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.

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 31, 2023. The study period included data from June 19, 2020 to September 30, 2022. 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												
	Total Patients		1-30 days		31-90 days		91-365 days		366-730 days		731+ days	
Exposures	**N**	**%**	**N**	**%**	**N**	**%**	**N**	**%**	**N**	**%**	**N**	**%**
Incident	34	100.0	3	8.8	8	23.5	22	64.7	1	2.9	0	0.0
Overall counts	41	100.0	3	7.3	11	26.8	26	63.4	1	2.4	0	0.0

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

Exposures	Total Patients		1-30 days		31-90 days		91-365 days		366-730 days		731+ days	
	N	%	N	%	N	%	N	%	N	%	N	%
Incident	**34**	**100.0**	**3**	**100.0**	**8**	**100.0**	**22**	**100.0**	**1**	**100.0**	**0**	**0.0**
Female	23	67.6	2	66.7	5	62.5	15	68.2	1	100.0	0	0.0
Male	11	32.4	1	33.3	3	37.5	7	31.8	0	0.0	0	0.0
Overall counts	**41**	**100.0**	**3**	**100.0**	**11**	**100.0**	**26**	**100.0**	**1**	**100.0**	**0**	**0.0**
Female	28	68.3	2	66.7	8	72.7	17	65.4	1	100.0	0	0.0
Male	13	31.7	1	33.3	3	27.3	9	34.6	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	**34**	**100.0**	**3**	**100.0**	**8**	**100.0**	**22**	**100.0**	**1**	**100.0**	**0**	**0.0**
18-21 years	1	2.9	0	0.0	0	0.0	1	4.5	0	0.0	0	0.0
22-44 years	11	32.4	0	0.0	3	37.5	7	31.8	1	100.0	0	0.0
45-64 years	22	64.7	3	100.0	5	62.5	14	63.6	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
Overall counts	**41**	**100.0**	**3**	**100.0**	**11**	**100.0**	**26**	**100.0**	**1**	**100.0**	**0**	**0.0**
18-21 years	1	2.4	0	0.0	0	0.0	1	3.8	0	0.0	0	0.0
22-44 years	15	36.6	0	0.0	4	36.4	10	38.5	1	100.0	0	0.0
45-64 years	24	58.5	3	100.0	6	54.5	15	57.7	0	0.0	0	0.0
65-74 years	1	2.4	0	0.0	1	9.1	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	34	130.26	86.79	8	84	112	141	472
Overall counts	41	126.24	81.08	8	84	112	140	472

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	**34**	**130.26**	**86.79**	**8**	**84**	**112**	**141**	**472**
Female	23	133.96	96.59	8	84	112	141	472
Male	11	122.55	65.06	29	84	108	140	269
Overall counts	**41**	**126.24**	**81.08**	**8**	**84**	**112**	**140**	**472**
Female	28	126.32	90.01	8	84	112	141	472
Male	13	126.08	60.71	29	84	117	140	269

