

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@sentinelsystem.org.



Overview for Request: cder mpl1r wp089

Request ID: cder_mpl1r_wp089_nsdp_v01

<u>Request Description:</u> The goal of this query was to examine utilization of metoclopramide among female members without evidence of liveborn delivery with type 2 diabetes. We also examined female members without evidence of liveborn delivery with a combination of type 2 diabetes and gastroparesis in the Sentinel Distributed Database (SDD).

Sentinel Routine Querying Module: Cohort Identification and Descriptive Analysis (CIDA) module, version 5.3.1

<u>Data Source:</u> We included data in this report from January 1, 2008 - September 30, 2015 from 17 Data Partners who contributed to the SDD. We distributed this request to Data Partners on May 24, 2018. See Appendix A for a list of dates of available data for each Data Partner.

<u>Study Design:</u> We designed this request to calculate summary statistics on length of treatment episodes and gaps between treatment episodes. We stratified results by age group.

Exposures of Interest: We defined the exposures of interest, oral and injectable metoclopramide, using National Drug Codes (NDCs) and Healthcare Common Procedure Coding System (HCPCS) procedure codes. Please see Appendix B for a list of generic and brand drug names and Appendix C for a list of HCPCS codes we used to define exposures in this request. We defined exposure episode lengths using dispensing days supplied to create a sequence of continuous exposure. We applied stockpiling of overlapping dispensings separately for the oral and injectable NDCs. We assigned one day supply for dispensings described by a procedure code. We used the maximum days supplied for same day dispensings.

Cohort Eligibility Criteria: We required members included in the cohort to be female members continuously enrolled in plans with medical and drug coverage for at least 365 days prior to the first valid metoclopramide dispensing, during which we allowed gaps in enrollment coverage of up to 45 days. To assess incidence, we excluded patients if they had a dispensing of metoclopramide in the 365 days preceding their index (first qualifying) metoclopramide dispensing. We included female members if they had no evidence of a live birth delivery within the 301 days following the metoclopramide dispensing, to account for the longest gestation calculated by Sentinel's Medication Exposure in Pregnancy Risk Evaluation Program (MEPREP)¹ algorithm. Please see Appendix D for Current Procedural Terminology, Fourth Edition (CPT-4) procedure codes and International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) diagnosis and procedure codes used to define live birth delivery in this request.

We included all eligible female members exposed to metoclopramide without a subsequent live birth delivery. In addition, this request investigated female members with a type 2 diabetes diagnosis within 365 days prior to the metoclopramide dispensing, and female members with both a diagnosis of gastroparesis and diagnosis of type 2 diabetes within 365 days prior to the metoclopramide dispensing. Please see Appendix E for ICD-9-CM diagnosis codes used to define Type 2 diabetes and gastroparesis.

We included all valid episodes during the query period, starting from the first incident dispensing; we allowed cohort re-entry. We included exposure episodes until the first occurrence of any of the following: disenrollment, death, Data Partner end date, or the end of the query period. We included the following age groups in the cohort: 40-44, 45-49, 50-54, 55-59, 60-64, 65-69, 70-74, 75-79, 80+ years.

<u>Sensitivity Analysis:</u> We conducted two sensitivity analyses for the allowable gap between dispensings that were bridged to create an exposure episode. First, we considered exposure episodes continuous if the gap in days supply is less than 50% of the prior dispensing. In addition, there was a 0 day allowable gap, which only allowed overlapping dispensings and abutting dispensings to be bridged into a continuous exposure episode.

Please see Appendix F for the specifications of parameters used in the analyses for this request.

<u>Limitations:</u> We used algorithms to define exposures and inclusion criteria that were imperfect; thus, it is possible that there may be misclassification. Therefore, data should be interpreted with this limitation in mind.

cder_mpl1r_wp089 Page 1 of 79



Overview for Request: cder_mpl1r_wp089

<u>Notes:</u> Please contact the Sentinel Operations Center (info@sentinelsystem.org) for questions and to provide comments/suggestions for future enhancements to this document.

cder_mpl1r_wp089 Page 2 of 79

¹Andrade, S. E., et al. (2012). "Medication Exposure in Pregnancy Risk Evaluation Program." Matern Child Health J 16(7):1349-1354



	Table of Contents
Glossary	List of Terms Found in this Report and their Definitions
<u>Table 1a</u>	Distribution of Days Supplied per Dispensing of Metoclopramide among Female Members with No Evidence of a Live Birth Delivery in the Sentinel Distributed Database between January 1, 2008 and September 30, 2015, by Age Group, for Episodes with Allowable Gaps of 50% of the Prior Dispensing
Table 1b	Distribution of Days Supplied per Dispensing of Metoclopramide among Female Members with Type 2 Diabetes and No Evidence of a Live Birth Delivery in the Sentinel Distributed Database Between January 1, 2008 and September 30, 2015, by Age Group, for Episodes with Allowable Gaps of 50% of the Prior Dispensing
Table 1c	Distribution of Days Supplied per Dispensing of Metoclopramide among Female Members with Gastroparesis, Type 2 Diabetes, and No Evidence of a Live Birth Delivery in the Sentinel Distributed Database Between January 1, 2008 and September 30, 2015, by Age Group, for Episodes with Allowable Gaps of 50% of the Prior Dispensing
<u>Table 2a</u>	Distribution of Days Supplied per Dispensing of Metoclopramide among Female Members with No Evidence of a Live Birth Delivery in the Sentinel Distributed Database between January 1, 2008 and September 30, 2015, by Age Group, for Episodes with Allowable Gaps of 0 Days
<u>Table 2b</u>	Distribution of Days Supplied per Dispensing of Metoclopramide among Female Members with Type 2 Diabetes and No Evidence of a Live Birth Delivery in the Sentinel Distributed Database between January 1, 2008 and September 30, 2015, by Age Group, for Episodes with Allowable Gaps of 0 Days
<u>Table 2c</u>	Distribution of Days Supplied per Dispensing of Metoclopramide among Female Members with Gastroparesis, Type 2 Diabetes, and No Evidence of a Live Birth Delivery in the Sentinel Distributed Database between January 1, 2008 and September 30, 2015, by Age Group, for Episodes with Allowable Gaps of 0 Days
<u>Table 3a</u>	Distribution of Treatment Episode Duration of Metoclopramide among Female Members with No Evidence of a Live Birth Delivery in the Sentinel Distributed Database between January 1, 2008 and September 30, 2015, by Age Group, for Episodes with Allowable Gaps of 50% of the Prior Dispensing
<u>Table 3b</u>	Distribution of Treatment Episode Duration of Metoclopramide among Female Members with Type 2 Diabetes and No Evidence of a Live Birth Delivery in the Sentinel Distributed Database between January 1, 2008 and September 30, 2015, by Age Group, for Episodes with Allowable Gaps of 50% of the Prior Dispensing
Table 3c	Distribution of Treatment Episode Duration of Metoclopramide among Female Members with Gastroparesis, Type 2 Diabetes, and No Evidence of a Live Birth Delivery in the Sentinel Distributed Database between January 1, 2008 and September 30, 2015, by Age Group, for Episodes with Allowable Gaps of 50% of the Prior Dispensing
<u>Table 4a</u>	Distribution of Treatment Episode Duration of Metoclopramide among Female Members with No Evidence of a Live Birth Delivery in the Sentinel Distributed Database between January 1, 2008 and September 30, 2015, by Age Group, for Episodes with Allowable Gaps of 0 Days
<u>Table 4b</u>	Distribution of Treatment Episode Duration of Metoclopramide among Female Members with Type 2 Diabetes and No Evidence of a Live Birth Delivery in the Sentinel Distributed Database between January 1, 2008 and September 30, 2015, by Age Group, for Episodes with Allowable Gaps of 0 Days

cder_mpl1r_wp089 Page 3 of 79



	Table of Contents
<u>Table 4c</u>	Distribution of Treatment Episode Duration of Metoclopramide among Female Members with Gastroparesis, Type 2 Diabetes, and No Evidence of a Live Birth Delivery in the Sentinel Distributed Database between January 1, 2008 and September 30, 2015, by Age Group, for Episodes with Allowable Gaps of 0 Days
<u>Table 5a</u>	Distribution of Cumulative Exposure Duration of Metoclopramide among Female Members with No Evidence of a Live Birth Delivery in the Sentinel Distributed Database between January 1, 2008 and September 30, 2015, by Age Group, for Episodes with Allowable Gaps of 50% of the Prior Dispensing
<u>Table 5b</u>	Distribution of Cumulative Exposure Duration of Metoclopramide among Female Members with Type 2 Diabetes and No Evidence of a Live Birth Delivery in the Sentinel Distributed Database between January 1, 2008 and September 30, 2015, by Age Group, for Episodes with Allowable Gaps of 50% of the Prior Dispensing
<u>Table 5c</u>	Distribution of Cumulative Exposure Duration of Metoclopramide among Female Members with Gastroparesis, Type 2 Diabetes, and No Evidence of a Live Birth Delivery in the Sentinel Distributed Database between January 1, 2008 and September 30, 2015, by Age Group, for Episodes with Allowable Gaps of 50% of the Prior Dispensing
<u>Table 6a</u>	Distribution of Cumulative Exposure Duration of Metoclopramide among Female Members with No Evidence of a Live Birth Delivery in the Sentinel Distributed Database between January 1, 2008 and September 30, 2015, by Age Group, for Episodes with Allowable Gaps of 0 Days
<u>Table 6b</u>	Distribution of Cumulative Exposure Duration of Metoclopramide among Female Members with Type 2 Diabetes and No Evidence of a Live Birth Delivery in the Sentinel Distributed Database between January 1, 2008 and September 30, 2015, by Age Group, for Episodes with Allowable Gaps of 0 Days
<u>Table 6c</u>	Distribution of Cumulative Exposure Duration of Metoclopramide among Female Members with Gastroparesis, Type 2 Diabetes, and No Evidence of a Live Birth Delivery in the Sentinel Distributed Database between January 1, 2008 and September 30, 2015, by Age Group, for Episodes with Allowable Gaps of 0 Days
<u>Table 7a</u>	Distribution of First Treatment Episode Duration of Metoclopramide among Female Members with No Evidence of a Live Birth Delivery in the Sentinel Distributed Database between January 1, 2008 and September 30, 2015, by Age Group, for Episodes with Allowable Gaps of 50% of the Prior Dispensing
<u>Table 7b</u>	Distribution of First Treatment Episode Duration of Metoclopramide among Female Members with Type 2 Diabetes and No Evidence of a Live Birth Delivery in the Sentinel Distributed Database between January 1, 2008 and September 30, 2015, by Age Group, for Episodes with Allowable Gaps of 50% of the Prior Dispensing
<u>Table 7c</u>	Distribution of First Treatment Episode Duration of Metoclopramide among Female Members with Gastroparesis, Type 2 Diabetes, and No Evidence of a Live Birth Delivery in the Sentinel Distributed Database between January 1, 2008 and September 30, 2015, by Age Group, for Episodes with Allowable Gaps of 50% of the Prior Dispensing

cder_mpl1r_wp089 Page 4 of 79



	Table of Contents
Table 8a	Distribution of First Treatment Episode Duration of Metoclopramide among Female Members with No Evidence of a Live Birth Delivery in the Sentinel Distributed Database between January 1, 2008 and September 30, 2015, by Age Group, for Episodes with Allowable Gaps of 0 Days
Table 8b	Distribution of First Treatment Episode Duration of Metoclopramide among Female Members with Type 2 Diabetes and No Evidence of a Live Birth Delivery in the Sentinel Distributed Database between January 1, 2008 and September 30, 2015, by Age Group, for Episodes with Allowable Gaps of 0 Days
<u>Table 8c</u>	Distribution of First Treatment Episode Duration of Metoclopramide among Female Members with Gastroparesis, Type 2 Diabetes, and No Evidence of a Live Birth Delivery in the Sentinel Distributed Database between January 1, 2008 and September 30, 2015, by Age Group, for Episodes with Allowable Gaps of 0 Days
<u>Table 9a</u>	Distribution of Second and Subsequent Treatment Episode Duration of Metoclopramide among Female Members with No Evidence of a Live Birth Delivery in the Sentinel Distributed Database between January 1, 2008 and September 30, 2015, by Age Group, for Episodes with Allowable Gaps of 50% of the Prior Dispensing
<u>Table 9b</u>	Distribution of Second and Subsequent Treatment Episode Duration of Metoclopramide among Female Members with Type 2 Diabetes and No Evidence of a Live Birth Delivery in the Sentinel Distributed Database between January 1, 2008 and September 30, 2015, by Age Group, for Episodes with Allowable Gaps of 50% of the Prior Dispensing
<u>Table 9c</u>	Distribution of Second and Subsequent Treatment Episode Duration of Metoclopramide among Female Members with Gastroparesis, Type 2 Diabetes, and No Evidence of a Live Birth Delivery in the Sentinel Distributed Database between January 1, 2008 and September 30, 2015, by Age Group, for Episodes with Allowable Gaps of 50% of the Prior Dispensing
Table 10a	Distribution of Second and Subsequent Treatment Episode Duration of Metoclopramide among Female Members with No Evidence of a Live Birth Delivery in the Sentinel Distributed Database between January 1, 2008 and September 30, 2015, by Age Group, for Episodes with Allowable Gaps of 0 Days
Table 10b	Distribution of Second and Subsequent Treatment Episode Duration of Metoclopramide among Female Members with Type 2 Diabetes and No Evidence of a Live Birth Delivery in the Sentinel Distributed Database between January 1, 2008 and September 30, 2015, by Age Group, for Episodes with Allowable Gaps of 0 Days
<u>Table 10c</u>	Distribution of Second and Subsequent Treatment Episode Duration of Metoclopramide among Female Members with Gastroparesis, Type 2 Diabetes, and No Evidence of a Live Birth Delivery in the Sentinel Distributed Database between January 1, 2008 and September 30, 2015, by Age Group, for Episodes with Allowable Gaps of 0 Days
<u>Table 11a</u>	Distribution of Treatment Episode Duration, for Episodes Greater than 12 Weeks, of Metoclopramide among Female Members with No Evidence of a Live Birth Delivery in the Sentinel Distributed Database between January 1, 2008 and September 30, 2015, by Age Group, for Episodes with Allowable Gaps of 50% of the Prior Dispensing

cder_mpl1r_wp089 Page 5 of 79



	Table of Contents
Table 11b	Distribution of Treatment Episode Duration, for Episodes Greater than 12 Weeks, of Metoclopramide among Female Members with Type 2 Diabetes and No Evidence of a Live Birth Delivery in the Sentinel Distributed Database between January 1, 2008 and September 30, 2015, by Age Group, for Episodes with Allowable Gaps of 50% of the Prior Dispensing
Table 11c	Distribution of Treatment Episode Duration, for Episodes Greater than 12 Weeks, of Metoclopramide among Female Members with Gastroparesis, Type 2 Diabetes, and No Evidence of a Live Birth Delivery in the Sentinel Distributed Database between January 1, 2008 and September 30, 2015, by Age Group, for Episodes with Allowable Gaps of 50% of the Prior Dispensing
<u>Table 12a</u>	Distribution of Treatment Episode Duration, for Episodes Greater than 12 Weeks, of Metoclopramide among Female Members with No Evidence of a Live Birth Delivery in the Sentinel Distributed Database between January 1, 2008 and September 30, 2015, by Age Group, for Episodes with Allowable Gaps of 0 Days
<u>Table 12b</u>	Distribution of Treatment Episode Duration, for Episodes Greater than 12 Weeks, of Metoclopramide among Female Members with Type 2 Diabetes and No Evidence of a Live Birth Delivery in the Sentinel Distributed Database between January 1, 2008 and September 30, 2015, by Age Group, for Episodes with Allowable Gaps of 0 Days
<u>Table 12c</u>	Distribution of Treatment Episode Duration, for Episodes Greater than 12 Weeks, of Metoclopramide among Female Members with Gastroparesis, Type 2 Diabetes, and No Evidence of a Live Birth Delivery in the Sentinel Distributed Database between January 1, 2008 and September 30, 2015, by Age Group, for Episodes with Allowable Gaps of 0 Days
<u>Table 13a</u>	Descriptive Statistics for Gaps (in Days) between Treatment Episodes, of Metoclopramide among Female Members with No Evidence of a Live Birth Delivery in the Sentinel Distributed Database between January 1, 2008 and September 30, 2015, by Age Group, for Episodes with Allowable Gaps of 50% of the Prior Dispensing
<u>Table 13b</u>	Descriptive Statistics for Gaps (in Days) between Treatment Episodes, of Metoclopramide among Female Members with Type 2 Diabetes and No Evidence of a Live Birth Delivery in the Sentinel Distributed Database between January 1, 2008 and September 30, 2015, by Age Group, for Episodes with Allowable Gaps of 50% of the Prior Dispensing
Table 13c	Descriptive Statistics for Gaps (in Days) between Treatment Episodes, of Metoclopramide among Female Members with Gastroparesis, Type 2 Diabetes, and No Evidence of a Live Birth Delivery in the Sentinel Distributed Database between January 1, 2008 and September 30, 2015, by Age Group, for Episodes with Allowable Gaps of 50% of the Prior Dispensing
<u>Table 14a</u>	Descriptive Statistics for Gaps (in Days) between Treatment Episodes, of Metoclopramide among Female Members with No Evidence of a Live Birth Delivery in the Sentinel Distributed Database between January 1, 2008 and September 30, 2015, by Age Group, for Episodes with Allowable Gaps of 0 Days
<u>Table 14b</u>	Descriptive Statistics for Gaps (in Days) between Treatment Episodes, of Metoclopramide among Female Members with Type 2 Diabetes and No Evidence of a Live Birth Delivery in the Sentinel Distributed Database between January 1, 2008 and September 30, 2015, by Age Group, for Episodes with Allowable Gaps of 0 Days

cder_mpl1r_wp089 Page 6 of 79



	Table of Contents
<u>Table 14c</u>	Descriptive Statistics for Gaps (in Days) between Treatment Episodes, of Metoclopramide among Female Members with Gastroparesis, Type 2 Diabetes, and No Evidence of a Live Birth Delivery in the Sentinel Distributed Database between January 1, 2008 and September 30, 2015, by Age Group, for Episodes with Allowable Gaps of 0 Days
<u>Table 15a</u>	Cohort Attrition Table, for Episodes with Allowable Gaps of 50% of the Prior Dispensing
<u>Table 15b</u>	Cohort Attrition Table, for Episodes with Allowable Gaps of 0 Days
Appendix A	Dates of Available Data for Each Data Partner until Request End Date (September 30, 2015)
Appendix B	List of Generic and Brand Drug Names Used to Define Exposures in this Request
Appendix C	List of Healthcare Common Procedure Coding System (HCPCS) Procedure Codes Used to Define the Exposure in this Request
Appendix D	List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) and Current Procedural Terminology, Fourth Edition (CPT-4) Diagnosis and Procedure Codes Used to Define the Live Birth Delivery in this Request
Appendix E	List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) Diagnosis Codes Used to Define Inclusion Criteria for Index-Defining Events
Appendix F	Specifications Defining Parameters in this Request

cder_mpl1r_wp089 Page 7 of 79



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 the Care Setting/PDX parameter.

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.

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 (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.

Computed Start Marketing Date - represents the first observed dispensing date among all valid users within a GROUP (scenario) within each Data Partner site.

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" sequence.

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

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

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.

Lookback Period - number of days wherein a member is required to have evidence of pre-existing condition (diagnosis/procedure/drug dispensing).

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.

cder_mpl1r_wp089 Page 8 of 79



Member-Years - sum of all days of enrollment with medical and drug coverage in the query period preceded by an exposure washout period all divided by 365.25.

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 requests.

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

Switch Evaluation Step Value - value used to differentiate evaluation step. Each switch pattern can support up to 2 evaluation steps (0 = switch pattern evaluation start; 1 = first evaluation; 2 = second evaluation).

Switch Gap Inclusion Indicator - indicator for whether gaps in treatment episodes that are included in a switch episode will be counted as part of the switch episode duration.

Switch Pattern Cohort Inclusion Date - indicates which date to use for inclusion into the switch pattern cohort of interest as well as optionally as the index date of the treatment episode initiating the switch pattern. Valid options are the product approval date, product marketing date, other requester defined date, or computed start marketing date.

Switch Pattern Cohort Inclusion Strategy - indicates how the switch pattern cohort inclusion date will be used: 01: used only as a switch cohort entry date. First treatment episode dispensing date is used as index for computing time to first switch; 02: used as switch cohort entry date and as initial switch step index date for computing time to first switch.

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

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 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

cder mpl1r wp089 Page 9 of 79



Table 1a. Distribution of Days Supplied per Dispensing of Metoclopramide among Female Members with No Evidence of a Live Birth Delivery in the Sentinel Distributed Database between January 1, 2008 and September 30, 2015, by Age Group, for Episodes with Allowable Gaps of 50% of the Prior Dispensing

	Number	Percent																
	40-44	Years	45-49	Years	50-54	Years	55-59	Years	60-64	Years	65-69	Years	70-74	Years	75-79	Years	80+1	Years
Total																		
Dispensings	227,058	100.0	264,514	100.0	310,184	100.0	309,858	100.0	282,115	100.0	436,579	100.0	408,442	100.0	328,970	100.0	552,420	100.0
Duration (Da	• •																	
1	110,469	48.7	115,040	43.5	123,785	39.9	105,788	34.1	87,825	31.1	142,085	32.5	122,794	30.1	82,664	25.1	87,506	15.8
2-7	24,837	10.9	26,021	9.8	28,641	9.2	27,206	8.8	24,566	8.7	36,075	8.3	33,222	8.1	27,435	8.3	50,930	9.2
8-14	14,954	6.6	17,180	6.5	19,278	6.2	19,862	6.4	19,544	6.9	31,193	7.1	30,282	7.4	27,105	8.2	51,634	9.3
15-21	9,983	4.4	12,938	4.9	14,901	4.8	16,507	5.3	15,818	5.6	23,992	5.5	24,056	5.9	20,595	6.3	37,800	6.8
22-28	5,036	2.2	6,988	2.6	9,337	3.0	10,135	3.3	10,108	3.6	13,499	3.1	13,296	3.3	11,975	3.6	29,357	5.3
29-45	58,484	25.8	81,312	30.7	106,513	34.3	120,714	39.0	114,056	40.4	170,986	39.2	167,488	41.0	146,352	44.5	278,161	50.4
46-60	778	0.3	988	0.4	1,456	0.5	1,682	0.5	1,775	0.6	2,971	0.7	2,928	0.7	2,312	0.7	3,483	0.6
61-89	260	0.1	291	0.1	457	0.1	528	0.2	631	0.2	869	0.2	803	0.2	648	0.2	878	0.2
90+	2,257	1.0	3,756	1.4	5,816	1.9	7,436	2.4	7,792	2.8	14,909	3.4	13,573	3.3	9,884	3.0	12,671	2.3
Distribution	(Days)																	
Min	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
1st	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
3rd	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
5th	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
10th	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
20th	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	5	-
25th	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	7	-
50th	3	-	6	-	8	-	15	-	15	-	15	-	20	-	25	-	30	-
Mean	12.0	-	13.9	-	15.5	-	17.5	-	18.5	-	18.6	-	19.2	-	20.2	-	21.9	-
Median	3	-	6	-	8	-	15	-	15	-	15	-	20	-	25	-	30	-
Mode	1	-	1	-	1	-	30	-	30	-	30	-	30	-	30	-	30	-
75th	30	-	30	-	30	-	30	-	30	-	30	-	30	-	30	-	30	-
80th	30	-	30	-	30	-	30	-	30	-	30	-	30	-	30	-	30	-
90th	30	-	30	-	30	-	30	-	30	-	30	-	30	-	30	-	30	-
95th	30	-	30	-	30	-	30	-	31	-	33	-	33	-	31	-	31	-
97th	30	-	30	-	32	-	50	-	60	-	90	-	90	-	90	-	50	-
99th	86	-	90	-	90	-	90	-	90	-	90	-	90	-	90	-	90	-
Max	170	-	500	-	625	-	450	-	240	-	240	-	272	-	360	-	360	-



Table 1b. Distribution of Days Supplied per Dispensing of Metoclopramide among Female Members with Type 2 Diabetes and No Evidence of a Live Birth Delivery in the Sentinel Distributed Database Between January 1, 2008 and September 30, 2015, by Age Group, for Episodes with Allowable Gaps of 50% of the Prior Dispensing

