

Disclaimer

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

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

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

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

If you are using a web page screen reader and are unable to access this document, please contact the Sentinel Operations Center for assistance at info@sentinelssystem.org.

Overview for Request: cder_mpl1r_wp291

Request ID: cder_mpl1r_wp291

Request Description: In this report, we characterized utilization patterns of Gimoti™ (metoclopramide nasal spray) approved on June 19, 2020, stratified by age and sex in the Sentinel Distributed Database (SDD).

Sentinel Routine Querying Module: Cohort Identification and Descriptive Analysis (CIDA) module, version 14.0.1.

Data Source: We distributed this query to six Sentinel Data Partners, including Medicare and Medicaid on December 12, 2024. Data from Medicare patients having both fee-for-service medical coverage and Part D drug coverage are included. The study period included data from June 19, 2020 through the most recent available data May 31, 2024. Please see Appendix A for a list of dates of available data for each Data Partner.

Study Design: We identified four cohorts of individuals aged 18 years and older who were dispensed metoclopramide nasal spray (brand name Gimoti™), with varying duration of exposure washout, episode gap and episode extension. We then characterized dispensing patterns by examining all episodes of use occurring after the initial exposure; specifically, cumulative exposure episode duration, first exposure episode duration, all exposure episode durations, days supplied per dispensing, and lengths of gaps between episodes, in the overall cohorts and stratified by age group and sex. This is a Type 5 analysis in the Query Request Package (QRP) documentation.

Exposure of Interest: We defined the exposure of interest, Gimoti™ (metoclopramide nasal spray), using National Drug Codes (NDCs) and index exposure was the first qualifying dispensing of the exposure during the study period. For all four cohorts, we included all valid exposure episodes during the study period; only the first valid episode's incidence was assessed using the washout period.

For the two cohorts that required a washout (incident use cohorts, see cohort eligibility criteria below), we defined new use as no evidence of any dispensing of Gimoti™ (metoclopramide nasal spray) in the 183 days before the index exposure date.

For the remaining two cohorts (prevalent use cohorts), we did not implement any exposure washout.

Please see Appendix B for a list of generic and brand names of medical products.

Cohort Eligibility Criteria: We defined four cohorts (two incident use and two prevalent use), using the following cohort eligibility criteria. The following age groups were included in all cohorts: 18-21, 22-44, 45-64, 65-74, 75+ years.

- The two incident use cohorts (cohorts one and three) required members to be enrolled in health plans with medical and drug coverage for at least 183 days prior to their index date, during which gaps in coverage of up to 45 days were allowed. An exposure washout of 183 days before index date was used to define incident use.
- The two prevalent use cohorts (cohorts two and four) did not require any pre-index enrollment in health plans with medical and drug coverage prior to their index date. No exposure washout was specified.

Episode Creation: We created exposure episodes based on the number of days of product supplied per dispensing in the outpatient pharmacy dispensing data.

- Cohorts one and two (56 days episode gap and extension): For these two cohorts (one incident use and one prevalent use), if a gap of up to 56 days occurred between consecutive dispensing claims of Gimoti™ (metoclopramide nasal spray), we bridged these claims into a single treatment episode. We extended the end of each exposure episode by 56 days.
- Cohorts three and four (zero day episode gap and extension): For these two cohorts (one incident use and one prevalent use), we did not allow for any gaps between successive dispensing claims to be bridged or allow for any extension of the exposure episode.

Please see Appendices C and D for the specifications defining parameters in this request and design diagrams of cohort entry requirements.

Limitations: Algorithms used to define exposures and inclusion/exclusion criteria are imperfect; thus, it is possible that there may be misclassification. Therefore, data should be interpreted with this limitation in mind.

Overview for Request: cder_mpl1r_wp291

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

Table of Contents

<u>Glossary (CIDA)</u>	List of Terms to Define the Cohort Identification and Descriptive Analysis (CIDA) Found in this Report
<u>Table 1a</u>	Categorical Summary of Days Supplied per Dispensing for Exposures of Interest in the Sentinel Distributed Database (SDD) from June 19, 2020 to May 31, 2024
<u>Table 1b</u>	Continuous Summary of Days Supplied per Dispensing for Exposures of Interest in the Sentinel Distributed Database (SDD) from June 19, 2020 to May 31, 2024
<u>Table 1c</u>	Categorical Summary of Days Supplied per Dispensing for Exposures of Interest in the Sentinel Distributed Database (SDD) from June 19, 2020 to May 31, 2024, by Sex
<u>Table 1d</u>	Continuous Summary of Days Supplied per Dispensing for Exposures of Interest in the Sentinel Distributed Database (SDD) from June 19, 2020 to May 31, 2024, by Sex
<u>Table 1e</u>	Categorical Summary of Days Supplied per Dispensing for Exposures of Interest in the Sentinel Distributed Database (SDD) from June 19, 2020 to May 31, 2024, by Age Group
<u>Table 1f</u>	Continuous Summary of Days Supplied per Dispensing for Exposures of Interest in the Sentinel Distributed Database (SDD) from June 19, 2020 to May 31, 2024, by Age Group
<u>Table 2a</u>	Categorical Summary of Patients' Cumulative Treatment Episode Durations for Exposures of Interest in the Sentinel Distributed Database (SDD) from June 19, 2020 to May 31, 2024
<u>Table 2b</u>	Continuous Summary of Patients' Cumulative Treatment Episode Durations for Exposures of Interest in the Sentinel Distributed Database (SDD) from June 19, 2020 to May 31, 2024
<u>Table 2c</u>	Categorical Summary of Patients' Cumulative Treatment Episode Durations for Exposures of Interest in the Sentinel Distributed Database (SDD) from June 19, 2020 to May 31, 2024, by Sex
<u>Table 2d</u>	Continuous Summary of Patients' Cumulative Treatment Episode Durations for Exposures of Interest in the Sentinel Distributed Database (SDD) from June 19, 2020 to May 31, 2024, by Sex
<u>Table 2e</u>	Categorical Summary of Patients' Cumulative Treatment Episode Durations for Exposures of Interest in the Sentinel Distributed Database (SDD) from June 19, 2020 to May 31, 2024, by Age Group
<u>Table 2f</u>	Continuous Summary of Patients' Cumulative Treatment Episode Durations for Exposures of Interest in the Sentinel Distributed Database (SDD) from June 19, 2020 to May 31, 2024, by Age Group
<u>Table 3a</u>	Categorical Summary of All Treatment Episodes for Exposures of Interest in the Sentinel Distributed Database (SDD) from June 19, 2020 to May 31, 2024
<u>Table 3b</u>	Continuous Summary of All Treatment Episodes for Exposures of Interest in the Sentinel Distributed Database (SDD) from June 19, 2020 to May 31, 2024
<u>Table 3c</u>	Categorical Summary of All Treatment Episodes for Exposures of Interest in the Sentinel Distributed Database (SDD) from June 19, 2020 to May 31, 2024, by Sex
<u>Table 3d</u>	Continuous Summary of All Treatment Episodes for Exposures of Interest in the Sentinel Distributed Database (SDD) from June 19, 2020 to May 31, 2024, by Sex
<u>Table 3e</u>	Categorical Summary of All Treatment Episodes for Exposures of Interest in the Sentinel Distributed Database (SDD) from June 19, 2020 to May 31, 2024, by Age Group
<u>Table 3f</u>	Continuous Summary of All Treatment Episodes for Exposures of Interest in the Sentinel Distributed Database (SDD) from June 19, 2020 to May 31, 2024, by Age Group
<u>Table 4a</u>	Categorical Summary of First Treatment Episodes for Exposures of Interest in the Sentinel Distributed Database (SDD) from June 19, 2020 to May 31, 2024
<u>Table 4b</u>	Continuous Summary of First Treatment Episodes for Exposures of Interest in the Sentinel Distributed Database (SDD) from June 19, 2020 to May 31, 2024
<u>Table 4c</u>	Categorical Summary of First Treatment Episodes for Exposures of Interest in the Sentinel Distributed Database (SDD) from June 19, 2020 to May 31, 2024, by Sex
<u>Table 4d</u>	Continuous Summary of First Treatment Episodes for Exposures of Interest in the Sentinel Distributed Database (SDD) from June 19, 2020 to May 31, 2024, by Sex
<u>Table 4e</u>	Categorical Summary of First Treatment Episodes for Exposures of Interest in the Sentinel Distributed Database (SDD) from June 19, 2020 to May 31, 2024, by Age Group
<u>Table 4f</u>	Continuous Summary of First Treatment Episodes for Exposures of Interest in the Sentinel Distributed Database (SDD) from June 19, 2020 to May 31, 2024, by Age Group

Table of Contents

<u>Table 5a</u>	Categorical Summary of Second and Subsequent Treatment Episodes for Exposures of Interest in the Sentinel Distributed Database (SDD) from June 19, 2020 to May 31, 2024
<u>Table 5b</u>	Continuous Summary of Second and Subsequent Treatment Episodes for Exposures of Interest in the Sentinel Distributed Database (SDD) from June 19, 2020 to May 31, 2024
<u>Table 5c</u>	Categorical Summary of Second and Subsequent Treatment Episodes for Exposures of Interest in the Sentinel Distributed Database (SDD) from June 19, 2020 to May 31, 2024, by Sex
<u>Table 5d</u>	Continuous Summary of Second and Subsequent Treatment Episodes for Exposures of Interest in the Sentinel Distributed Database (SDD) from June 19, 2020 to May 31, 2024, by Sex
<u>Table 5e</u>	Categorical Summary of Second and Subsequent Treatment Episodes for Exposures of Interest in the Sentinel Distributed Database (SDD) from June 19, 2020 to May 31, 2024, by Age Group
<u>Table 5f</u>	Continuous Summary of Second and Subsequent Treatment Episodes for Exposures of Interest in the Sentinel Distributed Database (SDD) from June 19, 2020 to May 31, 2024, by Age Group
<u>Table 6a</u>	Continuous Summary of All Treatment Episode Gaps for Exposures of Interest in the Sentinel Distributed Database (SDD) from June 19, 2020 to May 31, 2024
<u>Table 6b</u>	Continuous Summary of All Treatment Episode Gaps for Exposures of Interest in the Sentinel Distributed Database (SDD) from June 19, 2020 to May 31, 2024, by Sex
<u>Table 6c</u>	Continuous Summary of All Treatment Episode Gaps for Exposures of Interest in the Sentinel Distributed Database (SDD) from June 19, 2020 to May 31, 2024, by Age Group
<u>Table 7a</u>	Continuous Summary of First Treatment Episode Gaps for Exposures of Interest in the Sentinel Distributed Database (SDD) from June 19, 2020 to May 31, 2024
<u>Table 7b</u>	Continuous Summary of First Treatment Episode Gaps for Exposures of Interest in the Sentinel Distributed Database (SDD) from June 19, 2020 to May 31, 2024, by Sex
<u>Table 7c</u>	Continuous Summary of First Treatment Episode Gaps for Exposures of Interest in the Sentinel Distributed Database (SDD) from June 19, 2020 to May 31, 2024, by Age Group
<u>Table 8a</u>	Continuous Summary of Second and Subsequent Treatment Episode Gaps for Exposures of Interest in the Sentinel Distributed Database (SDD) from June 19, 2020 to May 31, 2024
<u>Table 8b</u>	Continuous Summary of Second and Subsequent Treatment Episode Gaps for Exposures of Interest in the Sentinel Distributed Database (SDD) from June 19, 2020 to May 31, 2024, by Sex
<u>Table 8c</u>	Continuous Summary of Second and Subsequent Treatment Episode Gaps for Exposures of Interest in the Sentinel Distributed Database (SDD) from June 19, 2020 to May 31, 2024, by Age Group
<u>Table 9a</u>	Summary of Filled Daily Dose in Each Dispensing for Exposures of Interest in the Sentinel Distributed Database (SDD) from June 19, 2020 to May 31, 2024
<u>Table 9b</u>	Summary of Filled Daily Dose in Each Dispensing for Exposures of Interest in the Sentinel Distributed Database (SDD) from June 19, 2020 to May 31, 2024, by Sex
<u>Table 9c</u>	Summary of Filled Daily Dose in Each Dispensing for Exposures of Interest in the Sentinel Distributed Database (SDD) from June 19, 2020 to May 31, 2024, by Age Group
<u>Table 10</u>	Summary of Episode Duration for First Treatment Episodes Ended due to End of Exposure Episode for Exposures of Interest in the Sentinel Distributed Database (SDD) from June 19, 2020 to May 31, 2024
<u>Table 11</u>	Summary of Episode Duration for First Treatment Episodes Ended due to Occurrence of User-Defined Censoring Criteria for Exposures of Interest in the Sentinel Distributed Database (SDD) from June 19, 2020 to May 31, 2024
<u>Table 12</u>	Summary of Episode Duration for First Treatment Episodes Ended due to Evidence of Death for Exposures of Interest in the Sentinel Distributed Database (SDD) from June 19, 2020 to May 31, 2024
<u>Table 13</u>	Summary of Episode Duration for First Treatment Episodes Ended due to Disenrollment for Exposures of Interest in the Sentinel Distributed Database (SDD) from June 19, 2020 to May 31, 2024
<u>Table 14</u>	Summary of Episode Duration for First Treatment Episodes Ended due to End of Data for Exposures of Interest in the Sentinel Distributed Database (SDD) from June 19, 2020 to May 31, 2024
<u>Table 15</u>	Summary of Episode Duration for First Treatment Episodes Ended due to End of Study Period for Exposures of Interest in the Sentinel Distributed Database (SDD) from June 19, 2020 to May 31, 2024

Table of Contents
<p><u>Table 16</u> Summary of Patient Level Cohort Attrition in the Sentinel Distributed Database (SDD) from June 19, 2020 to May 31, 2024</p> <p><u>Appendix A</u> Dates of Available Data for Each Data Partner (DP) as of Request Distribution Date (December 12, 2024)</p> <p><u>Appendix B</u> List of Generic and Brand Names of Medical Products Used to Define Exposures in this Request</p> <p><u>Appendix C</u> Specifications Defining Parameters in this Request</p> <p><u>Appendix D</u> Design Diagram for Cohort Defining Criteria</p>

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Evaluation Period - number of days relative to index wherein a member is required to have evidence of a condition

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

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

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

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

Member-Years - sum of all days of enrollment with medical and drug coverage in the query period preceded by an exposure

Minimum Days Supplied - specifies a minimum number of days in length of the days supplied for the episode to be considered.

