uL (dichotomous)	Index date to end of follow-up, where follow-up will be based on last dose of elranatamab (eg, 14 days after last recorded dose or 90 days after last recorded dose). See Section 9.7.6 for censoring criteria
Non-hematologic events			
Exploratory Obj 1	Hypogammaglobulinemia[1]	Medical claim with an ICD-10 code in the IP, non-IP, or pharmacy setting for hypogammaglobulinemia or event in the lab table where IGG value is ≤ 400 mg/dL (dichotomous)	Index date to end of follow-up, where follow-up will be based on last dose of elranatamab (eg, 14 days after last recorded dose or 90 days after last recorded dose). See Section 9.7.6 for censoring criteria
Exploratory Obj 1	Hypophosphataemia[1]	Medical claim with an ICD-10 code in the IP, 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 (eg, 14 days after last recorded dose or 90 days after last recorded dose). See Section 9.7.6 for censoring criteria

Exploratory Obj 1	Hypokalaemia[1]	Medical claim with an ICD-10 code in the IP, non-IP, or pharmacy setting for hypokalemia or event in the lab table where potassium serum is < 3.0 mmol/L (dichotomous)	Index date to end of follow-up, where follow-up will be based on last dose of elranatamab (eg, 14 days after last recorded dose or 90 days after last recorded dose). See Section 9.7.6 for censoring criteria
Exploratory Obj 1	Hepatotoxicity[1]	Medical claim with an ICD-10 code in the IP, 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 (eg, 14 days after last recorded dose or 90 days after last recorded dose). See Section 9.7.5 for censoring criteria
Exploratory Obj 1	Renal failure[2]	Medical claim with an ICD-10 code in the IP, 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 (eg, 14 days after last recorded dose or 90 days after last recorded dose). See Section 9.7.6 for censoring criteria
Exploratory Obj 1	Peripheral neuropathy[1]	Medical claim with an ICD-10 code in the IP, 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 (eg, 14 days after last recorded dose or 90 days after last recorded dose). See Section 9.7.6 for censoring criteria

Exploratory Obj 1	Arthralgia[3]	Medical claim with an ICD-10 code in the IP, 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 (eg, 14 days after last recorded dose or 90 days after last recorded dose). See Section 9.7.6 for censoring criteria
Hematologic events			
Exploratory Obj 1	Pyrexia[3]	Medical claim with an ICD-10 code in the IP, 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 (eg, 14 days after last recorded dose or 90 days after last recorded dose). See Section 9.7.6 for censoring criteria
Exploratory Obj 1	Hypotension[3]	Medical claim with an ICD-10 code in the IP, 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 (eg, 14 days after last recorded dose or 90 days after last recorded dose). See Section 9.7.6 for censoring criteria
Exploratory Obj 1	Fatigue[3]	Medical claim with an ICD-10 code in the IP, non-IP, or pharmacy setting for nausea or vomiting (dichotomous) Medical claim with an ICD-10 code in the IP, 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 (eg, 14 days after last recorded dose or 90 days after last recorded dose).

			See Section 9.7.6 for censoring criteria
Exploratory Obj 1	Nausea or vomiting[3]	Medical claim with an ICD-10 code in the IP, 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 (eg, 14 days after last recorded dose or 90 days after last recorded dose). See Section 9.7.6 for censoring criteria
Exploratory Obj 1	Diarrhea[3]	Medical claim with an ICD-10 code in the IP, 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 (eg, 14 days after last recorded dose or 90 days after last recorded dose). See Section 9.7.6 for censoring criteria
Exploratory Obj 1	Angioedema[3]	Medical claim with an ICD-10 code in the IP, 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 (eg, 14 days after last recorded dose or 90 days after last recorded dose). See Section 9.7.6 for censoring criteria
Exploratory Obj 1	Erythema[3]	Medical claim with an ICD-10 code in the IP, 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 (eg, 14 days after last recorded dose or 90 days after last recorded dose). See Section 9.7.6 for censoring criteria

Exploratory Obj 1	Muscle spasms[3]	Medical claim with an ICD-10 code in the IP, 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 (eg, 14 days after last recorded dose or 90 days after last recorded dose). See Section 9.7.6 for censoring criteria
Exploratory Obj 1	Musculoskeletal pain[3]	Medical claim with an ICD-10 code in the IP, 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 (eg, 14 days after last recorded dose or 90 days after last recorded dose). See Section 9.7.6 for censoring criteria
Exploratory Obj 1	COVID-19[2]	Medical claim with an ICD-10 code in the IP, 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 (eg, 14 days after last recorded dose or 90 days after last recorded dose). See Section 9.7.6 for censoring criteria
Infections			
Exploratory Obj 1	Sinusitis	Medical claim with an ICD-10 code in the IP, non-IP, or pharmacy setting for sinusitis (dichotomous)	Index date to end of follow-up, where follow-up will be based on last dose of elranatamab (eg, 14 days after last recorded dose or 90 days after last recorded dose).

			See Section 9.7.6 for censoring criteria
Exploratory Obj 1	Bronchitis	Medical claim with an ICD-10 code in the IP, non-IP, or pharmacy setting for bronchitis (dichotomous)	Index date to end of follow-up, where follow-up will be based on last dose of elranatamab (eg, 14 days after last recorded dose or 90 days after last recorded dose). See Section 9.7.6 for censoring criteria
Exploratory Obj 1 Exploratory Obj 1	Pneumonia[2]	Medical claim with an ICD-10 code in the IP, non-IP, or pharmacy setting for pneumonia (dichotomous)	Index date to end of follow-up, where follow-up will be based on last dose of elranatamab (eg, 14 days after last recorded dose or 90 days after last recorded dose). See Section 9.7.6 for censoring criteria
Exploratory Obj 1	Adenoviral pneumonia[2]	Medical claim with an ICD-10 code in the IP, 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 (eg, 14 days after last recorded dose or 90 days after last recorded dose). See Section 9.7.6 for censoring criteria
Exploratory Obj 1	Cytomegaloviral pneumonitis[2]	Medical claim with an ICD-10 code in the IP, 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 (eg, 14 days after last recorded dose or 90 days after last recorded dose).