	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent
	40-44	Years	45-49	Years	50-54	Years	55-59	Years	60-64	Years	65-69	Years	70-74	Years	75-79	Years	80+1	Years
Total																		
Dispensings	57,799	100.0	81,580	100.0	112,488	100.0	133,179	100.0	135,611	100.0	208,440	100.0	201,445	100.0	166,668	100.0	250,081	100.0
Duration (Da	ays)																	
1	21,578	37.3	26,005	31.9	31,800	28.3	33,491	25.1	32,119	23.7	51,741	24.8	45,254	22.5	31,581	18.9	31,101	12.4
2-7	4,871	8.4	6,374	7.8	8,614	7.7	9,977	7.5	10,174	7.5	15,566	7.5	14,798	7.3	12,755	7.7	22,066	8.8
8-14	3,535	6.1	5,333	6.5	7,095	6.3	8,652	6.5	9,500	7.0	15,799	7.6	15,628	7.8	14,225	8.5	23,955	9.6
15-21	2,500	4.3	4,016	4.9	5,732	5.1	7,779	5.8	7,669	5.7	12,381	5.9	12,558	6.2	10,863	6.5	17,730	7.1
22-28	1,588	2.7	2,919	3.6	3,828	3.4	4,797	3.6	5,205	3.8	7,555	3.6	7,583	3.8	6,707	4.0	13,991	5.6
29-45	22,200	38.4	34,658	42.5	51,531	45.8	63,315	47.5	65,153	48.0	95,650	45.9	96,887	48.1	83,956	50.4	133,975	53.6
46-60	277	0.5	426	0.5	673	0.6	825	0.6	884	0.7	1,462	0.7	1,422	0.7	1,236	0.7	1,389	0.6
61-89	86	0.1	114	0.1	210	0.2	305	0.2	357	0.3	467	0.2	450	0.2	312	0.2	382	0.2
90+	1,164	2.0	1,735	2.1	3,005	2.7	4,038	3.0	4,550	3.4	7,819	3.8	6,865	3.4	5,033	3.0	5,492	2.2
Distribution	(Days)																	
Min	1	-	1	-	1	-	1	=	1	-	1	-	1	-	1	-	1	-
1st	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
3rd	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
5th	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
10th	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
20th	1	-	1	-	1	-	1	-	1	-	1	-	1	-	3	-	7	-
25th	1	-	1	-	1	-	1	-	3	-	2	-	5	-	7	-	10	-
50th	10	-	20	-	27	-	30	-	30	-	30	-	30	-	30	-	30	-
Mean	16.6	-	18.3	-	19.8	-	20.8	-	21.4	-	21.2	-	21.6	-	22.1	-	22.8	-
Median	10	-	20	-	27	-	30	-	30	-	30	-	30	-	30	-	30	-
Mode	30	-	30	-	30	-	30	-	30	-	30	-	30	-	30	-	30	-
75th	30	-	30	-	30	-	30	-	30	-	30	-	30	-	30	-	30	-
80th	30	-	30	-	30	-	30	-	30	-	30	-	30	-	30	-	30	-
90th	30	-	30	-	30	-	30	-	30	-	30	-	30	-	30	-	30	-
95th	30	-	30	-	30	-	31	-	33	-	40	-	33	-	31	-	31	-
97th	34	-	40	-	60	-	90	-	90	-	90	-	90	-	90	-	45	-
99th	90	-	90	-	90	-	90	-	90	-	90	-	90	-	90	-	90	-
Max	120	-	180	-	625	-	450	-	240	-	240	-	270	-	360	-	180	-



Table 1c. Distribution of Days Supplied per Dispensing of Metoclopramide among Female Members with Gastroparesis, Type 2 Diabetes, and No Evidence of a Live Birth Delivery in the Sentinel Distributed Database Between January 1, 2008 and September 30, 2015, by Age Group, for Episodes with Allowable Gaps of 50% of the Prior Dispensing

	Number	Percent																
	40-44	Years	45-49	Years	50-54	Years	55-59	Years	60-64	Years	65-69	Years	70-74	Years	75-79	Years	408	Years
Total																		
Dispensings	12,380	100.0	17,596	100.0	23,216	100.0	25,666	100.0	24,834	100.0	33,654	100.0	30,344	100.0	23,685	100.0	29,923	100.0
Duration (Da	ays)																	
1	2,580	20.8	2,752	15.6	3,008	13.0	2,446	9.5	1,981	8.0	2,235	6.6	1,744	5.7	1,110	4.7	1,006	3.4
2-7	744	6.0	975	5.5	1,323	5.7	1,258	4.9	1,507	6.1	1,698	5.0	1,382	4.6	1,328	5.6	1,699	5.7
8-14	678	5.5	1,224	7.0	1,400	6.0	1,506	5.9	1,808	7.3	2,382	7.1	2,200	7.3	1,741	7.4	2,588	8.6
15-21	596	4.8	1,019	5.8	1,181	5.1	1,599	6.2	1,518	6.1	2,174	6.5	2,031	6.7	1,509	6.4	2,020	6.8
22-28	419	3.4	761	4.3	875	3.8	1,055	4.1	1,169	4.7	1,743	5.2	1,649	5.4	1,242	5.2	1,918	6.4
29-45	6,855	55.4	10,057	57.2	14,252	61.4	16,534	64.4	15,440	62.2	21,068	62.6	19,363	63.8	15,415	65.1	19,349	64.7
46-60	85	0.7	189	1.1	242	1.0	213	0.8	208	0.8	388	1.2	304	1.0	292	1.2	237	0.8
61-89	28	0.2	35	0.2	60	0.3	73	0.3	112	0.5	99	0.3	149	0.5	61	0.3	65	0.2
90+	395	3.2	584	3.3	875	3.8	982	3.8	1,091	4.4	1,867	5.5	1,522	5.0	987	4.2	1,041	3.5
Distribution	(Days)																	
Min	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
1st	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
3rd	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
5th	1	-	1	-	1	-	1	-	1	-	1	-	1	-	2	-	5	-
10th	1	-	1	-	1	-	3	-	5	-	7	-	7	-	7	-	9	-
20th	1	-	7	-	10	-	14	-	14	-	15	-	15	-	15	-	15	-
25th	7	-	10	-	15	-	20	-	17	-	21	-	23	-	23	-	22	-
50th	30	-	30	-	30	-	30	-	30	-	30	-	30	-	30	-	30	-
Mean	23.0	-	24.3	-	25.6	-	26.7	-	27.0	-	28.3	-	28.4	-	27.9	-	27.4	-
Median	30	-	30	-	30	-	30	-	30	-	30	-	30	-	30	-	30	-
Mode	30	-	30	-	30	-	30	-	30	-	30	-	30	-	30	-	30	-
75th	30	-	30	-	30	-	30	-	30	-	30	-	30	-	30	-	30	-
80th	30	-	30	-	30	-	30	-	30	-	30	-	30	-	30	-	30	-
90th	30	-	30	-	30	-	30	-	30	-	30	-	30	-	30	-	30	-
95th	33	-	40	-	50	-	45	-	60	-	90	-	90	-	60	-	37	-
97th	90	-	90	-	90	-	90	-	90	-	90	-	90	-	90	-	90	-
99th	90	-	90	-	90	-	90	-	90	-	90	-	90	-	90	-	90	-
Max	100	_	120	-	100	-	359	-	120	_	120	-	140	-	200	-	120	-



Table 2a. Distribution of Days Supplied per Dispensing of Metoclopramide among Female Members with No Evidence of a Live Birth Delivery in the Sentinel Distributed Database between January 1, 2008 and September 30, 2015, by Age Group, for Episodes with Allowable Gaps of 0 Days

	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent
	40-44	Years	45-49	Years	50-54	Years	55-59	Years	60-64	Years	65-69	Years	70-74	Years	75-79	Years	80+ Y	ears/
Total																		
Dispensings	227,058	100.0	264,514	100.0	310,184	100.0	309,858	100.0	282,115	100.0	436,579	100.0	408,442	100.0	328,970	100.0	552,420	100.0
Duration Gro	oups (Days)																
1	110,469	48.7	115,040	43.5	123,785	39.9	105,788	34.1	87,825	31.1	142,085	32.5	122,794	30.1	82,664	25.1	87,506	15.8
2-7	24,837	10.9	26,021	9.8	28,641	9.2	27,206	8.8	24,566	8.7	36,075	8.3	33,222	8.1	27,435	8.3	50,930	9.2
8-14	14,954	6.6	17,180	6.5	19,278	6.2	19,862	6.4	19,544	6.9	31,193	7.1	30,282	7.4	27,105	8.2	51,634	9.3
15-21	9,983	4.4	12,938	4.9	14,901	4.8	16,507	5.3	15,818	5.6	23,992	5.5	24,056	5.9	20,595	6.3	37,800	6.8
22-28	5,036	2.2	6,988	2.6	9,337	3.0	10,135	3.3	10,108	3.6	13,499	3.1	13,296	3.3	11,975	3.6	29,357	5.3
29-45	58,484	25.8	81,312	30.7	106,513	34.3	120,714	39.0	114,056	40.4	170,986	39.2	167,488	41.0	146,352	44.5	278,161	50.4
46-60	778	0.3	988	0.4	1,456	0.5	1,682	0.5	1,775	0.6	2,971	0.7	2,928	0.7	2,312	0.7	3,483	0.6
61-89	260	0.1	291	0.1	457	0.1	528	0.2	631	0.2	869	0.2	803	0.2	648	0.2	878	0.2
90+	2,257	1.0	3,756	1.4	5,816	1.9	7,436	2.4	7,792	2.8	14,909	3.4	13,573	3.3	9,884	3.0	12,671	2.3
Distribution	(Days)																	
Min	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
1st	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
3rd	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
5th	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
10th	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
20th	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	5	-
25th	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	7	-
50th	3	-	6	-	8	-	15	-	15	-	15	-	20	-	25	-	30	-
Mean	12.0	-	13.9	-	15.5	-	17.5	-	18.5	-	18.6	-	19.2	-	20.2	-	21.9	-
Median	3	-	6	-	8	-	15	-	15	-	15	-	20	-	25	-	30	-
Mode	1	-	1	-	1	-	30	-	30	-	30	-	30	-	30	-	30	-
75th	30	-	30	-	30	-	30	-	30	-	30	-	30	-	30	-	30	-
80th	30	-	30	-	30	-	30	-	30	-	30	-	30	-	30	-	30	-
90th	30	-	30	-	30	-	30	-	30	-	30	-	30	-	30	-	30	-
95th	30	-	30	-	30	-	30	-	31	-	33	-	33	-	31	-	31	-
97th	30	-	30	-	32	-	50	-	60	-	90	-	90	-	90	-	50	-
99th	86	-	90	-	90	-	90	-	90	-	90	-	90	-	90	-	90	-
Max	170	-	500	-	625	-	450	-	240	-	240	-	272	-	360	-	360	



Table 2b. Distribution of Days Supplied per Dispensing of Metoclopramide among Female Members with Type 2 Diabetes and No Evidence of a Live Birth Delivery in the Sentinel Distributed Database between January 1, 2008 and September 30, 2015, by Age Group, for Episodes with Allowable Gaps of 0 Days

	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent
	40-44	Years	45-49	Years	50-54	Years	55-59	Years	60-64	Years	65-69	Years	70-74	Years	75-79	Years	80+ \	Years
Total																		
Dispensings	57,799	100.0	81,580	100.0	112,488	100.0	133,179	100.0	135,611	100.0	208,440	100.0	201,445	100.0	166,668	100.0	250,081	100.0
Duration Gro	oups (Days)																
1	21,578	37.3	26,005	31.9	31,800	28.3	33,491	25.1	32,119	23.7	51,741	24.8	45,254	22.5	31,581	18.9	31,101	12.4
2-7	4,871	8.4	6,374	7.8	8,614	7.7	9,977	7.5	10,174	7.5	15,566	7.5	14,798	7.3	12,755	7.7	22,066	8.8
8-14	3,535	6.1	5,333	6.5	7,095	6.3	8,652	6.5	9,500	7.0	15,799	7.6	15,628	7.8	14,225	8.5	23,955	9.6
15-21	2,500	4.3	4,016	4.9	5,732	5.1	7,779	5.8	7,669	5.7	12,381	5.9	12,558	6.2	10,863	6.5	17,730	7.1
22-28	1,588	2.7	2,919	3.6	3,828	3.4	4,797	3.6	5,205	3.8	7,555	3.6	7,583	3.8	6,707	4.0	13,991	5.6
29-45	22,200	38.4	34,658	42.5	51,531	45.8	63,315	47.5	65,153	48.0	95,650	45.9	96,887	48.1	83,956	50.4	133,975	53.6
46-60	277	0.5	426	0.5	673	0.6	825	0.6	884	0.7	1,462	0.7	1,422	0.7	1,236	0.7	1,389	0.6
61-89	86	0.1	114	0.1	210	0.2	305	0.2	357	0.3	467	0.2	450	0.2	312	0.2	382	0.2
90+	1,164	2.0	1,735	2.1	3,005	2.7	4,038	3.0	4,550	3.4	7,819	3.8	6,865	3.4	5,033	3.0	5,492	2.2
Distribution	(Days)																	
Min	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
1st	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
3rd	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
5th	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
10th	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
20th	1	-	1	-	1	-	1	-	1	-	1	-	1	-	3	-	7	-
25th	1	-	1	-	1	-	1	-	3	-	2	-	5	-	7	-	10	-
50th	10	-	20	-	27	-	30	-	30	-	30	-	30	-	30	-	30	-
Mean	16.6	-	18.3	-	19.8	-	20.8	-	21.4	-	21.2	-	21.6	-	22.1	-	22.8	-
Median	10	-	20	-	27	-	30	-	30	-	30	-	30	-	30	-	30	-
Mode	30	-	30	-	30	-	30	-	30	-	30	-	30	-	30	-	30	-
75th	30	-	30	-	30	-	30	-	30	-	30	-	30	-	30	-	30	-
80th	30	-	30	-	30	-	30	-	30	-	30	-	30	-	30	-	30	-
90th	30	-	30	-	30	-	30	-	30	-	30	-	30	-	30	-	30	-
95th	30	-	30	-	30	-	31	-	33	-	40	-	33	-	31	-	31	-
97th	34	-	40	-	60	-	90	-	90	-	90	-	90	-	90	-	45	-
99th	90	-	90	-	90	-	90	-	90	-	90	-	90	-	90	-	90	-
Max	120	-	180	-	625	-	450	-	240	-	240	-	270	-	360	-	180	-



Table 2c. Distribution of Days Supplied per Dispensing of Metoclopramide among Female Members with Gastroparesis, Type 2 Diabetes, and No Evidence of a Live Birth Delivery in the Sentinel Distributed Database between January 1, 2008 and September 30, 2015, by Age Group, for Episodes with Allowable Gaps of 0 Days

	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent
	40-44	Years	45-49	Years	50-54	Years	55-59	Years	60-64	Years	65-69	Years	70-74	Years	75-79	Years	408	Years
Total																		
Dispensings	12,380	100.0	17,596	100.0	23,216	100.0	25,666	100.0	24,834	100.0	33,654	100.0	30,344	100.0	23,685	100.0	29,923	100.0
Duration Gro	oups (Days)																
1	2,580	20.8	2,752	15.6	3,008	13.0	2,446	9.5	1,981	8.0	2,235	6.6	1,744	5.7	1,110	4.7	1,006	3.4
2-7	744	6.0	975	5.5	1,323	5.7	1,258	4.9	1,507	6.1	1,698	5.0	1,382	4.6	1,328	5.6	1,699	5.7
8-14	678	5.5	1,224	7.0	1,400	6.0	1,506	5.9	1,808	7.3	2,382	7.1	2,200	7.3	1,741	7.4	2,588	8.6
15-21	596	4.8	1,019	5.8	1,181	5.1	1,599	6.2	1,518	6.1	2,174	6.5	2,031	6.7	1,509	6.4	2,020	6.8
22-28	419	3.4	761	4.3	875	3.8	1,055	4.1	1,169	4.7	1,743	5.2	1,649	5.4	1,242	5.2	1,918	6.4
29-45	6,855	55.4	10,057	57.2	14,252	61.4	16,534	64.4	15,440	62.2	21,068	62.6	19,363	63.8	15,415	65.1	19,349	64.7
46-60	85	0.7	189	1.1	242	1.0	213	0.8	208	0.8	388	1.2	304	1.0	292	1.2	237	0.8
61-89	28	0.2	35	0.2	60	0.3	73	0.3	112	0.5	99	0.3	149	0.5	61	0.3	65	0.2
90+	395	3.2	584	3.3	875	3.8	982	3.8	1,091	4.4	1,867	5.5	1,522	5.0	987	4.2	1,041	3.5
Distribution	(Days)																	
Min	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
1st	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
3rd	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
5th	1	-	1	-	1	-	1	-	1	-	1	-	1	-	2	-	5	-
10th	1	-	1	-	1	-	3	-	5	-	7	-	7	-	7	-	9	-
20th	1	-	7	-	10	-	14	-	14	-	15	-	15	-	15	-	15	-
25th	7	-	10	-	15	-	20	-	17	-	21	-	23	-	23	-	22	-
50th	30	-	30	-	30	-	30	-	30	-	30	-	30	-	30	-	30	-
Mean	23.0	-	24.3	-	25.6	-	26.7	-	27.0	-	28.3	-	28.4	-	27.9	-	27.4	-
Median	30	-	30	-	30	-	30	-	30	-	30	-	30	-	30	-	30	-
Mode	30	-	30	-	30	-	30	-	30	-	30	-	30	-	30	-	30	-
75th	30	-	30	-	30	-	30	-	30	-	30	-	30	-	30	-	30	-
80th	30	-	30	-	30	-	30	-	30	-	30	-	30	-	30	-	30	-
90th	30	-	30	-	30	-	30	-	30	-	30	-	30	-	30	-	30	-
95th	33	-	40	-	50	-	45	-	60	-	90	-	90	-	60	-	37	-
97th	90	-	90	-	90	-	90	-	90	-	90	-	90	-	90	-	90	-
99th	90	-	90	-	90	-	90	-	90	-	90	-	90	-	90	-	90	-
Max	100	-	120	-	100	-	359	-	120	-	120	-	140	-	200	-	120	-



Table 3a. Distribution of Treatment Episode Duration of Metoclopramide among Female Members with No Evidence of a Live Birth Delivery in the Sentinel Distributed Database between January 1, 2008 and September 30, 2015, by Age Group, for Episodes with Allowable Gaps of 50% of the Prior Dispensing

	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent
	40-44	Years	45-49	Years	50-54	Years	55-59	Years	60-64	Years	65-69	Years	70-74	Years	75-79	Years	80+ \	Years
Total																		
Episodes	186,743	100.0	207,269	100.0	235,422	100.0	224,722	100.0	198,106	100.0	311,981	100.0	284,598	100.0	214,807	100.0	299,385	100.0
Duration G	roups (Days)																
1	101,468	54.3	105,970	51.1	115,044	48.9	98,649	43.9	81,619	41.2	134,597	43.1	116,228	40.8	77,927	36.3	80,461	26.9
2-7	24,234	13.0	24,992	12.1	26,638	11.3	24,300	10.8	21,537	10.9	30,991	9.9	28,391	10.0	22,456	10.5	35,578	11.9
8-14	12,829	6.9	14,320	6.9	15,684	6.7	15,577	6.9	14,491	7.3	23,381	7.5	22,395	7.9	18,737	8.7	30,278	10.1
15-21	7,870	4.2	9,549	4.6	10,556	4.5	11,242	5.0	10,713	5.4	16,267	5.2	15,863	5.6	12,730	5.9	20,143	6.7
22-28	3,083	1.7	3,835	1.9	4,898	2.1	5,110	2.3	4,805	2.4	6,621	2.1	6,271	2.2	5,070	2.4	8,241	2.8
29-45	26,802	14.4	33,530	16.2	42,023	17.9	46,113	20.5	41,633	21.0	63,526	20.4	59,997	21.1	47,762	22.2	69,832	23.3
46-60	2,364	1.3	3,263	1.6	4,410	1.9	4,877	2.2	4,719	2.4	7,272	2.3	7,091	2.5	5,963	2.8	10,345	3.5
61-89	2,620	1.4	3,509	1.7	4,737	2.0	5,188	2.3	4,951	2.5	7,541	2.4	7,001	2.5	5,925	2.8	10,329	3.5
90+	5,473	2.9	8,301	4.0	11,432	4.9	13,666	6.1	13,638	6.9	21,785	7.0	21,361	7.5	18,237	8.5	34,178	11.4
Distribution	n (Days)																	
Min	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
1st	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
3rd	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
5th	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
10th	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
20th	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
25th	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
50th	1	-	1	-	2	-	5	-	7	-	6	-	7	-	10	-	15	-
Mean	14.9	-	18.3	-	21.1	-	24.9	-	27.2	-	26.9	-	28.5	-	32.0	-	41.7	-
Median	1	-	1	-	2	-	5	-	7	-	6	-	7	-	10	-	15	-
Mode	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
75th	15	-	22	-	30	-	30	-	30	-	30	-	30	-	30	-	30	-
80th	28	-	30	-	30	-	30	-	30	-	30	-	30	-	30	-	34	-
90th	30	-	30	-	30	-	56	-	60	-	60	-	60	-	68	-	90	-
95th	60	-	66	-	80	-	90	-	100	-	98	-	104	-	121	-	180	-
97th	82	-	96	-	115	-	135	-	152	-	153	-	164	-	187	-	260	-
99th	180	-	220	-	260	-	303	-	336	-	335	-	360	-	393	-	505	-
Max	2,104	-	2,261	-	2,410	-	2,630	-	2,678	-	2,739	-	2,758	-	2,481	-	2,418	-



Table 3b. Distribution of Treatment Episode Duration of Metoclopramide among Female Members with Type 2 Diabetes and No Evidence of a Live Birth Delivery in the Sentinel Distributed Database between January 1, 2008 and September 30, 2015, by Age Group, for Episodes with Allowable Gaps of 50% of the Prior Dispensing

	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent
	40-44	Years	45-49	Years	50-54	Years	55-59	Years	60-64	Years	65-69	Years	70-74	Years	75-79	Years	7 +08	Years
Total																		
Episodes	42,221	100.0	57,067	100.0	75,755	100.0	87,566	100.0	86,524	100.0	136,247	100.0	127,804	100.0	99,084	100.0	127,341	100.0
Duration G	roups (Days	5)																
1	19,311	45.7	23,462	41.1	28,896	38.1	30,764	35.1	29,404	34.0	48,471	35.6	42,286	33.1	29,330	29.6	28,168	22.1
2-7	4,387	10.4	5,718	10.0	7,234	9.5	8,124	9.3	8,248	9.5	12,355	9.1	11,797	9.2	9,803	9.9	14,365	11.3
8-14	2,832	6.7	4,093	7.2	5,399	7.1	6,319	7.2	6,649	7.7	11,021	8.1	10,973	8.6	9,072	9.2	13,495	10.6
15-21	1,830	4.3	2,800	4.9	3,674	4.8	4,863	5.6	4,758	5.5	7,750	5.7	7,662	6.0	6,242	6.3	9,075	7.1
22-28	817	1.9	1,411	2.5	1,947	2.6	2,223	2.5	2,223	2.6	3,236	2.4	3,153	2.5	2,436	2.5	3,720	2.9
29-45	8,807	20.9	12,926	22.7	18,417	24.3	22,381	25.6	21,900	25.3	32,969	24.2	31,816	24.9	24,931	25.2	31,858	25.0
46-60	867	2.1	1,386	2.4	2,073	2.7	2,512	2.9	2,575	3.0	3,953	2.9	3,884	3.0	3,312	3.3	5,000	3.9
61-89	1,038	2.5	1,464	2.6	2,306	3.0	2,787	3.2	2,727	3.2	4,176	3.1	3,882	3.0	3,318	3.3	5,004	3.9
90+	2,332	5.5	3,807	6.7	5,809	7.7	7,593	8.7	8,040	9.3	12,316	9.0	12,351	9.7	10,640	10.7	16,656	13.1
Distribution	n (Days)																	
Min	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
1st	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
3rd	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
5th	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
10th	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
20th	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
25th	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	4	-
50th	5	-	7	-	10	-	11	-	12	-	10	-	13	-	15	-	20	-
Mean	23.5	-	26.9	-	30.4	-	32.8	-	34.6	-	33.5	-	35.2	-	38.4	-	46.3	-
Median	5	-	7	-	10	-	11	-	12	-	10	-	13	-	15	-	20	-
Mode	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
75th	30	-	30	-	30	-	30	-	30	-	30	-	30	-	30	-	30	-
80th	30	-	30	-	30	-	30	-	30	-	30	-	30	-	30	-	52	-
90th	46	-	60	-	64	-	70	-	73	-	72	-	79	-	90	-	102	-
95th	90	-	96	-	110	-	120	-	128	-	125	-	134	-	151	-	192	-
97th	125	-	144	-	167	-	181	-	198	-	191	-	204	-	224	-	280	-
99th	288	-	325	-	360	-	373	-	401	-	392	-	420	-	440	-	528	-
Max	1,672	-	2,261	-	1,985	-	2,444	-	2,279	-	2,739	-	2,758	-	2,481	-	2,005	-



Table 3c. Distribution of Treatment Episode Duration of Metoclopramide among Female Members with Gastroparesis, Type 2 Diabetes, and No Evidence of a Live Birth Delivery in the Sentinel Distributed Database between January 1, 2008 and September 30, 2015, by Age Group, for Episodes with Allowable Gaps of 50% of the Prior Dispensing

	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent
	40-44	Years	45-49	Years	50-54	Years	55-59	Years	60-64	Years	65-69	Years	70-74	Years	75-79	Years	408	Years
Total																		
Episodes	7,716	100.0	10,601	100.0	13,288	100.0	14,154	100.0	13,235	100.0	17,776	100.0	15,834	100.0	11,572	100.0	12,653	100.0
Duration G	roups (Days	s)																
1	2,016	26.1	2,105	19.9	2,241	16.9	1,850	13.1	1,496	11.3	1,725	9.7	1,270	8.0	783	6.8	679	5.4
2-7	555	7.2	784	7.4	863	6.5	817	5.8	808	6.1	1,102	6.2	887	5.6	813	7.0	833	6.6
8-14	472	6.1	855	8.1	943	7.1	968	6.8	1,073	8.1	1,396	7.9	1,337	8.4	949	8.2	1,132	8.9
15-21	393	5.1	638	6.0	729	5.5	909	6.4	810	6.1	1,144	6.4	1,083	6.8	803	6.9	849	6.7
22-28	247	3.2	344	3.2	485	3.6	485	3.4	491	3.7	686	3.9	605	3.8	413	3.6	494	3.9
29-45	2,704	35.0	3,786	35.7	5,132	38.6	5,721	40.4	5,207	39.3	7,052	39.7	6,385	40.3	4,534	39.2	4,713	37.2
46-60	271	3.5	438	4.1	604	4.5	667	4.7	626	4.7	906	5.1	809	5.1	648	5.6	701	5.5
61-89	****	****	452	4.3	666	5.0	762	5.4	713	5.4	971	5.5	812	5.1	637	5.5	773	6.1
90+	****	****	1,199	11.3	1,625	12.2	1,975	14.0	2,011	15.2	2,794	15.7	2,646	16.7	1,992	17.2	2,479	19.6
Distribution	n (Days)																	
Min	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
1st	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
3rd	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
5th	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
10th	1	-	1	-	1	-	1	-	1	-	2	-	5	-	5	-	7	-
20th	1	-	2	-	6	-	10	-	10	-	10	-	11	-	12	-	14	-
25th	1	-	7	-	10	-	14	-	14	-	15	-	15	-	15	-	17	-
50th	30	-	30	-	30	-	30	-	30	-	30	-	30	-	30	-	30	-
Mean	38.1	-	41.6	-	46.4	-	50.1	-	52.5	-	55.6	-	56.3	-	59.0	-	66.9	-
Median	30	-	30	-	30	-	30	-	30	-	30	-	30	-	30	-	30	-
Mode	30	-	30	-	30	-	30	-	30	-	30	-	30	-	30	-	30	-
75th	30	-	30	-	30	-	40	-	49	-	55	-	60	-	60	-	62	-
80th	30	-	45	-	60	-	60	-	62	-	64	-	66	-	68	-	84	-
90th	75	-	90	-	92	-	100	-	107	-	114	-	120	-	127	-	147	-
95th	134	-	138	-	163	-	180	-	189	-	197	-	196	-	219	-	255	-
97th	192	-	208	-	228	-	244	-	267	-	279	-	278	-	304	-	371	-
99th	390	-	394	-	450	-	475	-	475	-	531	-	543	-	543	-	634	-
Max	1,606	-	2,261	-	1,788	-	2,243	-	1,825	-	2,141	-	2,758	-	2,018	-	1,508	-