Minimum Episode Duration - specifies a minimum number of days in length of the episode for it to be considered. Applied after any gaps are bridged and extension days added to the length of the exposure episode.

Monitoring Period - used to define time periods of interest for both sequential analysis and simple cohort characterization

Principal Diagnosis (PDX) - diagnosis or condition established to be chiefly responsible for admission of the patient to the hospital. 'P' = principal diagnosis, 'S' = secondary diagnosis, 'X' = unspecified diagnosis, '.' = blank. Along with the Care Setting values, forms

Query Period - period in which the modular program looks for exposures and outcomes of interest.

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

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

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

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

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

*all terms may not be used in this report

Table 1a. Categorical Summary of Days Supplied per Dispensing for Exposures of Interest in the Sentinel Distributed Database (SDD) from June 19, 2020 to May 31, 2024

	Total Number of Dispensings	Number of Dispensings by Days Supplied							
		1-30 Days		31-60 Days		61-90 Days		91+ Days	
		Number of Dispensings	Percent of Total Dispensings	Number of Dispensings	Percent of Total Dispensings	Number of Dispensings	Percent of Total Dispensings	Number of Dispensings	Percent of Total Dispensings
<i>Incident Cohort With Episode Gap and Episode Extension of 56 Days</i>	1,535	*****	*****	*****	*****	*****	*****	0	0.0%
<i>Prevalent Cohort With Episode Gap and Episode Extension of 56 Days</i>	1,775	*****	*****	*****	*****	*****	*****	0	0.0%
<i>Incident Cohort With Episode Gap and Episode Extension of 0 Days</i>	1,535	*****	*****	*****	*****	*****	*****	0	0.0%
<i>Prevalent Cohort With Episode Gap and Episode Extension of 0 Days</i>	1,775	*****	*****	*****	*****	*****	*****	0	0.0%

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

Table 1b. Continuous Summary of Days Supplied per Dispensing for Exposures of Interest in the Sentinel Distributed Database from June 19, 2020 to May 31, 2024

	Total Number of Dispensings	Distribution of Days Supplied by Dispensing						
		Minimum	Q1	Median	Q3	Maximum	Mean	Standard Deviation
<i>Incident Cohort With Episode Gap and Episode Extension of 56 Days</i>	1,535	1	28	28	28	86	27.4	4.5
<i>Prevalent Cohort With Episode Gap and Episode Extension of 56 Days</i>	1,775	1	28	28	28	86	27.3	4.6
<i>Incident Cohort With Episode Gap and Episode Extension of 0 Days</i>	1,535	1	28	28	28	86	27.4	4.5
<i>Prevalent Cohort With Episode Gap and Episode Extension of 0 Days</i>	1,775	1	28	28	28	86	27.3	4.6

Table 1c. Categorical Summary of Days Supplied per Dispensing for Exposures of Interest in the Sentinel Distributed Database (SDD) from June 19, 2020 to May 31, 2024, by Sex

	Total Number of Dispensings	Number of Dispensings by Days Supplied							
		1-30 Days		31-60 Days		61-90 Days		91+ Days	
		Number of Dispensings	Percent of Total Dispensings	Number of Dispensings	Percent of Total Dispensings	Number of Dispensings	Percent of Total Dispensings	Number of Dispensings	Percent of Total Dispensings
Incident Cohort With Episode Gap and Episode Extension of 56 Days									
	1,535	*****	*****	*****	*****	*****	*****	0	NaN
Female	1,137	*****	*****	*****	*****	*****	*****	0	NaN
Male	398	*****	*****	*****	*****	*****	*****	0	NaN
Prevalent Cohort With Episode Gap and Episode Extension of 56 Days									
	1,775	*****	*****	*****	*****	*****	*****	0	NaN
Female	1,335	*****	*****	*****	*****	*****	*****	0	NaN
Male	440	*****	*****	*****	*****	*****	*****	0	NaN
Incident Cohort With Episode Gap and Episode Extension of 0 Days									
	1,535	*****	*****	*****	*****	*****	*****	0	NaN
Female	1,137	*****	*****	*****	*****	*****	*****	0	NaN
Male	398	*****	*****	*****	*****	*****	*****	0	NaN
Prevalent Cohort With Episode Gap and Episode Extension of 0 Days									
	1,775	*****	*****	*****	*****	*****	*****	0	NaN
Female	1,335	*****	*****	*****	*****	*****	*****	0	NaN
Male	440	*****	*****	*****	*****	*****	*****	0	NaN

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

NaN: Not a Number

Table 1d. Continuous Summary of Days Supplied per Dispensing for Exposures of Interest in the Sentinel Distributed Database (SDD) from June 19, 2020 to May 31, 2024, by Sex

	Total Number of Dispensings	Distribution of Days Supplied by Dispensing						Standard Deviation
		Minimum	Q1	Median	Q3	Maximum	Mean	
Incident Cohort With Episode Gap and Episode Extension of 56 Days	1,535	1	28	28	28	86	27.4	4.5
Female	1,137	1	28	28	28	60	27.2	3.8
Male	398	1	28	28	28	86	27.7	6.1
Prevalent Cohort With Episode Gap and Episode Extension of 56 Days	1,775	1	28	28	28	86	27.3	4.6
Female	1,335	1	28	28	28	60	27.1	4.0
Male	440	1	28	28	28	86	27.7	6.0
Incident Cohort With Episode Gap and Episode Extension of 0 Days	1,535	1	28	28	28	86	27.4	4.5
Female	1,137	1	28	28	28	60	27.2	3.8
Male	398	1	28	28	28	86	27.7	6.1
Prevalent Cohort With Episode Gap and Episode Extension of 0 Days	1,775	1	28	28	28	86	27.3	4.6
Female	1,335	1	28	28	28	60	27.1	4.0
Male	440	1	28	28	28	86	27.7	6.0

Table 1e. Categorical Summary of Days Supplied per Dispensing for Exposures of Interest in the Sentinel Distributed Database (SDD) from June 19, 2020 to May 31, 2024, by Age Group

Total Number of Dispensings		Number of Dispensings by Days Supplied							
		1-30 Days		31-60 Days		61-90 Days		91+ Days	
		Number of Dispensings	Percent of Total	Number of Dispensings	Percent of Total	Number of Dispensings	Percent of Total	Number of Dispensings	Percent of Total
Incident Cohort With Episode Gap and Episode Extension of 56 Days									
1,535	*****	*****	*****	*****	*****	*****	100.0%	0	NaN
18-21 years	*****	*****	*****	*****	*****	*****	0.0%	0	NaN
22-44 years	342	*****	*****	*****	*****	*****	0.0%	0	NaN
45-64 years	781	*****	*****	*****	*****	*****	100.0%	0	NaN
65-74 years	265	*****	*****	*****	*****	*****	0.0%	0	NaN
≥ 75 years	*****	*****	*****	*****	*****	*****	0.0%	0	NaN
Prevalent Cohort With Episode Gap and Episode Extension of 56 Days									
1,775	*****	*****	*****	*****	*****	*****	100.0%	0	NaN
18-21 years	*****	*****	*****	*****	*****	*****	0.0%	0	NaN
22-44 years	399	*****	*****	*****	*****	*****	0.0%	0	NaN
45-64 years	884	*****	*****	*****	*****	*****	100.0%	0	NaN
65-74 years	331	*****	*****	*****	*****	*****	0.0%	0	NaN
≥ 75 years	*****	*****	*****	*****	*****	*****	0.0%	0	NaN
Incident Cohort With Episode Gap and Episode Extension of 0 Days									
1,535	*****	*****	*****	*****	*****	*****	100.0%	0	NaN
18-21 years	*****	*****	*****	*****	*****	*****	0.0%	0	NaN
22-44 years	342	*****	*****	*****	*****	*****	0.0%	0	NaN
45-64 years	781	*****	*****	*****	*****	*****	100.0%	0	NaN
65-74 years	265	*****	*****	*****	*****	*****	0.0%	0	NaN
≥ 75 years	*****	*****	*****	*****	*****	*****	0.0%	0	NaN
Prevalent Cohort With Episode Gap and Episode Extension of 0 Days									
1,775	*****	*****	*****	*****	*****	*****	100.0%	0	NaN

Table 1e. Categorical Summary of Days Supplied per Dispensing for Exposures of Interest in the Sentinel Distributed Database (SDD) from June 19, 2020 to May 31, 2024, by Age Group

	Total Number of Dispensings	Number of Dispensings by Days Supplied							
		1-30 Days		31-60 Days		61-90 Days		91+ Days	
		Number of Dispensings	Percent of Total	Number of Dispensings	Percent of Total	Number of Dispensings	Percent of Total	Number of Dispensings	Percent of Total
18-21 years	*****	*****	*****	*****	*****	*****	0.0%	0	NaN
22-44 years	399	*****	*****	*****	*****	*****	0.0%	0	NaN
45-64 years	884	*****	*****	*****	*****	*****	100.0%	0	NaN
65-74 years	331	*****	*****	*****	*****	*****	0.0%	0	NaN
≥ 75 years	*****	*****	*****	*****	*****	*****	0.0%	0	NaN

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

NaN: Not a Number

Table 1f. Continuous Summary of Days Supplied per Dispensing for Exposures of Interest in the Sentinel Distributed Database (SDD) from June 19, 2020 to May 31, 2024, by Age Group

	Total Number of Dispensings	Distribution of Days Supplied by Dispensing						Standard Deviation
		Minimum	Q1	Median	Q3	Maximum	Mean	
Incident Cohort With Episode Gap and Episode Extension of 56 Days	1,535	1	28	28	28	86	27.4	4.5
18-21 years	*****	28	28	28	28	28	28.0	0.0
22-44 years	342	1	28	28	28	60	27.1	4.5
45-64 years	781	1	28	28	28	86	27.4	5.2
65-74 years	265	6	28	28	28	30	27.6	2.7
≥ 75 years	*****	9	28	28	28	28	27.3	2.9
Prevalent Cohort With Episode Gap and Episode Extension of 56	1,775	1	28	28	28	86	27.3	4.6
18-21 years	*****	28	28	28	28	28	28.0	0.0
22-44 years	399	1	28	28	28	60	26.9	4.7
45-64 years	884	1	28	28	28	86	27.4	5.2
65-74 years	331	6	28	28	28	30	27.4	3.1
≥ 75 years	*****	9	28	28	28	28	27.2	3.2
Incident Cohort With Episode Gap and Episode Extension of 0 Days	1,535	1	28	28	28	86	27.4	4.5
18-21 years	*****	28	28	28	28	28	28.0	0.0
22-44 years	342	1	28	28	28	60	27.1	4.5
45-64 years	781	1	28	28	28	86	27.4	5.2
65-74 years	265	6	28	28	28	30	27.6	2.7
≥ 75 years	*****	9	28	28	28	28	27.3	2.9
Prevalent Cohort With Episode Gap and Episode Extension of 0	1,775	1	28	28	28	86	27.3	4.6
18-21 years	*****	28	28	28	28	28	28.0	0.0
22-44 years	399	1	28	28	28	60	26.9	4.7
45-64 years	884	1	28	28	28	86	27.4	5.2
65-74 years	331	6	28	28	28	30	27.4	3.1
≥ 75 years	*****	9	28	28	28	28	27.2	3.2

Table 2a. Categorical Summary of Patients' Cumulative Treatment Episode Durations for Exposures of Interest in the Sentinel Distributed Database (SDD) from June 19, 2020 to May 31, 2024

	Total Number of Patients	Number of Patients by Cumulative Treatment Episode Duration									
		1-30 Days		31-90 Days		91-365 Days		366-730 Days		731+ Days	
		Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients
<i>Incident Cohort With Episode Gap and Episode Extension of 56 Days</i>	492	31	6.3%	212	43.1%	224	45.5%	*****	*****	*****	*****
<i>Prevalent Cohort With Episode Gap and Episode Extension of 56 Days</i>	574	45	7.8%	240	41.8%	259	45.1%	*****	*****	*****	*****
<i>Incident Cohort With Episode Gap and Episode Extension of 0 Days</i>	492	211	42.9%	154	31.3%	*****	*****	*****	*****	0	0.0%
<i>Prevalent Cohort With Episode Gap and Episode Extension of 0 Days</i>	574	245	42.7%	183	31.9%	*****	*****	*****	*****	0	0.0%

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

Table 2b. Continuous Summary of Patients' Cumulative Treatment Episode Durations for Exposures of Interest in the Sentinel Distributed Database (SDD) from June 19, 2020 to May 31, 2024

	Total Number of Patients	Distribution of Cumulative Treatment Episode Duration, days						Standard Deviation
		Minimum	Q1	Median	Q3	Maximum	Mean	
<i>Incident Cohort With Episode Gap and Episode Extension of 56 Days</i>	492	1	84	96	168	793	138.9	111.1
<i>Prevalent Cohort With Episode Gap and Episode Extension of 56 Days</i>	574	1	84	94	163	793	136.6	112.0
<i>Incident Cohort With Episode Gap and Episode Extension of 0 Days</i>	492	1	28	56	108	600	85.4	90.9
<i>Prevalent Cohort With Episode Gap and Episode Extension of 0 Days</i>	574	1	28	56	97	616	84.3	90.9

Table 2c. Categorical Summary of Patients' Cumulative Treatment Episode Durations for Exposures of Interest in the Sentinel Distributed Database (SDD) from June 19, 2020 to May 31, 2024, by Sex

	Total Number of Patients	Number of Patients by Cumulative Treatment Episode Duration									
		1-30 Days		31-90 Days		91-365 Days		366-730 Days		731+ Days	
		Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients
Incident Cohort With Episode Gap and Episode Extension of 56 Days											
	492	31	100.0%	212	100.0%	224	100.0%	*****	*****	*****	*****
Female	362	*****	*****	143	67.5%	181	80.8%	13	*****	*****	*****
Male	130	*****	*****	69	32.5%	43	19.2%	*****	*****	*****	*****
Prevalent Cohort With Episode Gap and Episode Extension of 56 Days											
	574	45	100.0%	240	100.0%	259	100.0%	*****	*****	*****	*****
Female	425	*****	*****	164	68.3%	208	80.3%	17	*****	*****	*****
Male	149	*****	*****	76	31.7%	51	19.7%	*****	*****	*****	*****
Incident Cohort With Episode Gap and Episode Extension of 0 Days											
	492	211	100.0%	154	100.0%	*****	*****	*****	*****	0	NaN
Female	362	146	69.2%	119	77.3%	*****	*****	*****	*****	0	NaN
Male	130	65	30.8%	35	22.7%	*****	*****	*****	*****	0	NaN
Prevalent Cohort With Episode Gap and Episode Extension of 0 Days											
	574	245	100.0%	183	100.0%	*****	*****	*****	*****	0	NaN
Female	425	172	70.2%	139	76.0%	*****	*****	*****	*****	0	NaN
Male	149	73	29.8%	44	24.0%	*****	*****	*****	*****	0	NaN