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	**34**	**130.26**	**86.79**	**8**	**84**	**112**	**141**	**472**
18-21 years	1	256.00	-	256	256	256	256	256
22-44 years	11	171.64	123.05	50	84	140	269	472
45-64 years	22	103.86	47.39	8	84	112	140	201
65-74 years	0	-	-	-	-	-	-	-
75+ years	0	-	-	-	-	-	-	-
Overall counts	**41**	**126.24**	**81.08**	**8**	**84**	**112**	**140**	**472**
18-21 years	1	256.00	-	256	256	256	256	256
22-44 years	15	153.27	110.74	36	84	123	145	472
45-64 years	24	105.71	47.36	8	84	112	140	201
65-74 years	1	84.00	-	84	84	84	84	84
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	34	100.0	3	8.8	9	26.5	22	64.7	0	0.0	0	0.0
Overall counts	41	100.0	3	7.3	13	31.7	25	61.0	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	**34**	**100.0**	**3**	**100.0**	**9**	**100.0**	**22**	**100.0**	**0**	**0.0**	**0**	**0.0**
Female	23	67.6	2	66.7	6	66.7	15	68.2	0	0.0	0	0.0
Male	11	32.4	1	33.3	3	33.3	7	31.8	0	0.0	0	0.0
Overall counts	**41**	**100.0**	**3**	**100.0**	**13**	**100.0**	**25**	**100.0**	**0**	**0.0**	**0**	**0.0**
Female	28	68.3	2	66.7	9	69.2	17	68.0	0	0.0	0	0.0
Male	13	31.7	1	33.3	4	30.8	8	32.0	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	**34**	**100.0**	**3**	**100.0**	**9**	**100.0**	**22**	**100.0**	**0**	**0.0**	**0**	**0.0**
18-21 years	1	2.9	0	0.0	0	0.0	1	4.5	0	0.0	0	0.0
22-44 years	11	32.4	0	0.0	4	44.4	7	31.8	0	0.0	0	0.0
45-64 years	22	64.7	3	100.0	5	55.6	14	63.6	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
Overall counts	**41**	**100.0**	**3**	**100.0**	**13**	**100.0**	**25**	**100.0**	**0**	**0.0**	**0**	**0.0**
18-21 years	1	2.4	0	0.0	0	0.0	1	4.0	0	0.0	0	0.0
22-44 years	15	36.6	0	0.0	5	38.5	10	40.0	0	0.0	0	0.0
45-64 years	24	58.5	3	100.0	7	53.8	14	56.0	0	0.0	0	0.0
65-74 years	1	2.4	0	0.0	1	7.7	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	34	109.62	44.98	8	84	112	140	204
Overall counts	41	107.07	43.30	8	84	112	140	204

Table 4b: Descriptive statistics of first exposure episode duration, in days, by sex								
Exposures	**Total Episodes**	**Mean**	**STD**	**Min**	**Q1**	**Median**	**Q3**	**Max**
Incident	**34**	**109.62**	**44.98**	**8**	**84**	**112**	**140**	**204**
Female	23	108.91	45.98	8	84	112	140	185
Male	11	111.09	44.97	29	84	108	140	204
Overall counts	**41**	**107.07**	**43.30**	**8**	**84**	**112**	**140**	**204**
Female	28	105.75	44.63	8	84	112	140	185
Male	13	109.92	41.91	29	84	108	137	204

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	**34**	**109.62**	**44.98**	**8**	**84**	**112**	**140**	**204**
18-21 years	1	185.00	-	185	185	185	185	185
22-44 years	11	119.82	44.13	50	84	112	140	204
45-64 years	22	101.09	43.02	8	84	112	140	168
65-74 years	0	-	-	-	-	-	-	-
75+ years	0	-	-	-	-	-	-	-
Overall counts	**41**	**107.07**	**43.30**	**8**	**84**	**112**	**140**	**204**
18-21 years	1	185.00	-	185	185	185	185	185
22-44 years	15	115.27	43.65	36	84	112	140	204
45-64 years	24	99.67	41.39	8	84	110	139	168
65-74 years	1	84.00	-	84	84	84	84	84
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	7	100.0	0	0.0	5	71.4	2	28.6	0	0.0	0	0.0
Overall counts	8	100.0	0	0.0	6	75.0	2	25.0	0	0.0	0	0.0

Table 5b: Distribution of second and subsequent exposure episode duration, by length categories, in days, by sex

