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 Query Builder analysis.

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@sentinelsystem.org.

Overview

Query Builder Report: This report details the results of an analysis generated by the Sentinel Query Builder application. Query Builder enables FDA to visualize, draft, and create standardized medical product utilization queries examining dispensing patterns and cohort characteristics using a set of pre-defined parameters. This is a Type 5 (Medical Product Utilization) analysis as described in the Query Request Package (QRP) documentation.

Request Description: In this report we characterized dispensing patterns of Gimoti™ (metoclopramide nasal spray) approved on June 19, 2020, stratified by age and sex in the Merative™ MarketScan® database.

Sentinel Routine Querying Module: Cohort Identification and Descriptive Analysis (CIDA) module, version 11.0.0

Data Source: We executed this request on Merative™ MarketScan® Commercial Claims and Encounters Database and Medicare Supplemental Database, which included 154 million members, on October 17, 2022. The study period included data from June 19, 2020 to September 30, 2021. Please see Appendix A for data availability dates.

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

Notes: Please contact the Sentinel Operations Center (info@sentinelsystem.org) for questions and to provide comments/suggestions for future enhancements to this document. For more information on Sentinel Query Builder, please refer to the documentation (https://dev.sentinelsystem.org/projects/QB/repos/querybuilder/browse).

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Table 1a: Distribution of cumulative exposure duration, by length categories, in days

Exposures	Total Patients N	Total Patients %	1-30 days N	1-30 days %	31-90 days N	31-90 days %	91-365 days N	91-365 days %	366-730 days N	366-730 days %	731+ days N	731+ days %
Incident use	15	100.0	3	20.0	5	33.3	7	46.7	0	0.0	0	0.0
Prevalent use	18	100.0	3	16.7	6	33.3	9	50.0	0	0.0	0	0.0

Table 1b: Distribution of cumulative exposure duration, by length categories, in days, by sex												
	Total Patients		1-30 days		31-90 days		91-365 days		366-730 days		731+ days	
Exposures	N	%	N	%	N	%	N	%	N	%	N	%
Incident use	**15**	**100.0**	**3**	**100.0**	**5**	**100.0**	**7**	**100.0**	**0**	**0.0**	**0**	**0.0**
Female	11	73.3	3	100.0	3	60.0	5	71.4	0	0.0	0	0.0
Male	4	26.7	0	0.0	2	40.0	2	28.6	0	0.0	0	0.0
Prevalent use	**18**	**100.0**	**3**	**100.0**	**6**	**100.0**	**9**	**100.0**	**0**	**0.0**	**0**	**0.0**
Female	14	77.8	3	100.0	4	66.7	7	77.8	0	0.0	0	0.0
Male	4	22.2	0	0.0	2	33.3	2	22.2	0	0.0	0	0.0

Table 1c: Distribution of cumulative exposure duration, by length categories, in days, by age group (years)												
	Total Patients		1-30 days		31-90 days		91-365 days		366-730 days		731+ days	
Exposures	N	%	N	%	N	%	N	%	N	%	N	%
Incident use	**15**	**100.0**	**3**	**100.0**	**5**	**100.0**	**7**	**100.0**	**0**	**0.0**	**0**	**0.0**
18-21 years	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
22-44 years	6	40.0	2	66.7	1	20.0	3	42.9	0	0.0	0	0.0
45-64 years	9	60.0	1	33.3	4	80.0	4	57.1	0	0.0	0	0.0
65-74 years	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
75+ years	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Prevalent use	**18**	**100.0**	**3**	**100.0**	**6**	**100.0**	**9**	**100.0**	**0**	**0.0**	**0**	**0.0**
18-21 years	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
22-44 years	8	44.4	2	66.7	1	16.7	5	55.6	0	0.0	0	0.0
45-64 years	9	50.0	1	33.3	4	66.7	4	44.4	0	0.0	0	0.0
65-74 years	1	5.6	0	0.0	1	16.7	0	0.0	0	0.0	0	0.0
75+ years	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

Table 2a: Descriptive statistics of cumulative exposure duration, all episodes, in days								
Exposures	Total Patients	Mean	STD	Min	Q1	Median	Q3	Max
Incident use	15	77.00	45.24	10	39	84	112	156
Prevalent use	18	81.22	43.56	10	42	91	112	156