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

NaN: Not a Number

Table 2d. Continuous Summary of Patients' Cumulative Treatment Episode Durations for Exposures of Interest in the Sentinel Distributed Database (SDD) from June 19, 2020 to May 31, 2024, by Sex

	Total Number of Patients	Distribution of Cumulative Treatment Episode Duration, days						Standard Deviation
		Minimum	Q1	Median	Q3	Maximum	Mean	
Incident Cohort With Episode Gap and Episode Extension of 56 Days	492	1	84	96	168	793	138.9	111.1
Female	362	1	84	107	168	793	139.3	107.5
Male	130	4	84	84	161	716	137.9	120.9
Prevalent Cohort With Episode Gap and Episode Extension of 56 Days	574	1	84	94	163	793	136.6	112.0
Female	425	1	84	104	168	793	137.4	110.3
Male	149	4	80	84	151	716	134.1	117.3
Incident Cohort With Episode Gap and Episode Extension of 0 Days	492	1	28	56	108	600	85.4	90.9
Female	362	1	28	56	112	600	85.6	88.5
Male	130	4	28	34	84	512	84.9	97.6
Prevalent Cohort With Episode Gap and Episode Extension of 0 Days	574	1	28	56	97	616	84.3	90.9
Female	425	1	28	56	112	616	85.2	90.0
Male	149	4	28	40	84	512	81.7	93.4

Table 2e. Categorical Summary of Patients' Cumulative Treatment Episode Durations for Exposures of Interest in the Sentinel Distributed Database (SDD) from June 19, 2020 to May 31, 2024, by Age Group

Total Number of Patients	Number of Patients by Cumulative Treatment Episode Duration										
	1-30 Days		31-90 Days		91-365 Days		366-730 Days		731+ Days		
	Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients	
Incident Cohort With Episode Gap and Episode Extension of 56 Days											
492	31	100.0%	212	100.0%	224	100.0%	*****	*****	*****	*****	
18-21 years	*****	0	0.0%	*****	*****	*****	*****	0	0.0%	*****	*****
22-44 years	102	*****	*****	38	17.9%	51	22.8%	*****	*****	*****	*****
45-64 years	233	16	51.6%	93	43.9%	109	48.7%	14	*****	*****	*****
65-74 years	99	*****	*****	48	22.6%	44	19.6%	*****	*****	*****	*****
≥ 75 years	*****	*****	*****	*****	*****	*****	*****	*****	*****	*****	*****
Prevalent Cohort With Episode Gap and Episode Extension of 56 Days											
574	45	100.0%	240	100.0%	259	100.0%	*****	*****	*****	*****	
18-21 years	*****	0	0.0%	*****	*****	*****	*****	0	0.0%	*****	*****
22-44 years	118	*****	*****	42	17.5%	61	23.6%	*****	*****	*****	*****
45-64 years	271	21	46.7%	107	44.6%	126	48.6%	16	*****	*****	*****
65-74 years	123	11	24.4%	57	23.8%	50	19.3%	*****	*****	*****	*****
≥ 75 years	*****	*****	*****	*****	*****	*****	*****	*****	*****	*****	*****
Incident Cohort With Episode Gap and Episode Extension of 0 Days											
492	211	100.0%	154	100.0%	*****	*****	*****	*****	0	NaN	
18-21 years	*****	*****	*****	*****	*****	*****	*****	0	0.0%	0	NaN
22-44 years	102	37	17.5%	37	24.0%	25	*****	*****	*****	0	NaN
45-64 years	233	92	43.6%	73	47.4%	63	*****	*****	*****	0	NaN
65-74 years	99	47	22.3%	32	20.8%	18	*****	*****	*****	0	NaN
≥ 75 years	*****	*****	*****	*****	*****	*****	*****	0	0.0%	0	NaN

Table 2e. Categorical Summary of Patients' Cumulative Treatment Episode Durations for Exposures of Interest in the Sentinel Distributed Database (SDD) from June 19, 2020 to May 31, 2024, by Age Group

		Number of Patients by Cumulative Treatment Episode Duration									
		1-30 Days		31-90 Days		91-365 Days		366-730 Days		731+ Days	
Prevalent Cohort With Episode Gap and Episode											
Extension of 0 Days	574	245	100.0%	183	100.0%	*****	*****	*****	*****	0	NaN
18-21 years	*****	*****	*****	*****	*****	*****	*****	0	0.0%	0	NaN
22-44 years	118	41	16.7%	43	23.5%	31	*****	*****	*****	0	NaN
45-64 years	271	106	43.3%	87	47.5%	73	*****	*****	*****	0	NaN
65-74 years	123	61	24.9%	40	21.9%	19	*****	*****	*****	0	NaN
≥ 75 years	*****	*****	*****	*****	*****	*****	*****	0	0.0%	0	NaN

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

NaN: Not a Number

Table 2f. Continuous Summary of Patients' Cumulative Treatment Episode Durations for Exposures of Interest in the Sentinel Distributed Database (SDD) from June 19, 2020 to May 31, 2024, by Age Group

	Total Number of Patients	Distribution of Cumulative Treatment Episode Duration, days						Standard Deviation
		Minimum	Q1	Median	Q3	Maximum	Mean	
Incident Cohort With Episode Gap and Episode Extension of 56 Days								
	492	1	84	96	168	793	138.9	111.1
18-21 years	*****	57	75	84	168	223	121.4	71.1
22-44 years	102	7	84	111	168	703	141.9	113.6
45-64 years	233	1	84	112	171	793	145.7	117.8
65-74 years	99	6	84	84	145	716	130.2	100.0
≥ 75 years	*****	17	81	84	118	473	121.2	98.1
Prevalent Cohort With Episode Gap and Episode Extension of 56 Days								
	574	1	84	94	163	793	136.6	112.0
18-21 years	*****	57	75	84	168	223	121.4	71.1
22-44 years	118	7	84	112	168	703	142.2	113.2
45-64 years	271	1	84	112	171	793	142.0	114.8
65-74 years	123	6	84	84	140	716	126.1	111.6
≥ 75 years	*****	17	81	84	140	473	122.9	99.9
Incident Cohort With Episode Gap and Episode Extension of 0 Days								
	492	1	28	56	108	600	85.4	90.9
18-21 years	*****	28	28	28	56	140	56.0	48.5
22-44 years	102	7	28	56	102	600	90.7	98.1
45-64 years	233	1	28	56	114	557	92.0	94.1
65-74 years	99	6	28	56	84	467	73.8	79.8
≥ 75 years	*****	17	28	28	56	350	70.6	82.2
Prevalent Cohort With Episode Gap and Episode Extension of 0 Days								
	574	1	28	56	97	616	84.3	90.9
18-21 years	*****	28	28	28	56	140	56.0	48.5
22-44 years	118	7	28	56	102	600	91.1	96.2
45-64 years	271	1	28	56	112	557	89.2	90.7
65-74 years	123	6	28	40	84	616	73.7	90.4
≥ 75 years	*****	17	28	28	84	350	72.1	82.7

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

Table 3a. Categorical Summary of All Treatment Episodes for Exposures of Interest in the Sentinel Distributed Database (SDD) from June 19, 2020 to May 31, 2024

	Total Number of Episodes	Number of Treatment Episodes by Duration									
		1-30 Days		31-90 Days		91-365 Days		366-730 Days		731+ Days	
		Number of Episodes	Percent of Total Episodes	Number of Episodes	Percent of Total Episodes	Number of Episodes	Percent of Total Episodes	Number of Episodes	Percent of Total Episodes	Number of Episodes	Percent of Total Episodes
<i>Incident Cohort With Episode Gap and Episode Extension of 56 Days</i>	543	39	7.2%	239	44.0%	247	45.5%	*****	*****	*****	*****
<i>Prevalent Cohort With Episode Gap and Episode Extension of 56 Days</i>	632	54	8.5%	272	43.0%	285	45.1%	*****	*****	*****	*****
<i>Incident Cohort With Episode Gap and Episode Extension of 0 Days</i>	819	475	58.0%	272	33.2%	*****	*****	*****	*****	0	0.0%
<i>Prevalent Cohort With Episode Gap and Episode Extension of 0 Days</i>	946	547	57.8%	314	33.2%	*****	*****	*****	*****	0	0.0%

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

Table 3b. Continuous Summary of All Treatment Episodes for Exposures of Interest in the Sentinel Distributed Database (SDD) from June 19, 2020 to May 31, 2024

	Total Number of Episodes	Distribution of Treatment Episode Durations, days						
		Minimum	Q1	Median	Q3	Maximum	Mean	Standard Deviation
<i>Incident Cohort With Episode Gap and Episode Extension of 56 Days</i>	543	1	84	84	142	768	125.8	94.1
<i>Prevalent Cohort With Episode Gap and Episode Extension of 56 Days</i>	632	1	84	84	140	768	124.0	95.6
<i>Incident Cohort With Episode Gap and Episode Extension of 0 Days</i>	819	1	28	28	56	512	51.3	44.2
<i>Prevalent Cohort With Episode Gap and Episode Extension of 0 Days</i>	946	1	28	28	56	512	51.2	43.7

Table 3c. Categorical Summary of All Treatment Episodes for Exposures of Interest in the Sentinel Distributed Database (SDD) from June 19, 2020 to May 31, 2024, by Sex

		Number of Treatment Episodes by Duration									
		1-30 Days		31-90 Days		91-365 Days		366-730 Days		731+ Days	
		Number of Episodes	Percent of Total Episodes	Number of Episodes	Percent of Total Episodes	Number of Episodes	Percent of Total Episodes	Number of Episodes	Percent of Total Episodes	Number of Episodes	Percent of Total Episodes
Incident Cohort											
With Episode Gap and Episode											
Extension of 56 Days	543	39	100.0%	239	100.0%	247	100.0%	*****	*****	*****	*****
Female	398	28	71.8%	166	69.5%	194	78.5%	*****	*****	*****	*****
Male	145	11	28.2%	73	30.5%	53	21.5%	*****	*****	*****	*****
Prevalent Cohort											
With Episode Gap and Episode											
Extension of 56 Days	632	54	100.0%	272	100.0%	285	100.0%	*****	*****	*****	*****
Female	465	*****	*****	189	69.5%	225	78.9%	*****	*****	*****	*****
Male	167	*****	*****	83	30.5%	60	21.1%	*****	*****	*****	*****
Incident Cohort											
With Episode Gap and Episode											
Extension of 0 Days	819	475	100.0%	272	100.0%	*****	*****	*****	*****	0	NaN
Female	599	340	71.6%	202	74.3%	*****	*****	*****	*****	0	NaN
Male	220	135	28.4%	70	25.7%	*****	*****	*****	*****	0	NaN
Prevalent Cohort											
With Episode Gap and Episode											
Extension of 0 Days	946	547	100.0%	314	100.0%	*****	*****	*****	*****	0	NaN
Female	695	389	71.1%	236	75.2%	*****	*****	*****	*****	0	NaN
Male	251	158	28.9%	78	24.8%	*****	*****	*****	*****	0	NaN

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

NaN: Not a Number

Table 3d. Continuous Summary of All Treatment Episodes for Exposures of Interest in the Sentinel Distributed Database (SDD) from June 19, 2020 to May 31, 2024, by Sex

	Total Number of Episodes	Distribution of Treatment Episode Durations, days						Standard Deviation
		Minimum	Q1	Median	Q3	Maximum	Mean	
Incident Cohort With Episode Gap and Episode Extension of 56 Days	543	1	84	84	142	768	125.8	94.1
Female	398	1	84	102	142	768	126.7	93.2
Male	145	4	80	84	140	568	123.6	97.0
Prevalent Cohort With Episode Gap and Episode Extension of 56 Days	632	1	84	84	140	768	124.0	95.6
Female	465	1	84	95	142	768	125.6	95.8
Male	167	4	74	84	140	568	119.7	95.0
Incident Cohort With Episode Gap and Episode Extension of 0 Days	819	1	28	28	56	512	51.3	44.2
Female	599	1	28	28	56	364	51.7	41.8
Male	220	1	28	28	56	512	50.2	50.2
Prevalent Cohort With Episode Gap and Episode Extension of 0 Days	946	1	28	28	56	512	51.2	43.7
Female	695	1	28	28	58	364	52.1	42.1
Male	251	1	28	28	56	512	48.5	47.7

Table 3e. Categorical Summary of All Treatment Episodes for Exposures of Interest in the Sentinel Distributed Database (SDD) from June 19, 2020 to May 31, 2024, by Age Group

Total Number of Episodes		Number of Treatment Episodes by Duration									
		1-30 Days		31-90 Days		91-365 Days		366-730 Days		731+ Days	
		Number of Episodes	Percent of Total Episodes	Number of Episodes	Percent of Total Episodes	Number of Episodes	Percent of Total Episodes	Number of Episodes	Percent of Total Episodes	Number of Episodes	Percent of Total Episodes
Incident Cohort With Episode Gap and Episode											
Extension of 56 Days	543	39	100.0%	239	100.0%	247	100.0%	*****	*****	*****	*****
18-21 years	*****	0	0.0%	*****	*****	*****	*****	0	0.0%	*****	*****
22-44 years	111	*****	*****	44	18.4%	53	21.5%	*****	*****	*****	*****
45-64 years	261	20	51.3%	106	44.4%	125	50.6%	*****	*****	*****	*****
65-74 years	108	*****	*****	52	21.8%	48	19.4%	*****	*****	*****	*****
≥ 75 years	*****	*****	*****	*****	*****	*****	*****	0	0.0%	*****	*****
Prevalent Cohort With Episode Gap and Episode											
Extension of 56 Days	632	54	100.0%	272	100.0%	285	100.0%	*****	*****	*****	*****
18-21 years	*****	0	0.0%	*****	*****	*****	*****	0	0.0%	*****	*****
22-44 years	130	*****	*****	50	18.4%	64	22.5%	*****	*****	*****	*****
45-64 years	303	25	46.3%	123	45.2%	144	50.5%	*****	*****	*****	*****
65-74 years	132	*****	*****	61	22.4%	54	18.9%	*****	*****	*****	*****
≥ 75 years	*****	*****	*****	*****	*****	*****	*****	0	0.0%	*****	*****
Incident Cohort With Episode Gap and Episode											
Extension of 0 Days	819	475	100.0%	272	100.0%	*****	*****	*****	*****	0	NaN
18-21 years	*****	*****	*****	0	0.0%	*****	*****	*****	*****	0	NaN
22-44 years	181	101	21.3%	61	22.4%	*****	*****	*****	*****	0	NaN
45-64 years	404	223	46.9%	146	53.7%	*****	*****	*****	*****	0	NaN
65-74 years	147	92	19.4%	45	16.5%	*****	*****	*****	*****	0	NaN
≥ 75 years	*****	*****	*****	20	7.4%	*****	*****	*****	*****	0	NaN