Table 4a. Distribution of Treatment Episode Duration of Metoclopramide among Female Members with No Evidence of a Live Birth Delivery in the Sentinel Distributed Database between January 1, 2008 and September 30, 2015, by Age Group, for Episodes with Allowable Gaps of 0 Days

	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent
	40-44	Years	45-49	Years	50-54	Years	55-59	Years	60-64	Years	65-69	Years	70-74	Years	75-79	Years	80+ \	Years
Total																		
Episodes	198,660	100.0	225,068	100.0	259,434	100.0	252,088	100.0	224,608	100.0	352,427	100.0	324,379	100.0	249,219	100.0	364,401	100.0
Duration G	roups (Days)																
1	101,748	51.2	106,287	47.2	115,389	44.5	98,941	39.2	81,876	36.5	134,941	38.3	116,512	35.9	78,149	31.4	80,726	22.2
2-7	24,845	12.5	25,816	11.5	27,469	10.6	25,325	10.0	22,502	10.0	32,410	9.2	29,711	9.2	23,688	9.5	38,159	10.5
8-14	13,738	6.9	15,506	6.9	17,090	6.6	17,259	6.8	16,371	7.3	26,469	7.5	25,175	7.8	21,710	8.7	36,264	10.0
15-21	8,886	4.5	11,038	4.9	12,561	4.8	13,449	5.3	12,795	5.7	19,469	5.5	19,380	6.0	15,770	6.3	26,092	7.2
22-28	3,659	1.8	4,892	2.2	6,354	2.4	6,614	2.6	6,425	2.9	8,492	2.4	8,219	2.5	6,601	2.6	12,088	3.3
29-45	36,949	18.6	48,346	21.5	62,273	24.0	68,618	27.2	62,848	28.0	95,713	27.2	90,990	28.1	73,655	29.6	115,460	31.7
46-60	3,892	2.0	5,526	2.5	7,585	2.9	8,754	3.5	8,300	3.7	12,650	3.6	12,517	3.9	10,728	4.3	20,002	5.5
61-89	548	0.3	709	0.3	958	0.4	1,157	0.5	1,289	0.6	1,860	0.5	1,810	0.6	1,820	0.7	4,227	1.2
90+	4,395	2.2	6,948	3.1	9,755	3.8	11,971	4.7	12,202	5.4	20,423	5.8	20,065	6.2	17,098	6.9	31,383	8.6
Distribution	n (Days)																	
Min	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
1st	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
3rd	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
5th	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
10th	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
20th	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
25th	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	4	-
50th	1	-	3	-	5	-	8	-	10	-	10	-	10	-	15	-	22	-
Mean	13.6	-	16.4	-	18.5	-	21.5	-	23.3	-	23.1	-	24.2	-	26.7	-	33.2	-
Median	1	-	3	-	5	-	8	-	10	-	10	-	10	-	15	-	22	-
Mode	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	30	-
75th	21	-	30	-	30	-	30	-	30	-	30	-	30	-	30	-	30	-
80th	30	-	30	-	30	-	30	-	30	-	30	-	30	-	30	-	30	-
90th	30	-	30	-	30	-	30	-	43	-	45	-	60	-	60	-	60	-
95th	33	-	60	-	60	-	72	-	90	-	90	-	90	-	90	-	112	-
97th	60	-	90	-	90	-	90	-	92	-	90	-	102	-	120	-	157	-
99th	120	-	150	-	170	-	180	-	210	-	210	-	210	-	240	-	320	-
Max	1,710	-	1,700	-	2,180	-	2,460	-	1,827	-	2,039	-	2,200	-	1,788	-	1,830	-



Table 4b. Distribution of Treatment Episode Duration of Metoclopramide among Female Members with Type 2 Diabetes and No Evidence of a Live Birth Delivery in the Sentinel Distributed Database between January 1, 2008 and September 30, 2015, by Age Group, for Episodes with Allowable Gaps of 0 Days

	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent
	40-44	Years	45-49	Years	50-54	Years	55-59	Years	60-64	Years	65-69	Years	70-74	Years	75-79	Years	80+1	Years
Total																		
Episodes	46,944	100.0	64,774	100.0	87,591	100.0	102,500	100.0	101,718	100.0	158,799	100.0	150,509	100.0	118,624	100.0	158,776	100.0
Duration G	roups (Days	·)																
1	19,436	41.4	23,616	36.5	29,061	33.2	30,929	30.2	29,567	29.1	48,663	30.6	42,448	28.2	29,444	24.8	28,298	17.8
2-7	4,562	9.7	5,975	9.2	7,601	8.7	8,602	8.4	8,710	8.6	13,099	8.2	12,451	8.3	10,420	8.8	15,607	9.8
8-14	3,087	6.6	4,547	7.0	6,023	6.9	7,117	6.9	7,648	7.5	12,714	8.0	12,508	8.3	10,795	9.1	16,468	10.4
15-21	2,115	4.5	3,301	5.1	4,544	5.2	6,092	5.9	5,894	5.8	9,590	6.0	9,657	6.4	7,967	6.7	12,030	7.6
22-28	1,028	2.2	1,886	2.9	2,580	2.9	2,988	2.9	3,093	3.0	4,313	2.7	4,294	2.9	3,268	2.8	5,630	3.5
29-45	12,928	27.5	19,448	30.0	28,451	32.5	34,657	33.8	34,061	33.5	50,813	32.0	49,450	32.9	39,695	33.5	53,965	34.0
46-60	1,552	3.3	2,412	3.7	3,755	4.3	4,766	4.6	4,706	4.6	7,026	4.4	7,124	4.7	6,136	5.2	9,637	6.1
61-89	224	0.5	312	0.5	452	0.5	690	0.7	724	0.7	1,069	0.7	1,089	0.7	1,067	0.9	2,086	1.3
90+	2,012	4.3	3,277	5.1	5,124	5.8	6,659	6.5	7,315	7.2	11,512	7.2	11,488	7.6	9,832	8.3	15,055	9.5
Distribution	n (Days)																	
Min	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
1st	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
3rd	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
5th	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
10th	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
20th	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	3	-
25th	1	-	1	-	1	-	1	-	1	-	1	-	1	-	2	-	7	-
50th	7	-	10	-	15	-	20	-	20	-	15	-	20	-	23	-	30	-
Mean	20.5	-	23.0	-	25.4	-	27.0	-	28.5	-	27.8	-	28.9	-	31.1	-	36.0	-
Median	7	-	10	-	15	-	20	-	20	-	15	-	20	-	23	-	30	-
Mode	1	-	1	-	1	-	30	-	30	-	1	-	30	-	30	-	30	-
75th	30	-	30	-	30	-	30	-	30	-	30	-	30	-	30	-	30	-
80th	30	-	30	-	30	-	30	-	30	-	30	-	30	-	30	-	30	-
90th	30	-	36	-	60	-	60	-	60	-	60	-	60	-	60	-	75	-
95th	60	-	90	-	90	-	90	-	90	-	90	-	90	-	90	-	120	-
97th	90	-	90	-	100	-	120	-	120	-	120	-	120	-	144	-	180	-
99th	180	-	194	-	210	-	219.5	-	254	-	240	-	247	-	270	-	330	-
Max	1,672	-	1,584	-	1,985	-	1,680	-	1,752	-	2,010	-	2,200	-	1,788	-	1,800	-



Table 4c. Distribution of Treatment Episode Duration of Metoclopramide among Female Members with Gastroparesis, Type 2 Diabetes, and No Evidence of a Live Birth Delivery in the Sentinel Distributed Database between January 1, 2008 and September 30, 2015, by Age Group, for Episodes with Allowable Gaps of 0 Days

	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent
	40-44	Years	45-49	Years	50-54	Years	55-59	Years	60-64	Years	65-69	Years	70-74	Years	75-79	Years	408	Years
Total																		
Episodes	9,181	100.0	12,825	100.0	16,679	100.0	18,058	100.0	16,962	100.0	23,058	100.0	20,471	100.0	15,120	100.0	17,302	100.0
Duration G	roups (Days)																
1	2,071	22.6	2,173	16.9	2,308	13.8	1,905	10.5	1,540	9.1	1,770	7.7	1,318	6.4	810	5.4	700	4.0
2-7	596	6.5	841	6.6	955	5.7	928	5.1	917	5.4	1,240	5.4	976	4.8	917	6.1	986	5.7
8-14	540	5.9	980	7.6	1,098	6.6	1,161	6.4	1,288	7.6	1,738	7.5	1,596	7.8	1,196	7.9	1,504	8.7
15-21	487	5.3	777	6.1	909	5.4	1,166	6.5	1,081	6.4	1,530	6.6	1,462	7.1	1,013	6.7	1,213	7.0
22-28	321	3.5	477	3.7	635	3.8	667	3.7	676	4.0	956	4.1	879	4.3	600	4.0	739	4.3
29-45	3,981	43.4	5,735	44.7	8,158	48.9	9,126	50.5	8,340	49.2	11,303	49.0	10,068	49.2	7,395	48.9	8,158	47.2
46-60	479	5.2	719	5.6	1,041	6.2	1,257	7.0	1,125	6.6	1,634	7.1	1,485	7.3	1,148	7.6	1,412	8.2
61-89	****	****	92	0.7	133	0.8	178	1.0	202	1.2	263	1.1	282	1.4	196	1.3	306	1.8
90+	****	****	1,031	8.0	1,442	8.6	1,670	9.2	1,793	10.6	2,624	11.4	2,405	11.7	1,845	12.2	2,284	13.2
Distribution	n (Days)																	
Min	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
1st	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
3rd	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
5th	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	3	-
10th	1	-	1	-	1	-	1	-	3	-	5	-	7	-	7	-	8	-
20th	1	-	5	-	8	-	10	-	12	-	14	-	15	-	15	-	15	-
25th	5	-	10	-	13	-	15	-	15	-	20	-	20	-	20	-	20	-
50th	30	-	30	-	30	-	30	-	30	-	30	-	30	-	30	-	30	-
Mean	30.9	-	33.3	-	35.6	-	37.9	-	39.5	-	41.3	-	42.0	-	43.6	-	47.3	-
Median	30	-	30	-	30	-	30	-	30	-	30	-	30	-	30	-	30	-
Mode	30	-	30	-	30	-	30	-	30	-	30	-	30	-	30	-	30	-
75th	30	-	30	-	30	-	30	-	30	-	30	-	30	-	30	-	37	-
80th	30	-	30	-	30	-	30	-	34	-	43	-	50	-	58	-	60	-
90th	60	-	60	-	60	-	66	-	90	-	90	-	90	-	90	-	90	-
95th	90	-	90	-	90	-	100	-	107	-	120	-	120	-	120	-	150	-
97th	120	-	120	-	122	-	150	-	150	-	180	-	180	-	180	-	209	-
99th	240	-	256	-	254	-	277	-	297	-	300	-	300	-	330	-	400	-
Max	1,557	-	1,200	-	1,400	-	986	-	1,752	-	1,830	-	2,200	-	1,364	-	1,508	-

Data are not presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented. cder_mpl1r_wp089



Table 5a. Distribution of Cumulative Exposure Duration of Metoclopramide among Female Members with No Evidence of a Live Birth Delivery in the Sentinel Distributed Database between January 1, 2008 and September 30, 2015, by Age Group, for Episodes with Allowable Gaps of 50% of the Prior Dispensing

	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent
	40-44	Years	45-49	Years	50-54	Years	55-59	Years	60-64	Years	65-69	Years	70-74	Years	75-79	Years	80+ \	Y ears
Total Members	124,942	100.0	135,880	100.0	154,171	100.0	144,317	100.0	129,111	100.0	210,423	100.0	193,217	100.0	144,167	100.0	200,566	100.0
Duration Group	s (Days)																	
1	62,273	49.8	67,387	49.6	77,428	50.2	67,610	46.8	58,343	45.2	100,552	47.8	88,472	45.8	60,342	41.9	64,542	32.2
2-7	24,601	19.7	24,982	18.4	26,005	16.9	22,595	15.7	18,842	14.6	28,372	13.5	25,226	13.1	17,999	12.5	25,310	12.6
8-14	8,581	6.9	8,438	6.2	8,826	5.7	8,360	5.8	7,712	6.0	12,408	5.9	11,899	6.2	9,652	6.7	16,027	8.0
15-21	4,774	3.8	4,800	3.5	5,076	3.3	5,255	3.6	4,965	3.8	7,920	3.8	7,871	4.1	6,452	4.5	10,286	5.1
22-28	1,775	1.4	1,960	1.4	2,115	1.4	2,156	1.5	2,137	1.7	3,052	1.5	2,954	1.5	2,518	1.7	4,329	2.2
29-45	11,899	9.5	13,538	10.0	15,629	10.1	16,741	11.6	16,063	12.4	25,232	12.0	24,857	12.9	19,901	13.8	31,563	15.7
46-60	2,544	2.0	3,125	2.3	3,878	2.5	4,166	2.9	4,032	3.1	6,144	2.9	5,988	3.1	5,203	3.6	8,469	4.2
61-89	1,892	1.5	2,310	1.7	2,791	1.8	2,866	2.0	2,864	2.2	4,411	2.1	4,202	2.2	3,627	2.5	6,342	3.2
90+	6,603	5.3	9,340	6.9	12,423	8.1	14,568	10.1	14,153	11.0	22,332	10.6	21,748	11.3	18,473	12.8	33,698	16.8
Distribution (Da	ıys)																	
Min	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
1st	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
3rd	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
5th	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
10th	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
20th	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
25th	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
50th	2	-	2	-	1	-	2	-	2	-	2	-	2	-	5	-	10	-
Mean	22.3	-	27.9	-	32.2	-	38.8	-	41.8	-	39.9	-	42.0	-	47.6	-	62.2	-
Median	2	-	2	-	1	-	2	-	2	-	2	-	2	-	5	-	10	-
Mode	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
75th	12	-	15	-	20	-	30	-	30	-	30	-	30	-	30	-	42	-
80th	21	-	30	-	30	-	30	-	30	-	30	-	30	-	40	-	60	-
90th	36	-	60	-	60	-	90	-	90	-	90	-	91	-	110	-	160	-
95th	90	-	120	-	148	-	183	-	205	-	192	-	206	-	234	-	318	-
97th	150	-	196	-	245	-	302	-	326	-	307	-	327	-	364	-	457	-
99th	382	-	504	-	569	-	643	-	670	-	644	-	655	-	704	-	800	-
Max	2,400	-	2,769	-	2,672	-	2,630	-	2,708	-	2,739	-	2,783	-	2,491	-	2,418	-



Table 5b. Distribution of Cumulative Exposure Duration of Metoclopramide among Female Members with Type 2 Diabetes and No Evidence of a Live Birth Delivery in the Sentinel Distributed Database between January 1, 2008 and September 30, 2015, by Age Group, for Episodes with Allowable Gaps of 50% of the Prior Dispensing

	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent
	40-44	Years	45-49	Years	50-54	Years	55-59	Years	60-64	Years	65-69	Years	70-74	Years	75-79	Years	408 Y	Years
Total Members	22,681	100.0	30,728	100.0	41,514	100.0	49,045	100.0	50,544	100.0	84,564	100.0	80,069	100.0	62,201	100.0	81,531	100.0
Duration Group	s (Days)																	
1	8,753	38.6	11,740	38.2	16,052	38.7	18,421	37.6	19,023	37.6	34,100	40.3	30,527	38.1	21,739	34.9	21,790	26.7
2-7	4,230	18.6	5,105	16.6	6,386	15.4	6,860	14.0	6,656	13.2	10,373	12.3	9,609	12.0	7,128	11.5	9,607	11.8
8-14	1,570	6.9	1,995	6.5	2,456	5.9	2,920	6.0	3,090	6.1	5,261	6.2	5,266	6.6	4,289	6.9	6,685	8.2
15-21	889	3.9	1,116	3.6	1,512	3.6	1,909	3.9	1,999	4.0	3,419	4.0	3,498	4.4	2,986	4.8	4,305	5.3
22-28	327	1.4	528	1.7	686	1.7	794	1.6	888	1.8	1,331	1.6	1,410	1.8	1,141	1.8	1,909	2.3
29-45	2,974	13.1	4,216	13.7	5,660	13.6	7,008	14.3	7,414	14.7	12,043	14.2	12,048	15.0	9,691	15.6	13,918	17.1
46-60	709	3.1	1,036	3.4	1,563	3.8	1,915	3.9	1,931	3.8	3,190	3.8	3,086	3.9	2,751	4.4	3,963	4.9
61-89	637	2.8	871	2.8	1,165	2.8	1,426	2.9	1,473	2.9	2,308	2.7	2,217	2.8	1,921	3.1	3,000	3.7
90+	2,592	11.4	4,121	13.4	6,034	14.5	7,792	15.9	8,070	16.0	12,539	14.8	12,408	15.5	10,555	17.0	16,354	20.1
Distribution (Da	ıys)																	
Min	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
1st	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
3rd	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
5th	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
10th	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
20th	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
25th	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
50th	4	-	5	-	5	-	7	-	7	-	6	-	7	-	10	-	19	-
Mean	43.7	-	50	-	55.4	-	58.5	-	59.3	-	53.9	-	56.2	-	61.2	-	72.3	-
Median	4	-	5	-	5	-	7	-	7	-	6	-	7	-	10	-	19	-
Mode	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
75th	30	-	30	-	31	-	33	-	33	-	31	-	31	-	44	-	60	-
80th	33	-	44	-	56	-	60	-	60	-	60	-	60	-	61	-	90	-
90th	95	-	120	-	132	-	148	-	150	-	131	-	142	-	156	-	195	-
95th	210	-	250	-	284	-	300	-	307	-	270	-	284	-	311	-	361	-
97th	333	-	393	-	427	-	449	-	450	-	401	-	422	-	452	-	508	-
99th	671	-	725	-	809	-	813	-	809	-	772	-	767	-	775	-	830	-
Max	2,400	-	2,769	-	2,467	-	2,444	-	2,528	-	2,739	-	2,783	-	2,491	-	2,249	-



Table 5c. Distribution of Cumulative Exposure Duration of Metoclopramide among Female Members with Gastroparesis, Type 2 Diabetes, and No Evidence of a Live Birth Delivery in the Sentinel Distributed Database between January 1, 2008 and September 30, 2015, by Age Group, for Episodes with Allowable Gaps of 50% of the Prior Dispensing

	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent
	40-44	Years	45-49	Years	50-54	Years	55-59	Years	60-64	Years	65-69	Years	70-74	Years	75-79	Years	408	Years
Total Members	2,952	100.0	4,111	100.0	5,259	100.0	6,021	100.0	5,996	100.0	8,314	100.0	7,515	100.0	5,845	100.0	6,924	100.0
Duration Group	s (Days)																	
1	317	10.7	418	10.2	510	9.7	520	8.6	480	8.0	623	7.5	497	6.6	327	5.6	273	3.9
2-7	302	10.2	340	8.3	390	7.4	393	6.5	369	6.2	517	6.2	381	5.1	304	5.2	387	5.6
8-14	190	6.4	261	6.3	319	6.1	370	6.1	395	6.6	542	6.5	498	6.6	383	6.6	513	7.4
15-21	146	4.9	190	4.6	226	4.3	260	4.3	264	4.4	398	4.8	385	5.1	328	5.6	366	5.3
22-28	66	2.2	104	2.5	143	2.7	142	2.4	161	2.7	208	2.5	205	2.7	148	2.5	218	3.1
29-45	733	24.8	1,022	24.9	1,261	24.0	1,480	24.6	1,568	26.2	2,132	25.6	1,983	26.4	1,563	26.7	1,807	26.1
46-60	208	7.0	298	7.2	396	7.5	435	7.2	443	7.4	632	7.6	616	8.2	480	8.2	551	8.0
61-89	185	6.3	217	5.3	323	6.1	355	5.9	319	5.3	490	5.9	392	5.2	343	5.9	414	6.0
90+	805	27.3	1,261	30.7	1,691	32.2	2,066	34.3	1,997	33.3	2,772	33.3	2,558	34.0	1,969	33.7	2,395	34.6
Distribution (Da	ıys)																	
Min	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
1st	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
3rd	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
5th	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	3	-
10th	1	-	1	-	2	-	2	-	3	-	4	-	6	-	7	-	8	-
20th	7	-	10	-	10	-	13	-	14	-	14	-	15	-	16	-	17	-
25th	11	-	15	-	15	-	20	-	21	-	21	-	25	-	26	-	28	-
50th	30	-	31	-	32	-	38	-	33	-	36	-	39	-	40	-	40	-
Mean	99.6	-	107.3	-	117.3	-	117.9	-	116.0	-	118.9	-	118.7	-	116.9	-	122.3	-
Median	30	-	31	-	32	-	38	-	33	-	36	-	39	-	40	-	40	-
Mode	30	-	30	-	30	-	30	-	30	-	30	-	30	-	30	-	30	-
75th	92	-	109	-	120	-	121	-	120	-	120	-	121	-	120	-	125.5	-
80th	121	-	144	-	155	-	157	-	154	-	158	-	161.5	-	160	-	170	-
90th	260	-	288	-	324	-	310	-	310	-	310	-	324	-	315	-	331	-
95th	461	-	487	-	511	-	515	-	494	-	509	-	518	-	498	-	520	-
97th	610	-	634	-	677	-	680	-	654	-	698	-	666	-	643	-	665	-
99th	941	-	950	-	1063	-	1023	-	1022	-	1067	-	993	-	979	-	1024	-
Max	1658	-	2769	-	2051	-	2333	-	2458	-	2477	-	2783	-	2018	-	2230	



Table 6a. Distribution of Cumulative Exposure Duration of Metoclopramide among Female Members with No Evidence of a Live Birth Delivery in the Sentinel Distributed Database between January 1, 2008 and September 30, 2015, by Age Group, for Episodes with Allowable Gaps of 0 Days

	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent
	40-44	Years	45-49	Years	50-54	Years	55-59	Years	60-64	Years	65-69	Years	70-74	Years	75-79	Years	80+1	Years
Total Members	124,942	100.0	135,880	100.0	154,171	100.0	144,317	100.0	129,111	100.0	210,423	100.0	193,217	100.0	144,167	100.0	200,566	100.0
Duration Group	s (Days)																	
1	62,273	49.8	67,387	49.6	77,428	50.2	67,610	46.8	58,343	45.2	100,552	47.8	88,472	45.8	60,342	41.9	64,542	32.2
2-7	24,607	19.7	24,985	18.4	26,009	16.9	22,598	15.7	18,846	14.6	28,376	13.5	25,231	13.1	18,001	12.5	25,317	12.6
8-14	8,602	6.9	8,475	6.2	8,848	5.7	8,385	5.8	7,739	6.0	12,445	5.9	11,934	6.2	9,680	6.7	16,078	8.0
15-21	4,809	3.8	4,811	3.5	5,101	3.3	5,283	3.7	4,984	3.9	7,975	3.8	7,916	4.1	6,522	4.5	10,361	5.2
22-28	1,740	1.4	1,937	1.4	2,109	1.4	2,137	1.5	2,137	1.7	3,020	1.4	2,939	1.5	2,469	1.7	4,316	2.2
29-45	11,961	9.6	13,606	10.0	15,731	10.2	16,837	11.7	16,160	12.5	25,397	12.1	24,978	12.9	20,049	13.9	31,824	15.9
46-60	2,847	2.3	3,554	2.6	4,321	2.8	4,752	3.3	4,605	3.6	7,040	3.3	6,948	3.6	5,980	4.1	9,724	4.8
61-89	1,550	1.2	1,856	1.4	2,302	1.5	2,237	1.6	2,253	1.7	3,462	1.6	3,212	1.7	2,795	1.9	4,962	2.5
90+	6,553	5.2	9,269	6.8	12,322	8.0	14,478	10.0	14,044	10.9	22,156	10.5	21,587	11.2	18,329	12.7	33,442	16.7
Distribution (Da	ıys)																	
Min	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
1st	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
3rd	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
5th	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
10th	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
20th	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
25th	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
50th	2	-	2	-	1	-	2	-	2	-	2	-	2	-	5	-	10	-
Mean	21.7	-	27.1	-	31.2	-	37.6	-	40.5	-	38.6	-	40.7	-	46.1	-	60.4	-
Median	2	-	2	-	1	-	2	-	2	-	2	-	2	-	5	-	10	-
Mode	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
75th	12	-	15	-	20	-	30	-	30	-	30	-	30	-	30	-	41	-
80th	21	-	30	-	30	-	30	-	30	-	30	-	30	-	40	-	60	-
90th	35	-	60	-	60	-	90	-	90	-	90	-	90	-	106	-	151	-
95th	90	-	120	-	141	-	180	-	196	-	181	-	197	-	224	-	302	-
97th	147	-	187	-	240	-	298	-	309	-	300	-	310	-	354	-	446	-
99th	361	-	480	-	540	-	610	-	642	-	623	-	630	-	672	-	766	-
Max	2,285	-	2,605	-	2,594	-	2,586	-	2,580	-	2,679	-	2,759	-	2,429	-	2,377	-