Table 2b: Descriptive statistics of cumulative exposure duration, all episodes, in days, by sex								
Exposures	**Total Patients**	**Mean**	**STD**	**Min**	**Q1**	**Median**	**Q3**	**Max**
Incident use	**15**	**77.00**	**45.24**	**10**	**39**	**84**	**112**	**156**
Female	11	68.36	48.68	10	24	46	112	156
Male	4	100.75	25.05	84	84	91	118	137
Prevalent use	**18**	**81.22**	**43.56**	**10**	**42**	**91**	**112**	**156**
Female	14	75.64	46.75	10	39	82	112	156
Male	4	100.75	25.05	84	84	91	118	137

Table 2c: Descriptive statistics of cumulative exposure duration, all episodes, in days, by age group (years)								
Exposures	Total Patients	Mean	STD	Min	Q1	Median	Q3	Max
Incident use	**15**	**77.00**	**45.24**	**10**	**39**	**84**	**112**	**156**
18-21 years	0	-	-	-	-	-	-	-
22-44 years	6	69.00	57.62	10	14	68	98	156
45-64 years	9	82.33	37.78	24	46	84	112	137
65-74 years	0	-	-	-	-	-	-	-
75+ years	0	-	-	-	-	-	-	-
Prevalent use	**18**	**81.22**	**43.56**	**10**	**42**	**91**	**112**	**156**
18-21 years	0	-	-	-	-	-	-	-
22-44 years	8	81.75	54.29	10	27	98	120	156
45-64 years	9	82.33	37.78	24	46	84	112	137
65-74 years	1	67.00	-	67	67	67	67	67
75+ years	0	-	-	-	-	-	-	-

Table 3a: Distribution of first exposure episode duration, by length categories, in days												
	Total Episodes		1-30 days		31-90 days		91-365 days		366-730 days		731+ days	
Exposures	N	%	N	%	N	%	N	%	N	%	N	%
Incident use	15	100.0	3	20.0	5	33.3	7	46.7	0	0.0	0	0.0
Prevalent use	18	100.0	3	16.7	6	33.3	9	50.0	0	0.0	0	0.0

Table 3b: Distribution of first exposure episode duration, by length categories, in days, by sex												
	Total Episodes		1-30 days		31-90 days		91-365 days		366-730 days		731+ days	
Exposures	N	%	N	%	N	%	N	%	N	%	N	%
Incident use	15	100.0	3	100.0	5	100.0	7	100.0	0	0.0	0	0.0
Female	11	73.3	3	100.0	3	60.0	5	71.4	0	0.0	0	0.0
Male	4	26.7	0	0.0	2	40.0	2	28.6	0	0.0	0	0.0
Prevalent use	18	100.0	3	100.0	6	100.0	9	100.0	0	0.0	0	0.0
Female	14	77.8	3	100.0	4	66.7	7	77.8	0	0.0	0	0.0
Male	4	22.2	0	0.0	2	33.3	2	22.2	0	0.0	0	0.0

Table 3c: Distribution of first exposure episode duration, by length categories, in days, by age group (years)												
	Total Episodes		1-30 days		31-90 days		91-365 days		366-730 days		731+ days	
Exposures	N	%	N	%	N	%	N	%	N	%	N	%
Incident use	15	100.0	3	100.0	5	100.0	7	100.0	0	0.0	0	0.0
18-21 years	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
22-44 years	6	40.0	2	66.7	1	20.0	3	42.9	0	0.0	0	0.0
45-64 years	9	60.0	1	33.3	4	80.0	4	57.1	0	0.0	0	0.0
65-74 years	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
75+ years	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Prevalent use	18	100.0	3	100.0	6	100.0	9	100.0	0	0.0	0	0.0
18-21 years	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
22-44 years	8	44.4	2	66.7	1	16.7	5	55.6	0	0.0	0	0.0
45-64 years	9	50.0	1	33.3	4	66.7	4	44.4	0	0.0	0	0.0
65-74 years	1	5.6	0	0.0	1	16.7	0	0.0	0	0.0	0	0.0
75+ years	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

Table 4a: Descriptive statistics of first exposure episode duration, in days

Exposures	Total Episodes	Mean	STD	Min	Q1	Median	Q3	Max
Incident use	15	77.00	45.24	10	39	84	112	156
Prevalent use	18	81.22	43.56	10	42	91	112	156