Exposures	Total Episodes		1-30 days		31-90 days		91-365 days		366-730 days		731+ days	
	N	%	N	%	N	%	N	%	N	%	N	%
Incident	**7**	**100.0**	**0**	**0.0**	**5**	**100.0**	**2**	**100.0**	**0**	**0.0**	**0**	**0.0**
Female	5	71.4	0	0.0	3	60.0	2	100.0	0	0.0	0	0.0
Male	2	28.6	0	0.0	2	40.0	0	0.0	0	0.0	0	0.0
Overall counts	**8**	**100.0**	**0**	**0.0**	**6**	**100.0**	**2**	**100.0**	**0**	**0.0**	**0**	**0.0**
Female	5	62.5	0	0.0	3	50.0	2	100.0	0	0.0	0	0.0
Male	3	37.5	0	0.0	3	50.0	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	**7**	**100.0**	**0**	**0.0**	**5**	**100.0**	**2**	**100.0**	**0**	**0.0**	**0**	**0.0**
18-21 years	1	14.3	0	0.0	1	20.0	0	0.0	0	0.0	0	0.0
22-44 years	5	71.4	0	0.0	3	60.0	2	100.0	0	0.0	0	0.0
45-64 years	1	14.3	0	0.0	1	20.0	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
Overall counts	**8**	**100.0**	**0**	**0.0**	**6**	**100.0**	**2**	**100.0**	**0**	**0.0**	**0**	**0.0**
18-21 years	1	12.5	0	0.0	1	16.7	0	0.0	0	0.0	0	0.0
22-44 years	5	62.5	0	0.0	3	50.0	2	100.0	0	0.0	0	0.0
45-64 years	2	25.0	0	0.0	2	33.3	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	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	7	100.29	69.13	61	61	65	140	243
Overall counts	8	98.25	64.26	61	61	68	112	243

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	**7**	**100.29**	**69.13**	**61**	**61**	**65**	**140**	**243**
Female	5	115.20	78.70	61	61	71	140	243
Male	2	63.00	2.83	61	61	63	65	65
Overall counts	**8**	**98.25**	**64.26**	**61**	**61**	**68**	**112**	**243**
Female	5	115.20	78.70	61	61	71	140	243
Male	3	70.00	12.29	61	61	65	84	84

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	**7**	**100.29**	**69.13**	**61**	**61**	**65**	**140**	**243**
18-21 years	1	71.00	-	71	71	71	71	71
22-44 years	5	114.00	79.59	61	61	65	140	243
45-64 years	1	61.00	-	61	61	61	61	61
65-74 years	0	-	-	-	-	-	-	-
75+ years	0	-	-	-	-	-	-	-
Overall counts	**8**	**98.25**	**64.26**	**61**	**61**	**68**	**112**	**243**
18-21 years	1	71.00	-	71	71	71	71	71
22-44 years	5	114.00	79.59	61	61	65	140	243
45-64 years	2	72.50	16.26	61	61	73	84	84
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	41	100.0	3	7.3	14	34.1	24	58.5	0	0.0	0	0.0
Overall counts	49	100.0	3	6.1	19	38.8	27	55.1	0	0.0	0	0.0

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

Exposures	Total Episodes		1-30 days		31-90 days		91-365 days		366-730 days		731+ days	
	N	%	N	%	N	%	N	%	N	%	N	%
Incident	**41**	**100.0**	**3**	**100.0**	**14**	**100.0**	**24**	**100.0**	**0**	**0.0**	**0**	**0.0**
Female	28	68.3	2	66.7	9	64.3	17	70.8	0	0.0	0	0.0
Male	13	31.7	1	33.3	5	35.7	7	29.2	0	0.0	0	0.0
Overall counts	**49**	**100.0**	**3**	**100.0**	**19**	**100.0**	**27**	**100.0**	**0**	**0.0**	**0**	**0.0**
Female	33	67.3	2	66.7	12	63.2	19	70.4	0	0.0	0	0.0
Male	16	32.7	1	33.3	7	36.8	8	29.6	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	**41**	**100.0**	**3**	**100.0**	**14**	**100.0**	**24**	**100.0**	**0**	**0.0**	**0**	**0.0**
18-21 years	2	4.9	0	0.0	1	7.1	1	4.2	0	0.0	0	0.0
22-44 years	16	39.0	0	0.0	7	50.0	9	37.5	0	0.0	0	0.0
45-64 years	23	56.1	3	100.0	6	42.9	14	58.3	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
Overall counts	**49**	**100.0**	**3**	**100.0**	**19**	**100.0**	**27**	**100.0**	**0**	**0.0**	**0**	**0.0**
18-21 years	2	4.1	0	0.0	1	5.3	1	3.7	0	0.0	0	0.0
22-44 years	20	40.8	0	0.0	8	42.1	12	44.4	0	0.0	0	0.0
45-64 years	26	53.1	3	100.0	9	47.4	14	51.9	0	0.0	0	0.0
65-74 years	1	2.0	0	0.0	1	5.3	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	41	108.02	48.98	8	84	112	140	243
Overall counts	49	105.63	46.64	8	84	112	140	243