Table 6b. Distribution of Cumulative Exposure Duration of Metoclopramide among Female Members with Type 2 Diabetes and No Evidence of a Live Birth Delivery in the Sentinel Distributed Database between January 1, 2008 and September 30, 2015, by Age Group, for Episodes with Allowable Gaps of 0 Days

	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent
	40-44	Years	45-49	Years	50-54	Years	55-59	Years	60-64	Years	65-69	Years	70-74	Years	75-79	Years	408	Years
Total Members	22,681	100.0	30,728	100.0	41,514	100.0	49,045	100.0	50,544	100.0	84,564	100.0	80,069	100.0	62,201	100.0	81,531	100.0
Duration Group	s (Days)																	
1	8,753	38.6	11,740	38.2	16,052	38.7	18,421	37.6	19,023	37.6	34,100	40.3	30,527	38.1	21,739	34.9	21,790	26.7
2-7	4,232	18.7	5,108	16.6	6,387	15.4	6,860	14.0	6,657	13.2	10,375	12.3	9,610	12.0	7,129	11.5	9,612	11.8
8-14	1,569	6.9	2,001	6.5	2,463	5.9	2,929	6.0	3,095	6.1	5,273	6.2	5,281	6.6	4,302	6.9	6,703	8.2
15-21	898	4.0	1,123	3.7	1,522	3.7	1,921	3.9	2,012	4.0	3,442	4.1	3,517	4.4	3,014	4.8	4,331	5.3
22-28	321	1.4	519	1.7	679	1.6	788	1.6	890	1.8	1,321	1.6	1,409	1.8	1,128	1.8	1,916	2.4
29-45	2,991	13.2	4,241	13.8	5,713	13.8	7,050	14.4	7,467	14.8	12,124	14.3	12,110	15.1	9,763	15.7	14,023	17.2
46-60	800	3.5	1,163	3.8	1,726	4.2	2,188	4.5	2,192	4.3	3,662	4.3	3,604	4.5	3,165	5.1	4,549	5.6
61-89	543	2.4	738	2.4	986	2.4	1,148	2.3	1,201	2.4	1,827	2.2	1,686	2.1	1,484	2.4	2,399	2.9
90+	2,574	11.3	4,095	13.3	5,986	14.4	7,740	15.8	8,007	15.8	12,440	14.7	12,325	15.4	10,477	16.8	16,208	19.9
Distribution (Da	ys)																	
Min	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
1st	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
3rd	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
5th	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
10th	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
20th	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
25th	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
50th	4	-	5	-	5	-	7	-	7	-	6	-	7	-	10	-	19	-
Mean	42.4	-	48.4	-	53.5	-	56.5	-	57.3	-	52.1	-	54.3	-	59.3	-	70.1	-
Median	4	-	5	-	5	-	7	-	7	-	6	-	7	-	10	-	19	-
Mode	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
75th	30	-	30	-	30	-	33	-	33	-	31	-	31	-	42	-	60	-
80th	32	-	44	-	54	-	60	-	60	-	58	-	60	-	60	-	88	-
90th	91	-	120	-	125	-	141	-	149	-	122	-	137	-	150	-	187	-
95th	205	-	240	-	270	-	289	-	300	-	263	-	270	-	300	-	348	-
97th	318	-	375	-	410	-	426	-	424	-	390	-	406	-	433	-	485	-
99th	652	-	691	-	764	-	778	-	780	-	732	-	734	-	747	-	800	-
Max	2,285	-	2,605	-	2,398	-	2,322	-	2,460	-	2,679	-	2,759	-	2,429	-	2,219	-



Table 6c. Distribution of Cumulative Exposure Duration of Metoclopramide among Female Members with Gastroparesis, Type 2 Diabetes, and No Evidence of a Live Birth Delivery in the Sentinel Distributed Database between January 1, 2008 and September 30, 2015, by Age Group, for Episodes with Allowable Gaps of 0 Days

	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent
	40-44	Years	45-49	Years	50-54	Years	55-59	Years	60-64	Years	65-69	Years	70-74	Years	75-79	Years	* +08	Years
Total Members	2,952	100.0	4,111	100.0	5,259	100.0	6,021	100.0	5,996	100.0	8,314	100.0	7,515	100.0	5,845	100.0	6,924	100.0
Duration Group	s (Days)																	
1	317	10.7	418	10.2	510	9.7	520	8.6	480	8.0	623	7.5	497	6.6	327	5.6	273	3.9
2-7	302	10.2	340	8.3	390	7.4	393	6.5	369	6.2	518	6.2	381	5.1	304	5.2	387	5.6
8-14	190	6.4	262	6.4	320	6.1	372	6.2	396	6.6	543	6.5	498	6.6	384	6.6	517	7.5
15-21	148	5.0	192	4.7	226	4.3	262	4.4	267	4.5	399	4.8	389	5.2	333	5.7	368	5.3
22-28	65	2.2	102	2.5	143	2.7	141	2.3	158	2.6	209	2.5	205	2.7	147	2.5	219	3.2
29-45	740	25.1	1,031	25.1	1,276	24.3	1,492	24.8	1,581	26.4	2,146	25.8	1,999	26.6	1,579	27.0	1,821	26.3
46-60	230	7.8	320	7.8	456	8.7	493	8.2	515	8.6	747	9.0	715	9.5	562	9.6	641	9.3
61-89	159	5.4	192	4.7	253	4.8	301	5.0	240	4.0	381	4.6	298	4.0	246	4.2	321	4.6
90+	801	27.1	1,254	30.5	1,685	32.0	2,047	34.0	1,990	33.2	2,748	33.1	2,533	33.7	1,963	33.6	2,377	34.3
Distribution (Da	ays)																	
Min	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
1st	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
3rd	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
5th	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	3	-
10th	1	-	1	-	2	-	2	-	3	-	4	-	6	-	7	-	8	-
20th	7	-	10	-	10	-	13	-	14	-	14	-	15	-	16	-	17	-
25th	11	-	15	-	15	-	20	-	21	-	21	-	25	-	26	-	28	-
50th	30	-	31	-	32	-	38	-	33	-	36	-	38	-	39	-	40	-
Mean	96.2	-	103.8	-	113.0	-	113.6	-	111.8	-	114.5	-	114.5	-	112.9	-	118.2	-
Median	30	-	31	-	32	-	38	-	33	-	36	-	38	-	39	-	40	-
Mode	30	-	30	-	30	-	30	-	30	-	30	-	30	-	30	-	30	-
75th	90	-	105	-	120	-	120	-	120	-	120	-	120	-	120	-	120	-
80th	120	-	139	-	150	-	150	-	150	-	150	-	151	-	150	-	162	-
90th	248	-	272	-	307	-	300	-	300	-	300	-	307	-	300	-	315	-
95th	450	-	463	-	491	-	494	-	477	-	480	-	498	-	483	-	500	-
97th	589	-	613	-	630	-	634	-	630	-	655	-	637	-	618	-	643	-
99th	901	-	903	-	990	-	981	-	975	-	1020	-	960	-	947	-	990	-
Max	1615	-	2605	-	1920	-	2228	-	2368	-	2392	-	2759	-	1949	-	2191	-



Table 7a. Distribution of First Treatment Episode Duration of Metoclopramide among Female Members with No Evidence of a Live Birth Delivery in the Sentinel Distributed Database between January 1, 2008 and September 30, 2015, by Age Group, for Episodes with Allowable Gaps of 50% of the Prior Dispensing

	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent
	40-44	Years	45-49	Years	50-54	Years	55-59	Years	60-64	Years	65-69	Years	70-74	Years	75-79	Years	80+ \	Years
Total Episodes	124,942	100.0	135,880	100.0	154,171	100.0	144,317	100.0	129,111	100.0	210,423	100.0	193,217	100.0	144,167	100.0	200,566	100.0
Duration Groups	s (Days)																	
1	76,277	61.0	81,836	60.2	92,209	59.8	80,087	55.5	68,073	52.7	115,697	55.0	101,118	52.3	68,438	47.5	72,259	36.0
2-7	17,045	13.6	17,441	12.8	18,528	12.0	16,909	11.7	14,964	11.6	22,046	10.5	20,486	10.6	15,942	11.1	25,981	13.0
8-14	8,118	6.5	8,178	6.0	8,841	5.7	8,904	6.2	8,482	6.6	13,864	6.6	13,469	7.0	11,156	7.7	18,718	9.3
15-21	4,512	3.6	4,877	3.6	5,251	3.4	5,692	3.9	5,506	4.3	8,664	4.1	8,550	4.4	7,014	4.9	11,335	5.7
22-28	1,516	1.2	1,813	1.3	2,124	1.4	2,220	1.5	2,179	1.7	2,936	1.4	2,893	1.5	2,518	1.7	4,388	2.2
29-45	13,264	10.6	15,751	11.6	19,112	12.4	20,899	14.5	19,865	15.4	30,932	14.7	30,220	15.6	24,578	17.0	38,185	19.0
46-60	1,054	8.0	1,416	1.0	1,930	1.3	2,109	1.5	2,205	1.7	3,461	1.6	3,523	1.8	3,126	2.2	5,873	2.9
61-89	1,025	8.0	1,355	1.0	1,789	1.2	2,004	1.4	2,048	1.6	3,148	1.5	3,162	1.6	2,780	1.9	5,316	2.7
90+	2,131	1.7	3,213	2.4	4,387	2.8	5,493	3.8	5,789	4.5	9,675	4.6	9,796	5.1	8,615	6.0	18,511	9.2
Distribution (Day	ys)																	
Min	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
1st	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
3rd	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
5th	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
10th	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
20th	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
25th	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
50th	1	-	1	-	1	-	1	-	1	-	1	-	1	-	3	-	8	-
Mean	10.6	-	12.7	-	14.3	-	17.5	-	19.7	-	19.3	-	20.8	-	24.2	-	35.0	-
Median	1	-	1	-	1	-	1	-	1	-	1	-	1	-	3	-	8	-
Mode	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
75th	8	-	10	-	10	-	15	-	20	-	20	-	24	-	30	-	30	-
80th	12	-	15	-	20	-	30	-	30	-	30	-	30	-	30	-	30	-
90th	30	-	30	-	30	-	30	-	30	-	30	-	30	-	47	-	74	-
95th	30	-	33	-	53	-	62	-	72	-	73	-	90	-	90	-	150	-
97th	60	-	66	-	75	-	94	-	106	-	107	-	120	-	140	-	229	-
99th	120	-	150	-	182	-	226	-	264	-	267	-	280	-	331	-	469	-
Max	1,760	-	2,261	-	2,042	-	2,630	-	2,678	-	2,739	-	2,614	-	2,018	-	2,418	-



Table 7b. Distribution of First Treatment Episode Duration of Metoclopramide among Female Members with Type 2 Diabetes and No Evidence of a Live Birth Delivery in the Sentinel Distributed Database between January 1, 2008 and September 30, 2015, by Age Group, for Episodes with Allowable Gaps of 50% of the Prior Dispensing

	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent
	40-44	Years	45-49	Years	50-54	Years	55-59	Years	60-64	Years	65-69	Years	70-74	Years	75-79	Years	408 Y	Years
Total Episodes	22,681	100.0	30,728	100.0	41,514	100.0	49,045	100.0	50,544	100.0	84,564	100.0	80,069	100.0	62,201	100.0	81,531	100.0
Duration Group	s (Days)																	
1	12,267	54.1	15,791	51.4	20,811	50.1	23,217	47.3	23,282	46.1	40,443	47.8	35,770	44.7	25,247	40.6	24,876	30.5
2-7	2,643	11.7	3,434	11.2	4,482	10.8	5,168	10.5	5,299	10.5	8,347	9.9	8,151	10.2	6,595	10.6	10,187	12.5
8-14	1,514	6.7	2,020	6.6	2,623	6.3	3,293	6.7	3,582	7.1	6,180	7.3	6,260	7.8	5,139	8.3	8,055	9.9
15-21	848	3.7	1,227	4.0	1,658	4.0	2,200	4.5	2,288	4.5	3,892	4.6	3,941	4.9	3,356	5.4	4,899	6.0
22-28	306	1.3	510	1.7	702	1.7	865	1.8	927	1.8	1,338	1.6	1,402	1.8	1,166	1.9	1,957	2.4
29-45	3,675	16.2	5,366	17.5	7,513	18.1	9,459	19.3	9,768	19.3	15,482	18.3	15,459	19.3	12,542	20.2	17,311	21.2
46-60	317	1.4	519	1.7	843	2.0	1,037	2.1	1,122	2.2	1,833	2.2	1,850	2.3	1,678	2.7	2,774	3.4
61-89	321	1.4	504	1.6	770	1.9	969	2.0	1,041	2.1	1,692	2.0	1,729	2.2	1,502	2.4	2,505	3.1
90+	790	3.5	1,357	4.4	2,112	5.1	2,837	5.8	3,235	6.4	5,357	6.3	5,507	6.9	4,976	8.0	8,967	11.0
Distribution (Da	ıys)																	
Min	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
1st	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
3rd	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
5th	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
10th	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
20th	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
25th	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
50th	1	-	1	-	1	-	3	-	5	-	3	-	5	-	7	-	10	-
Mean	17.1	-	20.0	-	22.5	-	23.9	-	26.1	-	25.3	-	26.7	-	30.4	-	40.2	-
Median	1	-	1	-	1	-	3	-	5	-	3	-	5	-	7	-	10	-
Mode	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
75th	20	-	30	-	30	-	30	-	30	-	30	-	30	-	30	-	30	-
80th	30	-	30	-	30	-	30	-	30	-	30	-	30	-	30	-	30	-
90th	30	-	30	-	31	-	45	-	60	-	54	-	60	-	63	-	90	-
95th	60	-	70	-	90	-	90	-	94	-	92	-	100	-	120	-	177	-
97th	90	-	105	-	122	-	132	-	150	-	150	-	158	-	182	-	261	-
99th	211	-	264	-	300	-	303	-	361	-	334	-	354	-	396	-	505	-
Max	1,672	-	2,261	-	1,788	-	2,444	-	1,825	-	2,739	-	2,614	-	2,018	-	2,005	-



Table 7c. Distribution of First Treatment Episode Duration of Metoclopramide among Female Members with Gastroparesis, Type 2 Diabetes, and No Evidence of a Live Birth Delivery in the Sentinel Distributed Database between January 1, 2008 and September 30, 2015, by Age Group, for Episodes with Allowable Gaps of 50% of the Prior Dispensing

	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent
	40-44	Years	45-49	Years	50-54	Years	55-59	Years	60-64	Years	65-69	Years	70-74	Years	75-79	Years	7 +08	Years
Total Episodes	2,952	100.0	4,111	100.0	5,259	100.0	6,021	100.0	5,996	100.0	8,314	100.0	7,515	100.0	5,845	100.0	6,924	100.0
Duration Group	s (Days)																	
1	710	24.1	843	20.5	934	17.8	907	15.1	789	13.2	1,022	12.3	739	9.8	489	8.4	463	6.7
2-7	246	8.3	336	8.2	374	7.1	422	7.0	421	7.0	609	7.3	487	6.5	399	6.8	523	7.6
8-14	236	8.0	351	8.5	435	8.3	519	8.6	555	9.3	736	8.9	678	9.0	522	8.9	673	9.7
15-21	163	5.5	255	6.2	309	5.9	377	6.3	349	5.8	528	6.4	532	7.1	424	7.3	467	6.7
22-28	81	2.7	125	3.0	160	3.0	183	3.0	206	3.4	254	3.1	246	3.3	187	3.2	246	3.6
29-45	1,070	36.2	1,513	36.8	1,980	37.6	2,345	38.9	2,326	38.8	3,176	38.2	2,915	38.8	2,251	38.5	2,451	35.4
46-60	98	3.3	153	3.7	254	4.8	252	4.2	278	4.6	400	4.8	391	5.2	337	5.8	407	5.9
61-89	91	3.1	130	3.2	247	4.7	260	4.3	262	4.4	394	4.7	386	5.1	281	4.8	390	5.6
90+	257	8.7	405	9.9	566	10.8	756	12.6	810	13.5	1,195	14.4	1,141	15.2	955	16.3	1,304	18.8
Distribution (Da	ıys)																	
Min	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
1st	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
3rd	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
5th	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
10th	1	-	1	-	1	-	1	-	1	-	1	-	2	-	4	-	5	-
20th	1	-	1	-	5	-	7	-	7	-	8	-	10	-	10	-	10	-
25th	3	-	6	-	8	-	10	-	10	-	10	-	14	-	15	-	15	-
50th	30	-	30	-	30	-	30	-	30	-	30	-	30	-	30	-	30	-
Mean	38.1	-	39.4	-	45.1	-	46.8	-	49.6	-	52.7	-	53.1	-	59.1	-	65.9	-
Median	30	-	30	-	30	-	30	-	30	-	30	-	30	-	30	-	30	-
Mode	30	-	30	-	30	-	30	-	30	-	30	-	30	-	30	-	30	-
75th	30	-	30	-	30	-	30	-	33	-	40	-	50	-	60	-	60	-
80th	30	-	30	-	49	-	57	-	60	-	60	-	61	-	64	-	75	-
90th	69	-	83	-	90	-	92	-	99	-	105	-	113	-	125	-	146	-
95th	127	-	128	-	155	-	157	-	180	-	188	-	183	-	227	-	258	-
97th	196	-	190	-	224	-	234	-	267	-	270	-	260	-	326	-	378	-
99th	396	-	390	-	479	-	473	-	470	-	531	-	510	-	572	-	649	-
Max	1,606	-	2,261	-	1,788	-	1,588	-	1,825	-	2,141	-	1,381	-	2,018	-	1,508	-



Table 8a. Distribution of First Treatment Episode Duration of Metoclopramide among Female Members with No Evidence of a Live Birth Delivery in the Sentinel Distributed Database between January 1, 2008 and September 30, 2015, by Age Group, for Episodes with Allowable Gaps of 0 Days

	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent
	40-44	Years	45-49	Years	50-54	Years	55-59	Years	60-64	Years	65-69	Years	70-74	Years	75-79	Years	408	Years
Total Episodes	124,942	100.0	135,880	100.0	154,171	100.0	144,317	100.0	129,111	100.0	210,423	100.0	193,217	100.0	144,167	100.0	200,566	100.0
Duration Group	s (Days)																	
1	76,277	61.0	81,836	60.2	92,209	59.8	80,087	55.5	68,073	52.7	115,697	55.0	101,118	52.3	68,438	47.5	72,259	36.0
2-7	17,182	13.8	17,606	13.0	18,728	12.1	17,146	11.9	15,161	11.7	22,398	10.6	20,809	10.8	16,239	11.3	26,639	13.3
8-14	8,307	6.6	8,409	6.2	9,084	5.9	9,239	6.4	8,836	6.8	14,459	6.9	14,074	7.3	11,787	8.2	20,036	10.0
15-21	4,639	3.7	5,043	3.7	5,531	3.6	6,001	4.2	5,779	4.5	9,112	4.3	9,060	4.7	7,456	5.2	12,344	6.2
22-28	1,501	1.2	1,833	1.3	2,202	1.4	2,301	1.6	2,267	1.8	3,041	1.4	2,962	1.5	2,554	1.8	4,688	2.3
29-45	14,564	11.7	17,606	13.0	21,618	14.0	23,725	16.4	22,806	17.7	35,403	16.8	34,741	18.0	28,331	19.7	45,156	22.5
46-60	1,157	0.9	1,598	1.2	2,112	1.4	2,426	1.7	2,508	1.9	3,948	1.9	4,094	2.1	3,553	2.5	6,840	3.4
61-89	174	0.1	196	0.1	280	0.2	329	0.2	396	0.3	613	0.3	627	0.3	699	0.5	1,796	0.9
90+	1,141	0.9	1,753	1.3	2,407	1.6	3,063	2.1	3,285	2.5	5,752	2.7	5,732	3.0	5,110	3.5	10,808	5.4
Distribution (Da	ys)																	
Min	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
1st	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
3rd	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
5th	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
10th	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
20th	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
25th	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
50th	1	-	1	-	1	-	1	-	1	-	1	-	1	-	3	-	8	-
Mean	8.5	-	9.8	-	10.6	-	12.7	-	14.1	-	13.9	-	14.8	-	17.1	-	23.7	-
Median	1	-	1	-	1	-	1	-	1	-	1	-	1	-	3	-	8	-
Mode	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
75th	8	-	10	-	10	-	15	-	20	-	16	-	21	-	30	-	30	-
80th	11	-	15	-	16	-	30	-	30	-	30	-	30	-	30	-	30	-
90th	30	-	30	-	30	-	30	-	30	-	30	-	30	-	30	-	44	-
95th	30	-	30	-	30	-	30	-	42	-	45	-	60	-	60	-	90	-
97th	30	-	33	-	50	-	60	-	60	-	62	-	85	-	90	-	120	-
99th	70	-	90	-	90	-	120	-	120	-	120	-	143	-	177	-	268	-
Max	1,672		1,658		1,716		2,460		1,683		2,039	_	2,110		1,788		1,800	



Table 8b. Distribution of First Treatment Episode Duration of Metoclopramide among Female Members with Type 2 Diabetes and No Evidence of a Live Birth Delivery in the Sentinel Distributed Database between January 1, 2008 and September 30, 2015, by Age Group, for Episodes with Allowable Gaps of 0 Days

	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent
	40-44	Years	45-49	Years	50-54	Years	55-59	Years	60-64	Years	65-69	Years	70-74	Years	75-79	Years	80+ Y	Years
Total Episodes	22,681	100.0	30,728	100.0	41,514	100.0	49,045	100.0	50,544	100.0	84,564	100.0	80,069	100.0	62,201	100.0	81,531	100.0
Duration Group	s (Days)																	
1	12,267	54.1	15,791	51.4	20,811	50.1	23,217	47.3	23,282	46.1	40,443	47.8	35,770	44.7	25,247	40.6	24,876	30.5
2-7	2,670	11.8	3,491	11.4	4,560	11.0	5,262	10.7	5,378	10.6	8,510	10.1	8,286	10.3	6,742	10.8	10,483	12.9
8-14	1,558	6.9	2,083	6.8	2,717	6.5	3,439	7.0	3,760	7.4	6,489	7.7	6,578	8.2	5,478	8.8	8,673	10.6
15-21	882	3.9	1,280	4.2	1,767	4.3	2,355	4.8	2,431	4.8	4,145	4.9	4,229	5.3	3,600	5.8	5,372	6.6
22-28	310	1.4	531	1.7	741	1.8	903	1.8	967	1.9	1,417	1.7	1,464	1.8	1,207	1.9	2,119	2.6
29-45	4,133	18.2	6,129	19.9	8,666	20.9	10,907	22.2	11,350	22.5	17,954	21.2	17,986	22.5	14,632	23.5	20,736	25.4
46-60	366	1.6	587	1.9	948	2.3	1,214	2.5	1,309	2.6	2,096	2.5	2,210	2.8	1,933	3.1	3,212	3.9
61-89	58	0.3	82	0.3	121	0.3	176	0.4	217	0.4	325	0.4	384	0.5	401	0.6	856	1.0
90+	437	1.9	754	2.5	1,183	2.8	1,572	3.2	1,850	3.7	3,185	3.8	3,162	3.9	2,961	4.8	5,204	6.4
Distribution (Da	ys)																	
Min	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
1st	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
3rd	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
5th	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
10th	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
20th	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
25th	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
50th	1	-	1	-	1	-	3	-	5	-	3	-	5	-	7	-	10	-
Mean	12.8	-	14.5	-	16.0	-	16.8	-	17.9	-	17.7	-	18.7	-	21.1	-	27.0	-
Median	1	-	1	-	1	-	3	-	5	-	3	-	5	-	7	-	10	-
Mode	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
75th	15	-	25	-	30	-	30	-	30	-	30	-	30	-	30	-	30	-
80th	30	-	30	-	30	-	30	-	30	-	30	-	30	-	30	-	30	-
90th	30	-	30	-	30	-	30	-	30	-	30	-	30	-	31	-	60	-
95th	30	-	40	-	60	-	60	-	60	-	60	-	60	-	75	-	90	-
97th	60	-	60	-	73	-	90	-	90	-	90	-	90	-	90	-	137	-
99th	108	-	120	-	150	-	150	-	170	-	180	-	180	-	210	-	294	-
Max	1,672	-	1,584	-	1,668	-	1,680	-	1,683	-	1,903	-	1,560	-	1,788	-	1,800	-



Table 8c. Distribution of First Treatment Episode Duration of Metoclopramide among Female Members with Gastroparesis, Type 2 Diabetes, and No Evidence of a Live Birth Delivery in the Sentinel Distributed Database between January 1, 2008 and September 30, 2015, by Age Group, for Episodes with Allowable Gaps of 0 Days