Table 4b: Descriptive statistics of first exposure episode duration, in days, by sex								
Exposures	Total Episodes	Mean	STD	Min	Q1	Median	Q3	Max
Incident use	**15**	**77.00**	**45.24**	**10**	**39**	**84**	**112**	**156**
Female	11	68.36	48.68	10	24	46	112	156
Male	4	100.75	25.05	84	84	91	118	137
Prevalent use	**18**	**81.22**	**43.56**	**10**	**42**	**91**	**112**	**156**
Female	14	75.64	46.75	10	39	82	112	156
Male	4	100.75	25.05	84	84	91	118	137

Table 4c: Descriptive statistics of first exposure episode duration, in days, by age group (years)								
Exposures	**Total Episodes**	**Mean**	**STD**	**Min**	**Q1**	**Median**	**Q3**	**Max**
Incident use	**15**	**77.00**	**45.24**	**10**	**39**	**84**	**112**	**156**
18-21 years	0	-	-	-	-	-	-	-
22-44 years	6	69.00	57.62	10	14	68	98	156
45-64 years	9	82.33	37.78	24	46	84	112	137
65-74 years	0	-	-	-	-	-	-	-
75+ years	0	-	-	-	-	-	-	-
Prevalent use	**18**	**81.22**	**43.56**	**10**	**42**	**91**	**112**	**156**
18-21 years	0	-	-	-	-	-	-	-
22-44 years	8	81.75	54.29	10	27	98	120	156
45-64 years	9	82.33	37.78	24	46	84	112	137
65-74 years	1	67.00	-	67	67	67	67	67
75+ years	0	-	-	-	-	-	-	-

Table 5a: Distribution of second and subsequent exposure episode duration, by length categories, in days												
	Total Episodes		1-30 days		31-90 days		91-365 days		366-730 days		731+ days	
Exposures	N	%	N	%	N	%	N	%	N	%	N	%
Incident use	0	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Prevalent use	0	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

Table 5b: Distribution of second and subsequent exposure episode duration, by length categories, in days, by sex												
	Total Episodes		1-30 days		31-90 days		91-365 days		366-730 days		731+ days	
Exposures	N	%	N	%	N	%	N	%	N	%	N	%
Incident use	**0**	**0.0**	**0**	**0.0**	**0**	**0.0**	**0**	**0.0**	**0**	**0.0**	**0**	**0.0**
Female	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Male	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Prevalent use	**0**	**0.0**	**0**	**0.0**	**0**	**0.0**	**0**	**0.0**	**0**	**0.0**	**0**	**0.0**
Female	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Male	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

Table 5c: Distribution of second and subsequent exposure episode duration, by length categories, in days, by age group (years)												
	Total Episodes		1-30 days		31-90 days		91-365 days		366-730 days		731+ days	
Exposures	N	%	N	%	N	%	N	%	N	%	N	%
Incident use	**0**	**0.0**	**0**	**0.0**	**0**	**0.0**	**0**	**0.0**	**0**	**0.0**	**0**	**0.0**
18-21 years	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
22-44 years	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
45-64 years	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
65-74 years	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
75+ years	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Prevalent use	**0**	**0.0**	**0**	**0.0**	**0**	**0.0**	**0**	**0.0**	**0**	**0.0**	**0**	**0.0**
18-21 years	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
22-44 years	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
45-64 years	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
65-74 years	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
75+ years	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

Table 6a: Descriptive statistics of second and subsequent exposure episode duration, in days								
Exposures	Total Episodes	Mean	STD	Min	Q1	Median	Q3	Max
Incident use	0	-	-	-	-	-	-	-
Prevalent use	0	-	-	-	-	-	-	-

Table 6b: Descriptive statistics of second and subsequent exposure episode duration, in days, by sex								
Exposures	Total Episodes	Mean	STD	Min	Q1	Median	Q3	Max
Incident use	**0**	**-**	**-**	**-**	**-**	**-**	**-**	**-**
Female	0	-	-	-	-	-	-	-
Male	0	-	-	-	-	-	-	-
Prevalent use	**0**	**-**	**-**	**-**	**-**	**-**	**-**	**-**
Female	0	-	-	-	-	-	-	-
Male	0	-	-	-	-	-	-	-

Table 6c: Descriptive statistics of second and subsequent exposure episode duration, in days, by age group (years)								
Exposures	Total Episodes	Mean	STD	Min	Q1	Median	Q3	Max
Incident use	**0**	**-**	**-**	**-**	**-**	**-**	**-**	**-**
18-21 years	0	-	-	-	-	-	-	-
22-44 years	0	-	-	-	-	-	-	-
45-64 years	0	-	-	-	-	-	-	-
65-74 years	0	-	-	-	-	-	-	-
75+ years	0	-	-	-	-	-	-	-
Prevalent use	**0**	**-**	**-**	**-**	**-**	**-**	**-**	**-**
18-21 years	0	-	-	-	-	-	-	-
22-44 years	0	-	-	-	-	-	-	-
45-64 years	0	-	-	-	-	-	-	-
65-74 years	0	-	-	-	-	-	-	-
75+ years	0	-	-	-	-	-	-	-