			See Section 9.7.6 for censoring criteria
Exploratory Obj 1	Other pneumonia[2]	Medical claim with an ICD-10 code in the IP, 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 (eg, 14 days after last recorded dose or 90 days after last recorded dose). See Section 9.7.6 for censoring criteria
Exploratory Obj 1	Upper respiratory tract infection[2]	Medical claim with an ICD-10 code in the IP, 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 (eg, 14 days after last recorded dose or 90 days after last recorded dose). See Section 9.7.6 for censoring criteria
Exploratory Obj 1	Sepsis[2]	Medical claim with an ICD-10 code in the IP, 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 (eg, 14 days after last recorded dose or 90 days after last recorded dose). See Section 9.7.6 for censoring criteria
Exploratory Obj 1 Exploratory Obj 1	Cytomegaloviral infection[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 (eg, 14 days after last recorded dose or 90 days after last recorded dose). See Section 9.7.6 for censoring criteria

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 (eg, 14 days after last recorded dose or 90 days after last recorded dose). See Section 9.7.6 for censoring criteria
Exploratory Obj 1	Hepatitis C[2]	Medical claim with an ICD-10 code in the IP, 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 (eg, 14 days after last recorded dose or 90 days after last recorded dose). See Section 9.7.6 for censoring criteria
Exploratory Obj 1	Hepatitis B[2]	Medical claim with an ICD-10 code in the IP, 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 (eg., 14 days after last recorded dose or 90 days after last recorded dose). See Section 9.7.6 for censoring criteria
Exploratory Obj 1	Other infectious hepatitis[2]	Medical claim with an ICD-10 code in the IP, non-IP or pharmacy setting for other infectious hepatitis (dichotomous)	Index date to end of follow-up, where follow-up will be based on last dose of elranatamab (eg., 14 days after last recorded dose or 90 days after last recorded dose). See Section 9.7.6 for censoring criteria
Exploratory Obj 1	Helicobacter pylori[2]	Medical claim with an ICD-10 code in the IP, 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 (eg, 14 days after last

			recorded dose or 90 days after last recorded dose). See Section 9.7.6 for censoring criteria
Exploratory Obj 1	Candida esophagitis[2]	Medical claim with an ICD-10 code in the IP, 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 (eg, 14 days after last recorded dose or 90 days after last recorded dose). See Section 9.7.6 for censoring criteria
Exploratory Obj 1	Urinary tract infection[2]	Medical claim with an ICD-10 code in the IP, 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 (eg, 14 days after last recorded dose or 90 days after last recorded dose). See Section 9.7.6 for censoring criteria
Exploratory Obj 1	Time to infection onset	Time in days from index date to first infection for the following infections: COVID-19 Sinusitis Bronchitis Adenoviral pneumonia Cytomegaloviral pneumonitis Pneumonia Sepsis Cytomegaloviral infection	Index date until censor See Section 9.7.6 for censoring criteria

		PJP Hepatitis C Hepatitis B Other infectious hepatitis Helicobacter pylori Candida esophagitis Urinary tract infection	
Effectiveness			
Exploratory Obj 2	OS	Time (in months) from index date until date of death (continuous)	Index date until censor See Section 9.7.7 for censoring criteria
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 See Section 9.7.7 for censoring criteria

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 be conducted using Komodo Health's Healthcare Map™. The data source is a healthcare technology firm owning, linking, and integrating both open and closed-claims databases from over 150 public and private payers/insurers as well as clearinghouses across the US. The database linkage uses Datavant's encryption and tokenization technology. The data covers more than 330 million individuals including both current (alive) and historical (deceased during the time of study) patients. The database is closely aligned with the National Health Interview Survey population in terms of geography and demographics. 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. In this iteration of the Komodo Healthcare Map, only patients with at least one ICD diagnosis code for MM are included in the database.

Mortality records in the data source are obtained from government public records, private claims, and obituaries. For Health Insurance Portability and Accountability Act compliance reasons, mortality is truncated to the year/month of death (YYYY-MM-01). Multiple sources of data are then evaluated, and death dates within 30 days of each other are deduplicated. If multiple sources report different death dates for the same person, then the earlier date is taken.

In order to impute costs, Komodo Heath utilizes the data provided to them by their data sources as well as from as well as publicly available Centers for Medicare & Medicaid Services Medicare fee-for-service pricing tools and methodologies.

This study involved secondary research that utilized de-identified data licensed from a third party, Komodo, in compliance with 45 Code of Federal Regulations 164.514(a)-(c).

9.5. Study Size

This retrospective cohort study will be largely descriptive in nature; sample size calculations are not directly applicable. At the time of the study, the dataset included over 700,000 patients with a claim for MM and 56 patients with a claim for elranatamab. The results of this study will be updated on a quarterly basis becomes available.

9.6. Data Management

Komodo Health receives raw data from several heterogeneous sources. Prior to the creation of any schemas, the data is first ingested and inspected to ensure its quality compared to previous deliveries from that source. If the data passes these initial tests, it is then mapped, cleaned, and reassembled. This process accomplishes the following tasks:

- **Mapping** individual fields from each of our sources are standardized to a uniform schema. Concordance validation is performed to ensure that mapping of individual source fields was performed accurately.

- **Cleansing** of mapped fields to a standard format in aggregate as much as possible. Examples of cleansing steps that do not need to be performed at the source-level include adjusting date fields to a consistent format, adjusting NDC fields to a standard of 11 characters, removing decimal points from ICD codes, and converting revenue codes to a 4-digit format.

- **Reassembly** of cleansed fields to account for source-specific cleaning and transformation steps in order to optimize downstream deduplication.

This produces a non-deduplicated, standardized representation of data from all sources. To ensure de-duplication, Komodo Health performs combinations of automated and manual data quality testing throughout the ingestion, transformation, data product development and maintenance life cycle. This testing is led by Komodo Health's Data Quality team, which is distinct from, and independent of the team that develops and maintains the data products. Komodo Health believes that this independent quality assurance process limits the potential for bias.

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 prevalence and incidence, as well as the associated 95% CI for each AEs, will be estimated. Kaplan-Meier methods will be used to estimate the median time to event, including its 95% CIs.

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. Furthermore, baseline characteristics will be assessed among elranatamab or teclistamab patients with and without a laboratory observation.