	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent
	40-44	Years	45-49	Years	50-54	Years	55-59	Years	60-64	Years	65-69	Years	70-74	Years	75-79	Years	80+ Y	Years
Total Episodes	2,952	100.0	4,111	100.0	5,259	100.0	6,021	100.0	5,996	100.0	8,314	100.0	7,515	100.0	5,845	100.0	6,924	100.0
Duration Group	s (Days)																	
1	710	24.1	843	20.5	934	17.8	907	15.1	789	13.2	1,022	12.3	739	9.8	489	8.4	463	6.7
2-7	250	8.5	344	8.4	391	7.4	443	7.4	439	7.3	625	7.5	508	6.8	419	7.2	555	8.0
8-14	249	8.4	372	9.0	464	8.8	561	9.3	588	9.8	811	9.8	738	9.8	581	9.9	768	11.1
15-21	177	6.0	275	6.7	335	6.4	418	6.9	372	6.2	583	7.0	574	7.6	452	7.7	517	7.5
22-28	85	2.9	126	3.1	185	3.5	191	3.2	222	3.7	283	3.4	258	3.4	209	3.6	275	4.0
29-45	1,212	41.1	1,721	41.9	2,328	44.3	2,741	45.5	2,751	45.9	3,756	45.2	3,511	46.7	2,703	46.2	2,999	43.3
46-60	114	3.9	173	4.2	271	5.2	305	5.1	331	5.5	457	5.5	465	6.2	375	6.4	471	6.8
61-89	17	0.6	19	0.5	35	0.7	54	0.9	61	1.0	81	1.0	93	1.2	74	1.3	133	1.9
90+	138	4.7	238	5.8	316	6.0	401	6.7	443	7.4	696	8.4	629	8.4	543	9.3	743	10.7
Distribution (Da	ıys)																	
Min	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
1st	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
3rd	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
5th	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
10th	1	-	1	-	1	-	1	-	1	-	1	-	2	-	4	-	5	-
20th	1	-	1	-	5	-	7	-	7	-	8	-	10	-	10	-	10	-
25th	3	-	6	-	7	-	10	-	10	-	10	-	14	-	14	-	14	-
50th	30	-	30	-	30	-	30	-	30	-	30	-	30	-	30	-	30	-
Mean	26.7	-	28.7	-	31.2	-	31.4	-	33.8	-	35.8	-	36.5	-	39.0	-	42.7	-
Median	30	-	30	-	30	-	30	-	30	-	30	-	30	-	30	-	30	-
Mode	30	-	30	-	30	-	30	-	30	-	30	-	30	-	30	-	30	-
75th	30	-	30	-	30	-	30	-	30	-	30	-	30	-	30	-	30	-
80th	30	-	30	-	30	-	30	-	30	-	30	-	30	-	31	-	44	-
90th	40	-	52	-	60	-	60	-	60	-	60	-	60	-	70	-	90	-
95th	75	-	90	-	90	-	90	-	90	-	91	-	100	-	120	-	121	-
97th	90	-	110	-	120	-	120	-	120	-	150	-	140	-	152	-	181	-
99th	180	-	210	-	230	-	210	-	270	-	277	-	270	-	326	-	384	-
Max	1,430	-	1,187	-	1,400	-	981	-	1,436	-	1,830	-	1,381	-	1,364	-	1,508	-



Table 9a. Distribution of Second and Subsequent Treatment Episode Duration of Metoclopramide among Female Members with No Evidence of a Live Birth Delivery in the Sentinel Distributed Database between January 1, 2008 and September 30, 2015, by Age Group, for Episodes with Allowable Gaps of 50% of the Prior Dispensing

	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent
	40-44	Years	45-49	Years	50-54	Years	55-59	Years	60-64	Years	65-69	Years	70-74	Years	75-79	Years	80+1	Years
Total Episodes	61,801	100.0	71,389	100.0	81,251	100.0	80,405	100.0	68,995	100.0	101,558	100.0	91,381	100.0	70,640	100.0	98,819	100.0
Duration Group	s (Days)																	
1	25,191	40.8	24,134	33.8	22,835	28.1	18,562	23.1	13,546	19.6	18,900	18.6	15,110	16.5	9,489	13.4	8,202	8.3
2-7	7,189	11.6	7,551	10.6	8,110	10.0	7,391	9.2	6,573	9.5	8,945	8.8	7,905	8.7	6,514	9.2	9,597	9.7
8-14	4,711	7.6	6,142	8.6	6,843	8.4	6,673	8.3	6,009	8.7	9,517	9.4	8,926	9.8	7,581	10.7	11,560	11.7
15-21	3,358	5.4	4,672	6.5	5,305	6.5	5,550	6.9	5,207	7.5	7,603	7.5	7,313	8.0	5,716	8.1	8,808	8.9
22-28	1,567	2.5	2,022	2.8	2,774	3.4	2,890	3.6	2,626	3.8	3,685	3.6	3,378	3.7	2,552	3.6	3,853	3.9
29-45	13,538	21.9	17,779	24.9	22,911	28.2	25,214	31.4	21,768	31.6	32,594	32.1	29,777	32.6	23,184	32.8	31,647	32.0
46-60	1,310	2.1	1,847	2.6	2,480	3.1	2,768	3.4	2,514	3.6	3,811	3.8	3,568	3.9	2,837	4.0	4,472	4.5
61-89	1,595	2.6	2,154	3.0	2,948	3.6	3,184	4.0	2,903	4.2	4,393	4.3	3,839	4.2	3,145	4.5	5,013	5.1
90+	3,342	5.4	5,088	7.1	7,045	8.7	8,173	10.2	7,849	11.4	12,110	11.9	11,565	12.7	9,622	13.6	15,667	15.9
Distribution (Da	ys)																	
Min	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
1st	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
3rd	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
5th	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
10th	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	3	-
20th	1	-	1	-	1	-	1	-	2	-	3	-	5	-	7	-	10	-
25th	1	-	1	-	1	-	3	-	6	-	7	-	7	-	10	-	10	-
50th	7	-	10	-	15	-	25	-	30	-	30	-	30	-	30	-	30	-
Mean	23.8	-	29.0	-	33.8	-	38.3	-	41.4	-	42.6	-	44.8	-	47.8	-	55.3	-
Median	7	-	10	-	15	-	25	-	30	-	30	-	30	-	30	-	30	-
Mode	1	-	1	-	1	-	30	-	30	-	30	-	30	-	30	-	30	-
75th	30	-	30	-	30	-	30	-	30	-	30	-	30	-	30	-	49	-
80th	30	-	30	-	30	-	30	-	40	-	46	-	52	-	60	-	63	-
90th	48	-	61	-	71	-	90	-	90	-	90	-	90	-	98	-	120	-
95th	90	-	100	-	120	-	134	-	150	-	154	-	165	-	183	-	216	-
97th	122	-	151	-	180	-	197	-	215	-	219	-	239	-	261	-	307	-
99th	269	-	321	-	360	-	392	-	414	-	434	-	458	-	479	-	561	-
Max	2,104	-	1,849	-	2,410	-	2,243	-	2,279	-	2,204	-	2,758	-	2,481	-	1,830	-



Table 9b. Distribution of Second and Subsequent Treatment Episode Duration of Metoclopramide among Female Members with Type 2 Diabetes and No Evidence of a Live Birth Delivery in the Sentinel Distributed Database between January 1, 2008 and September 30, 2015, by Age Group, for Episodes with Allowable Gaps of 50% of the Prior Dispensing

	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent
	40-44	Years	45-49	Years	50-54	Years	55-59	Years	60-64	Years	65-69	Years	70-74	Years	75-79	Years	7 +08	Years
Total Episodes	19,540	100.0	26,339	100.0	34,241	100.0	38,521	100.0	35,980	100.0	51,683	100.0	47,735	100.0	36,883	100.0	45,810	100.0
Duration Group	s (Days)																	
1	7,044	36.0	7,671	29.1	8,085	23.6	7,547	19.6	6,122	17.0	8,028	15.5	6,516	13.7	4,083	11.1	3,292	7.2
2-7	1,744	8.9	2,284	8.7	2,752	8.0	2,956	7.7	2,949	8.2	4,008	7.8	3,646	7.6	3,208	8.7	4,178	9.1
8-14	1,318	6.7	2,073	7.9	2,776	8.1	3,026	7.9	3,067	8.5	4,841	9.4	4,713	9.9	3,933	10.7	5,440	11.9
15-21	982	5.0	1,573	6.0	2,016	5.9	2,663	6.9	2,470	6.9	3,858	7.5	3,721	7.8	2,886	7.8	4,176	9.1
22-28	511	2.6	901	3.4	1,245	3.6	1,358	3.5	1,296	3.6	1,898	3.7	1,751	3.7	1,270	3.4	1,763	3.8
29-45	5,132	26.3	7,560	28.7	10,904	31.8	12,922	33.5	12,132	33.7	17,487	33.8	16,357	34.3	12,389	33.6	14,547	31.8
46-60	550	2.8	867	3.3	1,230	3.6	1,475	3.8	1,453	4.0	2,120	4.1	2,034	4.3	1,634	4.4	2,226	4.9
61-89	717	3.7	960	3.6	1,536	4.5	1,818	4.7	1,686	4.7	2,484	4.8	2,153	4.5	1,816	4.9	2,499	5.5
90+	1,542	7.9	2,450	9.3	3,697	10.8	4,756	12.3	4,805	13.4	6,959	13.5	6,844	14.3	5,664	15.4	7,689	16.8
Distribution (Da	ys)																	
Min	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
1st	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
3rd	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
5th	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
10th	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	5	-
20th	1	-	1	-	1	-	2	-	5	-	6	-	7	-	8	-	10	-
25th	1	-	1	-	3	-	7	-	7	-	9	-	10	-	10	-	11	-
50th	10	-	20	-	30	-	30	-	30	-	30	-	30	-	30	-	30	-
Mean	30.9	-	35.0	-	39.9	-	44.1	-	46.6	-	46.8	-	49.4	-	51.9	-	57.0	-
Median	10	-	20	-	30	-	30	-	30	-	30	-	30	-	30	-	30	-
Mode	1	-	1	-	30	-	30	-	30	-	30	-	30	-	30	-	30	-
75th	30	-	30	-	30	-	30	-	30	-	30	-	33	-	45	-	60	-
80th	30	-	30	-	37	-	54	-	60	-	60	-	60	-	61	-	67	-
90th	66	-	74	-	90	-	90	-	96	-	95	-	102	-	113	-	127	-
95th	112	-	121	-	143	-	161	-	180	-	180	-	185	-	200	-	220	-
97th	165	-	182	-	207	-	227	-	240	-	243	-	269	-	282	-	308	-
99th	356	-	378	-	408	-	442	-	457	-	460	-	488	-	500	-	561	-
Max	1,590	-	1,849	-	1,985	-	2,243	-	2,279	-	2,204	-	2,758	-	2,481	-	1,778	



Table 9c. Distribution of Second and Subsequent Treatment Episode Duration of Metoclopramide among Female Members with Gastroparesis, Type 2 Diabetes, and No Evidence of a Live Birth Delivery in the Sentinel Distributed Database between January 1, 2008 and September 30, 2015, by Age Group, for Episodes with Allowable Gaps of 50% of the Prior Dispensing

	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent
	40-44	Years	45-49	Years	50-54	Years	55-59	Years	60-64	Years	65-69	Years	70-74	Years	75-79	Years	408 Y	Years
Total Episodes	4,764	100.0	6,490	100.0	8,029	100.0	8,133	100.0	7,239	100.0	9,462	100.0	8,319	100.0	5,727	100.0	5,729	100.0
Duration Group	s (Days)																	
1	1,306	27.4	1,262	19.4	1,307	16.3	943	11.6	707	9.8	703	7.4	531	6.4	294	5.1	216	3.8
2-7	309	6.5	448	6.9	489	6.1	395	4.9	387	5.3	493	5.2	400	4.8	414	7.2	310	5.4
8-14	236	5.0	504	7.8	508	6.3	449	5.5	518	7.2	660	7.0	659	7.9	427	7.5	459	8.0
15-21	230	4.8	383	5.9	420	5.2	532	6.5	461	6.4	616	6.5	551	6.6	379	6.6	382	6.7
22-28	166	3.5	219	3.4	325	4.0	302	3.7	285	3.9	432	4.6	359	4.3	226	3.9	248	4.3
29-45	1,634	34.3	2,273	35.0	3,152	39.3	3,376	41.5	2,881	39.8	3,876	41.0	3,470	41.7	2,283	39.9	2,262	39.5
46-60	173	3.6	285	4.4	350	4.4	415	5.1	348	4.8	506	5.3	418	5.0	311	5.4	294	5.1
61-89	227	4.8	322	5.0	419	5.2	502	6.2	451	6.2	577	6.1	426	5.1	356	6.2	383	6.7
90+	483	10.1	794	12.2	1,059	13.2	1,219	15.0	1,201	16.6	1,599	16.9	1,505	18.1	1,037	18.1	1,175	20.5
Distribution (Da	ys)																	
Min	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
1st	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
3rd	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
5th	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	4	-
10th	1	-	1	-	1	-	1	-	2	-	6	-	7	-	7	-	8	-
20th	1	-	2	-	7	-	10	-	10	-	15	-	15	-	15	-	15	-
25th	1	-	7	-	10	-	15	-	15	-	20	-	20	-	20	-	23	-
50th	30	-	30	-	30	-	30	-	30	-	30	-	30	-	30	-	30	-
Mean	38.1	-	43.1	-	47.3	-	52.6	-	55.0	-	58.2	-	59.2	-	59.0	-	68.2	-
Median	30	-	30	-	30	-	30	-	30	-	30	-	30	-	30	-	30	-
Mode	30	-	30	-	30	-	30	-	30	-	30	-	30	-	30	-	30	-
75th	30	-	30	-	30	-	56	-	60	-	60	-	60	-	60	-	66	-
80th	34	-	56.5	-	60	-	63	-	68	-	69	-	72	-	72	-	90	-
90th	90	-	90	-	98	-	102	-	118	-	120	-	122	-	128	-	150	-
95th	137	-	150	-	167	-	184	-	197	-	210	-	210	-	215	-	253	-
97th	192	-	214	-	232	-	254	-	269	-	288	-	296	-	290	-	366	-
99th	390	-	400	-	425	-	484	-	478	-	529	-	558	-	504	-	630	-
Max	1,241	-	1,269	-	1,697	-	2,243	-	1,252	-	2,140	-	2,758	-	1,364	-	1,338	-



Table 10a. Distribution of Second and Subsequent Treatment Episode Duration of Metoclopramide among Female Members with No Evidence of a Live Birth Delivery in the Sentinel Distributed Database between January 1, 2008 and September 30, 2015, by Age Group, for Episodes with Allowable Gaps of 0 Days

	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent
	40-44	Years	45-49	Years	50-54	Years	55-59	Years	60-64	Years	65-69	Years	70-74	Years	75-79	Years	80+	Years
Total Episodes	73,718	100.0	89,188	100.0	105,263	100.0	107,771	100.0	95,497	100.0	142,004	100.0	131,162	100.0	105,052	100.0	163,835	100.0
Duration Group	s (Days)																	
1	25,471	34.6	24,451	27.4	23,180	22.0	18,854	17.5	13,803	14.5	19,244	13.6	15,394	11.7	9,711	9.2	8,467	5.2
2-7	7,663	10.4	8,210	9.2	8,741	8.3	8,179	7.6	7,341	7.7	10,012	7.1	8,902	6.8	7,449	7.1	11,520	7.0
8-14	5,431	7.4	7,097	8.0	8,006	7.6	8,020	7.4	7,535	7.9	12,010	8.5	11,101	8.5	9,923	9.4	16,228	9.9
15-21	4,247	5.8	5,995	6.7	7,030	6.7	7,448	6.9	7,016	7.3	10,357	7.3	10,320	7.9	8,314	7.9	13,748	8.4
22-28	2,158	2.9	3,059	3.4	4,152	3.9	4,313	4.0	4,158	4.4	5,451	3.8	5,257	4.0	4,047	3.9	7,400	4.5
29-45	22,385	30.4	30,740	34.5	40,655	38.6	44,893	41.7	40,042	41.9	60,310	42.5	56,249	42.9	45,324	43.1	70,304	42.9
46-60	2,735	3.7	3,928	4.4	5,473	5.2	6,328	5.9	5,792	6.1	8,702	6.1	8,423	6.4	7,175	6.8	13,162	8.0
61-89	374	0.5	513	0.6	678	0.6	828	0.8	893	0.9	1,247	0.9	1,183	0.9	1,121	1.1	2,431	1.5
90+	3,254	4.4	5,195	5.8	7,348	7.0	8,908	8.3	8,917	9.3	14,671	10.3	14,333	10.9	11,988	11.4	20,575	12.6
Distribution (Da	ıys)																	
Min	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
1st	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
3rd	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
5th	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
10th	1	-	1	-	1	-	1	-	1	-	1	-	1	-	3	-	7	-
20th	1	-	1	-	1	-	5	-	7	-	7	-	10	-	10	-	12	-
25th	1	-	1	-	5	-	7	-	10	-	10	-	11	-	14	-	15	-
50th	10	-	20	-	30	-	30	-	30	-	30	-	30	-	30	-	30	-
Mean	22.3	-	26.4	-	30.1	-	33.4	-	35.7	-	36.7	-	38.1	-	39.8	-	44.9	-
Median	10	-	20	-	30	-	30	-	30	-	30	-	30	-	30	-	30	-
Mode	1	-	30	-	30	-	30	-	30	-	30	-	30	-	30	-	30	-
75th	30	-	30	-	30	-	30	-	30	-	30	-	30	-	30	-	30	-
80th	30	-	30	-	30	-	30	-	30	-	30	-	33	-	40	-	60	-
90th	30	-	60	-	60	-	60	-	67	-	90	-	90	-	90	-	90	-
95th	60	-	90	-	90	-	90	-	94	-	97	-	115	-	120	-	149	-
97th	90	-	100	-	120	-	120	-	150	-	150	-	150	-	180	-	194	-
99th	180	-	210	-	240	-	270	-	270	-	270	-	281	-	304	-	367	-
Max	1,710	-	1,700	-	2,180	-	2,009	-	1,827		2,010	-	2,200		1,749		1,830	-



Table 10b. Distribution of Second and Subsequent Treatment Episode Duration of Metoclopramide among Female Members with Type 2 Diabetes and No Evidence of a Live Birth Delivery in the Sentinel Distributed Database between January 1, 2008 and September 30, 2015, by Age Group, for Episodes with Allowable Gaps of 0 Days

	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent
	40-44	Years	45-49	Years	50-54	Years	55-59	Years	60-64	Years	65-69	Years	70-74	Years	75-79	Years	* +08	Years
Total Episodes	24,263	100.0	34,046	100.0	46,077	100.0	53,455	100.0	51,174	100.0	74,235	100.0	70,440	100.0	56,423	100.0	77,245	100.0
Duration Group	s (Days)																	
1	7,169	29.5	7,825	23.0	8,250	17.9	7,712	14.4	6,285	12.3	8,220	11.1	6,678	9.5	4,197	7.4	3,422	4.4
2-7	1,892	7.8	2,484	7.3	3,041	6.6	3,340	6.2	3,332	6.5	4,589	6.2	4,165	5.9	3,678	6.5	5,124	6.6
8-14	1,529	6.3	2,464	7.2	3,306	7.2	3,678	6.9	3,888	7.6	6,225	8.4	5,930	8.4	5,317	9.4	7,795	10.1
15-21	1,233	5.1	2,021	5.9	2,777	6.0	3,737	7.0	3,463	6.8	5,445	7.3	5,428	7.7	4,367	7.7	6,658	8.6
22-28	718	3.0	1,355	4.0	1,839	4.0	2,085	3.9	2,126	4.2	2,896	3.9	2,830	4.0	2,061	3.7	3,511	4.5
29-45	8,795	36.2	13,319	39.1	19,785	42.9	23,750	44.4	22,711	44.4	32,859	44.3	31,464	44.7	25,063	44.4	33,229	43.0
46-60	1,186	4.9	1,825	5.4	2,807	6.1	3,552	6.6	3,397	6.6	4,930	6.6	4,914	7.0	4,203	7.4	6,425	8.3
61-89	166	0.7	230	0.7	331	0.7	514	1.0	507	1.0	744	1.0	705	1.0	666	1.2	1,230	1.6
90+	1,575	6.5	2,523	7.4	3,941	8.6	5,087	9.5	5,465	10.7	8,327	11.2	8,326	11.8	6,871	12.2	9,851	12.8
Distribution (Da	ıys)																	
Min	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
1st	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
3rd	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
5th	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	3	-
10th	1	-	1	-	1	-	1	-	1	-	1	-	3	-	5	-	7	-
20th	1	-	1	-	5	-	7	-	9	-	10	-	10	-	10	-	14	-
25th	1	-	4	-	8	-	10	-	12	-	14	-	15	-	15	-	15	-
50th	24	-	30	-	30	-	30	-	30	-	30	-	30	-	30	-	30	-
Mean	27.6	-	30.6	-	33.8	-	36.5	-	38.9	-	39.3	-	40.5	-	42.1	-	45.4	-
Median	24	-	30	-	30	-	30	-	30	-	30	-	30	-	30	-	30	-
Mode	30	-	30	-	30	-	30	-	30	-	30	-	30	-	30	-	30	-
75th	30	-	30	-	30	-	30	-	30	-	30	-	30	-	30	-	32	-
80th	30	-	30	-	30	-	30	-	33	-	38	-	45	-	56	-	60	-
90th	60	-	60	-	60	-	75	-	90	-	90	-	90	-	90	-	90	-
95th	90	-	90	-	90	-	93	-	120	-	120	-	120	-	120	-	150	-
97th	120	-	120	-	120	-	150	-	177	-	176	-	180	-	180	-	196	-
99th	235	-	240	-	267	-	270	-	300	-	300	-	300	-	330	-	360	-
Max	1,590	-	1,391	-	1,985	-	1,525	-	1,752	-	2,010	-	2,200	-	1,440	-	1,680	-



Table 10c. Distribution of Second and Subsequent Treatment Episode Duration of Metoclopramide among Female Members with Gastroparesis, Type 2 Diabetes, and No Evidence of a Live Birth Delivery in the Sentinel Distributed Database between January 1, 2008 and September 30, 2015, by Age Group, for Episodes with Allowable Gaps of 0 Days

	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent
	40-44	Years	45-49	Years	50-54	Years	55-59	Years	60-64	Years	65-69	Years	70-74	Years	75-79	Years	80+ Y	Years
Total Episodes	6,229	100.0	8,714	100.0	11,420	100.0	12,037	100.0	10,966	100.0	14,744	100.0	12,956	100.0	9,275	100.0	10,378	100.0
Duration Group	s (Days)																	
1	1,361	21.8	1,330	15.3	1,374	12.0	998	8.3	751	6.8	748	5.1	579	4.5	321	3.5	237	2.3
2-7	346	5.6	497	5.7	564	4.9	485	4.0	478	4.4	615	4.2	468	3.6	498	5.4	431	4.2
8-14	291	4.7	608	7.0	634	5.6	600	5.0	700	6.4	927	6.3	858	6.6	615	6.6	736	7.1
15-21	310	5.0	502	5.8	574	5.0	748	6.2	709	6.5	947	6.4	888	6.9	561	6.0	696	6.7
22-28	236	3.8	351	4.0	450	3.9	476	4.0	454	4.1	673	4.6	621	4.8	391	4.2	464	4.5
29-45	2,769	44.5	4,014	46.1	5,830	51.1	6,385	53.0	5,589	51.0	7,547	51.2	6,557	50.6	4,692	50.6	5,159	49.7
46-60	365	5.9	546	6.3	770	6.7	952	7.9	794	7.2	1,177	8.0	1,020	7.9	773	8.3	941	9.1
61-89	51	0.8	73	0.8	98	0.9	124	1.0	141	1.3	182	1.2	189	1.5	122	1.3	173	1.7
90+	500	8.0	793	9.1	1,126	9.9	1,269	10.5	1,350	12.3	1,928	13.1	1,776	13.7	1,302	14.0	1,541	14.8
Distribution (Da	ays)																	
Min	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
1st	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-
3rd	1	-	1	-	1	-	1	-	1	-	1	-	1	-	1	-	3	-
5th	1	-	1	-	1	-	1	-	1	-	1	-	3	-	5	-	7	-
10th	1	-	1	-	1	-	5	-	7	-	9	-	10	-	10	-	10	-
20th	1	-	7	-	10	-	15	-	15	-	20	-	20	-	20	-	20	-
25th	6	-	10	-	15	-	24	-	23	-	25	-	25	-	26	-	29	-
50th	30	-	30	-	30	-	30	-	30	-	30	-	30	-	30	-	30	-
Mean	32.9	-	35.4	-	37.7	-	41.1	-	42.7	-	44.3	-	45.2	-	46.6	-	50.4	-
Median	30	-	30	-	30	-	30	-	30	-	30	-	30	-	30	-	30	-
Mode	30	-	30	-	30	-	30	-	30	-	30	-	30	-	30	-	30	-
75th	30	-	30	-	30	-	30	-	30	-	30	-	33	-	36	-	50	-
80th	30	-	30	-	30	-	44	-	58	-	60	-	60	-	60	-	60	-
90th	60	-	60	-	81.5	-	90	-	90	-	90	-	90	-	90	-	90	-
95th	90	-	90	-	100	-	120	-	120	-	120	-	120	-	140	-	150	-
97th	127	-	139	-	150	-	150	-	180	-	180	-	180	-	180	-	210	-
99th	270	-	270	-	267	-	308	-	300	-	302	-	300	-	332	-	404	-
Max	1,557	-	1,200	-	1,088	-	986	-	1,752	-	1,431	-	2,200	-	1,176	-	1,319	



Table 11a. Distribution of Treatment Episode Duration, for Episodes Greater than 12 Weeks, of Metoclopramide among Female Members with No Evidence of a Live Birth Delivery in the Sentinel Distributed Database between January 1, 2008 and September 30, 2015, by Age Group, for Episodes with Allowable Gaps of 50% of the Prior Dispensing