Table 7a: Distribution of all episode durations, by length categories, in days												
	Total Episodes		1-30 days		31-90 days		91-365 days		366-730 days		731+ days	
Exposures	N	%	N	%	N	%	N	%	N	%	N	%
Incident use	15	100.0	3	20.0	5	33.3	7	46.7	0	0.0	0	0.0
Prevalent use	18	100.0	3	16.7	6	33.3	9	50.0	0	0.0	0	0.0

Table 7b: Distribution of all episode durations, by length categories, in days, by sex

Exposures	Total Episodes N	Total Episodes %	1-30 days N	1-30 days %	31-90 days N	31-90 days %	91-365 days N	91-365 days %	366-730 days N	366-730 days %	731+ days N	731+ days %
Incident use	**15**	**100.0**	**3**	**100.0**	**5**	**100.0**	**7**	**100.0**	**0**	**0.0**	**0**	**0.0**
Female	11	73.3	3	100.0	3	60.0	5	71.4	0	0.0	0	0.0
Male	4	26.7	0	0.0	2	40.0	2	28.6	0	0.0	0	0.0
Prevalent use	**18**	**100.0**	**3**	**100.0**	**6**	**100.0**	**9**	**100.0**	**0**	**0.0**	**0**	**0.0**
Female	14	77.8	3	100.0	4	66.7	7	77.8	0	0.0	0	0.0
Male	4	22.2	0	0.0	2	33.3	2	22.2	0	0.0	0	0.0

Table 7c: Distribution of all episode durations, by length categories, in days, by age group (years)												
	Total Episodes		1-30 days		31-90 days		91-365 days		366-730 days		731+ days	
Exposures	N	%	N	%	N	%	N	%	N	%	N	%
Incident use	**15**	**100.0**	**3**	**100.0**	**5**	**100.0**	**7**	**100.0**	**0**	**0.0**	**0**	**0.0**
18-21 years	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
22-44 years	6	40.0	2	66.7	1	20.0	3	42.9	0	0.0	0	0.0
45-64 years	9	60.0	1	33.3	4	80.0	4	57.1	0	0.0	0	0.0
65-74 years	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
75+ years	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Prevalent use	**18**	**100.0**	**3**	**100.0**	**6**	**100.0**	**9**	**100.0**	**0**	**0.0**	**0**	**0.0**
18-21 years	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
22-44 years	8	44.4	2	66.7	1	16.7	5	55.6	0	0.0	0	0.0
45-64 years	9	50.0	1	33.3	4	66.7	4	44.4	0	0.0	0	0.0
65-74 years	1	5.6	0	0.0	1	16.7	0	0.0	0	0.0	0	0.0
75+ years	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

Table 8a: Descriptive statistics of all exposure episode durations, in days								
Exposures	Total Episodes	Mean	STD	Min	Q1	Median	Q3	Max
Incident use	15	77.00	45.24	10	39	84	112	156
Prevalent use	18	81.22	43.56	10	42	91	112	156

Table 8b: Descriptive statistics of all exposure episode durations, in days, by sex

Exposures	Total Episodes	Mean	STD	Min	Q1	Median	Q3	Max
Incident use	**15**	**77.00**	**45.24**	**10**	**39**	**84**	**112**	**156**
Female	11	68.36	48.68	10	24	46	112	156
Male	4	100.75	25.05	84	84	91	118	137
Prevalent use	**18**	**81.22**	**43.56**	**10**	**42**	**91**	**112**	**156**
Female	14	75.64	46.75	10	39	82	112	156
Male	4	100.75	25.05	84	84	91	118	137

Table 8c: Descriptive statistics of all exposure episode durations, in days, by age group (years)