9.7.2. Treatment Exposure Outcomes

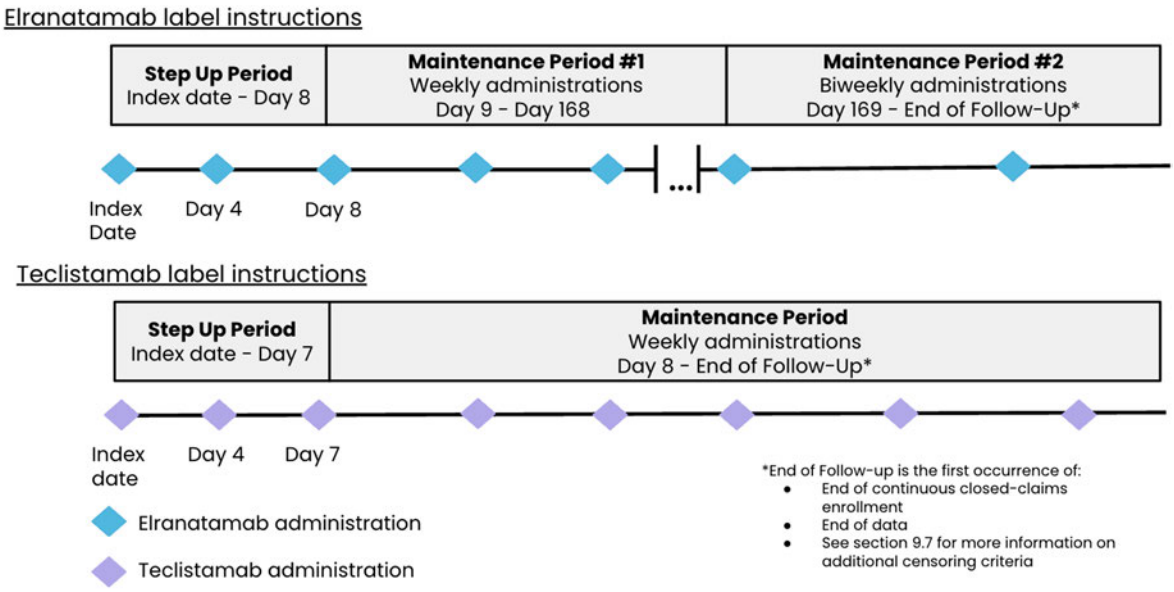
Treatment exposure outcomes include RAI and time between administrations. The assessment periods shown in Table 4 are based on the elranatamab label instructions and will be used to measure treatment and dosing-related outcomes for patients receiving elranatamab.[18] These periods are also provided in 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 during Step-Up	44mg/1.1mL
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

Figure 2. Dosing Schedule for Elranatamab and Teclistamab



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.[19] These periods are also provided in Figure 2.

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

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. Duration on treatment will be measured from the first administration to the last administration of the index drug.

Patients will be censored at the earliest of death, next treatment (CAR-T, BsABs, bendamustine, or belantamab), the end of observability, or the latest data at the time of the specified analysis.

9.7.3. 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). There will be two RAI assessments with two different denominators; the first denominator will assess RAI as specified in the label (see Table 4 and Table 5), the second denominator will assume an administration every week after the Step-Up Period. The numerator will remain the same across the three different RAI assessments.

$$RAI = \frac{Number\ of\ administrations\ received}{Number\ of\ expected\ administrations\ during\ the\ time\ period}$$

Treatment exposure outcomes will be assessed across the different maintenance and step-up period. Patients will be censored at the earliest of death, the last administration of the index drug, or the latest data at the time of the specified analysis.

9.7.4. Time to Discontinuation

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% CIs 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 the end of data.

The percentage of patients who reached the outcome, as well as the percentage of censored patients, will be reported.

9.7.5. Healthcare Resource Utilization and Cost

All-cause HCRU and MM-related HCRU (ie, HCRU with a diagnosis code or treatment for MM) will be measured as the total number of 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, pharmacy claims will count all claims including multiple on the same day 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. As the number of HCRU claims will vary by patient follow up time, results will also be reported as PPPM.

HCRU and associated costs will be measured across four different time periods. The first time period will be from 180 days prior to index date to one day prior to the index date, the second time period will be the index date until last recorded dose, the third time period will be during the step-up dosing period, the fourth time period will be the index date until discontinuation with an allowable 8-week gap of the index drug.

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 latest data at the time of the specified analysis.

9.7.6. Tolerability

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

$$Prevalence = \left(\frac{Number\ of\ patients\ with\ an\ event}{Total\ number\ of\ patients\ in\ the\ cohort}\right) \times 100$$

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

$$Incidence = \left(\frac{Number\ of\ patients\ with\ an\ event\ who\ did\ not\ have\ an\ event\ at\ baseline}{Total\ number\ of\ patients\ in\ the\ cohort}\right) \times 100$$

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, the end of continuous closed-claim coverage, the latest data at the time of the specified analysis, or next treatment (CAR-T, BsABs, bendamustine or belantamab).

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. Patients without an event will be censored at the earliest of the end of continuous closed-claim coverage or the end of data.

TTNT/D will be assessed as the time in months from index date until switch a new treatment or death. Patients without an event will be censored at the earliest of the end of continuous closed-claim coverage, or the end of data.

9.8. Quality Control

Redacted 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 (eg, using a diagnosis code as a rule-out criterion) or incorrect coding (eg, 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.

Databases that contain open and closed claims can offer information in real-time; they often are large in size and have a quick update cadence that allows for the immediate analysis of patient data. However, despite these strengths, there are some limitations associated with the use of open and closed claims. There is a risk of both patient and claim duplication, i.e., where the same patient shows up with a unique patient ID multiple times within the data. With a small cohort size, it may be hard to ascertain if such patients are unique to the dataset or if they are duplicates. Additionally, data providers such as Komodo are beholden to the suppliers of their claims data; therefore, if a data supplier withdraws and no replacement is found, then patient counts could drop across cuts.

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 AEs were not as severe in grade may not be captured.

Claims data such as Komodo Health 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.

The recency of elranatamab approval is important for interpreting results. The expected sample size is low, potentially resulting in uncertain estimates, as evidenced by wide CIs. 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 soon after approval may have more severe or advanced disease. Due to the recency of elranatamab approval, the generalizability of outcomes may be limited to a short period following initiation.