Table 3e. Categorical Summary of All Treatment Episodes for Exposures of Interest in the Sentinel Distributed Database (SDD) from June 19, 2020 to May 31, 2024, by Age Group

Total Number of Episodes		Number of Treatment Episodes by Duration									
		1-30 Days		31-90 Days		91-365 Days		366-730 Days		731+ Days	
		Number of Episodes	Percent of Total Episodes	Number of Episodes	Percent of Total Episodes	Number of Episodes	Percent of Total Episodes	Number of Episodes	Percent of Total Episodes	Number of Episodes	Percent of Total Episodes
Prevalent Cohort With Episode Gap and Episode Extension of 0 Days											
946	547	100.0%	314	100.0%	*****	*****	*****	*****	0	NaN	
18-21 years	*****	*****	*****	0	0.0%	*****	*****	*****	*****	0	NaN
22-44 years	207	116	21.2%	66	21.0%	*****	*****	*****	*****	0	NaN
45-64 years	462	255	46.6%	168	53.5%	*****	*****	*****	*****	0	NaN
65-74 years	182	113	20.7%	56	17.8%	*****	*****	*****	*****	0	NaN
≥ 75 years	*****	57	10.4%	*****	*****	*****	*****	*****	*****	0	NaN

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

NaN: Not a Number

Table 3f. Continuous Summary of All Treatment Episodes for Exposures of Interest in the Sentinel Distributed Database (SDD) from June 19, 2020 to May 31, 2024, by Age Group

		Distribution of Treatment Episode Durations, days							
		Minimum	Q1	Median	Q3	Maximum	Mean	Standard Deviation	
Incident Cohort With Episode Gap and Episode Extension of 56 Days		543	1	84	84	142	768	125.8	94.1
18-21 years	*****	57	75	84	84	223	101.2	60.6	
22-44 years	111	7	84	104	141	703	130.4	102.7	
45-64 years	261	1	84	112	147	768	130.0	100.1	
65-74 years	108	6	84	84	141	514	119.3	75.4	
≥ 75 years	*****	14	81	84	118	361	112.7	82.8	
Prevalent Cohort With Episode Gap and Episode Extension of 56 Days		632	1	84	84	140	768	124.0	95.6
18-21 years	*****	57	75	84	84	223	101.2	60.6	
22-44 years	130	7	84	104	141	703	129.1	99.4	
45-64 years	303	1	84	106	146	768	127.0	97.5	
65-74 years	132	6	84	84	140	713	117.5	93.3	
≥ 75 years	*****	14	81	84	140	361	114.8	86.0	
Incident Cohort With Episode Gap and Episode Extension of 0 Days		819	1	28	28	56	512	51.3	44.2
18-21 years	*****	28	28	28	28	112	40.0	31.7	
22-44 years	181	1	28	28	56	310	51.1	41.1	
45-64 years	404	1	28	28	83	512	53.0	46.2	
65-74 years	147	6	28	28	56	364	49.7	45.9	
≥ 75 years	*****	14	28	28	56	196	46.8	37.8	
Prevalent Cohort With Episode Gap and Episode Extension of 0 Days		946	1	28	28	56	512	51.2	43.7
18-21 years	*****	28	28	28	28	112	40.0	31.7	
22-44 years	207	1	28	28	56	310	51.9	42.6	
45-64 years	462	1	28	28	65	512	52.3	44.7	
65-74 years	182	6	28	28	56	364	49.8	45.7	
≥ 75 years	*****	14	28	28	56	196	46.7	36.8	

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

Table 4a. Categorical Summary of First Treatment Episodes for Exposures of Interest in the Sentinel Distributed Database (SDD) from June 19, 2020 to May 31, 2024

	Total Number of Patients	Number of Patients by First Treatment Episode Duration									
		1-30 Days		31-90 Days		91-365 Days		366-730 Days		731+ Days	
		Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients
<i>Incident Cohort With Episode Gap and Episode Extension of 56 Days</i>	492	31	6.3%	223	45.3%	222	45.1%	*****	*****	*****	*****
<i>Prevalent Cohort With Episode Gap and Episode Extension of 56 Days</i>	574	45	7.8%	252	43.9%	258	44.9%	*****	*****	*****	*****
<i>Incident Cohort With Episode Gap and Episode Extension of 0 Days</i>	492	278	56.5%	161	32.7%	*****	*****	*****	*****	0	0.0%
<i>Prevalent Cohort With Episode Gap and Episode Extension of 0 Days</i>	574	320	55.7%	193	33.6%	*****	*****	*****	*****	0	0.0%

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

Table 4b. Continuous Summary of First Treatment Episodes for Exposures of Interest in the Sentinel Distributed Database (SDD) from June 19, 2020 to May 31, 2024

	Total Number of Patients	Distribution of First Treatment Episode Duration, days						
		Minimum	Q1	Median	Q3	Maximum	Mean	Standard Deviation
<i>Incident Cohort With Episode Gap and Episode Extension of 56 Days</i>	492	1	84	84	142	768	126.3	94.5
<i>Prevalent Cohort With Episode Gap and Episode Extension of 56 Days</i>	574	1	84	84	140	768	124.4	96.1
<i>Incident Cohort With Episode Gap and Episode Extension of 0 Days</i>	492	1	28	28	84	512	55.3	49.5
<i>Prevalent Cohort With Episode Gap and Episode Extension of 0 Days</i>	574	1	28	28	84	512	54.6	48.0

Table 4c. Categorical Summary of First Treatment Episodes for Exposures of Interest in the Sentinel Distributed Database from June 19, 2020 to May 31, 2024, by Sex

	Total Number of Patients	Number of Patients by First Treatment Episode Duration									
		1-30 Days		31-90 Days		91-365 Days		366-730 Days		731+ Days	
		Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients
Incident Cohort With Episode Gap and Episode Extension of 56 Days											
	492	31	100.0%	223	100.0%	222	100.0%	*****	*****	*****	*****
Female	362	*****	*****	153	68.6%	176	79.3%	*****	*****	*****	*****
Male	130	*****	*****	70	31.4%	46	20.7%	*****	*****	*****	*****
Prevalent Cohort With Episode Gap and Episode Extension of 56 Days											
	574	45	100.0%	252	100.0%	258	100.0%	*****	*****	*****	*****
Female	425	*****	*****	174	69.0%	205	79.5%	*****	*****	*****	*****
Male	149	*****	*****	78	31.0%	53	20.5%	*****	*****	*****	*****
Incident Cohort With Episode Gap and Episode Extension of 0 Days											
	492	278	100.0%	161	100.0%	*****	*****	*****	*****	0	NaN
Female	362	197	70.9%	125	77.6%	*****	*****	*****	*****	0	NaN
Male	130	81	29.1%	36	22.4%	*****	*****	*****	*****	0	NaN
Prevalent Cohort With Episode Gap and Episode Extension of 0 Days											
	574	320	100.0%	193	100.0%	*****	*****	*****	*****	0	NaN
Female	425	227	70.9%	150	77.7%	*****	*****	*****	*****	0	NaN
Male	149	93	29.1%	43	22.3%	*****	*****	*****	*****	0	NaN

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

NaN: Not a Number

Table 4d. Continuous Summary of First Treatment Episodes for Exposures of Interest in the Sentinel Distributed Database (SDD) from June 19, 2020 to May 31, 2024, by Sex

	Total Number of Patients	Distribution of First Treatment Episode Duration, days						Standard Deviation
		Minimum	Q1	Median	Q3	Maximum	Mean	
Incident Cohort With Episode Gap and Episode Extension of 56 Days	492	1	84	84	142	768	126.3	94.5
Female	362	1	84	99	142	768	127.4	94.1
Male	130	4	84	84	140	568	123.1	96.1
Prevalent Cohort With Episode Gap and Episode Extension of 56 Days	574	1	84	84	140	768	124.4	96.1
Female	425	1	84	95	142	768	125.9	96.7
Male	149	4	80	84	140	568	120.1	94.4
Incident Cohort With Episode Gap and Episode Extension of 0 Days	492	1	28	28	84	512	55.3	49.5
Female	362	1	28	28	84	364	55.1	44.8
Male	130	4	28	28	56	512	55.6	61.1
Prevalent Cohort With Episode Gap and Episode Extension of 0 Days	574	1	28	28	84	512	54.6	48.0
Female	425	1	28	28	84	364	55.0	44.2
Male	149	4	28	28	56	512	53.5	57.8

Table 4e. Categorical Summary of First Treatment Episodes for Exposures of Interest in the Sentinel Distributed Database (SDD) from June 19, 2020 to May 31, 2024, by Age Group

		Number of Patients by First Treatment Episode Duration									
		1-30 Days		31-90 Days		91-365 Days		366-730 Days		731+ Days	
		Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients
Incident Cohort With Episode Gap and Episode Extension of 56 Days											
	492	31	100.0%	223	100.0%	222	100.0%	*****	*****	*****	*****
18-21 years	*****	0	0.0%	*****	*****	*****	*****	0	0.0%	*****	*****
22-44 years	102	*****	*****	40	17.9%	50	22.5%	*****	*****	*****	*****
45-64 years	233	*****	*****	98	43.9%	110	49.5%	*****	*****	*****	*****
65-74 years	99	*****	*****	49	22.0%	*****	*****	*****	*****	*****	*****
≥ 75 years	*****	*****	*****	*****	*****	*****	*****	0	0.0%	*****	*****
Prevalent Cohort With Episode Gap and Episode Extension of 56 Days											
	574	45	100.0%	252	100.0%	258	100.0%	*****	*****	*****	*****
18-21 years	*****	0	0.0%	*****	*****	*****	*****	0	0.0%	*****	*****
22-44 years	118	*****	*****	45	17.9%	60	23.3%	*****	*****	*****	*****
45-64 years	271	*****	*****	112	44.4%	128	49.6%	*****	*****	*****	*****
65-74 years	123	*****	*****	58	23.0%	50	19.4%	*****	*****	*****	*****
≥ 75 years	*****	*****	*****	*****	*****	*****	*****	0	0.0%	*****	*****
Incident Cohort With Episode Gap and Episode Extension of 0 Days											
	492	278	100.0%	161	100.0%	*****	*****	*****	*****	0	NaN
18-21 years	*****	*****	*****	0	0.0%	0	0.0%	*****	*****	0	NaN
22-44 years	102	53	19.1%	34	21.1%	*****	*****	*****	*****	0	NaN
45-64 years	233	118	42.4%	88	54.7%	*****	*****	*****	*****	0	NaN
65-74 years	99	64	23.0%	*****	*****	*****	*****	*****	*****	0	NaN
≥ 75 years	*****	*****	*****	*****	*****	*****	*****	*****	*****	0	NaN

Table 4e. Categorical Summary of First Treatment Episodes for Exposures of Interest in the Sentinel Distributed Database (SDD) from June 19, 2020 to May 31, 2024, by Age Group

	Total Number of Patients	Number of Patients by First Treatment Episode Duration									
		1-30 Days		31-90 Days		91-365 Days		366-730 Days		731+ Days	
		Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients
Prevalent Cohort With Episode Gap and Episode Extension of 0 Days	574	320	100.0%	193	100.0%	*****	*****	*****	*****	0	NaN
18-21 years	*****	*****	*****	0	0.0%	0	0.0%	*****	*****	0	NaN
22-44 years	118	60	18.8%	38	19.7%	*****	*****	*****	*****	0	NaN
45-64 years	271	135	42.2%	107	55.4%	*****	*****	*****	*****	0	NaN
65-74 years	123	79	24.7%	*****	*****	*****	*****	*****	*****	0	NaN
≥ 75 years	*****	*****	*****	*****	*****	*****	*****	*****	*****	0	NaN

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

NaN: Not a Number

Table 4f. Continuous Summary of First Treatment Episodes for Exposures of Interest in the Sentinel Distributed Database

	Total Number of Patients	Distribution of First Treatment Episode Duration, days						Standard Deviation
		Minimum	Q1	Median	Q3	Maximum	Mean	
Incident Cohort With Episode Gap and Episode Extension of 56 Days	492	1	84	84	142	768	126.3	94.5
18-21 years	*****	57	75	84	84	223	104.6	67.1
22-44 years	102	7	84	106	142	703	131.4	102.2
45-64 years	233	1	84	106	147	768	131.2	102.0
65-74 years	99	6	84	84	142	514	119.9	75.5
≥ 75 years	*****	17	81	84	112	352	108.7	77.2
Prevalent Cohort With Episode Gap and Episode Extension of 56	574	1	84	84	140	768	124.4	96.1
18-21 years	*****	57	75	84	84	223	104.6	67.1
22-44 years	118	7	84	106	142	703	130.6	98.9
45-64 years	271	1	84	104	145	768	127.8	98.9
65-74 years	123	6	84	84	140	713	117.8	94.6
≥ 75 years	*****	17	81	84	112	352	111.2	81.4
Incident Cohort With Episode Gap and Episode Extension of 0 Days	492	1	28	28	84	512	55.3	49.5
18-21 years	*****	28	28	28	28	28	28.0	0.0
22-44 years	102	7	28	28	84	310	57.8	46.6
45-64 years	233	1	28	28	84	512	59.7	54.1
65-74 years	99	6	28	28	56	364	48.5	44.8
≥ 75 years	*****	17	28	28	56	196	46.0	41.7
Prevalent Cohort With Episode Gap and Episode Extension of 0	574	1	28	28	84	512	54.6	48.0
18-21 years	*****	28	28	28	28	28	28.0	0.0
22-44 years	118	7	28	29	84	310	59.1	47.8
45-64 years	271	1	28	31	84	512	58.4	51.8
65-74 years	123	6	28	28	56	364	47.2	41.9
≥ 75 years	*****	17	28	28	56	196	45.6	40.9