	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent
	40-44	Years	45-49	Years	50-54	Years	55-59	Years	60-64	Years	65-69	Years	70-74	Years	75-79	Years	408	Years
Total Episodes	5,560	100.0	8,416	100.0	11,580	100.0	13,870	100.0	13,836	100.0	22,106	100.0	21,654	100.0	18,504	100.0	34,830	100.0
Duration Group	os (Days)																	
85-89	87	1.6	115	1.4	148	1.3	204	1.5	198	1.4	321	1.5	293	1.4	267	1.4	652	1.9
90+	5,473	98.4	8,301	98.6	11,432	98.7	13,666	98.5	13,638	98.6	21,785	98.5	21,361	98.6	18,237	98.6	34,178	98.1
Distribution (D	ays)																	
Min	85	-	85	-	85	-	85	-	85	-	85	-	85	-	85	-	85	-
1st	87	-	88	-	88	-	88	-	88	-	87	-	88	-	88	-	87	-
3rd	90	-	90	-	90	-	90	-	90	-	90	-	90	-	90	-	90	-
5th	90	-	90	-	90	-	90	-	90	-	90	-	90	-	90	-	90	-
10th	90	-	90	-	90	-	90	-	90	-	90	-	90	-	90	-	90	-
20th	92	-	91	-	91	-	90	-	91	-	90	-	90	-	90	-	95	-
25th	96	-	95	-	96	-	95	-	95	-	92	-	93	-	95	-	102	-
50th	129	-	128	-	131	-	131	-	133	-	130	-	132	-	138	-	152	-
Mean	198.6	-	205.2	-	208.2	-	208.0	-	209.4	-	207.2	-	208.1	-	213.4	-	228.4	-
Median	129	-	128	-	131	-	131	-	133	-	130	-	132	-	138	-	152	-
Mode	90	-	90	-	90	-	90	-	90	-	90	-	90	-	90	-	90	-
75th	212	-	217	-	222	-	224	-	226	-	225	-	228	-	240	-	268	-
80th	247	-	257	-	264	-	268	-	270	-	270	-	270	-	280	-	307	-
90th	382	-	407	-	408	-	403	-	407	-	409	-	419	-	427	-	466	-
95th	555.5	-	606	-	599	-	592	-	611	-	597	-	589	-	602	-	642	-
97th	702	-	746	-	773	-	749	-	764	-	753	-	744	-	750	-	789	-
99th	981	-	1112	-	1137	-	1156	-	1124	-	1074	-	1047	-	1066	-	1085	-
Max	2,104	-	2,261	-	2,410	-	2,630	-	2,678	-	2,739	-	2,758	-	2,481	-	2,418	-



Table 11b. Distribution of Treatment Episode Duration, for Episodes Greater than 12 Weeks, of Metoclopramide among Female Members with Type 2 Diabetes and No Evidence of a Live Birth Delivery in the Sentinel Distributed Database between January 1, 2008 and September 30, 2015, by Age Group, for Episodes with Allowable Gaps of 50% of the Prior Dispensing

	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent
	40-44	Years	45-49	Years	50-54	Years	55-59	Years	60-64	Years	65-69	Years	70-74	Years	75-79	Years	80+ Y	Years
Total Episodes	2,363	100.0	3,860	100.0	5,869	100.0	7,714	100.0	8,141	100.0	12,501	100.0	12,527	100.0	10,790	100.0	16,977	100.0
Duration Grou	os (Days)																	
85-89	31	1.3	53	1.4	60	1.0	121	1.6	101	1.2	185	1.5	176	1.4	150	1.4	321	1.9
90+	2,332	98.7	3,807	98.6	5,809	99.0	7,593	98.4	8,040	98.8	12,316	98.5	12,351	98.6	10,640	98.6	16,656	98.1
Distribution (D	ays)																	
Min	85	-	85	-	85	-	85	-	85	-	85	-	85	-	85	-	85	-
1st	88	-	87	-	89	-	87	-	88	-	87	-	88	-	88	-	87	-
3rd	90	-	90	-	90	-	90	-	90	-	90	-	90	-	90	-	90	-
5th	90	-	90	-	90	-	90	-	90	-	90	-	90	-	90	-	90	-
10th	90	-	90	-	90	-	90	-	90	-	90	-	90	-	90	-	90	-
20th	92	-	91	-	92	-	91	-	91	-	90	-	90	-	91	-	95	-
25th	97	-	95	-	98	-	95	-	96	-	94	-	95	-	97	-	102	-
50th	134	-	128	-	134	-	133	-	135	-	134	-	137	-	141	-	151	-
Mean	204.9	-	205.4	-	210.6	-	205.4	-	211.8	-	209.2	-	209.4	-	212.9	-	224.7	-
Median	134	-	128	-	134	-	133	-	135	-	134	-	137	-	141	-	151	-
Mode	90	-	90	-	90	-	90	-	90	-	90	-	90	-	90	-	90	-
75th	222	-	224	-	227	-	224	-	231	-	231	-	236	-	240	-	263	-
80th	269	-	266	-	270	-	269	-	273	-	270	-	274	-	280	-	302	-
90th	411	-	405.5	-	420	-	399	-	418	-	409	-	424	-	422	-	455	-
95th	577	-	602	-	611	-	576	-	614	-	590	-	584	-	590	-	629	-
97th	703	-	736	-	780	-	722	-	771	-	752	-	723	-	727	-	753	-
99th	980	-	1044	-	1102	-	1072	-	1082	-	1074	-	982	-	1030	-	1049	-
Max	1,672	-	2,261	-	1,985	-	2,444	-	2,279	-	2,739	-	2,758	-	2,481	-	2,005	-



Table 11c. Distribution of Treatment Episode Duration, for Episodes Greater than 12 Weeks, of Metoclopramide among Female Members with Gastroparesis, Type 2 Diabetes, and No Evidence of a Live Birth Delivery in the Sentinel Distributed Database between January 1, 2008 and September 30, 2015, by Age Group, for Episodes with Allowable Gaps of 50% of the Prior Dispensing

	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent
	40-44	Years	45-49	Years	50-54	Years	55-59	Years	60-64	Years	65-69	Years	70-74	Years	75-79	Years	408	Years
Total Episodes	744	100.0	1,217	100.0	1,640	100.0	2,008	100.0	2,033	100.0	2,837	100.0	2,688	100.0	2,006	100.0	2,528	100.0
Duration Grou	ps (Days)																	
85-89	****	****	18	1.5	15	0.9	33	1.6	22	1.1	43	1.5	42	1.6	14	0.7	49	1.9
90+	****	****	1,199	98.5	1,625	99.1	1,975	98.4	2,011	98.9	2,794	98.5	2,646	98.4	1,992	99.3	2,479	98.1
Distribution (D	ays)																	
Min	85	-	85	-	85	-	85	-	85	-	85	-	85	-	85	-	85	-
1st	90	-	87	-	90	-	87	-	89	-	87	-	87	-	90	-	87	-
3rd	90	-	90	-	90	-	90	-	90	-	90	-	90	-	90	-	90	-
5th	90	-	90	-	90	-	90	-	90	-	90	-	90	-	90	-	90	-
10th	90	-	90	-	90	-	90	-	90	-	90	-	90	-	90	-	90	-
20th	95	-	90	-	93	-	91	-	91	-	90	-	90	-	92	-	95	-
25th	98	-	94	-	99	-	95	-	97	-	95	-	96	-	99	-	101	-
50th	137	-	124	-	135	-	130.5	-	133	-	134	-	133	-	147	-	148	-
Mean	203.7	-	194.4	-	207.4	-	200.5	-	201.5	-	211.1	-	202.3	-	212.3	-	224.7	-
Median	137	-	124	-	135	-	130.5	-	133	-	134	-	133	-	147	-	148	-
Mode	90	-	90	-	90	-	90	-	90	-	90	-	90	-	90	-	90	-
75th	217.5	-	212	-	222.5	-	220	-	226	-	231	-	220	-	243	-	255.5	-
80th	266	-	248	-	257	-	257	-	264	-	270	-	254	-	277	-	301	-
90th	396	-	374	-	402	-	390	-	385	-	416	-	412	-	420	-	469	-
95th	546	-	570	-	599.5	-	560	-	558	-	611	-	584	-	572	-	634	-
97th	678	-	638	-	746	-	689	-	700	-	787	-	684	-	695	-	782	-
99th	1076	-	1018	-	1110	-	981	-	975	-	1108	-	962	-	985	-	1070	-
Max	1,606	-	2,261	-	1,788	-	2,243	-	1,825	-	2,141	-	2,758	-	2,018	-	1,508	-

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



Table 12a. Distribution of Treatment Episode Duration, for Episodes Greater than 12 Weeks, of Metoclopramide among Female Members with No Evidence of a Live Birth Delivery in the Sentinel Distributed Database between January 1, 2008 and September 30, 2015, by Age Group, for Episodes with Allowable Gaps of 0 Days

	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent
	40-44	Years	45-49	Years	50-54	Years	55-59	Years	60-64	Years	65-69	Years	70-74	Years	75-79	Years	80+	Years
Total Episodes	4,445	100.0	7,023	100.0	9,833	100.0	12,104	100.0	12,348	100.0	20,654	100.0	20,274	100.0	17,308	100.0	31,901	100.0
Duration Group	os (Days)																	
85-89	50	1.1	75	1.1	78	0.8	133	1.1	146	1.2	231	1.1	209	1.0	210	1.2	518	1.6
90+	4,395	98.9	6,948	98.9	9,755	99.2	11,971	98.9	12,202	98.8	20,423	98.9	20,065	99.0	17,098	98.8	31,383	98.4
Distribution (D	ays)																	
Min	85	-	85	-	85	-	85	-	85	-	85	-	85	-	85	-	85	-
1st	88	-	89	-	90	-	89	-	88	-	88	-	89	-	88	-	88	-
3rd	90	-	90	-	90	-	90	-	90	-	90	-	90	-	90	-	90	-
5th	90	-	90	-	90	-	90	-	90	-	90	-	90	-	90	-	90	-
10th	90	-	90	-	90	-	90	-	90	-	90	-	90	-	90	-	90	-
20th	90	-	90	-	90	-	90	-	90	-	90	-	90	-	90	-	90	-
25th	90	-	90	-	90	-	90	-	90	-	90	-	90	-	90	-	90	-
50th	100	-	100	-	100	-	100	-	100	-	91	-	100	-	105	-	120	-
Mean	162.9	-	163.7	-	164.4	-	162.6	-	163.2	-	157.6	-	157.0	-	162.4	-	180.2	-
Median	100	-	100	-	100	-	100	-	100	-	91	-	100	-	105	-	120	-
Mode	90	-	90	-	90	-	90	-	90	-	90	-	90	-	90	-	90	-
75th	180	-	180	-	180	-	180	-	180	-	180	-	180	-	180	-	195	-
80th	182.5	-	180	-	180	-	180	-	190	-	180	-	180	-	189	-	228	-
90th	300	-	300	-	300	-	299	-	300	-	270	-	270	-	300	-	345	-
95th	420	-	448	-	443	-	420	-	422	-	401	-	399	-	423	-	482	-
97th	540	-	570	-	570	-	540	-	540	-	510	-	510	-	533	-	600	-
99th	883	-	885	-	876	-	856	-	817	-	802	-	773	-	803	-	890	-
Max	1,710	-	1,700	-	2,180	-	2,460	-	1,827	-	2,039	-	2,200	-	1,788	-	1,830	-



Table 12b. Distribution of Treatment Episode Duration, for Episodes Greater than 12 Weeks, of Metoclopramide among Female Members with Type 2 Diabetes and No Evidence of a Live Birth Delivery in the Sentinel Distributed Database between January 1, 2008 and September 30, 2015, by Age Group, for Episodes with Allowable Gaps of 0 Days

	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent
	40-44	Years	45-49	Years	50-54	Years	55-59	Years	60-64	Years	65-69	Years	70-74	Years	75-79	Years	408	Years
Total Episodes	2,034	100.0	3,320	100.0	5,163	100.0	6,746	100.0	7,401	100.0	11,654	100.0	11,624	100.0	9,960	100.0	15,304	100.0
Duration Group	os (Days)																	
85-89	22	1.1	43	1.3	39	0.8	87	1.3	86	1.2	142	1.2	136	1.2	128	1.3	249	1.6
90+	2,012	98.9	3,277	98.7	5,124	99.2	6,659	98.7	7,315	98.8	11,512	98.8	11,488	98.8	9,832	98.7	15,055	98.4
Distribution (D	ays)																	
Min	85	-	85	-	85	-	85	-	85	-	85	-	85	-	85	-	85	-
1st	89	-	88	-	90	-	88	-	88	-	88	-	88	-	88	-	88	-
3rd	90	-	90	-	90	-	90	-	90	-	90	-	90	-	90	-	90	-
5th	90	-	90	-	90	-	90	-	90	-	90	-	90	-	90	-	90	-
10th	90	-	90	-	90	-	90	-	90	-	90	-	90	-	90	-	90	-
20th	90	-	90	-	90	-	90	-	90	-	90	-	90	-	90	-	90	-
25th	90	-	90	-	90	-	90	-	90	-	90	-	90	-	90	-	90	-
50th	105	-	100	-	100	-	100	-	103	-	100	-	102	-	120	-	120	-
Mean	161.4	-	161.2	-	162.6	-	158.6	-	163.7	-	160.3	-	159.3	-	164.5	-	179.2	-
Median	105	-	100	-	100	-	100	-	103	-	100	-	102	-	120	-	120	-
Mode	90	-	90	-	90	-	90	-	90	-	90	-	90	-	90	-	90	-
75th	180	-	180	-	180	-	180	-	180	-	180	-	180	-	180	-	194	-
80th	181	-	186.5	-	180	-	180	-	199	-	181	-	180	-	202	-	224	-
90th	300	-	288	-	300	-	291	-	300	-	286	-	280	-	300	-	336	-
95th	420	-	420.5	-	443	-	405	-	429	-	410	-	420	-	430.5	-	480	-
97th	540	-	553	-	552	-	510	-	540	-	520	-	522	-	540	-	600	-
99th	764	-	802	-	861	-	765	-	810	-	800	-	766	-	794	-	856	-
Max	1,672	-	1,584	-	1,985	-	1,680	-	1,752	-	2,010	-	2,200	-	1,788	-	1,800	-



Table 12c. Distribution of Treatment Episode Duration, for Episodes Greater than 12 Weeks, of Metoclopramide among Female Members with Gastroparesis, Type 2 Diabetes, and No Evidence of a Live Birth Delivery in the Sentinel Distributed Database between January 1, 2008 and September 30, 2015, by Age Group, for Episodes with Allowable Gaps of 0 Days

	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent
	40-44	Years	45-49	Years	50-54	Years	55-59	Years	60-64	Years	65-69	Years	70-74	Years	75-79	Years	¥0+ °	Years
Total Episodes	642	100.0	1,046	100.0	1,451	100.0	1,694	100.0	1,813	100.0	2,657	100.0	2,438	100.0	1,863	100.0	2,323	100.0
Duration Grou	os (Days)¹																	
85-89	****	****	15	1.4	****	****	24	1.4	20	1.1	33	1.2	33	1.4	18	1.0	39	1.7
90+	****	****	1,031	98.6	****	****	1,670	98.6	1,793	98.9	2,624	98.8	2,405	98.6	1,845	99.0	2,284	98.3
Distribution (D	ays)																	
Min	85	-	85	-	85	-	85	-	85	-	85	-	85	-	85	-	85	-
1st	90	-	88	-	90	-	87	-	89	-	88	-	88	-	90	-	87	-
3rd	90	-	90	-	90	-	90	-	90	-	90	-	90	-	90	-	90	-
5th	90	-	90	-	90	-	90	-	90	-	90	-	90	-	90	-	90	-
10th	90	-	90	-	90	-	90	-	90	-	90	-	90	-	90	-	90	-
20th	90	-	90	-	90	-	90	-	90	-	90	-	90	-	90	-	90	-
25th	90	-	90	-	90	-	90	-	90	-	90	-	90	-	90	-	90	-
50th	110	-	100	-	100	-	105	-	100	-	100	-	100.5	-	120	-	120	-
Mean	160.3	-	156.2	-	156.2	-	157.2	-	155.8	-	157.9	-	155.4	-	163.5	-	175.1	-
Median	110	-	100	-	100	-	105	-	100	-	100	-	100.5	-	120	-	120	-
Mode	90	-	90	-	90	-	90	-	90	-	90	-	90	-	90	-	90	-
75th	180	-	180	-	180	-	180	-	170	-	180	-	180	-	180	-	180	-
80th	195	-	180	-	180	-	180	-	180	-	180	-	180	-	209	-	217	-
90th	300	-	277	-	270	-	300	-	276	-	273	-	270	-	300	-	332	-
95th	412	-	416	-	390	-	410	-	390	-	413	-	390	-	416	-	469	-
97th	461	-	515	-	535	-	496	-	490	-	531	-	480	-	520	-	600	-
99th	722	-	645	-	755	-	773	-	752	-	725	-	764	-	736	-	840	-
Max	1,557	-	1,200	-	1,400	-	986	-	1,752	-	1,830	-	2,200	-	1,364	-	1,508	-

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



Table 13a. Descriptive Statistics for Gaps (in Days) between Treatment Episodes of Metoclopramide among Female Members with No Evidence of a Live Birth Delivery in the Sentinel Distributed Database between January 1, 2008 and September 30, 2015, by Age Group, for Episodes with Allowable Gaps of 50% of the Prior Dispensing

Gap Number ¹	Number	Percent	Median	Mean	Standard Deviation
Age Group: 40-44 years					
Total Episodes	186,743	100.0	295	525.4	595.5
1	28,117	15.1	138	309.3	409.2
2	11,829	6.3	83	200.3	288.3
3	6,425	3.4	62	152.6	228.7
4	4,000	2.1	53	125.8	189.8
5	2,694	1.4	47	114.5	187.0
6	1,913	1.0	45	97.1	156.9
Age Group: 45-49 years					
Total Episodes	207,269	100.0	292	531.4	605.1
1	31,680	15.3	128	302.8	403.8
2	13,534	6.5	78	200.7	299.6
3	7,637	3.7	60	143.8	217.7
4	4,789	2.3	50	116.4	179.8
5	3,307	1.6	46	106.7	178.2
6	2,317	1.1	43	92.1	146.1
Age Group: 50-54 years					
Total Episodes	235,422	100.0	282	526.5	605.7
1	35,380	15.0	111	286.8	401.6
2	15,154	6.4	66	178.6	274.4
3	8,638	3.7	55	136.0	217.8
4	5,595	2.4	49	110.8	178.1
5	3,909	1.7	44	96.7	151.0
6	2,791	1.2	41	88.1	139.5
Age Group: 55-59 years					
Total Episodes	224,722	100.0	255	501.4	590.6
1	34,418	15.3	96	265.9	382.2
2	15,169	6.8	61	168.1	265.1
3	8,720	3.9	51	126.6	209.2
4	5,596	2.5	45	100.1	167.0
5	3,904	1.7	42	90.1	146.7
6	2,805	1.2	41	76.7	107.5
Age Group: 60-64 years					
Total Episodes	198,106	100.0	231	457.0	544.8
1	30,179	15.2	80	236.6	346.3
2	13,246	6.7	55	150.6	237.0
3	7,533	3.8	48	115.9	184.3
4	4,783	2.4	42	94.5	152.1
				00.0	1000
5	3,227	1.6	40	80.6	126.2

cder_mpl1r_wp089 Page 46 of 79



Table 13a. Descriptive Statistics for Gaps (in Days) between Treatment Episodes of Metoclopramide among Female Members with No Evidence of a Live Birth Delivery in the Sentinel Distributed Database between January 1, 2008 and September 30, 2015, by Age Group, for Episodes with Allowable Gaps of 50% of the Prior Dispensing

Gap Number ¹	Number	Percent	Median	Mean	Standard Deviation
Age Group: 65-69 years					
Total Episodes	311,981	100.0	280	494.8	545.6
1	46,529	14.9	86	247.0	349.7
2	19,416	6.2	57	153.1	240.2
3	10,778	3.5	48	114.7	185.4
4	6,779	2.2	45	96.0	151.9
5	4,571	1.5	41	82.9	124.1
6	3,236	1.0	39	76.6	124.5
Age Group: 70-74 years					
Total Episodes	284,598	100.0	293	503.3	546.2
1	42,198	14.8	83	242.2	341.5
2	17,341	6.1	55	147.1	230.5
3	9,618	3.4	48	110.9	174.1
4	6,088	2.1	41	90.7	143.2
5	4,083	1.4	39	80.3	127.8
6	2,843	1.0	38	72.0	108.7
Age Group: 75-79 years					
Total Episodes	214,807	100.0	267	491.4	548.2
1	32,362	15.1	71	218.4	320.4
2	13,723	6.4	52	139.0	218.2
3	7,526	3.5	44	104.7	168.3
4	4,725	2.2	41	86.1	133.6
5	3,189	1.5	37	75.3	119.5
6	2,251	1.0	35	66.4	92.9
Age Group: 80+ years					
Total Episodes	299,385	100.0	180	417.8	509.3
1	45,245	15.1	54	172.3	270.7
2	19,327	6.5	43	112.5	182.1
3	10,590	3.5	38	90.9	149.5
4	6,548	2.2	36	75.1	116.6
5	4,378	1.5	34	68.9	110.2
6	3,055	1.0	33	63.3	104.1

¹ Gap number indicates the sequential number of the gaps identified between episodes. The number of episodes with a gap of 1, represents members with at least two episodes. Note only the first 6 episodes are presented in this table.

cder_mpl1r_wp089 Page 47 of 79



Table 13b. Descriptive Statistics for Gaps (in Days) between Treatment Episodes of Metoclopramide among Female Members with Type 2 Diabetes and No Evidence of a Live Birth Delivery in the Sentinel Distributed Database between January 1, 2008 and September 30, 2015, by Age Group, for Episodes with Allowable Gaps of 50% of the Prior Dispensing