9.10. Other Aspects

Not applicable.

10. PROTECTION OF HUMAN PARTICIPANTS

10.1. Patient Information

This study involves data that exist in deidentified/anonymized structured format and contain no patient personal information.

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),[20] Best Practices for Conducting and Reporting Pharmacoepidemiologic Safety Studies Using Electronic Healthcare Data Sets,[21] and the 2015 International Society of Pharmacoepidemiology GPP.[22]

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 (ie, identify a potential association between) a particular product and medical event for any individual. Thus, the minimum criteria for reporting an AE (ie, 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 (eg, 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.

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14. LIST OF TABLES

15. LIST OF FIGURES

ANNEX 1. LIST OF STANDALONE DOCUMENTS

Number	Document Reference Number	Date	Title
1	1	23 May 2024	ALTITUDE_Table_Shells
2	2	31 July 2024	C1071039 - Real-world usage of ELREXFIO (ALTITUDE) (003)_Abstract

ANNEX 2. ADDITIONAL INFORMATION

Variable	Role	Data Source(s)	Codes	Source
Elranatamab	Inclusion criteria	Claims data	HCPCS: C9165, J1323 NDC: 00069449401, 00069449402, 00069252201, 00069252202 ICD-10 Procedure code: XW013L9 Generic name: Elranatamab	ELREXFIO Outpatient Billing (2024) ELREXFIO Inpatient Billing (2024)
Teclistamab	Inclusion criteria (Exploratory cohort)	Claims data	HCPCS (Mapped via SEER using generic name): J9380, C9148 NDC: 57894044901, 57894045001 ICD-10 Procedure code: XW01348 Generic name: Teclistamab	Janssen Biotech (2023) SEER (2024)
Multiple Myeloma	Inclusion criteria, Outcome - HCRU	Claims data	C90.0x	ELREXFIO Outpatient Billing (2024)
Age	Inclusion criteria, Baseline characteristic - Demographic	Claims data	N/A	N/A
Sex	Baseline characteristic - Demographic	Claims data	N/A	N/A
Race/Ethnicity	Baseline characteristic - Demographic	Claims data	N/A	N/A

Insurance type	Baseline characteristic - Demographic	Claims data	N/A	
Care setting	Baseline characteristic - Clinical	Claims data	See rows below: "Inpatient," "Outpatient," and "Emergency Department"	N/A
Hematopoietic stem cell transplantation	Baseline characteristic - Treatments	Claims data	CPT: 38240, 38241, 38242, 38243 ICD-10 Diagnosis: T86.0, T86.00, T86.01, T86.02, T86.03, T86.09, T86.5, Z48.290, Z94.81 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	Chaudhry et al. (2022) LeMaistre et al. (2013)
BCMA-directed therapy (Excluding bispecific antibodies)	Baseline characteristic - Treatments, Outcome - HCRU	Claims data	CPT: 0540T HCPCS: C9069*, J9037*, Q2055, Q2056 ICD-10 procedure: XW033A7, XW043A7, XW033K7, XW043K7 NDC (Mapped via SEER using generic name): 57894011101, 57894011102, 59572051501, 59572051502, 59572051503, 00173089601 Generic names: Idecabtagene Vicleucel, Ciltacabtagene Autoleucel, Belantamab	Idecabtagene vicleucel billing guide Ciltacabtagene autoleucel billing guide SEER (2024)

			*Belantamab HCPCS codes were mapped via SEER	
CAR-T	Baseline characteristic - Treatments, Outcome - HCRU	Claims data	CPT: 0540T HCPCS: Q2055, Q2056 ICD-10 procedure: XW033A7, XW043A7, XW033K7, XW043K7 NDC (Mapped via SEER using generic name): 57894011101, 57894011102, 59572051501, 59572051502, 59572051503 Generic names: Idecabtagene Vicleucel, Ciltacabtagene Autoleucel	idecabtagene vicleucel billing guide ciltacabtagene autoleucel billing guide SEER (2024)
Talquetamab	Baseline characteristic - Treatments, Outcome - HCRU	Claims data	HCPCS (Mapped via SEER using generic name): C9163 NDC (Mapped via SEER using generic name): 57894046901, 57894047001 Generic name: Talquetamab	SEER (2024) NCCN (2024)
Proteasome inhibitors	Baseline characteristic - Treatments, Outcome - HCRU	Claims data	HCPCS (Mapped via SEER using generic name): J9041, S0115, J9047, C9295, J9046, J9048, J9049, J9044, J9051 NDC (Mapped via SEER using generic name): 00409170301, 00409170401, 10019099101, 25021024410, 50742048401, 51817058601, 55150033701, 63323082110, 68001054036, 70710141101, 70771170801, 00143909801, 00409170001, 00781325870, 68001054136, 70511016105, 70511016202, 71288011810, 72205018301, 72266024301, 72266024401, 43598042660, 63020007801, 63020007802, 63020007901, 63020007902, 63020008001, 63020008002, 60505605004, 68001053436, 83090000801, 43598086560, 70860022510, 76075010301, 63020004901, 76075010101, 76075010201 Generic names: Bortezomib, Carfilzomib, Ixazomib	Ito et al. (2020) SEER (2024) NCCN (2024)