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

Table 5a. Categorical Summary of Second and Subsequent Treatment Episodes for Exposures of Interest in the Sentinel Distributed Database (SDD) from June 19, 2020 to May 31, 2024

	Number of Episodes	Number of Treatment Episodes by Duration (Excluding First Treatment Episode)									
		1-30 Days		31-90 Days		91-365 Days		366-730 Days		731+ Days	
		of Episodes	Total Episodes	Number of Episodes	Total Episodes	Number of Episodes	Total Episodes	Number of Episodes	Total Episodes	Number of Episodes	Total Episodes
<i>Incident Cohort With Episode Gap and Episode Extension of 56 Days</i>	51	*****	*****	*****	*****	25	49.0%	*****	*****	0	0.0%
<i>Prevalent Cohort With Episode Gap and Episode Extension of 56 Days</i>	58	*****	*****	20	34.5%	27	46.6%	*****	*****	0	0.0%
<i>Incident Cohort With Episode Gap and Episode Extension of 0 Days</i>	327	197	60.2%	111	33.9%	19	5.8%	0	0.0%	0	0.0%
<i>Prevalent Cohort With Episode Gap and Episode Extension of 0 Days</i>	372	227	61.0%	121	32.5%	24	6.5%	0	0.0%	0	0.0%

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

Table 5b. Continuous Summary of Second and Subsequent Treatment Episodes for Exposures of Interest in the Sentinel Distributed Database (SDD) from June 19, 2020 to May 31, 2024

	Total Number of Episodes	Distribution of Treatment Episode Durations Excluding First Treatment Episode, days						Standard Deviation
		Minimum	Q1	Median	Q3	Maximum	Mean	
<i>Incident Cohort With Episode Gap and Episode Extension of 56 Days</i>	51	14	74	112	146	410	121.8	91.1
<i>Prevalent Cohort With Episode Gap and Episode Extension of 56 Days</i>	58	14	74	99	146	410	120.5	91.2
<i>Incident Cohort With Episode Gap and Episode Extension of 0 Days</i>	327	1	28	28	56	308	45.4	33.7
<i>Prevalent Cohort With Episode Gap and Episode Extension of 0 Days</i>	372	1	28	28	56	308	45.9	35.4

Table 5c. Categorical Summary of Second and Subsequent Treatment Episodes for Exposures of Interest in the Sentinel Distributed Database (SDD) from June 19, 2020 to May 31, 2024, by Sex

	Total Number	Number of Treatment Episodes by Duration (Excluding First Treatment Episode)									
		1-30 Days		31-90 Days		91-365 Days		366-730 Days		731+ Days	
		Number of	Percent of Total	Number of Episodes	Percent of Total	Number of Episodes	Percent of Total	Number of Episodes	Percent of Total	Number of Episodes	Percent of Total
Incident Cohort With Episode Gap and Episode	51	*****	*****	*****	*****	25	100.0%	*****	*****	0	NaN
Female	36	*****	*****	*****	*****	*****	*****	*****	*****	0	NaN
Male	15	*****	*****	*****	*****	*****	*****	*****	*****	0	NaN
Prevalent Cohort With Episode Gap and Episode	58	*****	*****	20	100.0%	27	100.0%	*****	*****	0	NaN
Female	40	*****	*****	*****	*****	*****	*****	*****	*****	0	NaN
Male	18	*****	*****	*****	*****	*****	*****	*****	*****	0	NaN
Incident Cohort With Episode Gap and Episode	327	197	100.0%	111	100.0%	19	100.0%	0	NaN	0	NaN
Female	237	143	72.6%	*****	*****	*****	*****	0	NaN	0	NaN
Male	90	54	27.4%	*****	*****	*****	*****	0	NaN	0	NaN
Prevalent Cohort With Episode Gap and Episode	372	227	100.0%	121	100.0%	24	100.0%	0	NaN	0	NaN
Female	270	162	71.4%	*****	*****	*****	*****	0	NaN	0	NaN
Male	102	65	28.6%	*****	*****	*****	*****	0	NaN	0	NaN

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

NaN: Not a Number

Table 5d. Continuous Summary of Second and Subsequent Treatment Episodes for Exposures of Interest in the Sentinel Distributed Database (SDD) from June 19, 2020 to May 31, 2024, by Sex

	Total Number of Episodes	Distribution of Treatment Episode Durations Excluding First Treatment Episode, days						Standard Deviation
		Minimum	Q1	Median	Q3	Maximum	Mean	
Incident Cohort With Episode Gap and Episode Extension of 56 Days	51	14	74	112	146	410	121.8	91.1
Female	36	14	83	112	140	410	119.3	84.6
Male	15	14	30	140	156	370	127.9	108.2
Prevalent Cohort With Episode Gap and Episode Extension of 56 Days	58	14	74	99	146	410	120.5	91.2
Female	40	14	81	112	143	410	122.5	86.9
Male	18	14	30	85	152	370	116.2	102.6
Incident Cohort With Episode Gap and Episode Extension of 0 Days	327	1	28	28	56	308	45.4	33.7
Female	237	1	28	28	56	308	46.5	36.2
Male	90	1	28	28	56	168	42.4	26.2
Prevalent Cohort With Episode Gap and Episode Extension of 0 Days	372	1	28	28	56	308	45.9	35.4
Female	270	1	28	28	56	308	47.6	38.3
Male	102	1	28	28	56	168	41.2	25.5

Table 5e. Categorical Summary of Second and Subsequent Treatment Episodes for Exposures of Interest in the Sentinel Distributed Database (SDD) from June 19, 2020 to May 31, 2024, by Age Group

Total Number of Episodes		Number of Treatment Episodes by Duration (Excluding First Treatment Episode)									
		1-30 Days		31-90 Days		91-365 Days		366-730 Days		731+ Days	
		Number of Episodes	Percent of Total Episodes	Number of Episodes	Percent of Total Episodes	Number of Episodes	Percent of Total Episodes	Number of Episodes	Percent of Total Episodes	Number of Episodes	Percent of Total Episodes
Incident Cohort With Episode Gap and Episode Extension of 56											
Days	51	*****	*****	*****	*****	25	100.0%	*****	*****	0	NaN
18-21 years	*****	0	0.0%	*****	*****	0	0.0%	0	0.0%	0	NaN
22-44 years	*****	*****	*****	*****	*****	*****	*****	*****	*****	0	NaN
45-64 years	28	*****	*****	*****	*****	15	60.0%	*****	*****	0	NaN
65-74 years	*****	*****	*****	*****	*****	*****	*****	0	0.0%	0	NaN
≥ 75 years	*****	*****	*****	0	0.0%	*****	*****	0	0.0%	0	NaN
Prevalent Cohort With Episode Gap and Episode Extension of 56											
Days	58	*****	*****	20	100.0%	27	100.0%	*****	*****	0	NaN
18-21 years	*****	0	0.0%	*****	*****	0	0.0%	0	0.0%	0	NaN
22-44 years	12	*****	*****	*****	*****	*****	*****	*****	*****	0	NaN
45-64 years	32	*****	*****	*****	*****	16	59.3%	*****	*****	0	NaN
65-74 years	*****	*****	*****	*****	*****	*****	*****	0	0.0%	0	NaN
≥ 75 years	*****	*****	*****	0	0.0%	*****	*****	0	0.0%	0	NaN
Incident Cohort With Episode Gap and Episode Extension of 0											
Days	327	197	100.0%	111	100.0%	19	100.0%	0	NaN	0	NaN
18-21 years	*****	*****	*****	0	0.0%	*****	*****	0	NaN	0	NaN
22-44 years	79	48	24.4%	*****	*****	*****	*****	0	NaN	0	NaN
45-64 years	171	105	53.3%	*****	*****	*****	*****	0	NaN	0	NaN
65-74 years	48	28	14.2%	*****	*****	*****	*****	0	NaN	0	NaN
≥ 75 years	*****	*****	*****	*****	*****	*****	*****	0	NaN	0	NaN

Table 5e. Categorical Summary of Second and Subsequent Treatment Episodes for Exposures of Interest in the Sentinel Distributed Database (SDD) from June 19, 2020 to May 31, 2024, by Age Group

Total Number of Episodes	Number of Treatment Episodes by Duration (Excluding First Treatment Episode)										
	1-30 Days		31-90 Days		91-365 Days		366-730 Days		731+ Days		
	Number of Episodes	Percent of Total Episodes	Number of Episodes	Percent of Total Episodes	Number of Episodes	Percent of Total Episodes	Number of Episodes	Percent of Total Episodes	Number of Episodes	Percent of Total Episodes	
Prevalent Cohort With Episode Gap and Episode Extension of 0 Days	372	227	100.0%	121	100.0%	24	100.0%	0	NaN	0	NaN
18-21 years	*****	*****	*****	0	0.0%	*****	*****	0	NaN	0	NaN
22-44 years	89	56	24.7%	*****	*****	*****	*****	0	NaN	0	NaN
45-64 years	191	120	52.9%	*****	*****	*****	*****	0	NaN	0	NaN
65-74 years	59	34	15.0%	*****	*****	*****	*****	0	NaN	0	NaN
≥ 75 years	*****	*****	*****	13	10.7%	*****	*****	0	NaN	0	NaN

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

NaN: Not a Number

Table 5f. Continuous Summary of Second and Subsequent Treatment Episodes for Exposures of Interest in the Sentinel Distributed Database

	Total Number of Episodes	Distribution of Treatment Episode Durations Excluding First Treatment Episode, days						
		Minimum	Q1	Median	Q3	Maximum	Mean	Standard Deviation
Incident Cohort With Episode Gap and Episode Extension of 56 Days								
	51	14	74	112	146	410	121.8	91.1
18-21 years	*****	84	84	84	84	84	84.0	NaN
22-44 years	*****	18	84	86	112	410	118.1	114.0
45-64 years	28	14	74	113	149	370	120.8	84.0
65-74 years	*****	23	84	84	140	280	113.4	78.0
≥ 75 years	*****	14	77	145	256	361	166.3	143.8
Prevalent Cohort With Episode Gap and Episode Extension of 56 Days								
	58	14	74	99	146	410	120.5	91.2
18-21 years	*****	84	84	84	84	84	84.0	NaN
22-44 years	12	17	59	85	112	410	114.7	107.6
45-64 years	32	14	74	112	149	370	120.2	85.2
65-74 years	*****	23	84	84	140	280	113.4	78.0
≥ 75 years	*****	14	77	145	256	361	166.3	143.8
Incident Cohort With Episode Gap and Episode Extension of 0 Days								
	327	1	28	28	56	308	45.4	33.7
18-21 years	*****	28	28	70	112	112	70.0	59.4
22-44 years	79	1	28	28	56	224	42.5	30.9
45-64 years	171	1	28	28	56	224	44.0	30.3
65-74 years	48	12	28	28	56	308	52.2	48.3
≥ 75 years	*****	14	28	28	84	112	48.3	29.4
Prevalent Cohort With Episode Gap and Episode Extension of 0 Days								
	372	1	28	28	56	308	45.9	35.4
18-21 years	*****	28	28	70	112	112	70.0	59.4
22-44 years	89	1	28	28	56	224	42.5	32.5
45-64 years	191	1	28	28	56	224	43.8	30.2
65-74 years	59	12	28	28	56	308	55.3	52.7
≥ 75 years	*****	14	28	28	84	112	48.8	28.4

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

NaN: Not a Number

Table 6a. Continuous Summary of All Treatment Episode Gaps for Exposures of Interest in the Sentinel Distributed Database (SDD) from June 19, 2020 to May 31, 2024

	Total Number of Gaps	Distribution of Treatment Episode Gap Durations, days						Standard Deviation
		Minimum	Q1	Median	Q3	Maximum	Mean	
<i>Incident Cohort With Episode Gap and Episode Extension of 56 Days</i>	51	1	31	55	117	750	97.7	127.5
<i>Prevalent Cohort With Episode Gap and Episode Extension of 56 Days</i>	58	1	27	55	98	750	91.7	121.6
<i>Incident Cohort With Episode Gap and Episode Extension of 0 Days</i>	327	1	6	14	29	806	35.6	72.1
<i>Prevalent Cohort With Episode Gap and Episode Extension of 0 Days</i>	372	1	6	14	30	806	34.8	69.0

Table 6b. Continuous Summary of All Treatment Episode Gaps for Exposures of Interest in the Sentinel Distributed Database (SDD) from June 19, 2020 to May 31, 2024, by Sex

	Total Number of Gaps	Distribution of Treatment Episode Gap Durations, days						Standard Deviation
		Minimum	Q1	Median	Q3	Maximum	Mean	
Incident Cohort With Episode Gap and Episode Extension of 56 Days	51	1	31	55	117	750	97.7	127.5
Female	36	1	33	56	126	750	105.0	143.6
Male	15	1	31	50	78	255	80.2	78.0
Prevalent Cohort With Episode Gap and Episode Extension of 56 Days	58	1	27	55	98	750	91.7	121.6
Female	40	1	29	56	108	750	98.6	138.0
Male	18	1	21	50	78	255	76.2	74.4
Incident Cohort With Episode Gap and Episode Extension of 0 Days	327	1	6	14	29	806	35.6	72.1
Female	237	1	7	13	28	806	35.9	77.4
Male	90	1	6	16	30	311	34.7	56.2
Prevalent Cohort With Episode Gap and Episode Extension of 0 Days	372	1	6	14	30	806	34.8	69.0
Female	270	1	6	13	29	806	34.6	73.5
Male	102	1	5	16	31	311	35.1	55.6

Table 6c. Continuous Summary of All Treatment Episode Gaps for Exposures of Interest in the Sentinel Distributed Database