Total Episodes 42,221 100.0 183 395.6 496.1 1 7,797 18.5 119 272.1 362.8 2 3,921 9.3 77 185.4 270.9 3 2,283 5.4 57 145.8 222.7 4 1,458 3.5 51 116.0 171.2 5 1,004 2.4 47 105.6 172.8 6 730 1.7 46 87.4 124.2 Age Group: 45-49 years Total Episodes 57,067 100.0 183 408.3 511.5 1 10,313 18.1 111 269.9 361.5 2 5,146 9.0 71 182.8 270.2 3 3,080 5.4 55 133.5 202.7 4 1,996 3.5 49 108.5 166.2 5 1,414 2.5 44 95.6 150.1 6 1,001 18 42 89.4 145.1 6 1,001 18 42 89.4 145.1 Age Group: 50-54 years Total Episodes 75,755 100.0 178 408.0 516.4 1 13,357 17.6 97 251.8 349.7 2 6,586 8.7 63 165.3 251.2 3 3,980 5.3 54 106.4 166.8 5 1,888 2.5 44 91.4 136.2 6 1,22 18.8 41 84.0 118.3 Age Group: 55-59 years Total Episodes 87,566 100.0 173 406.5 513.0 1 15,361 17.5 89 237.3 337.4 2 7,460 8.5 60 156.8 244.9 3 4,441 5.1 51 120.5 192.8 44.9 4 2,902 3.3 44 94.6 146.8 54.4 3 4,441 5.1 51 120.5 192.8 44.9 4 2,902 3.3 44 94.6 146.8 55.5 130.0 1 15,361 17.5 89 237.3 337.4 2 7,460 8.5 60 156.8 244.9 3 4,441 5.1 51 120.5 192.8 44.9 4 2,902 3.3 44 94.6 146.8 55.5 130.0 1 15,361 17.5 89 237.3 337.4 2 7,460 8.5 60 156.8 244.2 3 4,441 5.1 51 120.5 192.8 44.2 3 4,441 5.1 51 120.5 192.8 44.2 3 4,441 5.1 51 120.5 192.8 44.2 3 4,441 5.1 51 120.5 192.8 44.2 3 4,441 5.1 51 120.5 192.8 44.2 3 4,441 5.1 51 120.5 192.8 44.2 3 4,441 5.1 51 120.5 192.8 44.2 3 4,441 5.1 51 120.5 192.8 44.2 3 4,441 5.1 51 120.5 192.8 44.2 3 4,441 5.1 51 120.5 192.8 44.2 3 4,441 5.1 51 120.5 192.8 44.2 4 2,902 3.3 44 94.6 146.8 137.4 6 1,458 17.7 77 223.0 326.1 2 7,460 8.5 60 156.8 244.2 3 4,483 4.8 49 113.9 177.1 4 2,699 3.1 42 95.5 146.5 228.8 13.4 49 113.9 177.1 4 2,699 3.1 42 95.5 146.5 228.8 13.9 177.1 4 2,699 3.1 42 95.9 133.9 177.1	Gap Number ¹	Number	Percent	Median	Mean	Standard Deviation
1	Age Group: 40-44 years					
2 3,921 9.3 77 185.4 270.9 3 2,283 5.4 57 145.8 222.7 4 1,458 3.5 51 116.0 171.2 5 1,004 2.4 47 105.6 172.8 6 730 1.7 46 87.4 124.2 Age Group: 45-49 years Total Episodes 57,067 100.0 183 408.3 511.5 1 10,313 18.1 111 269.9 361.5 2 5,146 9.0 71 182.8 270.2 3 3,080 5.4 55 133.5 202.7 4 1,996 3.5 49 108.5 166.2 5 1,414 2.5 44 95.6 150.1 6 1,001 1.8 42 89.4 145.1 Total Episodes 75,755 100.0 178 408.0 516.4	Total Episodes	42,221	100.0	183	395.6	496.1
3 2,283 5,4 57 145.8 222.7 4 1,458 3.5 51 116.0 171.2 5 1,004 2,4 47 105.6 172.8 6 730 1.7 46 87.4 124.2 Age Group: 45-49 years Total Episodes 57,067 100.0 183 408.3 511.5 1 10,313 18.1 111 269.9 351.5 2 5,146 9.0 71 182.8 270.2 3 3,080 5.4 55 133.5 202.7 4 1,1996 3.5 49 108.5 166.2 5 1,414 2.5 44 95.6 150.1 6 1,001 1.8 42 89.4 145.1 Age Croup: 50-54 years Total Episodes 75,755 100.0 178 408.0 516.4 1 13,357 17.6<	1	7,797	18.5	119	272.1	362.8
4 1,458 3.5 51 116.0 171.2 5 1,004 2.4 47 105.6 172.8 6 730 1.7 46 87.4 124.2 Age Group: 45-49 years Total Episodes 57,067 100.0 183 408.3 511.5 1 10,313 18.1 111 269.9 361.5 2 5,146 9.0 71 182.8 270.2 4 1,996 3.5 49 108.5 166.2 5 1,414 2.5 44 95.6 150.1 6 1,001 1.8 42 89.4 145.1 Age Group: 50-54 years Total Episodes 75,755 100.0 178 408.0 516.4 1 13,357 17.6 97 251.8 349.7 2 6,586 8.7 63 165.3 251.2 3 3,980 5.3 54 124.8 192	2	3,921	9.3	77	185.4	270.9
5 1,004 2.4 47 105.6 172.8 6 730 1.7 46 87.4 124.2 Age Group: 45-49 years 36 87.4 124.2 Total Episodes 57,067 100.0 183 408.3 511.5 1 10,313 18.1 111 269.9 361.5 2 5,146 9.0 71 182.8 270.2 3 3,080 5.4 55 133.5 202.7 4 1,996 3.5 49 108.5 166.2 5 1,414 2.5 44 95.6 150.1 6 1,001 1.8 42 89.4 145.1 Age Group: 50-54 years 7 75.755 100.0 178 408.0 516.4 1 13,357 17.6 97 251.8 349.7 2 6,586 8.7 63 165.3 251.2 3 3,980 5.3 <th< td=""><td>3</td><td>2,283</td><td>5.4</td><td>57</td><td>145.8</td><td>222.7</td></th<>	3	2,283	5.4	57	145.8	222.7
6 730 1.7 46 87.4 124.2 Age Group: 45-49 years Total Episodes 57,067 100.0 183 408.3 511.5 1 10,313 18.1 111 269.9 361.5 2 5,146 9.0 71 182.8 270.2 3 3,080 5.4 55 133.5 202.7 4 1,996 3.5 49 108.5 166.2 5 1,414 2.5 44 95.6 150.1 6 1,001 1.8 42 89.4 145.1 Age Group: 50-54 years Total Episodes 75,755 100.0 178 408.0 516.4 1 13,357 17.6 97 251.8 349.7 2 6,586 8.7 63 165.3 251.2 3 3,980 5.3 54 124.8 192.0 4 2,636 3.5 48	4	1,458	3.5	51	116.0	171.2
Age Group: 45-49 years Total Episodes 57,067 100.0 183 408.3 511.5 1 10,313 18.1 111 269.9 361.5 2 5,146 9.0 71 182.8 270.2 3 3,080 5.4 55 133.5 202.7 4 1,996 3.5 49 108.5 166.2 5 1,414 2.5 44 95.6 150.1 6 1,001 1.8 42 89.4 145.1 Age Group: 50-54 years Total Episodes 75,755 100.0 178 408.0 516.4 1 13,357 17.6 97 251.8 349.7 2 6,586 8.7 63 165.3 251.2 3 3,980 5.3 54 124.8 192.0 4 2,636 3.5 48 106.4 166.8 55 1,858 25 44 91.4 136.2 6 1,329 1.8 41 84.0 118.3 Age Group: 55-59 years Total Episodes 87,566 100.0 173 406.5 513.0 1 15,361 17.5 89 237.3 337.4 2 7,460 8.5 60 156.8 244.2 3 4,441 5.1 51 51 120.5 192.8 44.2 3 4,441 5.1 51 51 120.5 192.8 44.2 3 4,441 5.1 51 51 120.5 192.8 45.2 4 2,902 3.3 44 94.6 146.8 55 60 156.8 244.2 3 4,441 5.1 51 51 120.5 192.8 66 1,458 17.4 66 1,458 17.4 66 1,458 17.4 60 156.8 244.2 3 4,441 5.1 51 51 120.5 192.8 66 1,458 17.4 60 166.8 137.4 66 1,458 17.4 60 156.8 244.2 3 4,441 5.1 51 51 120.5 192.8 66 1,458 17.4 60 156.8 244.2 3 4,441 5.1 51 51 120.5 192.8 66 1,458 17.4 60 166.8 137.4 166.8 137.4 166.9 17.5 192.8 166.9 156.8 244.2 166.8 17.4 1	5	1,004	2.4	47	105.6	172.8
Total Episodes 57,067 100.0 183 408.3 511.5 1 10,313 18.1 111 269.9 361.5 2 5,146 9.0 71 182.8 270.2 3 3,080 5.4 55 133.5 202.7 4 1,996 3.5 49 108.5 166.2 5 1,414 2.5 44 95.6 150.1 6 1,001 1.8 42 89.4 145.1 Age Group: 50-54 years Total Episodes 75,755 100.0 178 408.0 516.4 1 13,357 17.6 97 251.8 349.7 2 6,586 8.7 63 165.3 251.2 3 3,980 5.3 54 124.8 192.0 4 2,636 3.5 48 106.4 166.8 5 1,858 2.5 44 91.4 136.2	6	730	1.7	46	87.4	124.2
1 10,313 18.1 111 269.9 361.5 2 5,146 9.0 71 182.8 270.2 3 3,080 5.4 55 133.5 202.7 4 1,996 3.5 49 108.5 166.2 5 1,414 2.5 44 95.6 150.1 6 1,001 1.8 42 89.4 145.1 Age Group: 50-54 years Total Episodes 75,755 100.0 178 408.0 516.4 1 1 13,357 17.6 97 251.8 349.7 2 6,586 8.7 63 165.3 251.2 3 3,980 5.3 54 124.8 192.0 4 2,636 3.5 48 106.4 166.8 5 1,858 2.5 44 91.4 136.2 6 1,329 1.8 41 84.0 118.3 Age Group: 55-59 years Total Episodes 87,566 100.0 173 406.5 513.0 1 1 15,361 17.5 89 237.3 337.4 2 7,460 8.5 60 156.8 244.2 3 4,441 5.1 51 120.5 192.8 4 2,902 3.3 44 94.6 146.8 5 2,031 2.3 43 88.6 137.4 6 1,458 1.7 40 75.6 107.3 Age Group: 66-64 years Total Episodes 86,524 100.0 169 394.0 495.2 1 14,885 17.2 77 223.0 326.1 2 7,097 8.2 55 146.5 228.8 3 4,183 4.8 49 113.9 177.1 4 2,659 3.1 42 95.9 153.2 5 1,804 2.1 40 80.9 124.9	Age Group: 45-49 years					
2 5,146 9.0 71 182.8 270.2 3 3,080 5.4 55 133.5 202.7 4 1,996 3.5 49 108.5 166.2 5 1,414 2.5 44 95.6 150.1 6 1,001 1.8 42 89.4 145.1 Age Group: 50-54 years Total Episodes 75,755 100.0 178 408.0 516.4 1 13,357 17.6 97 251.8 349.7 2 6,586 8.7 63 165.3 251.2 3 3,980 5.3 54 124.8 192.0 4 2,636 3.5 48 106.4 166.8 5 1,858 2.5 44 91.4 136.2 6 1,329 1.8 41 84.0 118.3 Age Group: 55-59 years Total Episodes 87,566 100.0	Total Episodes	57,067	100.0	183	408.3	511.5
3 3,080 5.4 55 133.5 202.7 4 1,996 3.5 49 108.5 166.2 5 1,414 2.5 44 95.6 150.1 6 1,001 1.8 42 89.4 145.1 Age Group: 50-54 years Total Episodes 75,755 100.0 178 408.0 516.4 1 13,357 17.6 97 251.8 349.7 2 6,586 8.7 63 165.3 251.2 3 3,980 5.3 54 124.8 192.0 4 2,636 3.5 48 106.4 166.8 5 1,858 2.5 44 91.4 136.2 6 1,329 1.8 41 84.0 118.3 Age Group: 55-59 years Total Episodes 87,566 100.0 173 406.5 513.0 1 15,361 17.5	1	10,313	18.1	111	269.9	361.5
4 1,996 3.5 49 108.5 166.2 5 1,414 2.5 44 95.6 150.1 6 1,001 1.8 42 89.4 145.1 Age Group: 50-54 years Total Episodes 75,755 100.0 178 408.0 516.4 1 13,357 17.6 97 251.8 349.7 2 6,586 8.7 63 165.3 251.2 3 3,980 5.3 54 124.8 192.0 4 2,636 3.5 48 106.4 166.8 5 1,858 2.5 44 91.4 136.2 6 1,329 1.8 41 84.0 118.3 Age Group: 55-59 years Total Episodes 87,566 100.0 173 406.5 513.0 1 15,361 17.5 89 237.3 337.4 2 7,460 8.5 60 156.8 244.2 3 4,441 5.1	2	5,146	9.0	71	182.8	270.2
5 1,414 2.5 44 95.6 150.1 6 1,001 1.8 42 89.4 145.1 Age Group: 50-54 years Total Episodes 75,755 100.0 178 408.0 516.4 1 13,357 17.6 97 251.8 349.7 2 6,586 8.7 63 165.3 251.2 3 3,980 5.3 54 124.8 192.0 4 2,636 3.5 48 106.4 166.8 5 1,858 2.5 44 91.4 136.2 6 1,329 1.8 41 84.0 118.3 Age Group: 55-59 years Total Episodes 87,566 100.0 173 406.5 513.0 1 15,361 17.5 89 237.3 337.4 2 7,460 8.5 60 156.8 244.2 3 4,441 5.1 51	3	3,080	5.4	55	133.5	202.7
6 1,001 1.8 42 89.4 145.1 Age Group: 50-54 years Total Episodes 75,755 100.0 178 408.0 516.4 1 13,357 17.6 97 251.8 349.7 2 6,586 8.7 63 165.3 251.2 3 3,980 5.3 54 124.8 192.0 4 2,636 3.5 48 106.4 166.8 5 1,858 2.5 44 91.4 136.2 6 1,329 1.8 41 84.0 183 Ase Group: 55-59 years Total Episodes 87,566 100.0 173 406.5 513.0 1 15,361 17.5 89 237.3 337.4 2 7,460 8.5 60 156.8 244.2 3 4,441 5.1 51 120.5 192.8 4 2,902 3.3 44 94.6 <td>4</td> <td>1,996</td> <td>3.5</td> <td>49</td> <td>108.5</td> <td>166.2</td>	4	1,996	3.5	49	108.5	166.2
Age Group: 50-54 years Total Episodes 75,755 100.0 178 408.0 516.4 1 13,357 17.6 97 251.8 349.7 2 6,586 8.7 63 165.3 251.2 3 3,980 5.3 54 124.8 192.0 4 2,636 3.5 48 106.4 166.8 5 1,858 2.5 44 91.4 136.2 6 1,329 1.8 41 84.0 118.3 Age Group: 55-59 years Total Episodes 87,566 100.0 173 406.5 513.0 1 15,361 17.5 89 237.3 337.4 2 7,460 8.5 60 156.8 244.2 3 4,441 5.1 51 120.5 192.8 4 2,902 3.3 44 94.6 146.8 5 2,031 2.3 43 88.6 137.4 6 1,458 1.7 40 75.6 107.3 Age Group: 60-64 years Total Episodes 86,524 100.0 169 394.0 495.2 1 14,885 17.2 77 223.0 326.1 2 7,097 8.2 55 146.5 228.8 3 4,183 4.8 49 113.9 177.1 4 2,659 3.1 42 95.9 153.2 5 1,804 2.1 40 80.9 124.9	5	1,414	2.5	44	95.6	150.1
Total Episodes 75,755 100.0 178 408.0 516.4 1 13,357 17.6 97 251.8 349.7 2 6,586 8.7 63 165.3 251.2 3 3,980 5.3 54 124.8 192.0 4 2,636 3.5 48 106.4 166.8 5 1,858 2.5 44 91.4 136.2 6 1,329 1.8 41 84.0 118.3 Age Group: 55-59 years Total Episodes 87,566 100.0 173 406.5 513.0 1 15,361 17.5 89 237.3 337.4 2 7,460 8.5 60 156.8 244.2 3 4,441 5.1 51 120.5 192.8 4 2,902 3.3 44 94.6 146.8 5 2,031 2.3 43 88.6 137.4 6 1,458 1.7 40 75.6 107.3 Age Group: 60-64 years Total Episodes 86,524 100.0 169 394.0 495.2 1 14,885 17.2 77 223.0 326.1 2 7,097 8.2 55 146.5 228.8 3 4,183 4.8 49 113.9 177.1 4 2,659 3.1 42 95.9 153.2 5 1,804 2.1 40 80.9 124.9	6	1,001	1.8	42	89.4	145.1
1 13,357 17.6 97 251.8 349.7 2 6,586 8.7 63 165.3 251.2 3 3,980 5.3 54 124.8 192.0 4 2,636 3.5 48 106.4 166.8 5 1,858 2.5 44 91.4 136.2 6 1,329 1.8 41 84.0 118.3 Age Group: 55-59 years Total Episodes 87,566 100.0 173 406.5 513.0 1 15,361 17.5 89 237.3 337.4 2 7,460 8.5 60 156.8 244.2 3 4,441 5.1 51 120.5 192.8 4 2,902 3.3 44 94.6 146.8 5 2,031 2.3 43 88.6 137.4 6 1,458 1.7 40 75.6 107.3 Age Group: 60-64 years Total Episodes 86,524 100.0	Age Group: 50-54 years					
2 6,586 8.7 63 165.3 251.2 3 3,980 5.3 54 124.8 192.0 4 2,636 3.5 48 106.4 166.8 5 1,858 2.5 44 91.4 136.2 6 1,329 1.8 41 84.0 118.3 Age Group: 55-59 years Total Episodes 87,566 100.0 173 406.5 513.0 1 15,361 17.5 89 237.3 337.4 2 7,460 8.5 60 156.8 244.2 3 4,441 5.1 51 120.5 192.8 4 2,902 3.3 44 94.6 146.8 5 2,031 2.3 43 88.6 137.4 6 1,458 1.7 40 75.6 107.3 Age Group: 60-64 years Total Episodes 86,524 100.0 169 394.0 495.2 1 14,885 17.2 77 223.0 326.1 2 7,097 8.2 55 146.5 228.8 3 4,183 4.8 49 113.9 177.1 4 2,659 3.1 42 95.9 153.2 5 1,804 2.1 40 80.9 124.9	Total Episodes	75,755	100.0	178	408.0	516.4
3 3,980 5.3 54 124.8 192.0 4 2,636 3.5 48 106.4 166.8 5 1,858 2.5 44 91.4 136.2 6 1,329 1.8 41 84.0 118.3 Age Group: 55-59 years Total Episodes 87,566 100.0 173 406.5 513.0 1 15,361 17.5 89 237.3 337.4 2 7,460 8.5 60 156.8 244.2 3 4,441 5.1 51 120.5 192.8 4 2,902 3.3 44 94.6 146.8 5 2,031 2.3 43 88.6 137.4 6 1,458 1.7 40 75.6 107.3 Age Group: 60-64 years Total Episodes 86,524 100.0 169 394.0 495.2 1 14,885 17.2 77 223.0 326.1 2 7,097 8.2	1	13,357	17.6	97	251.8	349.7
4 2,636 3.5 48 106.4 166.8 5 1,858 2.5 44 91.4 136.2 6 1,329 1.8 41 84.0 118.3 Age Group: 55-59 years Total Episodes 87,566 100.0 173 406.5 513.0 1 15,361 17.5 89 237.3 337.4 2 7,460 8.5 60 156.8 244.2 3 4,441 5.1 51 120.5 192.8 4 2,902 3.3 44 94.6 146.8 5 2,031 2.3 43 88.6 137.4 6 1,458 1.7 40 75.6 107.3 Age Group: 60-64 years Total Episodes 86,524 100.0 169 394.0 495.2 1 14,885 17.2 77 223.0 326.1 2 7,097 8.2 55 146.5 228.8 3 4,183 4.8	2	6,586	8.7	63	165.3	251.2
5 1,858 2.5 44 91.4 136.2 6 1,329 1.8 41 84.0 118.3 Age Group: 55-59 years Total Episodes 87,566 100.0 173 406.5 513.0 1 15,361 17.5 89 237.3 337.4 2 7,460 8.5 60 156.8 244.2 3 4,441 5.1 51 120.5 192.8 4 2,902 3.3 44 94.6 146.8 5 2,031 2.3 43 88.6 137.4 6 1,458 1.7 40 75.6 107.3 Age Group: 60-64 years Total Episodes 86,524 100.0 169 394.0 495.2 1 14,885 17.2 77 223.0 326.1 2 7,097 8.2 55 146.5 228.8 3 4,183 4.8 49 113.9 177.1 4 2,659 3.1 42	3	3,980	5.3	54	124.8	192.0
6 1,329 1.8 41 84.0 118.3 Age Group: 55-59 years Total Episodes 87,566 100.0 173 406.5 513.0 1 15,361 17.5 89 237.3 337.4 2 7,460 8.5 60 156.8 244.2 3 4,441 5.1 51 120.5 192.8 4 2,902 3.3 44 94.6 146.8 5 2,031 2.3 43 88.6 137.4 6 1,458 1.7 40 75.6 107.3 Age Group: 60-64 years Total Episodes 86,524 100.0 169 394.0 495.2 1 14,885 17.2 77 223.0 326.1 2 7,097 8.2 55 146.5 228.8 3 4,183 4.8 49 113.9 177.1 4 2,659 3.1 42 95.9 153.2 5 1,804 2.1 40 80.9 124.9	4	2,636	3.5	48	106.4	166.8
Age Group: 55-59 years Total Episodes 87,566 100.0 173 406.5 513.0 1 15,361 17.5 89 237.3 337.4 2 7,460 8.5 60 156.8 244.2 3 4,441 5.1 51 120.5 192.8 4 2,902 3.3 44 94.6 146.8 5 2,031 2.3 43 88.6 137.4 6 1,458 1.7 40 75.6 107.3 Age Group: 60-64 years Total Episodes 86,524 100.0 169 394.0 495.2 1 14,885 17.2 77 223.0 326.1 2 7,097 8.2 55 146.5 228.8 3 4,183 4.8 49 113.9 177.1 4 2,659 3.1 42 95.9 153.2 5 1,804 2.1 40	5	1,858	2.5	44	91.4	136.2
Total Episodes 87,566 100.0 173 406.5 513.0 1 15,361 17.5 89 237.3 337.4 2 7,460 8.5 60 156.8 244.2 3 4,441 5.1 51 120.5 192.8 4 2,902 3.3 44 94.6 146.8 5 2,031 2.3 43 88.6 137.4 6 1,458 1.7 40 75.6 107.3 Age Group: 60-64 years Total Episodes 86,524 100.0 169 394.0 495.2 1 14,885 17.2 77 223.0 326.1 2 7,097 8.2 55 146.5 228.8 3 4,183 4.8 49 113.9 177.1 4 2,659 3.1 42 95.9 153.2 5 1,804 2.1 40 80.9 124.9	6	1,329	1.8	41	84.0	118.3
1 15,361 17.5 89 237.3 337.4 2 7,460 8.5 60 156.8 244.2 3 4,441 5.1 51 120.5 192.8 4 2,902 3.3 44 94.6 146.8 5 2,031 2.3 43 88.6 137.4 6 1,458 1.7 40 75.6 107.3 Age Group: 60-64 years Total Episodes 86,524 100.0 169 394.0 495.2 1 14,885 17.2 77 223.0 326.1 2 7,097 8.2 77 223.0 326.1 2 7,097 8.2 55 146.5 228.8 3 4,183 4.8 49 113.9 177.1 4 2,659 3.1 42 95.9 153.2 5 1,804 2.1 40 80.9 124.9	Age Group: 55-59 years					
2 7,460 8.5 60 156.8 244.2 3 4,441 5.1 51 120.5 192.8 4 2,902 3.3 44 94.6 146.8 5 2,031 2.3 43 88.6 137.4 6 1,458 1.7 40 75.6 107.3 Age Group: 60-64 years Total Episodes 86,524 100.0 169 394.0 495.2 1 14,885 17.2 77 223.0 326.1 2 7,097 8.2 55 146.5 228.8 3 4,183 4.8 49 113.9 177.1 4 2,659 3.1 42 95.9 153.2 5 1,804 2.1 40 80.9 124.9	Total Episodes	87,566	100.0	173	406.5	513.0
3 4,441 5.1 51 120.5 192.8 4 2,902 3.3 44 94.6 146.8 5 2,031 2.3 43 88.6 137.4 6 1,458 1.7 40 75.6 107.3 Age Group: 60-64 years Total Episodes 86,524 100.0 169 394.0 495.2 1 14,885 17.2 77 223.0 326.1 2 7,097 8.2 55 146.5 228.8 3 4,183 4.8 49 113.9 177.1 4 2,659 3.1 42 95.9 153.2 5 1,804 2.1 40 80.9 124.9	1	15,361	17.5	89	237.3	337.4
4 2,902 3.3 44 94.6 146.8 5 2,031 2.3 43 88.6 137.4 6 1,458 1.7 40 75.6 107.3 Age Group: 60-64 years Total Episodes 86,524 100.0 169 394.0 495.2 1 14,885 17.2 77 223.0 326.1 2 7,097 8.2 55 146.5 228.8 3 4,183 4.8 49 113.9 177.1 4 2,659 3.1 42 95.9 153.2 5 1,804 2.1 40 80.9 124.9	2	7,460	8.5	60	156.8	244.2
5 2,031 2.3 43 88.6 137.4 6 1,458 1.7 40 75.6 107.3 Age Group: 60-64 years Total Episodes 86,524 100.0 169 394.0 495.2 1 14,885 17.2 77 223.0 326.1 2 7,097 8.2 55 146.5 228.8 3 4,183 4.8 49 113.9 177.1 4 2,659 3.1 42 95.9 153.2 5 1,804 2.1 40 80.9 124.9	3	4,441	5.1	51	120.5	192.8
6 1,458 1.7 40 75.6 107.3 Age Group: 60-64 years Total Episodes 86,524 100.0 169 394.0 495.2 1 14,885 17.2 77 223.0 326.1 2 7,097 8.2 55 146.5 228.8 3 4,183 4.8 49 113.9 177.1 4 2,659 3.1 42 95.9 153.2 5 1,804 2.1 40 80.9 124.9	4	2,902	3.3	44	94.6	146.8
Age Group: 60-64 years Total Episodes 86,524 100.0 169 394.0 495.2 1 14,885 17.2 77 223.0 326.1 2 7,097 8.2 55 146.5 228.8 3 4,183 4.8 49 113.9 177.1 4 2,659 3.1 42 95.9 153.2 5 1,804 2.1 40 80.9 124.9	5	2,031	2.3	43	88.6	137.4
Total Episodes 86,524 100.0 169 394.0 495.2 1 14,885 17.2 77 223.0 326.1 2 7,097 8.2 55 146.5 228.8 3 4,183 4.8 49 113.9 177.1 4 2,659 3.1 42 95.9 153.2 5 1,804 2.1 40 80.9 124.9	6	1,458	1.7	40	75.6	107.3
1 14,885 17.2 77 223.0 326.1 2 7,097 8.2 55 146.5 228.8 3 4,183 4.8 49 113.9 177.1 4 2,659 3.1 42 95.9 153.2 5 1,804 2.1 40 80.9 124.9	Age Group: 60-64 years					
2 7,097 8.2 55 146.5 228.8 3 4,183 4.8 49 113.9 177.1 4 2,659 3.1 42 95.9 153.2 5 1,804 2.1 40 80.9 124.9	Total Episodes	86,524	100.0	169	394.0	495.2
3 4,183 4.8 49 113.9 177.1 4 2,659 3.1 42 95.9 153.2 5 1,804 2.1 40 80.9 124.9	1	14,885	17.2	77	223.0	326.1
4 2,659 3.1 42 95.9 153.2 5 1,804 2.1 40 80.9 124.9	2	7,097	8.2	55	146.5	228.8
5 1,804 2.1 40 80.9 124.9	3	4,183	4.8	49	113.9	177.1
	4	2,659	3.1	42	95.9	153.2
6 1,276 1.5 40 72.9 102.0	5	1,804	2.1	40	80.9	124.9
	6	1,276		40	72.9	102.0

cder_mpl1r_wp089 Page 48 of 79



Table 13b. Descriptive Statistics for Gaps (in Days) between Treatment Episodes of Metoclopramide among Female Members with Type 2 Diabetes and No Evidence of a Live Birth Delivery in the Sentinel Distributed Database between January 1, 2008 and September 30, 2015, by Age Group, for Episodes with Allowable Gaps of 50% of the Prior Dispensing

Gap Number ¹	Number	Percent	Median	Mean	Standard Deviation
Age Group: 65-69 years					
Total Episodes	136,247	100.0	208	428.5	503.7
1	22,682	16.6	76	222.8	321.3
2	10,253	7.5	57	147.1	227.4
3	5,783	4.2	48	114.5	183.5
4	3,649	2.7	44	93.6	149.2
5	2,436	1.8	41	83.0	121.2
6	1,731	1.3	40	75.5	110.6
Age Group: 70-74 years					
Total Episodes	127,804	100.0	211	435.7	507.7
1	21,007	16.4	76	219.6	315.0
2	9,380	7.3	55	142.6	221.0
3	5,349	4.2	47	109.2	168.7
4	3,371	2.6	42	90.3	137.7
5	2,269	1.8	39	81.4	130.0
6	1,570	1.2	39	73.4	107.8
Age Group: 75-79 years					
Total Episodes	99,084	100.0	196	425.2	505.3
1	16,402	16.6	67	199.9	294.1
2	7,342	7.4	49	130.0	204.4
3	4,068	4.1	44	101.1	160.3
4	2,556	2.6	40	83.6	127.3
5	1,710	1.7	35	71.3	103.6
6	1,210	1.2	34	65.8	92.4
Age Group: 80+ years					
Total Episodes	127,341	100.0	137	368.2	472.9
1	20,891	16.4	53	162.9	256.5
2	9,254	7.3	43	112.6	180.9
3	5,058	4.0	38	90.4	147.2
4	3,106	2.4	35	71.8	109.9
5	2,032	1.6	33	66.8	107.7
6	1,389	1.1	33	60.8	92.1