IMiD	Baseline characteristic - Treatments, Outcome - HCRU	Claims data	NDC (Mapped via SEER using generic name): 00480124228, 00480124328, 00480124421, 00480124621, 43598051601, 43598051663, 43598051501, 43598051521, 43598051401, 43598051421, 43598051301, 43598051321, 43598051201, 43598051263, 43598051101, 43598051163, 47781048401, 47781048428, 47781048501, 47781048528, 47781048601, 47781048677, 47781048801, 47781048877, 69097038173, 69097038273, 69097038381, 69097038581, 70710103101, 70710103107, 70710103201, 70710103207, 70710103301, 70710103308, 70710103501, 70710103508, 70771167701, 70771167707, 70771167801, 70771167807, 70771167901, 70771167908, 70771168101, 70771168108, 76282069748, 76282069848, 76282069947, 76282070148, 00378193501, 00378193528, 00378194201, 00378194221, 31722025701, 31722025728, 31722025801, 31722025828, 31722025901, 31722025928, 31722026001, 31722026021, 31722026101, 31722026121, 31722026201, 31722026221, 00480124128, 00480124521, 47781048301, 47781048328, 47781048701, 47781048777, 59651034201, 59651034207, 59651034228, 59651034301, 59651034307, 59651034328, 59651034401, 59651034407, 59651034428, 59651034501, 59651034507, 59651034521, 59651034601, 59651034607, 59651034621, 59651034701, 59651034707, 59651034721, 60505453202, 60505453602, 63304004101, 63304004127, 63304004201, 63304004227, 63304004301, 63304004327, 63304004401, 63304004422, 63304004501, 63304004522, 63304004601, 63304004622, 69097038481, 69097060473, 70710103001, 70710103007, 70710103401, 70710103408, 70771167601, 70771167607, 70771168001, 70771168008, 00378193601, 00378193628, 00378193701, 00378193728, 00378194001, 00378194021, 00378194101, 00378194121, 59572020514, 59572020517, 59572020594, 59572020597, 59572021015, 59572021095, 59572021513, 59572021593, 59572022016, 59572022096, 60505453301, 60505453302, 60505453401, 60505453402, 60505453501, 60505453502, 60505453701, 60505453702, 76282069648, 76282070047, 59572040200, 59572040228, 59572040500, 59572040528, 59572041000, 59572041028, 59572041500, 59572041521, 59572042000,	Minařík et al. 2022 SEER (2024) NCCN (2024)

			59572042021, 59572042500, 59572042521, 59572050100, 59572050121, 59572050200, 59572050221, 59572050300, 59572050321, 59572050400, 59572050421 Generic names: Lenalidomide, Thalidomide, Pomalidomide	
Steroids	Baseline characteristic - Treatments, Outcome - HCRU	Claims data	HCPCS (Mapped via SEER using generic name): J8540, J1100, J1094, J7509, J1040, J1030, J1020, J2930, J2920, J7510, J2650, J7512, J7506, J1010, J2919 Generic names (Mapped to NDC codes via First Data Bank): Dexamethasone, Methylprednisolone, Prednisone, Prednisolone* *Prednisolone is not listed in NCCN	Usmani et al. 2016 NCCN (2024) SEER (2024)
CD38 mAbs	Baseline characteristic - Treatments, Outcome - HCRU	Claims data	HCPCS (Mapped via SEER using generic name): J9415, C9476, J9227, J9144, C9062 NDC (Mapped via SEER using generic name): 57894050301, 00024065401, 00024065601, 57894050205, 57894050220, 57894050505, 57894050520 Generic names: Daratumumab, Isatuximab	NCCN (2024) Gozzetti et al. 2022
mAbs	Baseline characteristic - Treatments, Outcome - HCRU	Claims data	HCPCS (Mapped via SEER using generic name): J9415, C9476, J9227, J9144, C9062, C9477, J9176 NDC (Mapped via SEER using generic name): 57894050301, 00024065401, 00024065601, 57894050205, 57894050220, 57894050505, 57894050520, 00003229111, 00003452211 Generic names: Daratumumab, Isatuximab, Elotuzumab	SEER (2024) NCCN (2024) Wudhikarn et al. 2020
Chemotherapies	Baseline characteristic - Treatments, Outcome - HCRU	Claims data	HCPCS (Mapped via SEER using generic name): C9243, J9033, J9034, J9060, J9062, C9418, J9091, J9070, J9092, J9080, J9090, C9420, C9421, J9093, J9094, J9095, J9096, J9097, J8530, J9100, C9422, J9110, J9098, J9000, C9415, J9002, Q2048, Q2049, Q2050, J9001, J9181, J9182, C9425,	Cowan et al. (2022) NCCN (2024)

			J8560, C9414, J9245, J8600, J8610, J9250, J9260, J9036, J9246, C9080, C9024, J9247, C9087, J9071, J9056, J9058, J9059, J9072, J9255, J9073, J9074, J9075, J9248, J9249, J8611, J8612 Generic names (Mapped via SEER using generic name): Melphalan, Bendamustine, Cyclophosphamide, Doxorubicin, Etoposide, Cisplatin, Methotrexate*, Cytarabine* *Methotrexate and cytarabine are not in NCCN; however, they have been used in the treatment of multiple myeloma with central nervous system relapse	SEER (2024)
Small molecule inhibitors	Baseline characteristic - Treatments, Outcome - HCRU	Claims data	NDC (Mapped via SEER using generic name): 00074057611, 00074057622, 00074057630, 00074057634, 00074057928, 00074056111, 00074056114, 00074056607, 00074056611 Generic name: Venetoclax	SEER (2024) NCCN (2024)
Nuclear export inhibitors	Baseline characteristic - Treatments, Outcome - HCRU	Claims data	NDC (Mapped via SEER using generic name): 72237010101, 72237010102, 72237010103, 72237010104, 72237010105, 72237010106, 72237010107, 72237010202, 72237010206, 72237010207, 72237010305, 72237010401 Generic name: Selinexor	Vogl et al. (2018) SEER (2024) NCCN (2024)
Antivirals	Baseline characteristic - Treatments	Claims data	HCPCS/CPT (Mapped via Athena – OHDSI using generic name): J0741, J0741, J0739, J0248, C9077, C9077, J1574, J0750, J0751, 4153F, 67027, G9017, G9018, G9019, G9020, G9033, G9034, G9035, G9036, J0133, J0740, J1324, J1455, J1570, J1825, J1830, J3485, J7310, J9212, J9213, J9214, J9215, S0104, S0137, S0140, S0145, S0146, S0148, J1826, C9412, Q4075, S0071, J0751, J0750 Generic names* (Mapped to NDC codes via First Data Bank): Abacavir, Acyclovir, Adefovir, Amantadine, Amprenavir, Alpha Interferon, Atazanavir, Asunaprevir, Baloxavir,	LiverTox Athena – OHDSI