Exposures	Total Episodes	Mean	STD	Min	Q1	Median	Q3	Max
Incident use	**15**	**77.00**	**45.24**	**10**	**39**	**84**	**112**	**156**
18-21 years	0	-	-	-	-	-	-	-
22-44 years	6	69.00	57.62	10	14	68	98	156
45-64 years	9	82.33	37.78	24	46	84	112	137
65-74 years	0	-	-	-	-	-	-	-
75+ years	0	-	-	-	-	-	-	-
Prevalent use	**18**	**81.22**	**43.56**	**10**	**42**	**91**	**112**	**156**
18-21 years	0	-	-	-	-	-	-	-
22-44 years	8	81.75	54.29	10	27	98	120	156
45-64 years	9	82.33	37.78	24	46	84	112	137
65-74 years	1	67.00	-	67	67	67	67	67
75+ years	0	-	-	-	-	-	-	-

Table 9a: Distribution of days supplied per dispensing, by length categories										
	Total Dispensings		1-30 days		31-60 days		61-90 days		91+ days	
Exposures	N	%	N	%	N	%	N	%	N	%
Incident use	30	100.0	30	100.0	0	0.0	0	0.0	0	0.0
Prevalent use	36	100.0	36	100.0	0	0.0	0	0.0	0	0.0

Table 9b: Distribution of days supplied per dispensing, by length categories, by sex										
	Total Dispensings		1-30 days		31-60 days		61-90 days		91+ days	
Exposures	N	%	N	%	N	%	N	%	N	%
Incident use	**30**	**100.0**	**30**	**100.0**	**0**	**0.0**	**0**	**0.0**	**0**	**0.0**
Female	23	76.7	23	76.7	0	0.0	0	0.0	0	0.0
Male	7	23.3	7	23.3	0	0.0	0	0.0	0	0.0
Prevalent use	**36**	**100.0**	**36**	**100.0**	**0**	**0.0**	**0**	**0.0**	**0**	**0.0**
Female	29	80.6	29	80.6	0	0.0	0	0.0	0	0.0
Male	7	19.4	7	19.4	0	0.0	0	0.0	0	0.0

Table 9c: Distribution of days supplied per dispensing, by length categories, by age group (years)										
	Total Dispensings		1-30 days		31-60 days		61-90 days		91+ days	
Exposures	N	%	N	%	N	%	N	%	N	%
Incident use	**30**	**100.0**	**30**	**100.0**	**0**	**0.0**	**0**	**0.0**	**0**	**0.0**
18-21 years	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
22-44 years	14	46.7	14	46.7	0	0.0	0	0.0	0	0.0
45-64 years	16	53.3	16	53.3	0	0.0	0	0.0	0	0.0
65-74 years	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
75+ years	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Prevalent use	**36**	**100.0**	**36**	**100.0**	**0**	**0.0**	**0**	**0.0**	**0**	**0.0**
18-21 years	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
22-44 years	19	52.8	19	52.8	0	0.0	0	0.0	0	0.0
45-64 years	16	44.4	16	44.4	0	0.0	0	0.0	0	0.0
65-74 years	1	2.8	1	2.8	0	0.0	0	0.0	0	0.0
75+ years	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

Table 10a: Descriptive statistics of days supplied per dispensing

Exposures	Total Dispensings	Mean	STD	Min	Q1	Median	Q3	Max
Incident use	30	25.43	5.64	10	28	28	28	28
Prevalent use	36	25.86	5.23	10	28	28	28	28

Table 10b: Descriptive statistics of days supplied per dispensing, by sex								
Exposures	Total Dispensings	Mean	STD	Min	Q1	Median	Q3	Max
Incident use	**30**	**25.43**	**5.64**	**10**	**28**	**28**	**28**	**28**
Female	23	24.65	6.26	10	24	28	28	28
Male	7	28.00	0.00	28	28	28	28	28
Prevalent use	**36**	**25.86**	**5.23**	**10**	**28**	**28**	**28**	**28**
Female	29	25.34	5.72	10	28	28	28	28
Male	7	28.00	0.00	28	28	28	28	28

Table 10c: Descriptive statistics of days supplied per dispensing, by age group (years)

Exposures	Total Dispensings	Mean	STD	Min	Q1	Median	Q3	Max
Incident use	**30**	**25.43**	**5.64**	**10**	**28**	**28**	**28**	**28**
18-21 years	0	-	-	-	-	-	-	-
22-44 years	14	24.50	7.00	10	28	28	28	28
45-64 years	16	26.25	4.19	14	28	28	28	28
65-74 years	0	-	-	-	-	-	-	-
75+ years	0	-	-	-	-	-	-	-
Prevalent use	**36**	**25.86**	**5.23**	**10**	**28**	**28**	**28**	**28**
18-21 years	0	-	-	-	-	-	-	-
22-44 years	19	25.42	6.16	10	28	28	28	28
45-64 years	16	26.25	4.19	14	28	28	28	28
65-74 years	1	28.00	-	28	28	28	28	28
75+ years	0	-	-	-	-	-	-	-