	Total Number of Gaps	Distribution of Treatment Episode Gap Durations, days						Standard Deviation
		Minimum	Q1	Median	Q3	Maximum	Mean	
Incident Cohort With Episode Gap and Episode Extension of 56 Days	51	1	31	55	117	750	97.7	127.5
18-21 years	*****	146	146	146	146	146	146.0	NaN
22-44 years	*****	6	38	57	117	216	86.1	74.3
45-64 years	28	1	24	52	76	376	73.5	88.3
65-74 years	*****	1	50	75	135	255	102.7	89.7
≥ 75 years	*****	6	22	163	519	750	270.5	343.6
Prevalent Cohort With Episode Gap and Episode Extension of 56	58	1	27	55	98	750	91.7	121.6
18-21 years	*****	146	146	146	146	146	146.0	NaN
22-44 years	12	4	21	41	91	216	68.3	71.2
45-64 years	32	1	24	54	78	376	73.3	84.1
65-74 years	*****	1	50	75	135	255	102.7	89.7
≥ 75 years	*****	6	22	163	519	750	270.5	343.6
Incident Cohort With Episode Gap and Episode Extension of 0 Days	327	1	6	14	29	806	35.6	72.1
18-21 years	*****	27	27	115	202	202	114.5	123.7
22-44 years	79	1	3	10	21	272	25.8	49.4
45-64 years	171	1	7	14	30	432	33.3	56.4
65-74 years	48	1	8	16	32	311	42.8	68.1
≥ 75 years	*****	1	7	10	31	806	59.9	163.1
Prevalent Cohort With Episode Gap and Episode Extension of 0	372	1	6	14	30	806	34.8	69.0
18-21 years	*****	27	27	115	202	202	114.5	123.7
22-44 years	89	1	3	10	24	272	26.4	47.6
45-64 years	191	1	7	15	33	432	33.8	55.9
65-74 years	59	1	8	15	30	311	36.8	62.8
≥ 75 years	*****	1	8	14	31	806	55.4	152.4

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

NaN: Not a Number

Table 7a. Continuous Summary of First Treatment Episode Gaps for Exposures of Interest in the Sentinel Distributed Database (SDD) from June 19, 2020 to May 31, 2024

	Total Number of Patients	Distribution of First Treatment Episode Gap Duration, days						
		Minimum	Q1	Median	Q3	Maximum	Mean	Standard Deviation
<i>Incident Cohort With Episode Gap and Episode Extension of 56 Days</i>	45	1	31	55	117	750	101.5	134.2
<i>Prevalent Cohort With Episode Gap and Episode Extension of 56 Days</i>	52	1	24	55	108	750	94.2	127.2
<i>Incident Cohort With Episode Gap and Episode Extension of 0 Days</i>	150	1	8	16	34	806	42.3	87.6
<i>Prevalent Cohort With Episode Gap and Episode Extension of 0 Days</i>	172	1	8	16	40	806	42.3	83.8

Table 7b. Continuous Summary of First Treatment Episode Gaps for Exposures of Interest in the Sentinel Distributed Database (SDD) from June 19, 2020 to May 31, 2024, by Sex

	Total Number of Patients	Distribution of First Treatment Episode Gap Duration, days						Standard Deviation
		Minimum	Q1	Median	Q3	Maximum	Mean	
Incident Cohort With Episode Gap and Episode Extension of 56 Days	45	1	31	55	117	750	101.5	134.2
Female	34	1	35	57	135	750	109.9	146.3
Male	11	1	21	49	77	255	75.7	87.4
Prevalent Cohort With Episode Gap and Episode Extension of 56 Days	52	1	24	55	108	750	94.2	127.2
Female	38	1	30	57	117	750	102.6	140.5
Male	14	1	21	47	77	255	71.5	80.8
Incident Cohort With Episode Gap and Episode Extension of 0 Days	150	1	8	16	34	806	42.3	87.6
Female	113	1	8	14	33	806	44.1	96.2
Male	37	1	9	22	40	311	36.9	54.5
Prevalent Cohort With Episode Gap and Episode Extension of 0 Days	172	1	8	16	40	806	42.3	83.8
Female	128	1	8	14	36	806	43.1	91.6
Male	44	1	9	23	46	311	39.8	55.8

Table 7c. Continuous Summary of First Treatment Episode Gaps for Exposures of Interest in the Sentinel Distributed Database (SDD) from June 19, 2020 to May 31, 2024, by Age Group

	Total Number of Patients	Distribution of First Treatment Episode Gap Duration, days						Standard Deviation
		Minimum	Q1	Median	Q3	Maximum	Mean	
Incident Cohort With Episode Gap and Episode Extension of 56 Days	45	1	31	55	117	750	101.5	134.2
18-21 years	*****	146	146	146	146	146	146.0	NaN
22-44 years	*****	6	41	61	157	216	92.4	76.9
45-64 years	26	1	27	52	74	376	72.3	88.9
65-74 years	*****	1	30	98	239	255	120.2	108.0
≥ 75 years	*****	6	22	163	519	750	270.5	343.6
Prevalent Cohort With Episode Gap and Episode Extension of 56	52	1	24	55	108	750	94.2	127.2
18-21 years	*****	146	146	146	146	146	146.0	NaN
22-44 years	11	4	20	44	117	216	71.3	73.9
45-64 years	30	1	27	54	77	376	72.2	84.3
65-74 years	*****	1	30	98	239	255	120.2	108.0
≥ 75 years	*****	6	22	163	519	750	270.5	343.6
Incident Cohort With Episode Gap and Episode Extension of 0 Days	150	1	8	16	34	806	42.3	87.6
18-21 years	*****	27	27	115	202	202	114.5	123.7
22-44 years	31	1	5	11	27	272	32.1	64.2
45-64 years	74	1	8	18	42	362	34.6	50.4
65-74 years	30	2	8	20	30	311	36.9	62.9
≥ 75 years	*****	1	9	15	62	806	111.6	227.9
Prevalent Cohort With Episode Gap and Episode Extension of 0	172	1	8	16	40	806	42.3	83.8
18-21 years	*****	27	27	115	202	202	114.5	123.7
22-44 years	36	1	5	11	31	272	33.4	60.8
45-64 years	87	1	8	17	46	362	36.8	52.1
65-74 years	33	2	8	16	27	311	34.3	60.5
≥ 75 years	*****	1	9	24	62	806	107.5	219.5

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

Table 8a. Continuous Summary of Second and Subsequent Treatment Episode Gaps for Exposures of Interest in the Sentinel Distributed Database (SDD) from June 19, 2020 to May 31, 2024

		Total Number of Gaps	Distribution of Treatment Episode Durations Excluding First Treatment Episode Gap, days					
			Minimum	Q1	Median	Q3	Maximum	Mean Standard Deviation
<i>Incident Cohort With Episode Gap and Episode Extension of 56 Days</i>	*****	10	36	63	78	167	69.3	54.1
<i>Prevalent Cohort With Episode Gap and Episode Extension of 56 Days</i>	*****	10	36	63	78	167	69.3	54.1
<i>Incident Cohort With Episode Gap and Episode Extension of 0 Days</i>	177	1	3	12	24	432	29.9	55.3
<i>Prevalent Cohort With Episode Gap and Episode Extension of 0 Days</i>	200	1	3	12	24	432	28.3	52.5

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

Table 8b. Continuous Summary of Second and Subsequent Treatment Episode Gaps for Exposures of Interest in the Sentinel Distributed Database (SDD) from June 19, 2020 to May 31, 2024, by Sex

	Total Number of Gaps	Distribution of Treatment Episode Durations Excluding First Treatment Episode Gap, days						Standard Deviation
		Minimum	Q1	Median	Q3	Maximum	Mean	
Incident Cohort With Episode Gap and Episode Extension of 56 Days	*****	10	36	63	78	167	69.3	54.1
Female	*****	10	10	23	36	36	23.0	18.4
Male	*****	50	63	77	123	167	92.5	51.2
Prevalent Cohort With Episode Gap and Episode Extension of 56 Days	*****	10	36	63	78	167	69.3	54.1
Female	*****	10	10	23	36	36	23.0	18.4
Male	*****	50	63	77	123	167	92.5	51.2
Incident Cohort With Episode Gap and Episode Extension of 0 Days	177	1	3	12	24	432	29.9	55.3
Female	124	1	3	12	24	432	28.5	54.3
Male	53	1	3	14	23	295	33.2	57.9
Prevalent Cohort With Episode Gap and Episode Extension of 0 Days	200	1	3	12	24	432	28.3	52.5
Female	142	1	3	12	24	432	27.0	51.3
Male	58	1	3	14	24	295	31.5	55.7

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

Table 8c. Continuous Summary of Second and Subsequent Treatment Episode Gaps for Exposures of Interest in the Sentinel Distributed Database (SDD) from June 19, 2020 to May 31, 2024, by Age Group

	Total Number of Gaps	Distribution of Treatment Episode Durations Excluding First Treatment Episode Gap, days						Standard Deviation
		Minimum	Q1	Median	Q3	Maximum	Mean	
Incident Cohort With Episode Gap and Episode Extension of 56 Days	*****	10	36	63	78	167	69.3	54.1
18-21 years	0	NaN	NaN	NaN	NaN	NaN	NaN	NaN
22-44 years	*****	36	36	36	36	36	36.0	NaN
45-64 years	*****	10	10	89	167	167	88.5	111.0
65-74 years	*****	50	50	75	78	78	67.7	15.4
≥ 75 years	0	NaN	NaN	NaN	NaN	NaN	NaN	NaN
Prevalent Cohort With Episode Gap and Episode Extension of 56 Days	*****	10	36	63	78	167	69.3	54.1
18-21 years	0	NaN	NaN	NaN	NaN	NaN	NaN	NaN
22-44 years	*****	36	36	36	36	36	36.0	NaN
45-64 years	*****	10	10	89	167	167	88.5	111.0
65-74 years	*****	50	50	75	78	78	67.7	15.4
≥ 75 years	0	NaN	NaN	NaN	NaN	NaN	NaN	NaN
Incident Cohort With Episode Gap and Episode Extension of 0 Days	177	1	3	12	24	432	29.9	55.3
18-21 years	0	NaN	NaN	NaN	NaN	NaN	NaN	NaN
22-44 years	48	1	2	7	18	173	21.7	37.1
45-64 years	97	1	4	14	24	432	32.3	60.8
65-74 years	18	1	10	16	106	295	52.6	76.8
≥ 75 years	14	1	6	10	16	31	11.8	9.0
Prevalent Cohort With Episode Gap and Episode Extension of 0 Days	200	1	3	12	24	432	28.3	52.5
18-21 years	0	NaN	NaN	NaN	NaN	NaN	NaN	NaN
22-44 years	53	1	2	7	18	173	21.6	36.0
45-64 years	104	1	4	14	25	432	31.3	59.0
65-74 years	26	1	4	14	31	295	40.0	66.6
≥ 75 years	17	1	7	10	16	31	12.5	8.5

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

NaN: Not a Number

Table 9a. Summary of Filled Daily Dose in Each Dispensing for Exposures of Interest in the Sentinel Distributed Database (SDD) from June 19, 2020 to May 31, 2024

	Total Number of Dispensings	Number of Dispensings by Filled Daily Dose								Distribution of Filled Daily Dose			
		Dose Group 1		Dose Group 2		Dose Group 3		Dose Group 4					
		Number of Dispensings	Percent of Total Dispensing s	Number of Dispensings	Percent of Total Dispensing s	Number of Dispensing s	Percent of Total Dispensing s	Number of Dispensing s	Percent of Total Dispensing s	Minimum	Maximum	Mean	Standard Deviation
<i>Incident Cohort With Episode Gap and Episode Extension of 56 Days¹</i>	1,535	1,535	100.0%	0	0.0%	0	0.0%	0	0.0%	4.5	5.4	5.3	0.1
<i>Prevalent Cohort With Episode Gap and Episode Extension of 56 Days²</i>	1,775	1,775	100.0%	0	0.0%	0	0.0%	0	0.0%	4.5	5.4	5.3	0.1
<i>Incident Cohort With Episode Gap and Episode Extension of 0 Days³</i>	1,535	1,535	100.0%	0	0.0%	0	0.0%	0	0.0%	4.5	5.4	5.3	0.1
<i>Prevalent Cohort With Episode Gap and Episode Extension of 0 Days⁴</i>	1,775	1,775	100.0%	0	0.0%	0	0.0%	0	0.0%	4.5	5.4	5.3	0.1

¹Incident Cohort With Episode Gap and Episode Extension of 56 Days: Dose Group 1 = 1-30 mg; Dose Group 2 = 31-60 mg; Dose Group 3 = 61-90 mg; Dose Group 4 = 91+ mg

Table 9b. Summary of Filled Daily Dose in Each Dispensing for Exposures of Interest in the Sentinel Distributed Database (SDD) from June 19, 2020 to May 31, 2024, by Sex

		Number of Dispensings by Filled Daily Dose							
		Dose Group 1		Dose Group 2		Dose Group 3		Dose Group 4	
		Number of Dispensings	Percent of Total	Number of Dispensings	Percent of Total	Number of Dispensings	Percent of Total	Number of Dispensings	Percent of Total
With Episode Gap and Episode Extension of 56 Days ¹									
	1,535	1,535	100.0%	0	NaN	0	NaN	0	NaN
Female	1,137	1,137	74.1%	0	NaN	0	NaN	0	NaN
Male	398	398	25.9%	0	NaN	0	NaN	0	NaN
Prevalent Cohort With Episode Gap and Episode Extension of 56 Days ²									
	1,775	1,775	100.0%	0	NaN	0	NaN	0	NaN
Female	1,335	1,335	75.2%	0	NaN	0	NaN	0	NaN
Male	440	440	24.8%	0	NaN	0	NaN	0	NaN
Incident Cohort With Episode Gap and Episode Extension of 0 Days ³									
	1,535	1,535	100.0%	0	NaN	0	NaN	0	NaN
Female	1,137	1,137	74.1%	0	NaN	0	NaN	0	NaN
Male	398	398	25.9%	0	NaN	0	NaN	0	NaN
Prevalent Cohort With Episode Gap and Episode Extension of 0 Days ⁴									
	1,775	1,775	100.0%	0	NaN	0	NaN	0	NaN
Female	1,335	1,335	75.2%	0	NaN	0	NaN	0	NaN
Male	440	440	24.8%	0	NaN	0	NaN	0	NaN

¹Incident Cohort With Episode Gap and Episode Extension of 56 Days: Dose Group 1 = 1-30 mg; Dose Group 2 = 31-60 mg; Dose Group 3 = 61-90 mg; Dose Group 4 = 91+ mg

²Prevalent Cohort With Episode Gap and Episode Extension of 56 Days: Dose Group 1 = 1-30 mg; Dose Group 2 = 31-60 mg; Dose Group 3 = 61-90 mg; Dose Group 4 = 91+ mg