			Bictegravir, Brivudin, Brincidofovir, Boceprevir, Cabotegravir, Cidofovir, Daclatasvir, Dasabuvir, Darunavir, Delavirdine, Didanosine, Dolutegravir, Doravirine, Efavirenz, Elbasvir, Elvitegravir, Emtricitabine, Enfuvirtide, Entecavir, Etravirine, Famciclovir, Fosamprenavir, Foscarnet, Fostemsavir, Ganciclovir, Grazoprevir, Glecaprevir, Ibalizumab, Indinavir, Lamivudine, Ledipasvir, Letermovir, Lopinavir, Maraviroc, Maribavir, Molnupiravir, Nelfinavir, Nevirapine, Nirmatrelvir, Ombitasvir, Oseltamivir, Paritaprevir, Pibrentasvir, Raltegravir, Remdesivir, Rilpivirine, Ribavirin, Rimantadine, Ritonavir, Saquinavir, Simeprevir, Sofosbuvir, Stavudine, Sofosbuvir, Tecovirimat, Tenofovir, Telaprevir, Telbivudine, Tipranavir, Valacyclovir, Valganciclovir, Velpatasvir, Voxilaprevir, Zanamivir, Zidovudine *Therapies in combination with any of the listed generic names will be included	
Antibiotics	Baseline characteristic - Treatments	Claims data	HCPCS/CPT (Mapped via Athena – OHDSI using generic name): J0561, J0278, S0016, S0072, G9313, G9314, G9315, J0290, J0295, J0714, J0456, Q0144, J0688, 4041F, G8198, G8199, G8527, J0690, J0699, J0693, J0698, J0714, J0713, C9452, J0695, J0696, 4041F, G8198, G8199, G8527, J0697, J0720, J0742, J0743, C9479, J0744, J7342, S0024, J0736, S0077, J1364, J1362, J1580, J1956, J2021, J2020, C9001, J2184, J2185, J2186, J1836, S0030, J2281, J2280, J2543, S0081, C9039, J0291, J3320, J3000, S0039, C9452, J0695, J2543, J3090, C9446, S0039, J2186, J3372, J3371, 4047F, 4048F, G8152, G8191, G8192, G8195, G8197, G8503, G8504, J3370, G8630, G8629 Generic names* (mapped to NDC codes via First Data Bank): Benzylpenicillin, Cefalexin, Cloxacillin, Doxycycline, Nitrofurantoin, Phenoxymethylpenicillin, Cefixime, Colistin, Fosfomycin, Clofazimine, Dapsone, Rifampicin, Ethambutol, Isoniazid, Pyrazinamide, Rifapentine, Bedaquiline, Cycloserine, Terizidone, Protionamide, Imipenem, P-Aminosalicylate, Pretomanid, Amikacin, Amoxicillin, Ampicillin, Avibactam,	WHO (2023) Athena – OHDSI

			Azithromycin, Cefazolin, Cefiderocol, Cefotaxime, Ceftazidime, Ceftolozane, Ceftriaxone, Cefuroxime, Chloramphenicol, Cilastatin, Ciprofloxacin, Clarithromycin, Clindamycin, Delamanid, Erythromycin, Ethionamide, Gentamicin, Levofloxacin, Linezolid, Meropenem, Metronidazole, Moxifloxacin, Piperacillin, Plazomicin, Polymyxin, Spectinomycin, Streptomycin, Sulfamethoxazole, Tazobactam, Tedizolid, Trimethoprim, Vaborbactam, Vancomycin, Rifabutin *Therapies in combination with any of the listed generic names will be included	
Antifungals	Baseline characteristic - Treatments	Claims data	HCPCS (Mapped via Athena – OHDSI using generic name): J0285, J0287, J0288, J0289, J0286, K0453, J1450, S0029, J1835, S0096, J2247, C9227, J2248, J3465, J0637, C9019, J0348 Generic name* (mapped to NDC codes via First Data Bank): Amphotericin B, Clotrimazole, Fluconazole, Flucytosine, Griseofulvin, Itraconazole, Nystatin, Voriconazole, Micafungin, Caspofungin, Anidulafungin *Therapies in combination with any of the listed generic names will be included	WHO (2023) Athena – OHDSI
Intravenous immunoglobulin	Baseline characteristic - Treatments, Dexamethasone	Claims data	HCPCS (Mapped via Athena – OHDSI using brand name): J1556, C9130, J1557, J1559, C9270, Q4097, Q4092, Q4091, Q4088, Q4087, J1572, J1569, J1568, J1562, J1459, J1576, J1555, C9072, J1551, J1554, J1558 Brand Name (mapped to NDC codes via First Data Bank): Asceniv, Bivigam, Gammaplex, Privigen, Octagam, Flebogamma/Flebogamma Dif, Panzyga, Gammagard Liquid, Flebogamma, Gamunex, Gamimune N, LAndoglobulin, Polygam S/D, Gammagard S-D, Gammagard S/D, Gammagard,	Mayo Clinic (2024) Athena – OHDSI

			Panglobulin, Carimune, Carimune Nf Nanofiltered, Venoglobulin-S, Iveegam En, Flebogamma Dif	
Other hematological malignancies	Baseline characteristic - Clinical	Claims data	ICD-10 Diagnosis: Lymphoma; malignant plasma cell neoplasm; leukemia; other and unspecified malignant neoplasms of lymphoid, hematopoietic, and related tissue; and myelodysplastic syndrome: C81-C96, D46 (Excluding C90.0x)	Maziarz et al. (2024)
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-C58.x, C60-63.x, C76.x, C80.1	Glasheen et al. (2019)
Plasma cell leukemia	Baseline characteristic - Clinical	Claims data	ICD-10 Diagnosis: C90.1x	Wu et al. (2017)
Graft vs host disease	Baseline characteristic - Clinical	Claims data	ICD-10 Diagnosis: D89.81x	Huang et al. (2023)
Benign bone lesions	Baseline characteristic - Clinical	Claims data	ICD-10 Diagnosis: D16.0-D16.9, M85.0, M85.4-M85.6, D48.0	Muran et al. (2023)
Peripheral neuropathy	Baseline characteristic - Clinical, AE	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, 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,	Song et al. (2019)