Table 8b: Descriptive statistics of all exposure episode durations, in days, by sex								
Exposures	Total Episodes	Mean	STD	Min	Q1	Median	Q3	Max
Incident	**41**	**108.02**	**48.98**	**8**	**84**	**112**	**140**	**243**
Female	28	110.04	51.44	8	78	112	140	243
Male	13	103.69	44.85	29	84	95	137	204
Overall counts	**49**	**105.63**	**46.64**	**8**	**84**	**112**	**140**	**243**
Female	33	107.18	49.66	8	84	112	140	243
Male	16	102.44	41.04	29	84	90	130	204

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	**41**	**108.02**	**48.98**	**8**	**84**	**112**	**140**	**243**
18-21 years	2	128.00	80.61	71	71	128	185	185
22-44 years	16	118.00	54.73	50	75	112	140	243
45-64 years	23	99.35	42.86	8	84	112	140	168
65-74 years	0	-	-	-	-	-	-	-
75+ years	0	-	-	-	-	-	-	-
Overall counts	**49**	**105.63**	**46.64**	**8**	**84**	**112**	**140**	**243**
18-21 years	2	128.00	80.61	71	71	128	185	185
22-44 years	20	114.95	52.32	36	75	112	140	243
45-64 years	26	97.58	40.51	8	84	102	137	168
65-74 years	1	84.00	-	84	84	84	84	84
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	100	100.0	100	100.0	0	0.0	0	0.0	0	0.0
Overall counts	115	100.0	115	100.0	0	0.0	0	0.0	0	0.0

Table 9b: Distribution of days supplied per dispensing, by length categories, by sex

Exposures	Total Dispensings		1-30 days		31-60 days		61-90 days		91+ days	
	N	%	N	%	N	%	N	%	N	%
Incident	**100**	**100.0**	**100**	**100.0**	**0**	**0.0**	**0**	**0.0**	**0**	**0.0**
Female	68	68.0	68	68.0	0	0.0	0	0.0	0	0.0
Male	32	32.0	32	32.0	0	0.0	0	0.0	0	0.0
Overall counts	**115**	**100.0**	**115**	**100.0**	**0**	**0.0**	**0**	**0.0**	**0**	**0.0**
Female	77	67.0	77	67.0	0	0.0	0	0.0	0	0.0
Male	38	33.0	38	33.0	0	0.0	0	0.0	0	0.0

Table 9c: Distribution of days supplied per dispensing, by length categories, by age group (years)

Exposures	Total Dispensings		1-30 days		31-60 days		61-90 days		91+ days	
	N	%	N	%	N	%	N	%	N	%
Incident	**100**	**100.0**	**100**	**100.0**	**0**	**0.0**	**0**	**0.0**	**0**	**0.0**
18-21 years	7	7.0	7	7.0	0	0.0	0	0.0	0	0.0
22-44 years	40	40.0	40	40.0	0	0.0	0	0.0	0	0.0
45-64 years	53	53.0	53	53.0	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
75+ years	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Overall counts	**115**	**100.0**	**115**	**100.0**	**0**	**0.0**	**0**	**0.0**	**0**	**0.0**
18-21 years	7	6.1	7	6.1	0	0.0	0	0.0	0	0.0
22-44 years	51	44.3	51	44.3	0	0.0	0	0.0	0	0.0
45-64 years	56	48.7	56	48.7	0	0.0	0	0.0	0	0.0
65-74 years	1	0.9	1	0.9	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	100	26.43	5.24	5	28	28	28	28
Overall counts	115	26.32	5.37	5	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	**100**	**26.43**	**5.24**	**5**	**28**	**28**	**28**	**28**
Female	68	26.56	4.95	5	28	28	28	28
Male	32	26.16	5.88	5	28	28	28	28
Overall counts	**115**	**26.32**	**5.37**	**5**	**28**	**28**	**28**	**28**
Female	77	26.47	5.13	5	28	28	28	28
Male	38	26.03	5.90	5	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	**100**	**26.43**	**5.24**	**5**	**28**	**28**	**28**	**28**
18-21 years	7	26.14	4.91	15	28	28	28	28
22-44 years	40	27.38	3.13	9	28	28	28	28
45-64 years	53	25.75	6.40	5	28	28	28	28
65-74 years	0	-	-	-	-	-	-	-
75+ years	0	-	-	-	-	-	-	-
Overall counts	**115**	**26.32**	**5.37**	**5**	**28**	**28**	**28**	**28**
18-21 years	7	26.14	4.91	15	28	28	28	28
22-44 years	51	26.80	4.43	8	28	28	28	28
45-64 years	56	25.88	6.24	5	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	6	41.83	34.23	7	21	34	50	105
Overall counts	7	42.71	31.34	7	21	38	50	105