³Incident Cohort With Episode Gap and Episode Extension of 0 Days: Dose Group 1 = 1-30 mg; Dose Group 2 = 31-60 mg; Dose Group 3 = 61-90 mg; Dose Group 4 = 91+ mg

⁴Prevalent Cohort With Episode Gap and Episode Extension of 0 Days: Dose Group 1 = 1-30 mg; Dose Group 2 = 31-60 mg; Dose Group 3 = 61-90 mg; Dose Group 4 = 91+ mg

NaN: Not a Number

Table 9c. Summary of Filled Daily Dose in Each Dispensing for Exposures of Interest in the Sentinel Distributed Database

Total Number of Dispensings		Number of Dispensings by Filled Daily Dose							
		Dose Group 1		Dose Group 2		Dose Group 3		Dose Group 4	
		Number of Dispensings	Percent of Total	Number of Dispensings	Percent of Total	Number of Dispensings	Percent of Total	Number of Dispensings	Percent of Total
Incident Cohort With Episode Gap and Episode Extension of 56 Days ¹									
	1,535	1,535	100.0%	0	NaN	0	NaN	0	NaN
18-21 years	*****	*****	*****	0	NaN	0	NaN	0	NaN
22-44 years	342	342	22.3%	0	NaN	0	NaN	0	NaN
45-64 years	781	781	50.9%	0	NaN	0	NaN	0	NaN
65-74 years	265	265	17.3%	0	NaN	0	NaN	0	NaN
≥ 75 years	*****	*****	*****	0	NaN	0	NaN	0	NaN
Prevalent Cohort With Episode Gap and Episode Extension of 56 Days ²									
	1,775	1,775	100.0%	0	NaN	0	NaN	0	NaN
18-21 years	*****	*****	*****	0	NaN	0	NaN	0	NaN
22-44 years	399	399	22.5%	0	NaN	0	NaN	0	NaN
45-64 years	884	884	49.8%	0	NaN	0	NaN	0	NaN
65-74 years	331	331	18.6%	0	NaN	0	NaN	0	NaN
≥ 75 years	*****	*****	*****	0	NaN	0	NaN	0	NaN
Incident Cohort With Episode Gap and Episode Extension of 0 Days ³									
	1,535	1,535	100.0%	0	NaN	0	NaN	0	NaN
18-21 years	*****	*****	*****	0	NaN	0	NaN	0	NaN
22-44 years	342	342	22.3%	0	NaN	0	NaN	0	NaN
45-64 years	781	781	50.9%	0	NaN	0	NaN	0	NaN
65-74 years	265	265	17.3%	0	NaN	0	NaN	0	NaN
≥ 75 years	*****	*****	*****	0	NaN	0	NaN	0	NaN
Prevalent Cohort With Episode Gap and Episode Extension of 0 Days ⁴									
	1,775	1,775	100.0%	0	NaN	0	NaN	0	NaN

Table 9c. Summary of Filled Daily Dose in Each Dispensing for Exposures of Interest in the Sentinel Distributed Database

	Total Number of Dispensings	Number of Dispensings by Filled Daily Dose							
		Dose Group 1		Dose Group 2		Dose Group 3		Dose Group 4	
		Number of Dispensings	Percent of Total	Number of Dispensings	Percent of Total	Number of Dispensings	Percent of Total	Number of Dispensings	Percent of Total
18-21 years	*****	*****	*****	0	NaN	0	NaN	0	NaN
22-44 years	399	399	22.5%	0	NaN	0	NaN	0	NaN
45-64 years	884	884	49.8%	0	NaN	0	NaN	0	NaN
65-74 years	331	331	18.6%	0	NaN	0	NaN	0	NaN
≥ 75 years	*****	*****	*****	0	NaN	0	NaN	0	NaN

¹Incident Cohort With Episode Gap and Episode Extension of 56 Days: Dose Group 1 = 1-30 mg; Dose Group 2 = 31-60 mg; Dose Group 3 = 61-90 mg; Dose Group 4 = 91+ mg

²Prevalent Cohort With Episode Gap and Episode Extension of 56 Days: Dose Group 1 = 1-30 mg; Dose Group 2 = 31-60 mg; Dose Group 3 = 61-90 mg; Dose Group 4 = 91+ mg

³Incident Cohort With Episode Gap and Episode Extension of 0 Days: Dose Group 1 = 1-30 mg; Dose Group 2 = 31-60 mg; Dose Group 3 = 61-90 mg; Dose Group 4 = 91+ mg

⁴Prevalent Cohort With Episode Gap and Episode Extension of 0 Days: Dose Group 1 = 1-30 mg; Dose Group 2 = 31-60 mg; Dose Group 3 = 61-90 mg; Dose Group 4 = 91+ mg

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

NaN: Not a Number

Table 10. Summary of Episode Duration for First Treatment Episodes Ended due to End of Exposure Episode for Exposures of Interest in the Sentinel Distributed Database (SDD) from June 19, 2020 to May 31, 2024

Number of Patients Censored due to End of Exposure Episode by Episode Length												
			1-30 days		31-90 days		91-365 days		366-730 days		731+ days	
	Total Number of Patients	Total Number of Patients Censored due to End of Exposure Episode ¹	Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients
Incident Cohort With Episode Gap and Episode Extension of 56 Days	492	326	0	0.0%	153	46.9%	*****	*****	*****	*****	*****	*****
Prevalent Cohort With Episode Gap and Episode Extension of 56 Days	574	372	0	0.0%	169	45.4%	192	51.6%	*****	*****	*****	*****
Incident Cohort With Episode Gap and Episode Extension of 0 Days	492	487	276	56.7%	158	32.4%	*****	*****	*****	*****	0	0.0%
Prevalent Cohort With Episode Gap and Episode Extension of 0 Days	574	564	315	55.9%	189	33.5%	*****	*****	*****	*****	0	0.0%

¹Represents episodes censored due to end of the exposure episode. In as-treated analyses, exposure episodes are defined using days supplied as recorded in outpatient pharmacy dispensing records, and episodes end after days supplied are exhausted or a pre-determined maximum episode duration is met. In point exposure analyses, exposure episodes end when a pre-determined maximum episode duration is met.

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

Table 10. Summary of Episode Duration for First Treatment Episodes Ended due to End of Exposure Episode for Exposures of Interest in the Sentinel Distributed Database (SDD) from June 19, 2020 to May 31, 2024

Distribution of Treatment Episode Length, in Days							
	Minimum	Q1	Median	Q3	Maximum	Mean	Standard Deviation
<i>Incident Cohort With Episode Gap and Episode Extension of 56 Days</i>	84	84	112	141	768	133.5	82.1
<i>Prevalent Cohort With Episode Gap and Episode Extension of 56 Days</i>	84	84	112	141	768	134.7	85.5
<i>Incident Cohort With Episode Gap and Episode Extension of 0 Days</i>	1	28	28	84	512	55.4	49.7
<i>Prevalent Cohort With Episode Gap and Episode Extension of 0 Days</i>	1	28	28	84	512	54.9	48.2

¹Represents episodes censored due to end of the exposure episode. In as-treated analyses, exposure episodes are defined using days supplied as recorded in outpatient pharmacy dispensing records, and episodes end after days supplied are exhausted or a pre-determined maximum episode duration is met. In point exposure analyses, exposure episodes end when a pre-determined maximum episode duration is met.

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

Table 11. Summary of Episode Duration for First Treatment Episodes Ended due to Occurrence of User-Defined Censoring Criteria for Exposures of Interest in the Sentinel

			Number of Patients Censored due to Occurrence of User-Defined Censoring Criteria by Episode Length									
			1-30 days		31-90 days		91-365 days		366-730 days		731+ days	
	Total Number of Patients	Total Number of Patients Censored due to Occurrence of User-Defined Censoring Criteria ¹										
			Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients
<i>Incident Cohort With Episode Gap and Episode Extension of 56 Days</i>	492	0	0	NaN	0	NaN	0	NaN	0	NaN	0	NaN
<i>Prevalent Cohort With Episode Gap and Episode Extension of 56 Days</i>	574	0	0	NaN	0	NaN	0	NaN	0	NaN	0	NaN
<i>Incident Cohort With Episode Gap and Episode Extension of 0 Days</i>	492	0	0	NaN	0	NaN	0	NaN	0	NaN	0	NaN
<i>Prevalent Cohort With Episode Gap and Episode Extension of 0 Days</i>	574	0	0	NaN	0	NaN	0	NaN	0	NaN	0	NaN

¹Represents episodes censored due to occurrence of additional user-defined criteria using drug, procedure, diagnosis, and/or laboratory codes.

NaN: Not a Number

Table 11. Summary of Episode Duration for First Treatment Episodes Ended due to Occurrence of User-Defined Censoring Criteria for Exposures of Interest in the Sentinel

Distribution of Treatment Episode Length, in Days							
	Minimum	Q1	Median	Q3	Maximum	Mean	Standard Deviation
<i>Incident Cohort With Episode Gap and Episode Extension of 56</i>	NaN	NaN	NaN	NaN	NaN	NaN	NaN
<i>Prevalent Cohort With Episode Gap and Episode Extension of 56 Days</i>	NaN	NaN	NaN	NaN	NaN	NaN	NaN
<i>Incident Cohort With Episode Gap and Episode Extension of 0</i>	NaN	NaN	NaN	NaN	NaN	NaN	NaN
<i>Prevalent Cohort With Episode Gap and Episode Extension of 0 Days</i>	NaN	NaN	NaN	NaN	NaN	NaN	NaN

¹Represents episodes censored due to occurrence of additional user-defined criteria using drug, procedure, diagnosis, and/or laboratory codes.
 NaN: Not a Number

Table 12. Summary of Episode Duration for First Treatment Episodes Ended due to Evidence of Death for Exposures of Interest in the Sentinel Distributed Database (SDD)

Number of Patients Censored due to Evidence of Death by Episode Length												
			1-30 days		31-90 days		91-365 days		366-730 days		731+ days	
	Total Number of Patients	of Patients Censored due to Evidence of Death ¹	Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients
<i>Incident Cohort With Episode Gap and Episode Extension of 56 Days</i>	492	*****	*****	*****	*****	*****	*****	*****	0	0.0%	0	0.0%
<i>Prevalent Cohort With Episode Gap and Episode Extension of 56 Days</i>	574	*****	*****	*****	*****	*****	*****	*****	0	0.0%	0	0.0%
<i>Incident Cohort With Episode Gap and Episode Extension of 0 Days</i>	492	*****	*****	*****	*****	*****	0	0.0%	0	0.0%	0	0.0%
<i>Prevalent Cohort With Episode Gap and Episode Extension of 0 Days</i>	574	*****	*****	*****	*****	*****	0	0.0%	0	0.0%	0	0.0%

¹Represents episodes censored due to evidence of death. Death data source and completeness varies by Data Partner.

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

Table 12. Summary of Episode Duration for First Treatment Episodes Ended due to Evidence of Death for Exposures of Interest in the Sentinel Distributed Database (SDD)

Distribution of Treatment Episode Length, in Days							
	Minimum	Q1	Median	Q3	Maximum	Mean	Standard Deviation
<i>Incident Cohort With Episode Gap and Episode Extension of 56 Days</i>	22	49	81	95	119	72.0	32.2
<i>Prevalent Cohort With Episode Gap and Episode Extension of 56 Days</i>	22	41	69	89	119	67.0	33.0
<i>Incident Cohort With Episode Gap and Episode Extension of 0 Days</i>	22	22	52	82	82	52.0	42.4
<i>Prevalent Cohort With Episode Gap and Episode Extension of 0 Days</i>	22	22	32	82	82	45.3	32.1

¹Represents episodes censored due to evidence of death. Death data source and completeness varies by Data Partner.

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

Table 13. Summary of Episode Duration for First Treatment Episodes Ended due to Disenrollment for Exposures of Interest in the Sentinel Distributed Database (SDD) from

Number of Patients Censored due to Disenrollment by Episode Length												
			1-30 days		31-90 days		91-365 days		366-730 days		731+ days	
	Total Number of Patients	Total Number of Patients Censored due to Disenrollment ¹	Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients
<i>Incident Cohort With Episode Gap and Episode Extension of 56 Days</i>	492	150	*****	*****	59	39.3%	55	36.7%	*****	*****	0	0.0%
<i>Prevalent Cohort With Episode Gap and Episode Extension of 56 Days</i>	574	176	*****	*****	67	38.1%	61	34.7%	*****	*****	0	0.0%
<i>Incident Cohort With Episode Gap and Episode Extension of 0 Days</i>	492	51	29	56.9%	*****	*****	*****	*****	0	0.0%	0	0.0%
<i>Prevalent Cohort With Episode Gap and Episode Extension of 0 Days</i>	574	67	39	58.2%	*****	*****	*****	*****	0	0.0%	0	0.0%

¹Represents episodes censored due to disenrollment from health plan. Data Partners often artificially assign a "disenrollment" date equal to data end date for members still enrolled on that date.