Table 11a: Descriptive statistics of the length of the first gap between treatment episodes, in days								
Exposures	Total Gaps	Mean	STD	Min	Q1	Median	Q3	Max
Incident use	0	-	-	-	-	-	-	-
Prevalent use	0	-	-	-	-	-	-	-

Table 11b: Descriptive statistics of the length of the first gap between treatment episodes, in days, by sex								
Exposures	**Total Gaps**	**Mean**	**STD**	**Min**	**Q1**	**Median**	**Q3**	**Max**
Incident use	**0**	**-**	**-**	**-**	**-**	**-**	**-**	**-**
Female	0	-	-	-	-	-	-	-
Male	0	-	-	-	-	-	-	-
Prevalent use	**0**	**-**	**-**	**-**	**-**	**-**	**-**	**-**
Female	0	-	-	-	-	-	-	-
Male	0	-	-	-	-	-	-	-

Table 11c: Descriptive statistics of the length of the first gap between treatment episodes, in days, by age group (years)								
Exposures	**Total Gaps**	**Mean**	**STD**	**Min**	**Q1**	**Median**	**Q3**	**Max**
Incident use	**0**	**-**	**-**	**-**	**-**	**-**	**-**	**-**
18-21 years	0	-	-	-	-	-	-	-
22-44 years	0	-	-	-	-	-	-	-
45-64 years	0	-	-	-	-	-	-	-
65-74 years	0	-	-	-	-	-	-	-
75+ years	0	-	-	-	-	-	-	-
Prevalent use	**0**	**-**	**-**	**-**	**-**	**-**	**-**	**-**
18-21 years	0	-	-	-	-	-	-	-
22-44 years	0	-	-	-	-	-	-	-
45-64 years	0	-	-	-	-	-	-	-
65-74 years	0	-	-	-	-	-	-	-
75+ years	0	-	-	-	-	-	-	-

Table 12a: Descriptive statistics of the length of second and subequent gaps between treatment episodes, in days								
Exposures	Total Gaps	Mean	STD	Min	Q1	Median	Q3	Max
Incident use	0	-	-	-	-	-	-	-
Prevalent use	0	-	-	-	-	-	-	-

Table 12b: Descriptive statistics of the length of second and subsequent gaps between treatment episodes, in days, by sex								
Exposures	Total Gaps	Mean	STD	Min	Q1	Median	Q3	Max
Incident use	**0**	**-**	**-**	**-**	**-**	**-**	**-**	**-**
Female	0	-	-	-	-	-	-	-
Male	0	-	-	-	-	-	-	-
Prevalent use	**0**	**-**	**-**	**-**	**-**	**-**	**-**	**-**
Female	0	-	-	-	-	-	-	-
Male	0	-	-	-	-	-	-	-

Table 12c: Descriptive statistics of the length of second and subequent gaps between treatment episodes, in days, by age group (years)								
Exposures	Total Gaps	Mean	STD	Min	Q1	Median	Q3	Max
Incident use	**0**	**-**	**-**	**-**	**-**	**-**	**-**	**-**
18-21 years	0	-	-	-	-	-	-	-
22-44 years	0	-	-	-	-	-	-	-
45-64 years	0	-	-	-	-	-	-	-
65-74 years	0	-	-	-	-	-	-	-
75+ years	0	-	-	-	-	-	-	-
Prevalent use	**0**	**-**	**-**	**-**	**-**	**-**	**-**	**-**
18-21 years	0	-	-	-	-	-	-	-
22-44 years	0	-	-	-	-	-	-	-
45-64 years	0	-	-	-	-	-	-	-
65-74 years	0	-	-	-	-	-	-	-
75+ years	0	-	-	-	-	-	-	-

Table 13a: Descriptive statistics of the length of all gaps between treatment episodes, in days								
Exposures	Total Gaps	Mean	STD	Min	Q1	Median	Q3	Max
Incident use	0	-	-	-	-	-	-	-
Prevalent use	0	-	-	-	-	-	-	-