			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, PJP, Hepatitis C, Hepatitis B, Other infectious hepatitis, Helicobacter pylori, Candida esophagitis, Urinary tract infection	N/A
Use of intravenous anti-infective	Baseline characteristic - Clinical	Claims data	See "Antivirals," "Antibiotics," and "Antifungals" and where service category = injection/infusion drugs or where route = injectable or route array has injectable in it OR HCPCS/CPT codes that indicate IV administration of an anti-infective	N/A
Absolute neutrophil count (for Neutropenia)	Baseline characteristic - Clinical, AE	Claims data	White blood cell count x the percentage of neutrophils White blood cell count: Results_value in the lab results table where the result_abbrev is wbc and result_units are thousand per µL Percent Neutrophil: Results_value in the lab results table where the result_abbrev is neutrophils percent and result_units are percent White blood cell count and percent neutrophil results must occur on the same day	Severe Chronic Neutropenia International Registry
Neutropenia	Baseline characteristic - Clinical, AE	Claims data	ICD-10 Diagnosis: D70.x or Absolute neutrophil count < 1500 cells per µL	Kim et al. (2022) Lustberg et al. (2012)

Hypercalcemia	Baseline characteristic - Clinical	Claims data	ICD-10 Diagnosis: E83.52 or value in the GDD table where test is hypercalemia and result_units are mg/dL and result_value is > 11.5	Kumi et al. (2024) CTCAE v6 (2020)
Hepatotoxicity	Baseline characteristic - Clinical, AE	Claims data	ICD-10 Diagnosis: K71.x	Banerjee et al. (2023)
Amyloidosis	Baseline characteristic - Clinical	Claims data	ICD-10 Diagnosis: E85.4x, E85.8x, E85.9x	Quock et al. (2018)
Hypertension	Baseline characteristic - Clinical	Claims data	ICD-10 Diagnosis: I10x-I15x	Angier et al. (2019)
Extramedullary plasmacytoma	Baseline characteristic - Clinical	Claims data	ICD-10 Diagnosis: C90.2x	Ellington et al. (2021)
CCI score	Baseline characteristic - Clinical	Claims data	See components below	Glasheen et al. (2019)
Myocardial infarction	Baseline characteristic - Clinical	Claims data	ICD-10 Diagnosis: I21.x, I22.x, I25.2	Glasheen et al. (2019)
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	Glasheen et al. (2019)
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	Glasheen et al. (2019)

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	Glasheen et al. (2019)
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	Glasheen et al. (2019)
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	Glasheen et al. (2019)
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	Glasheen et al. (2019)
Peptic ulcer disease	Baseline characteristic - Clinical	Claims data	ICD-10 Diagnosis: K25.x, K26.x, K27.x, K28.x	Glasheen et al. (2019)
Mild 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	Glasheen et al. (2019)
Moderate or severe liver disease	Baseline characteristic - Clinical	Claims data	ICD-10 Diagnosis: I85.0x, I86.4, K70.4x, K71.1x, K72.1x, K72.9x, K76.5, K76.6, K76.7	Glasheen et al. (2019)
Diabetes without chronic complications	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	Glasheen et al. (2019)
Diabetes with chronic complications	Baseline characteristic - Clinical	Claims data	ICD-10 Diagnosis: 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	Glasheen et al. (2019)

Mild or moderate 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	Glasheen et al. (2019)
Severe renal disease	Baseline characteristic - Clinical	Claims data	ICD-10 Diagnosis: I12.0, I13.11, I13.2, N18.5, N18.6, N19.x, N25.0, Z49.x, Z99.2	Glasheen et al. (2019)
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	Glasheen et al. (2019)
Human immunodeficiency virus	Baseline characteristic - Clinical	Claims data	ICD-10 Diagnosis: B20.x	Glasheen et al. (2019)
Metastatic solid tumor	Baseline characteristic - Clinical	Claims data	ICD-10 Diagnosis: C77.x, C78.x, C79.x, C80.0, C80.2	Glasheen et al. (2019)
Any 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, C47.x, C48.x, C49.x, C50.x, C51-C58.x, C60-C63.x, C76.x, C80.1, C81.x, C82.x, C83.x, C84.x, C85.x, C88.x, C9x.x	Glasheen et al. (2019)
Albumin serum	Baseline characteristic - Lab	Claims data	An event in the lab results table where the result_abbrev is albumin serum and result_units are g per dL	
ALT	Baseline characteristic - Lab	Claims data	An event in the lab results table where the result_abbrev is ALT and result_units are IU per L	
AST	Baseline characteristic - Lab	Claims data	An event in the lab results table where the result_abbrev is AST and result_units are IU per L	
Neutrophil count	Baseline characteristic - Lab	Claims data	An event in the lab results table where the result_abbrev is neutrophils count and result_units are thousand per µL	

Creatinine	Baseline characteristic - Lab	Claims data	An event in the lab results table where the result_abbrev is creatinine serum and result_units are mg per dL	
Hemoglobin	Baseline characteristic - Lab	Claims data	An event in the lab results table where the result_abbrev is hemoglobin and result_units are g per dL	
Lymphocyte count	Baseline characteristic - Lab	Claims data	An event in the lab results table where the result_abbrev is lymphocytes count and result_units are thousand per µL	
Monocyte count	Baseline characteristic - Lab	Claims data	An event in the lab results table where the result_abbrev is monocytes count and result_units are thousand per µL	
Platelet Count	Baseline characteristic - Lab	Claims data	An event in the lab results table where the result_abbrev is platelets and result_units are thousand per µL	
ImmunoglobulinA	Baseline characteristic - Lab	Claims data	An event in the lab results table where the result_abbrev is IGA and result_units are mg per dL	
ImmunoglobulinG	Baseline characteristic - Lab	Claims data	An event in the lab results table where the result_abbrev is IGG and result_units are mg per dL	
ImmunoglobulinE	Baseline characteristic - Lab	Claims data	An event in the lab results table where the result_abbrev is IGE and result_units are IU per mL	
ImmunoglobulinM	Baseline characteristic - Lab	Claims data	An event in the lab results table where the result_abbrev is IGM and result_units are mg per dL	
Bone marrow plasma cell perccent	Baseline characteristic - Lab	Claims data	An event in the GDD table where the test is bone_marrow and result_units are percent	
M-Protein	Baseline characteristic - Lab	Claims data	An event in the GDD table where the test is m-spike and result_units are mg/dL	
Use of premedication	Outcome - Dosing and Administration Patterns	Claims data	HCPCS (Mapped via SEER [Dexamethasone only] or Athena – OHDSI using generic name): J0136, J0137, J0134, J0131, C9283, G6039, J1200, Q0163, J8540, J1100, J1094	SEER (2024) ELREXFIO Label