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

Table 13. Summary of Episode Duration for First Treatment Episodes Ended due to Disenrollment for Exposures of Interest in the Sentinel Distributed Database (SDD)

Distribution of Treatment Episode Length, in Days							
	Minimum	Q1	Median	Q3	Maximum	Mean	Standard Deviation
<i>Incident Cohort With Episode Gap and Episode Extension of 56 Days</i>	1	41	74	152	703	117.4	118.3
<i>Prevalent Cohort With Episode Gap and Episode Extension of 56 Days</i>	1	36	71	151	703	111.8	116.2
<i>Incident Cohort With Episode Gap and Episode Extension of 0 Days</i>	1	16	24	52	310	49.5	61.8
<i>Prevalent Cohort With Episode Gap and Episode Extension of 0 Days</i>	1	16	24	50	310	45.3	55.5

¹Represents episodes censored due to disenrollment from health plan. Data Partners often artificially assign a "disenrollment" date equal to data end date for members still enrolled on that

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

Table 14. Summary of Episode Duration for First Treatment Episodes Ended due to End of Data for Exposures of Interest in the Sentinel Distributed Database (SDD) from

Number of Patients Censored due to End of Data by Episode Length												
			1-30 days		31-90 days		91-365 days		366-730 days		731+ days	
	Total Number of Patients	Total Number of Patients Censored due to End of Data ¹	Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients	Number of Patients	Percent of Total Patients
Incident Cohort With Episode Gap and Episode Extension of 56 Days	492	135	*****	*****	57	42.2%	47	34.8%	*****	*****	0	0.0%
Prevalent Cohort With Episode Gap and Episode Extension of 56 Days	574	159	*****	*****	65	40.9%	51	32.1%	*****	*****	0	0.0%
Incident Cohort With Episode Gap and Episode Extension of 0 Days	492	40	24	60.0%	*****	*****	*****	*****	0	0.0%	0	0.0%
Prevalent Cohort With Episode Gap and Episode Extension of 0 Days	574	55	34	61.8%	*****	*****	*****	*****	0	0.0%	0	0.0%

¹Represents episodes censored due to Data Partner data end date. This end date represents the last day of the most recent year-month in which all of a Data Partner's data tables in the Sentinel

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

Table 14. Summary of Episode Duration for First Treatment Episodes Ended due to End of Data for Exposures of Interest in the Sentinel Distributed Database (SDD)

Distribution of Treatment Episode Length, in Days							
	Minimum	Q1	Median	Q3	Maximum	Mean	Standard Deviation
<i>Incident Cohort With Episode Gap and Episode Extension of 56 Days</i>	2	41	74	151	703	117.4	120.5
<i>Prevalent Cohort With Episode Gap and Episode Extension of 56 Days</i>	2	38	71	145	703	111.2	118.4
<i>Incident Cohort With Episode Gap and Episode Extension of 0 Days</i>	2	15	24	49	310	50.1	66.7
<i>Prevalent Cohort With Episode Gap and Episode Extension of 0 Days</i>	2	12	24	49	310	44.3	59.0

¹Represents episodes censored due to Data Partner data end date. This end date represents the last day of the most recent year-month in which all of a Data Partner's data tables in the

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

Table 15. Summary of Episode Duration for First Treatment Episodes Ended due to End of Study Period for Exposures of Interest in the Sentinel Distributed Database (SDD)

Number of Patients Censored due to End of Study Period by Episode Length												
			1-30 days		31-90 days		91-365 days		366-730 days		731+ days	
	Total Number of Patients	Total Number of Patients Censored due to End of Study Period ¹	Percent of		Percent		Number		Percent		Percent	
			Number of Patients	Total Patients	Number of Patients	of Total Patients	of Patients	of Total Patients	Number of Patients	nt of Total Patients	Number of Patients	of Total Patients
<i>Incident Cohort With Episode Gap and Episode Extension of 56 Days</i>	492	0	0	NaN	0	NaN	0	NaN	0	NaN	0	NaN
<i>Prevalent Cohort With Episode Gap and Episode Extension of 56 Days</i>	574	0	0	NaN	0	NaN	0	NaN	0	NaN	0	NaN
<i>Incident Cohort With Episode Gap and Episode Extension of 0 Days</i>	492	0	0	NaN	0	NaN	0	NaN	0	NaN	0	NaN
<i>Prevalent Cohort With Episode Gap and Episode Extension of 0 Days</i>	574	0	0	NaN	0	NaN	0	NaN	0	NaN	0	NaN

¹Represents episodes censored due to user-specified study end date.

NaN: Not a Number

Table 15. Summary of Episode Duration for First Treatment Episodes Ended due to End of Study Period for Exposures of Interest in the Sentinel Distributed Database (SDD)

Distribution of Treatment Episode Length, in Days							
	Minimum	Q1	Median	Q3	Maximum	Mean	Standard Deviation
<i>Incident Cohort With Episode Gap and Episode Extension of 56 Days</i>	NaN	NaN	NaN	NaN	NaN	NaN	NaN
<i>Prevalent Cohort With Episode Gap and Episode Extension of 56 Days</i>	NaN	NaN	NaN	NaN	NaN	NaN	NaN
<i>Incident Cohort With Episode Gap and Episode Extension of 0 Days</i>	NaN	NaN	NaN	NaN	NaN	NaN	NaN
<i>Prevalent Cohort With Episode Gap and Episode Extension of 0 Days</i>	NaN	NaN	NaN	NaN	NaN	NaN	NaN

¹Represents episodes censored due to user-specified study end date.
 NaN: Not a Number

Table 16. Summary of Patient-Level Cohort Attrition in the Sentinel Distributed Database (SDD) from June 19, 2020 to May 31, 2024

	Incident Cohort With Episode Gap and Episode Extension of 56 Days		Prevalent Cohort With Episode Gap and Episode Extension of 56 Days		Incident Cohort With Episode Gap and Episode Extension of 0 Days		Prevalent Cohort With Episode Gap and Episode Extension of 0 Days	
	Remaining	Excluded	Remaining	Excluded	Remaining	Excluded	Remaining	Excluded
Members meeting enrollment and demographic requirements								
Enrolled at any point during the query period	259,688,931	N/A	259,688,931	N/A	259,688,931	N/A	259,688,931	N/A
Had required coverage type (medical and/or drug coverage)	194,743,666	64,945,265	194,743,666	64,945,265	194,743,666	64,945,265	194,743,666	64,945,265
Enrolled during specified age range	146,053,842	48,689,824	146,053,842	48,689,824	146,053,842	48,689,824	146,053,842	48,689,824
Had requestable medical charts	146,053,842	0	146,053,842	0	146,053,842	0	146,053,842	0
Met demographic requirements (sex, race, and Hispanic origin)	146,000,378	53,464	146,000,378	53,464	146,000,378	53,464	146,000,378	53,464
Members with a valid index event								
Had any cohort-defining claim during the query period	574	145,999,804	574	145,999,804	574	145,999,804	574	145,999,804
Claim recorded during specified age range	574	0	574	0	574	0	574	0
Episode defining index claim recorded during the query	574	0	574	0	574	0	574	0
Members with required pre-index history								
Had sufficient pre-index continuous enrollment	492	82	574	0	492	82	574	0
Met inclusion and exclusion criteria	492	0	574	0	492	0	574	0
Members with required post-index follow-up								
Had sufficient post-index continuous enrollment	492	0	574	0	492	0	574	0
Final cohort								
Number of members	492	N/A	574	N/A	492	N/A	574	N/A

N/A: Not Applicable

Appendix A. Dates of Available Data for Each Data Partner (DP) as of Request Distribution Date (December 12, 2024)

Masked DP ID	DP Start Date	DP End Date ¹
DP01	01/01/2006	02/29/2024
DP02	01/01/2007	02/29/2024
DP03	01/01/2008	12/31/2023
DP04	01/01/2014	12/31/2021
DP05	01/01/2008	05/31/2024
DP06	01/01/2010	12/31/2023

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

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

Generic Name	Brand Name
Metoclopramide HCl	
metoclopramide HCl	Gimoti

Appendix C. Specifications Defining Parameters in this Request

The Center for Drug Evaluation and Research (CDER) has requested execution of the Cohort Identification and Descriptive Analysis (CIDA) tool 14.0.1 to characterized dispensing patterns of Gimoti™ (metoclopramide nasal spray) in the Sentinel Distributed Database (SDD).

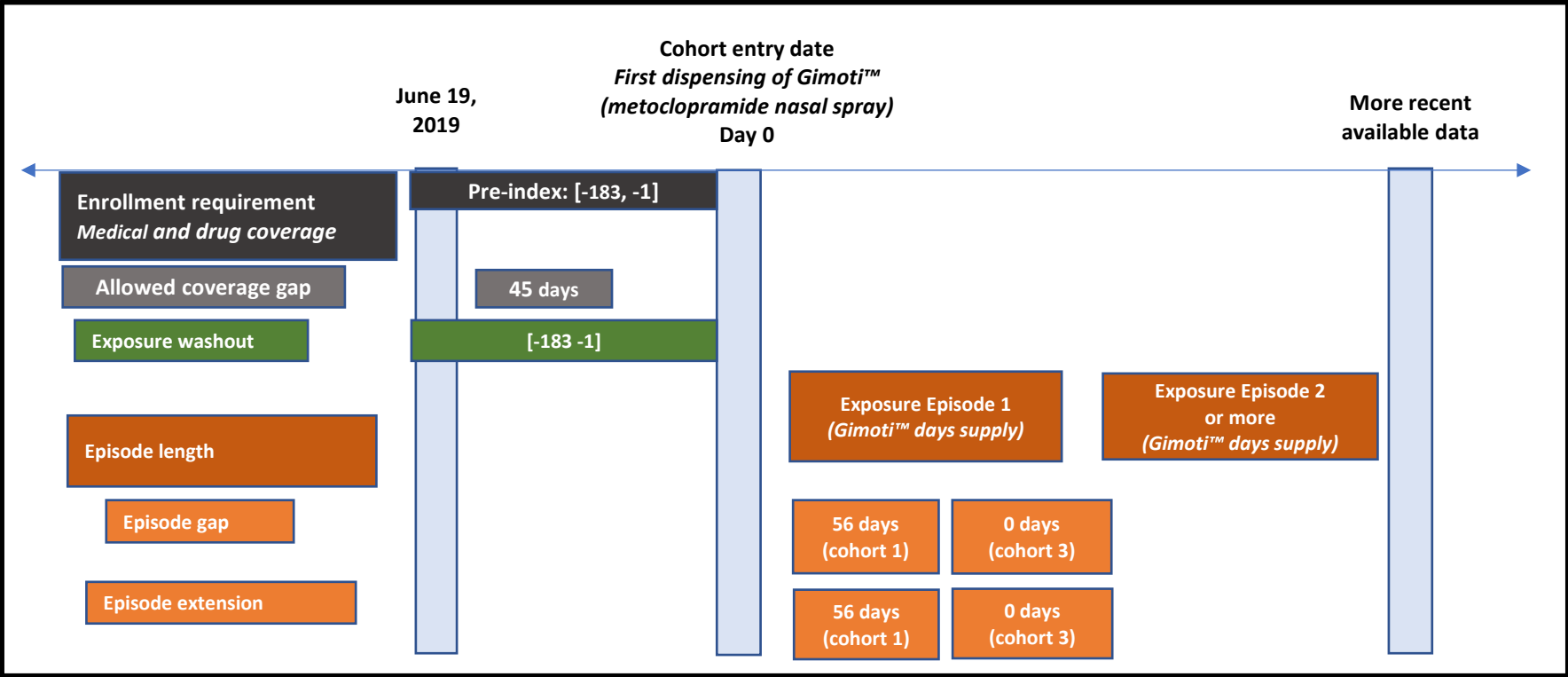
Query period: June 19, 2020-May 31, 2024
Coverage requirement: Medical & Drug Coverage
Minimum Post-Index Required Days: 0
Enrollment Gap: 45
Age Groups: 18-21,22-44,45-64,65-74,75+
Demographic Restrictions: F, M
Stratifications: Age group, Sex, Calendar year
Data Restrictions: n/a
Chart Availability Restriction Indicator: N: Don't Exclude members for whom medical charts cannot be requested for the entire study period
Envelope macro: 1: Do not run envelope on IP ADate. Reclassify institutional stay (IS), outpatient (AV), emergency department (ED), and other ambulatory (OA) encounters that occur during an inpatient stay as inpatient (IP) encounters. Do not reclassify if encounter occurs on day of admission (ADate).
Freeze data: No
Drop Censor Output Indicator: Indicates if counts of episodes censored by death and query end should be excluded from output to prevent death small cells from

Exposure														
Scenario	Index Exposure	Cohort definition	Minimum Pre-Index Enrollment Days:	Type 5 Exposure Washout Period	Exclude Evidence of Days Supply if Event Washout Includes Dispensings	Care Setting	Treatment Episode Gap Type	Exposure Episode Gap	Exposure Episode Extension Period	Create Baseline Table?	Forced Supply to Attach to Dispensings	End At-Risk Period at Evidence of	Current Filled Daily Dose Category	Episode Duration Categories
1	metoclopramide HCl (Gimoti)	04: cohort includes all valid exposure episodes during the query period. Only the first valid episode's incidence is assessed using TSWASHPER.	183	183	N: Lookback period should search for evidence of a date or an interval	Any	F: Fixed episode gap. The value specified in EPISODEGAP will be used to determine if two consecutive claims are in the same episode.	56 days	56 days	N: baseline table will NOT be produced for corresponding COHORTGRP	blank	*Death *DP End Date *Query End Date *Occurrence of an exposure or event	1-30 31-60 61-90 91+	1-30 31-90 91-365 366-730 731+
2	metoclopramide HCl (Gimoti)	04: cohort includes all valid exposure episodes during the query period. Only the first valid episode's incidence is assessed using TSWASHPER.	0	0	N: Lookback period should search for evidence of a date or an interval	Any	F: Fixed episode gap. The value specified in EPISODEGAP will be used to determine if two consecutive claims are in the same episode.	56 days	56 days	N: baseline table will NOT be produced for corresponding COHORTGRP	blank	*Death *DP End Date *Query End Date *Occurrence of an exposure or event	1-30 31-60 61-90 91+	1-30 31-90 91-365 366-730 731+

Appendix C. Specifications Defining Parameters in this Request													
3	metoclopramide HCl (Gimoti)	04: cohort includes all valid exposure episodes during the query period. Only the first valid episode's incidence is assessed using T5WASHPER.	183	183	N: Lookback period should search for evidence of a date or an interval	Any	F: Fixed episode gap. The value specified in EPISODEGAP will be used to determine if two consecutive claims are in the same episode.	0 days	0 days	N: baseline table will NOT be produced for corresponding COHORTGRP	blank	*Death *DP End Date *Query End Date *Occurrence of an exposure or event	1-30 31-60 61-90 91+ 1-30 31-90 91-365 366-730 731+
4	metoclopramide HCl (Gimoti)	04: cohort includes all valid exposure episodes during the query period. Only the first valid episode's incidence is assessed using T5WASHPER.	0	0	N: Lookback period should search for evidence of a date or an interval	Any	F: Fixed episode gap. The value specified in EPISODEGAP will be used to determine if two consecutive claims are in the same episode.	0 days	0 days	N: baseline table will NOT be produced for corresponding COHORTGRP	blank	*Death *DP End Date *Query End Date *Occurrence of an exposure or event	1-30 31-60 61-90 91+ 1-30 31-90 91-365 366-730 731+
International Classification of Diseases, Ninth Revision (ICD-9), International Classification of Diseases, Tenth Revision (ICD-10), Healthcare Common Procedure Coding System (HCPCS), and CPT (Current Procedural Terminology) codes are provided by Optum360. National Drug Codes (NDCs) are checked against FirstDataBank's FDBMedKnowledge®													

Appendix D. Design Diagram for Cohort Defining Criteria

First Qualifying or Incident Users



Appendix D. Design Diagram for Cohort Defining Criteria

Prevalent Users