Table 13b: Descriptive statistics of the length of all gaps between treatment episodes, in days, by sex								
Exposures	Total Gaps	Mean	STD	Min	Q1	Median	Q3	Max
Incident use	**0**	**-**	**-**	**-**	**-**	**-**	**-**	**-**
Female	0	-	-	-	-	-	-	-
Male	0	-	-	-	-	-	-	-
Prevalent use	**0**	**-**	**-**	**-**	**-**	**-**	**-**	**-**
Female	0	-	-	-	-	-	-	-
Male	0	-	-	-	-	-	-	-

Table 13c: Descriptive statistics of the length of all gaps between treatment episodes, in days, by age group (years)								
Exposures	Total Gaps	Mean	STD	Min	Q1	Median	Q3	Max
Incident use	**0**	**-**	**-**	**-**	**-**	**-**	**-**	**-**
18-21 years	0	-	-	-	-	-	-	-
22-44 years	0	-	-	-	-	-	-	-
45-64 years	0	-	-	-	-	-	-	-
65-74 years	0	-	-	-	-	-	-	-
75+ years	0	-	-	-	-	-	-	-
Prevalent use	**0**	**-**	**-**	**-**	**-**	**-**	**-**	**-**
18-21 years	0	-	-	-	-	-	-	-
22-44 years	0	-	-	-	-	-	-	-
45-64 years	0	-	-	-	-	-	-	-
65-74 years	0	-	-	-	-	-	-	-
75+ years	0	-	-	-	-	-	-	-

Table 14a: Counts of reason for censoring, all episodes and first episode										
	Total		Disenrollment		Evidence of death		DP*/Query end date		Episode end	
	N	%	N	%	N	%	N	%	N	%
Exposures										
Incident use	15	100.0	10	66.7	0	0.0	9	60.0	5	33.3
Prevalent use	18	100.0	12	66.7	0	0.0	11	61.1	6	33.3
Patients' First Episode										
Incident use	15	100.0	10	66.7	0	0.0	9	60.0	5	33.3
Prevalent use	18	100.0	12	66.7	0	0.0	11	61.1	6	33.3

*DP = Data Partner

Table 15a: Cohort Attrition Table	
Attrition Criteria	**Members**
Incident_use	
Initial Member Count - Members with a non-missing birth date/sex at any enrollment episode overlapping the query period	27,477,751 (100.0%)
Exclusion - Members must be excluded if they only have enrollment episodes with DrugCov=N and MedCov=Y or A during the query period	26,742,455 (97.3%)
Exclusion - Members must be excluded if they only have enrollment episodes with DrugCov=Y and MedCov=N during the query period	26,742,455 (97.3%)
Exclusion - Members must be excluded if they only have enrollment episodes with DrugCov=Y and MedCov=N and DrugCov=N and MedCov=Y or A during the query period	26,742,455 (97.3%)
Exclusion - Members must satisfy the age range condition within the query period	21,321,175 (77.6%)
Exclusion - Members must meet chart availability criterion within the query period	21,321,175 (77.6%)
Exclusion - Members must satisfy the demographic (sex, race and hispanic) condition	21,321,175 (77.6%)
Exclusion - Members must have at least one claim with cohort-identifying codes within the query period	18 (0.0%)
Exclusion - Members must have at least one cohort episode index date within the age range condition	18 (0.0%)
Exclusion - Members must have at least one episode defining index claim during the query period	18 (0.0%)
Exclusion - Members must have at least one cohort episode incident with respect to other criteria	18 (0.0%)
Exclusion - Members must have at least one cohort episode satisfying the pre-index enrollment criterion	15 (0.0%)
Exclusion - Members must have at least one cohort episode satisfying all exclusion and inclusion criteria	15 (0.0%)
Exclusion - Members must have at least one cohort episode satisfying the post-index enrollment criterion	15 (0.0%)
Prevalent_use	
Initial Member Count - Members with a non-missing birth date/sex at any enrollment episode overlapping the query period	27,477,751 (100.0%)
Exclusion - Members must be excluded if they only have enrollment episodes with DrugCov=N and MedCov=Y or A during the query period	26,742,455 (97.3%)
Exclusion - Members must be excluded if they only have enrollment episodes with DrugCov=Y and MedCov=N during the query period	26,742,455 (97.3%)
Exclusion - Members must be excluded if they only have enrollment episodes with DrugCov=Y and MedCov=N and DrugCov=N and MedCov=Y or A during the query period	26,742,455 (97.3%)
Exclusion - Members must satisfy the age range condition within the query period	21,321,175 (77.6%)
Exclusion - Members must meet chart availability criterion within the query period	21,321,175 (77.6%)
Exclusion - Members must satisfy the demographic (sex, race and hispanic) condition	21,321,175 (77.6%)
Exclusion - Members must have at least one claim with cohort-identifying codes within the query period	18 (0.0%)
Exclusion - Members must have at least one cohort episode index date within the age range condition	18 (0.0%)
Exclusion - Members must have at least one episode defining index claim during the query period	18 (0.0%)
Exclusion - Members must have at least one cohort episode incident with respect to other criteria	18 (0.0%)
Exclusion - Members must have at least one cohort episode satisfying the pre-index enrollment criterion	18 (0.0%)
Exclusion - Members must have at least one cohort episode satisfying all exclusion and inclusion criteria	18 (0.0%)
Exclusion - Members must have at least one cohort episode satisfying the post-index enrollment criterion	18 (0.0%)