			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”	
OP	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”	
ED	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)	AE	Claims data	ICD-10 Diagnosis: D89.83x	Hoover et al. (2024)
Immune effector cell-associated neurotoxicity Syndrome (ICANS)	AE	Claims data	ICD-10 Diagnosis: G92.0x	Hoover et al. (2024)
Anemia	AE	Claims data	ICD-10 Diagnosis: D64.1, D64.2, D64.3, D64.81, D64.89, D64.9 or value in the lab results table where the result_abbrev is hemoglobin and result_units are g per dL and value is <10.0	Kilgore et al. (2021) CTCAE v6.0 (2024)
Lymphocytopenia	AE	Claims data	ICD-10 Diagnosis: D72.810 or value in the lab results table where the result_abbrev is lymphocytes count, result_units are thousand per uL and result_value is <1.5	Papanastasiou et al. (2023) NIH (2022)
Hypogammaglobulinemia	AE	Claims data	ICD-10 Diagnosis: D80.1, D80.3 value in the lab results table where the result_abbrev is IGG, result_units are mg per dL and result_value is ≤ 400	Wallace et al. (2021) Mohan et al. (2024)

Disorders of phosphorus metabolism and phosphatases (including hypophosphatemia)	AE	Claims data	ICD-10 Diagnosis: E83.3	Kim et al. (2023)
Hypokalaemia	AE	Claims data	ICD-10 Diagnosis: E87.6 or value in the lab results table where the result_abbrev is potassium serum and result_units are mmol per L and result_value is < 3.0	Almadani et al. (2024) CTCAE v6.0 (2020)
Arthralgia (joint pain)	AE	Claims data	ICD-10 Diagnosis: M25.5x	Taquet et al. (2022)
Pyrexia (fever)	AE	Claims data	ICD-10 Diagnosis: R50.x	Crabb et al. (2020)
Hypotension	AE	Claims data	ICD-10 Diagnosis: I95.0, I95.81, I95.89, I95.9	Hunley et al. (2021)
Fatigue	AE	Claims data	ICD-10 Diagnosis: R53.x, G93.3x	Cohen et al. (2021)
Nausea or vomiting	AE	Claims data	ICD-10 Diagnosis: R11.x	Peng et al. (2018)
Diarrhea	AE	Claims data	ICD-10 Diagnosis: R19.7, K59.1	Beckman et al. (2015)
Rash	AE	Claims data	ICD-10 Diagnosis: R21	Chen et al. (2022)

Angioedema	AE	Claims data	ICD-10 Diagnosis: D84.1	Sun et al. (2018)
Erythema	AE	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	Sun et al. (2018)
Muscle spasms	AE	Claims data	ICD-10 Diagnosis: M62.83	Jesus et al. (2022)
Musculoskeletal pain	AE	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	Clinical Classifications Software Refined for ICD-10-CM
COVID-19	AE - infection	Claims data	ICD-10 Diagnosis: U07.1	Pfaff et al. (2023)
Adenoviral pneumonia	AE - infection	Claims data	ICD-10 Diagnosis: J12.0	Cocoros et al. (2024)

Cytomegaloviral pneumonitis	AE - infection	Claims data	ICD-10 Diagnosis: B25.0	ICD-10data.com
Other pneumonia	AE - infection	Claims data	ICD-10 Diagnosis: J12.1, J12.2, J12.81, J12.3, J12.89, J12.9, J13, J18.1, J15.0, J15.1, J14, J15.4, J15.3, J15.20, J15.211, J15.212, J15.29, J15.8, J15.5, J15.6, A48.1, J15.9, J15.7, J16.0, J16.8, A37.01, A37.11, A37.81, A37.91, A22.1, B44.0, J17, B77.81, J18.0, J18.8, J18.9, J10.00, J10.01, J10.08, J11.00, J11.08	Smithee et al. (2020)
Pneumonia	AE - infection	Claims data	An ICD-10 Diagnosis Code for any of the following types of pneumonia. See the following rows for infection type: Adenoviral pneumonia, cytomegaloviral pneumonia, other pneumonia	
Upper respiratory tract infection	AE - infection	Claims data	ICD-10 Diagnosis: A38.0-A38.9, J02.0-J03.91, J01.00-J01.91, J09.x1-J11.89, J00, J04.0-J06.9, H65.00-H65.199, H68.011-H68.019, J20.0-J20.9, J45.20-J45.998, J45.21, J45.31, J45.41, J45.51, J45.901	Butler et al. (2023)
Acute sinusitis	AE - infection	Claims data	ICD-10 Diagnosis: J01.x0	Savage et al. (2023)
Bronchitis	AE - infection	Claims data	ICD-10 Diagnosis: J20.0-J20.9	Butler et al. (2023
Sepsis	AE - infection	Claims data	ICD-10 Diagnosis: A02.1, A22.7, A26.7, A32.7, A40.0, A40.1, A40.3, A40.8, A40.9, 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, A41.9, A42.7, A54.86, B37.7, R65.20, R65.2	Prasad et al. (2021)
Cytomegaloviral disease (including cytomegaloviral infection)	AE - infection	Claims data	ICD-10 Diagnosis: B25.x	Grosse et al. (2022)
PJP	AE - infection	Claims data	ICD-10 Diagnosis: B59	Boone et al. (2022)

Hepatitis C	AE - infection	Claims data	ICD-10 Diagnosis: B17.1x, B18.2, B19.2x	Kim et al. (2018)
Hepatitis B	AE - infection	Claims data	ICD-10 Diagnosis: B16.x, B17.0, B18.0, B18.1, B19.1x	Kim et al. (2018)
Other infectious hepatitis	AE - infection	Claims data	ICD-10 Diagnosis: B17.2, B17.8, B17.9, B18.8, B18.9, B19.0, B19.9, B26.81, B58.1	Lo et al. (2021)
Helicobacter pylori	AE - infection	Claims data	ICD-10 Diagnosis: B96.81	Shah et al. (2023)
Candida esophagitis	AE - infection	Claims data	ICD-10 Diagnosis: B37.81	Gold et al. (2024)
Urinary tract infection	AE - infection	Claims data	ICD-10 Diagnosis: N39.0	Papp et al. (2023)

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