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	**6**	**41.83**	**34.23**	**7**	**21**	**34**	**50**	**105**
Female	4	45.00	42.10	7	19	34	72	105
Male	2	35.50	20.51	21	21	36	50	50
Overall counts	**7**	**42.71**	**31.34**	**7**	**21**	**38**	**50**	**105**
Female	4	45.00	42.10	7	19	34	72	105
Male	3	39.67	16.20	21	21	48	50	50

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	**6**	**41.83**	**34.23**	**7**	**21**	**34**	**50**	**105**
18-21 years	1	105.00	-	105	105	105	105	105
22-44 years	4	31.25	18.14	7	19	34	44	50
45-64 years	1	21.00	-	21	21	21	21	21
65-74 years	0	-	-	-	-	-	-	-
75+ years	0	-	-	-	-	-	-	-
Overall counts	**7**	**42.71**	**31.34**	**7**	**21**	**38**	**50**	**105**
18-21 years	1	105.00	-	105	105	105	105	105
22-44 years	4	31.25	18.14	7	19	34	44	50
45-64 years	2	34.50	19.09	21	21	35	48	48
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	1	19.00	-	19	19	19	19	19
Overall counts	1	19.00	-	19	19	19	19	19

Table 12b: Descriptive statistics of the length of second and subequent gaps between treatment episodes, in days, by sex

Exposures	Total Gaps	Mean	STD	Min	Q1	Median	Q3	Max
Incident	**1**	**19.00**	**-**	**19**	**19**	**19**	**19**	**19**
Female	1	19.00	-	19	19	19	19	19
Male	0	-	-	-	-	-	-	-
Overall counts	**1**	**19.00**	**-**	**19**	**19**	**19**	**19**	**19**
Female	1	19.00	-	19	19	19	19	19
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	**1**	**19.00**	**-**	**19**	**19**	**19**	**19**	**19**
18-21 years	0	-	-	-	-	-	-	-
22-44 years	1	19.00	-	19	19	19	19	19
45-64 years	0	-	-	-	-	-	-	-
65-74 years	0	-	-	-	-	-	-	-
75+ years	0	-	-	-	-	-	-	-
Overall counts	**1**	**19.00**	**-**	**19**	**19**	**19**	**19**	**19**
18-21 years	0	-	-	-	-	-	-	-
22-44 years	1	19.00	-	19	19	19	19	19
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	7	38.57	32.42	7	19	30	50	105
Overall counts	8	39.75	30.20	7	20	34	49	105

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	**7**	**38.57**	**32.42**	**7**	**19**	**30**	**50**	**105**
Female	5	39.80	38.27	7	19	30	38	105
Male	2	35.50	20.51	21	21	36	50	50
Overall counts	**8**	**39.75**	**30.20**	**7**	**20**	**34**	**49**	**105**
Female	5	39.80	38.27	7	19	30	38	105
Male	3	39.67	16.20	21	21	48	50	50