Appendix A. Dates of Available Data for Each Data Partner (DP) up to Request End Date (09/30/2021) as of Query Distribution Date		
Data Partner (Masked)	Start Date	End Date
DP01	01/01/2010	09/30/2021

Appendix B. Specifications Used to Define Parameters in this Query

Global Values

Enrollment Criteria:**Medical and Drug Coverage**
Enrollment Gap (Days):**45**
Age Groups (Years):**18-21, 22-44, 45-64, 65-74, 75+**
Reporting Output:**All tables**
Query Period: **06/19/2020-09/30/2021**
Baseline Characteristics Table:**No**
Baseline Evaluation Window (Day):

#	Cohort Name	Index Exposure	Pre-Index Enrollment Period (Days)	Washout Period (Days)	Treatment Episode Gap (Days)	Treatment Episode Extension (Days)	Inclusion/ Exclusion	Criteria	Criteria Definition	Evaluation Period Start (Day)	Evaluation Period End (Day)
1	Prevalent_use	Gimoti[1]	0	-	56	56	--	--	--	--	--
							--	--	--	--	--
2	Incident_use	Gimoti[2]	183	183	56	56	--	--	--	--	--
							--	--	--	--	--

ICD-9,ICD-10,HCPCS AND CPT are provided by Optum360
NDCs are checked against First Data Bank's MedKnowledge.

Appendix of Generic Names and Chronic Conditions

[1]   See Appendix C

[2]   See Appendix C

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

Age Groups - Age groups of members included in the cohort. Strata also used for reporting purposes.

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

Baseline Characteristics Table - Optional table containing general characteristics of study population, including background rates of 27 chronic conditions from the CMS Chronic Condition Warehouse (see above if table requested). Users define an evaluation period for the presence of baseline characteristics.

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

Charlson/Elixhauser Combined Comorbidity Score - Calculated based on comorbidities observed during a requester-defined window around the exposure episode start date (e.g., in the 183 days prior to index).

Cohort Definition - Cohort includes all valid exposure episodes during the query period. Only the first valid episode's incidence is assessed using the washout period.

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

Enrollment Criteria - Type of coverage required during enrollment period. By default, all patients must have medical and drug coverage.

Enrollment Gap - Allowed gap between coverage periods.

Episodes - Treatment episodes; length of episode is determined by days supplied in one dispensing or consecutive dispensings bridged by the episode gap.

Inclusion/Exclusion - Contains the comprehensive set of codes used to define additional cohort inclusion and/or exclusion criteria (e.g., restrict cohort to individuals with evidence of a pre-existing condition 183 days before the index date). Criteria could be defined with complex algorithms (e.g., diagnosis codes and drug codes) defined under Criteria Definition.

Inpatient Hospital Stay (IP) - A care setting value including 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) - A care setting value including hospice, skilled nursing facility (SNF), rehab center, nursing home, residential, overnight non-hospital dialysis and other non-hospital stays.

Other Ambulatory Visit (OA) - A care setting value including 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.

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

Query Period - The period of time which patients can contribute index-defining exposure/events. Data prior to the start date may be used to determine enrollment, washout, and other cohort inclusion criteria.

Treatment Episode Extension - The episode extension adds the selected number of days to the end of an episode to count as exposed time.

Treatment Episode Gap - The maximum number of days allowed between two dispensings to consider them part of the same episode.

Washout Period - The period before an exposure episode during which an individual cannot have evidence of incidence-defining criteria.

Appendix C. List of Generic Names of Medical Products Used to Define Index Exposures in this Request

Generic Name
Metoclopramide
Metoclopramide HCL