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	**7**	**38.57**	**32.42**	**7**	**19**	**30**	**50**	**105**
18-21 years	1	105.00	-	105	105	105	105	105
22-44 years	5	28.80	16.63	7	19	30	38	50
45-64 years	1	21.00	-	21	21	21	21	21
65-74 years	0	-	-	-	-	-	-	-
75+ years	0	-	-	-	-	-	-	-
Overall counts	**8**	**39.75**	**30.20**	**7**	**20**	**34**	**49**	**105**
18-21 years	1	105.00	-	105	105	105	105	105
22-44 years	5	28.80	16.63	7	19	30	38	50
45-64 years	2	34.50	19.09	21	21	35	48	48
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	41	100.0	14	34.1	0	0.0	0	0.0	27	65.9
Overall counts	49	100.0	16	32.7	0	0.0	0	0.0	33	67.3
Patients' First Episode										
Incident	34	100.0	9	26.5	0	0.0	0	0.0	25	73.5
Overall counts	41	100.0	11	26.8	0	0.0	0	0.0	30	73.2

*DP = Data Partner

Table 15a: Cohort Attrition Table	
Attrition Criteria	**Members**
Incident	
Initial Member Count - Members with a non-missing birth date/sex at any enrollment episode overlapping the query period	34,231,429 (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	32,562,135 (95.1%)
Exclusion - Members must be excluded if they only have enrollment episodes with DrugCov=Y and MedCov=N during the query period	32,562,135 (95.1%)
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	32,562,135 (95.1%)
Exclusion - Members must satisfy the age range condition within the query period	26,677,264 (77.9%)
Exclusion - Members must meet chart availability criterion within the query period	26,677,264 (77.9%)
Exclusion - Members must satisfy the demographic (sex, race and hispanic) condition	26,677,264 (77.9%)
Exclusion - Members must have at least one claim with cohort-identifying codes within the query period	41 (0.0%)
Exclusion - Members must have at least one cohort episode index date within the age range condition	41 (0.0%)
Exclusion - Members must have at least one episode defining index claim during the query period	41 (0.0%)
Exclusion - Members must have at least one cohort episode incident with respect to other criteria	41 (0.0%)
Exclusion - Members must have at least one cohort episode satisfying the pre-index enrollment criterion	34 (0.0%)
Exclusion - Members must have at least one cohort episode satisfying all exclusion and inclusion criteria	34 (0.0%)
Exclusion - Members must have at least one cohort episode satisfying the post-index enrollment criterion	34 (0.0%)
Overall_counts	
Initial Member Count - Members with a non-missing birth date/sex at any enrollment episode overlapping the query period	34,231,429 (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	32,562,135 (95.1%)
Exclusion - Members must be excluded if they only have enrollment episodes with DrugCov=Y and MedCov=N during the query period	32,562,135 (95.1%)
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	32,562,135 (95.1%)
Exclusion - Members must satisfy the age range condition within the query period	26,677,264 (77.9%)
Exclusion - Members must meet chart availability criterion within the query period	26,677,264 (77.9%)
Exclusion - Members must satisfy the demographic (sex, race and hispanic) condition	26,677,264 (77.9%)
Exclusion - Members must have at least one claim with cohort-identifying codes within the query period	41 (0.0%)
Exclusion - Members must have at least one cohort episode index date within the age range condition	41 (0.0%)
Exclusion - Members must have at least one episode defining index claim during the query period	41 (0.0%)
Exclusion - Members must have at least one cohort episode incident with respect to other criteria	41 (0.0%)
Exclusion - Members must have at least one cohort episode satisfying the pre-index enrollment criterion	41 (0.0%)
Exclusion - Members must have at least one cohort episode satisfying all exclusion and inclusion criteria	41 (0.0%)
Exclusion - Members must have at least one cohort episode satisfying the post-index enrollment criterion	41 (0.0%)

Appendix A:	Dates of Available Data for Each Data Partner (DP) up to End Date (9/30/2022) as of Query Distribution Date (10/31/23)	
Data Partner (Masked)	**Start Date**	**End Date**
DP01	01/01/2010	09/30/2022

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**- **09/30/2022**

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	Overall_counts	Gimoti[1]	0	0	56	56	--	--	--	--	--
							--	--	--	--	--
2	Incident	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

   - 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