¹ Gap number indicates the sequential number of the gaps identified between episodes. The number of episodes with a gap of 1, represents members with at least two episodes. Note only the first 6 episodes are presented in this table.

cder_mpl1r_wp089 Page 49 of 79



Table 13c. Descriptive Statistics for Gaps (in Days) between Treatment Episodes of Metoclopramide among Female Members with Gastroparesis, Type 2 Diabetes, and No Evidence of a Live Birth Delivery in the Sentinel Distributed Database between January 1, 2008 and September 30, 2015, by Age Group, for Episodes with Allowable Gaps of 50% of the Prior Dispensing

Total Episodes 7,716 100.0 88 249.1 367.6 1 1,579 20.5 75 191.4 275.7 2 956 12.4 66 154.5 229.6 3 615 8.0 52 127.2 182.6 4 413 5.4 51 121.1 182.4 5 302 3.9 49 97.9 144.7 6 213 2.8 44 77.0 106.8 Age Group: 45-49 years Total Episodes 10,601 100.0 86 253.5 380.6 1 2,137 20.2 79 196.4 282.1 2 1,256 11.8 60 145.4 221.0 3 822 7.8 54 122.1 178.3 4 552 5.2 50 103.3 171.7 5 400 3.8 47 84.1 123.4 6 292 2.8 45 85.5 117.1 Age Group: 50-54 years Total Episodes 13,288 100.0 78 252.8 387.9 1 1 2,631 19.8 66 183.4 278.7 2 1,549 11.7 57 136.0 212.9 3 1,027 7.7 50 110.4 174.7 4 696 5.2 51 104.1 147.5 5 499 3.8 44 93.2 146.0 6 368 2.8 43 84.8 124.1 Age Group: 55-59 years Total Episodes 14,154 100.0 80 255.4 386.2 1 2,931 20.7 59 128.1 190.9 3 1,077 7.7 50 110.4 174.7 4 696 5.2 51 104.1 147.5 5 499 3.8 44 93.2 146.0 6 368 2.8 43 84.8 124.1 Age Group: 55-59 years Total Episodes 14,154 100.0 80 255.4 386.2 1 2,931 20.7 59 128.1 190.9 3 1,073 7.6 47 105.7 168.4 4 695 4.9 45 89.1 130.6 5 489 3.5 44 90.4 173.1 97.2 Age Group: 60-64 years	Gap Number ¹	Number	Percent	Median	Mean	Standard Deviation
1	Age Group: 40-44 years					
2 956 12.4 66 154.5 229.6 3 615 8.0 52 177.2 182.6 4 413 5.4 51 121.1 182.4 5 302 3.9 49 97.9 144.7 6 213 2.8 44 77.0 106.8 Age Group: 45-49 years Total Episodes 10.601 100.0 86 253.5 380.6 1 2,137 20.2 79 196.4 282.1 2 1,256 11.8 60 145.4 221.0 3 822 7.8 54 122.1 178.3 4 552 5.2 50 103.3 171.7 5 400 3.8 47 84.1 123.4 6 292 2.8 45 85.5 117.1 Total Episodes 13,288 100.0 78 252.8 387.9	Total Episodes	7,716	100.0	88	249.1	367.6
3 615 8.0 52 127.2 182.6 4 413 5.4 51 121.1 182.4 5 302 3.9 49 97.9 144.7 6 213 2.8 44 77.0 106.8 Age Group: 45-49 years Total Episodes 10,601 100.0 86 253.5 380.6 1 2,137 20.2 79 196.4 282.1 2 1,256 11.8 60 145.4 282.1 3 822 7.8 54 122.1 178.3 4 552 5.2 50 103.3 171.7 5 400 3.8 47 84.1 122.1 178.3 4 552 5.2 50 103.3 171.7 17.1 17.1 17.1 17.1 17.1 17.1 17.1 17.1 17.1 17.1 17.1 17.1 17.1 17.1 1	1	1,579	20.5	75	191.4	275.7
4 413 5.4 51 121.1 182.4 5 302 3.9 49 97.9 144.7 6 213 2.8 44 77.0 106.8 Age Group: 45-49 years Total Episodes 10,601 100.0 86 253.5 380.6 1 2,137 20.2 79 196.4 282.1 2 1,256 11.8 60 145.4 221.0 3 822 7.8 54 122.1 178.3 4 552 5.2 50 103.3 171.7 5 400 3.8 47 84.1 123.4 6 292 2.8 45 85.5 117.1 Age Group: 50-54 years Total Episodes 13,288 100.0 78 252.8 387.9 1 2,631 19.8 66 183.4 278.7 2 1,549 11.7	2	956	12.4	66	154.5	229.6
5 302 3.9 49 97.9 144.7 6 213 2.8 44 77.0 106.8 Age Group: 45-49 years Total Episodes 10,601 100.0 86 253.5 380.6 1 2,137 20.2 79 196.4 282.1 2 1,256 11.8 60 145.4 221.0 3 822 7.8 54 122.1 178.3 4 552 5.2 50 103.3 171.7 5 400 3.8 47 84.1 123.4 6 292 2.8 45 85.5 117.1 Age Group: 50-54 years Total Episodes 13,288 100.0 78 252.8 387.9 1 2,631 19.8 66 183.4 278.7 2 1,549 11.7 57 136.0 212.9 3 1,027 7.7 50	3	615	8.0	52	127.2	182.6
6 213 2.8 44 77.0 106.8 Age Group: 45-49 years Total Episodes 10,601 100.0 86 253.5 380.6 1 2,137 20.2 79 194.4 282.1 2 1,256 11.8 60 145.4 221.0 3 822 7.8 54 122.1 178.3 4 552 5.2 50 103.3 171.7 5 400 3.8 47 84.1 123.4 6 292 2.8 45 85.5 171.1 Age Group: 50-54 years Total Episodes 13,288 100.0 78 252.8 387.9 1 2,631 19.8 66 183.4 278.7 2 1,549 11.7 57 136.0 212.9 3 1,027 7.7 50 110.4 147.5 5 499 3.8 44 93.2 <td>4</td> <td>413</td> <td>5.4</td> <td>51</td> <td>121.1</td> <td>182.4</td>	4	413	5.4	51	121.1	182.4
Age Group: 45-49 years	5	302	3.9	49	97.9	144.7
Total Episodes 10,601 100.0 86 253.5 380.6 1 2,137 20.2 79 196.4 282.1 2 1,256 11.8 60 145.4 221.0 3 822 7.8 54 122.1 178.3 4 552 5.2 50 103.3 171.7 5 400 3.8 47 84.1 123.4 6 292 2.8 45 85.5 117.1 Age Group: 50-54 years Total Episodes 13,288 100.0 78 252.8 387.9 1 2,631 19.8 66 183.4 278.7 2 1,549 11.7 57 136.0 212.9 3 1,027 7.7 50 110.4 174.7 4 696 5.2 51 104.1 147.5 5 499 3.8 44 93.2 146.0	6	213	2.8	44	77.0	106.8
1 2,137 20.2 79 196.4 282.1 2 1,256 11.8 60 145.4 221.0 3 822 7.8 54 122.1 178.3 4 552 5.2 50 103.3 171.7 5 400 3.8 47 84.1 123.4 6 292 2.8 45 85.5 117.1 Age Group: 50-54 years Total Episodes 13,288 100.0 78 252.8 387.9 1 2,631 19.8 66 183.4 278.7 2 1,549 11.7 57 136.0 212.9 3 1,027 7.7 50 110.4 174.7 4 696 5.2 51 104.1 147.5 5 499 3.8 44 93.2 146.0 6 368 2.8 43 84.8 124.1 Ag	Age Group: 45-49 years					
2 1,256 11.8 60 145.4 221.0 3 822 7.8 54 122.1 178.3 4 552 5.2 50 103.3 171.7 5 400 3.8 47 84.1 123.4 6 292 2.8 45 85.5 117.1 Age Group: 50-54 years Total Episodes 13,288 100.0 78 252.8 387.9 1 2,631 19.8 66 183.4 278.7 2 1,549 11.7 57 136.0 212.9 3 1,027 7.7 50 110.4 174.7 4 696 5.2 51 104.1 147.5 5 499 3.8 44 93.2 146.0 6 368 2.8 43 84.8 124.1 Age Group: 55-59 years Total Episodes 14,154 100.0 8	Total Episodes	10,601	100.0	86	253.5	380.6
3 822 7.8 54 122.1 178.3 4 552 5.2 50 103.3 171.7 5 400 3.8 47 84.1 123.4 6 292 2.8 45 85.5 117.1 Age Group: 50-54 years Total Episodes 13,288 100.0 78 252.8 387.9 1 2,631 19.8 66 183.4 278.7 2 1,549 11.7 57 136.0 212.9 3 1,027 7.7 50 110.4 174.7 4 696 5.2 51 104.1 147.5 5 499 3.8 44 93.2 146.0 6 368 2.8 43 84.8 124.1 Age Group: 55-59 years Total Episodes 14,154 100.0 80 255.4 386.2 1 2,931 20.7 59 165.2 249.4 2 1,705 12.0 59	1	2,137	20.2	79	196.4	282.1
4 552 5.2 50 103.3 171.7 5 400 3.8 47 84.1 123.4 6 292 2.8 45 85.5 117.1 Age Group: 50-54 years Total Episodes 13,288 100.0 78 252.8 387.9 1 2,631 19.8 66 183.4 278.7 2 1,549 11.7 57 136.0 212.9 3 1,027 7.7 50 110.4 174.7 4 696 5.2 51 104.1 147.5 5 499 3.8 44 93.2 146.0 6 368 2.8 43 84.8 124.1 Age Group: 55-59 years Total Episodes 14,154 100.0 80 255.4 386.2 1 2,931 20.7 59 165.2 249.4 2 1,705 12.0 <t< td=""><td>2</td><td>1,256</td><td>11.8</td><td>60</td><td>145.4</td><td>221.0</td></t<>	2	1,256	11.8	60	145.4	221.0
5 400 3.8 47 84.1 123.4 6 292 2.8 45 85.5 117.1 Age Group: 50-54 years Total Episodes 13,288 100.0 78 252.8 387.9 1 2,631 19.8 66 183.4 278.7 2 1,549 11.7 57 136.0 212.9 3 1,027 7.7 50 110.4 174.7 4 696 5.2 51 104.1 147.5 5 499 3.8 44 93.2 146.0 6 368 2.8 43 84.8 124.1 Age Group: 55-59 years Total Episodes 14,154 100.0 80 255.4 386.2 1 2,931 20.7 59 165.2 249.4 2 1,705 12.0 59 128.1 190.9 3 1,073 7.6 47 105.7 168.4 4 695 4.9 45 89.1	3	822	7.8	54	122.1	178.3
6 292 2.8 45 85.5 117.1 Age Group: 50-54 years Total Episodes 13,288 100.0 78 252.8 387.9 1 2,631 19.8 66 183.4 278.7 2 1,549 11.7 57 136.0 212.9 3 1,027 7.7 50 110.4 174.7 4 696 5.2 51 104.1 147.5 5 499 3.8 44 93.2 146.0 6 368 2.8 43 84.8 124.1 Age Group: 55-59 years Total Episodes 14,154 100.0 80 255.4 386.2 1 2,931 20.7 59 165.2 249.4 2 1,705 12.0 59 128.1 190.9 3 1,073 7.6 47 105.7 168.4 4 695 4.9 45 <td< td=""><td>4</td><td>552</td><td>5.2</td><td>50</td><td>103.3</td><td>171.7</td></td<>	4	552	5.2	50	103.3	171.7
Age Group: 50-54 years Total Episodes 13,288 100.0 78 252.8 387.9 1 2,631 19.8 66 183.4 278.7 2 1,549 11.7 57 136.0 212.9 3 1,027 7.7 50 110.4 174.7 4 696 5.2 51 104.1 147.5 5 499 3.8 44 93.2 146.0 6 368 2.8 43 84.8 124.1 Age Group: 55-59 years Total Episodes 14,154 100.0 80 255.4 386.2 1 2,931 20.7 59 165.2 249.4 2 1,705 12.0 59 128.1 190.9 3 1,073 7.6 47 105.7 168.4 4 695 4.9 45 89.1 130.6 5 489 3.5 44 90.4 142.1 <td>5</td> <td>400</td> <td>3.8</td> <td>47</td> <td>84.1</td> <td>123.4</td>	5	400	3.8	47	84.1	123.4
Total Episodes 13,288 100.0 78 252.8 387.9 1 2,631 19.8 66 183.4 278.7 2 1,549 11.7 57 136.0 212.9 3 1,027 7.7 50 110.4 174.7 4 696 5.2 51 104.1 147.5 5 499 3.8 44 93.2 146.0 6 368 2.8 43 84.8 124.1 Aper Group: 55-59 years Total Episodes 14,154 100.0 80 255.4 386.2 1 2,931 20.7 59 165.2 249.4 2 1,705 12.0 59 128.1 190.9 3 1,073 7.6 47 105.7 168.4 4 695 4.9 45 89.1 130.6 5 489 3.5 44 90.4 142.1 6 <td>6</td> <td>292</td> <td>2.8</td> <td>45</td> <td>85.5</td> <td>117.1</td>	6	292	2.8	45	85.5	117.1
1 2,631 19.8 66 183.4 278.7 2 1,549 11.7 57 136.0 212.9 3 1,027 7.7 50 110.4 174.7 4 696 5.2 51 104.1 147.5 5 499 3.8 44 93.2 146.0 6 368 2.8 43 84.8 124.1 Age Group: 55-59 years Total Episodes 14,154 100.0 80 255.4 386.2 1 2,931 20.7 59 165.2 249.4 2 1,705 12.0 59 128.1 190.9 3 1,073 7.6 47 105.7 168.4 4 695 4.9 45 89.1 130.6 5 489 3.5 44 90.4 142.1 6 345 2.4 41 73.1 97.2 Age Group: 60-64 years Total Episodes 13,235 100.0 80 258.4	Age Group: 50-54 years					
2 1,549 11.7 57 136.0 212.9 3 1,027 7.7 50 110.4 174.7 4 696 5.2 51 104.1 147.5 5 499 3.8 44 93.2 146.0 6 368 2.8 43 84.8 124.1 Age Group: 55-59 years Total Episodes 14,154 100.0 80 255.4 386.2 1 2,931 20.7 59 165.2 249.4 2 1,705 12.0 59 128.1 190.9 3 1,073 7.6 47 105.7 168.4 4 695 4.9 45 89.1 130.6 5 489 3.5 44 90.4 142.1 6 345 2.4 41 73.1 97.2 Age Group: 60-64 years Total Episodes 13,235 100.0 80 258.4 386.0 1 2,698 20.4 57 164.	Total Episodes	13,288	100.0	78	252.8	387.9
3 1,027 7.7 50 110.4 174.7 4 696 5.2 51 104.1 147.5 5 499 3.8 44 93.2 146.0 6 368 2.8 43 84.8 124.1 Age Group: 55-59 years Total Episodes 14,154 100.0 80 255.4 386.2 1 2,931 20.7 59 165.2 249.4 2 1,705 12.0 59 128.1 190.9 3 1,073 7.6 47 105.7 168.4 4 695 4.9 45 89.1 130.6 5 489 3.5 44 90.4 142.1 6 345 2.4 41 73.1 97.2 Age Group: 60-64 years Total Episodes 13,235 100.0 80 258.4 386.0 1 2,698 20.4 57 164.3	1	2,631	19.8	66	183.4	278.7
4 696 5.2 51 104.1 147.5 5 499 3.8 44 93.2 146.0 6 368 2.8 43 84.8 124.1 Age Group: 55-59 years Total Episodes 14,154 100.0 80 255.4 386.2 1 2,931 20.7 59 165.2 249.4 2 1,705 12.0 59 128.1 190.9 3 1,073 7.6 47 105.7 168.4 4 695 4.9 45 89.1 130.6 5 489 3.5 44 90.4 142.1 6 345 2.4 41 73.1 97.2 Age Group: 60-64 years Total Episodes 13,235 100.0 80 258.4 386.0 1 2,698 20.4 57 164.3 256.5 2 1,518 11.5 52 122.2 194.5 3 932 7.0 50 101.7<	2	1,549	11.7	57	136.0	212.9
5 499 3.8 44 93.2 146.0 6 368 2.8 43 84.8 124.1 Age Group: 55-59 years Total Episodes 14,154 100.0 80 255.4 386.2 1 2,931 20.7 59 165.2 249.4 2 1,705 12.0 59 128.1 190.9 3 1,073 7.6 47 105.7 168.4 4 695 4.9 45 89.1 130.6 5 489 3.5 44 90.4 142.1 6 345 2.4 41 73.1 97.2 Age Group: 60-64 years Total Episodes 13,235 100.0 80 258.4 386.0 1 2,698 20.4 57 164.3 256.5 2 1,518 11.5 52 122.2 194.5 3 932 7.0 50 101.7 141.1 4 608 4.6 45 108.3<	3	1,027	7.7	50	110.4	174.7
6 368 2.8 43 84.8 124.1 Age Group: 55-59 years Total Episodes 14,154 100.0 80 255.4 386.2 1 2,931 20.7 59 165.2 249.4 2 1,705 12.0 59 128.1 190.9 3 1,073 7.6 47 105.7 168.4 4 695 4.9 45 89.1 130.6 5 489 3.5 44 90.4 142.1 6 345 2.4 41 73.1 97.2 Age Group: 60-64 years Total Episodes 13,235 100.0 80 258.4 386.0 1 2,698 20.4 57 164.3 256.5 2 1,518 11.5 52 122.2 194.5 3 932 7.0 50 101.7 141.1 4 608 4.6 45 108	4	696	5.2	51	104.1	147.5
Age Group: 55-59 years Total Episodes 14,154 100.0 80 255.4 386.2 1 2,931 20.7 59 165.2 249.4 2 1,705 12.0 59 128.1 190.9 3 1,073 7.6 47 105.7 168.4 4 695 4.9 45 89.1 130.6 5 489 3.5 44 90.4 142.1 6 345 2.4 41 73.1 97.2 Age Group: 60-64 years Total Episodes 13,235 100.0 80 258.4 386.0 1 2,698 20.4 57 164.3 256.5 2 1,518 11.5 52 122.2 194.5 3 932 7.0 50 101.7 141.1 4 608 4.6 45 108.3 175.8	5	499	3.8	44	93.2	146.0
Total Episodes 14,154 100.0 80 255.4 386.2 1 2,931 20.7 59 165.2 249.4 2 1,705 12.0 59 128.1 190.9 3 1,073 7.6 47 105.7 168.4 4 695 4.9 45 89.1 130.6 5 489 3.5 44 90.4 142.1 6 345 2.4 41 73.1 97.2 Age Group: 60-64 years Total Episodes 13,235 100.0 80 258.4 386.0 1 2,698 20.4 57 164.3 256.5 2 1,518 11.5 52 122.2 194.5 3 932 7.0 50 101.7 141.1 4 608 4.6 45 108.3 175.8	6	368	2.8	43	84.8	124.1
1 2,931 20.7 59 165.2 249.4 2 1,705 12.0 59 128.1 190.9 3 1,073 7.6 47 105.7 168.4 4 695 4.9 45 89.1 130.6 5 489 3.5 44 90.4 142.1 6 345 2.4 41 73.1 97.2 Age Group: 60-64 years Total Episodes 13,235 100.0 80 258.4 386.0 1 2,698 20.4 57 164.3 256.5 2 1,518 11.5 52 122.2 194.5 3 932 7.0 50 101.7 141.1 4 608 4.6 45 108.3 175.8	Age Group: 55-59 years					
2 1,705 12.0 59 128.1 190.9 3 1,073 7.6 47 105.7 168.4 4 695 4.9 45 89.1 130.6 5 489 3.5 44 90.4 142.1 6 345 2.4 41 73.1 97.2 Age Group: 60-64 years Total Episodes 13,235 100.0 80 258.4 386.0 1 2,698 20.4 57 164.3 256.5 2 1,518 11.5 52 122.2 194.5 3 932 7.0 50 101.7 141.1 4 608 4.6 45 108.3 175.8	Total Episodes	14,154	100.0	80	255.4	386.2
3 1,073 7.6 47 105.7 168.4 4 695 4.9 45 89.1 130.6 5 489 3.5 44 90.4 142.1 6 345 2.4 41 73.1 97.2 Age Group: 60-64 years Total Episodes 13,235 100.0 80 258.4 386.0 1 2,698 20.4 57 164.3 256.5 2 1,518 11.5 52 122.2 194.5 3 932 7.0 50 101.7 141.1 4 608 4.6 45 108.3 175.8	1	2,931	20.7	59	165.2	249.4
4 695 4.9 45 89.1 130.6 5 489 3.5 44 90.4 142.1 6 345 2.4 41 73.1 97.2 Age Group: 60-64 years Total Episodes 13,235 100.0 80 258.4 386.0 1 2,698 20.4 57 164.3 256.5 2 1,518 11.5 52 122.2 194.5 3 932 7.0 50 101.7 141.1 4 608 4.6 45 108.3 175.8	2	1,705	12.0	59	128.1	190.9
5 489 3.5 44 90.4 142.1 6 345 2.4 41 73.1 97.2 Age Group: 60-64 years Total Episodes 13,235 100.0 80 258.4 386.0 1 2,698 20.4 57 164.3 256.5 2 1,518 11.5 52 122.2 194.5 3 932 7.0 50 101.7 141.1 4 608 4.6 45 108.3 175.8	3	1,073	7.6	47	105.7	168.4
6 345 2.4 41 73.1 97.2 Age Group: 60-64 years Total Episodes 13,235 100.0 80 258.4 386.0 1 2,698 20.4 57 164.3 256.5 2 1,518 11.5 52 122.2 194.5 3 932 7.0 50 101.7 141.1 4 608 4.6 45 108.3 175.8	4	695	4.9	45	89.1	130.6
Age Group: 60-64 years Total Episodes 13,235 100.0 80 258.4 386.0 1 2,698 20.4 57 164.3 256.5 2 1,518 11.5 52 122.2 194.5 3 932 7.0 50 101.7 141.1 4 608 4.6 45 108.3 175.8	5	489	3.5	44	90.4	142.1
Total Episodes 13,235 100.0 80 258.4 386.0 1 2,698 20.4 57 164.3 256.5 2 1,518 11.5 52 122.2 194.5 3 932 7.0 50 101.7 141.1 4 608 4.6 45 108.3 175.8	6	345	2.4	41	73.1	97.2
1 2,698 20.4 57 164.3 256.5 2 1,518 11.5 52 122.2 194.5 3 932 7.0 50 101.7 141.1 4 608 4.6 45 108.3 175.8	Age Group: 60-64 years					
2 1,518 11.5 52 122.2 194.5 3 932 7.0 50 101.7 141.1 4 608 4.6 45 108.3 175.8	Total Episodes	13,235	100.0	80	258.4	386.0
3 932 7.0 50 101.7 141.1 4 608 4.6 45 108.3 175.8	1	2,698	20.4	57	164.3	256.5
4 608 4.6 45 108.3 175.8	2	1,518	11.5	52	122.2	194.5
	3	932	7.0	50	101.7	141.1
5 414 3.1 40 81.5 104.1	4	608	4.6	45	108.3	175.8
	5	414	3.1	40	81.5	104.1

cder_mpl1r_wp089 Page 50 of 79



Table 13c. Descriptive Statistics for Gaps (in Days) between Treatment Episodes of Metoclopramide among Female Members with Gastroparesis, Type 2 Diabetes, and No Evidence of a Live Birth Delivery in the Sentinel Distributed Database between January 1, 2008 and September 30, 2015, by Age Group, for Episodes with Allowable Gaps of 50% of the Prior Dispensing

Gap Number ¹	Number	Percent	Median	Mean	Standard Deviation
6	291	2.2	41	74.2	97.8
Age Group: 65-69 years					
Total Episodes	17,776	100.0	79	273.3	406.5
1	3,647	20.5	53	156.9	254.7
2	1,940	10.9	53	124.0	200.2
3	1,164	6.5	44	97.9	150.8
4	765	4.3	43	88.6	146.0
5	526	3.0	39	82.8	112.4
6	369	2.1	41	72.3	105.1
Age Group: 70-74 years					
Total Episodes	15,834	100.0	81	275.1	404.5
1	3,185	20.1	57	155.5	237.8
2	1,680	10.6	52	122.6	194.4
3	999	6.3	46	96.3	146.0
4	664	4.2	40	81.3	120.9
5	450	2.8	37	76.9	139.5
6	323	2.0	39	74.9	105.9
Age Group: 75-79 years					
Total Episodes	11,572	100.0	82	287.9	415.7
1	2,315	20.0	52	154.3	245.0
2	1,195	10.3	45	105.9	162.6
3	703	6.1	45	93.3	135.6
4	459	4.0	42	80.7	133.2
5	276	2.4	35	72.3	94.5
6	180	1.6	36	66.2	98.4
Age Group: 80+ years					
Total Episodes	12,653	100.0	68	265.9	404.1
1	2,509	19.8	43	122.9	210.4
2	1,201	9.5	42	107.3	175.5
3	689	5.4	41	89.1	142.5
4	434	3.4	38	68.4	100.8
5	272	2.1	34	62.5	94.2
6	182	1.4	36	54.0	61.4

¹ Gap number indicates the sequential number of the gaps identified between episodes. The number of episodes with a gap of 1, represents members with at least two episodes. Note only the first 6 episodes are presented in this table.

cder_mpl1r_wp089 Page 51 of 79



Table 14a. Descriptive Statistics for Gaps (in Days) between Treatment Episodes of Metoclopramide among Female Members with No Evidence of a Live Birth Delivery in the Sentinel Distributed Database between January 1, 2008 and September 30, 2015, by Age Group, for Episodes with Allowable Gaps of 0 Days

Gap Number ¹	Number	Percent	Median	Mean	Standard Deviation
Age Group: 40-44 years					
Total Episodes	198,660	100.0	256	494.3	590.3
1	29,442	14.8	116	289.5	404.0
2	13,234	6.7	61	178.0	282.4
3	7,662	3.9	44	130.3	220.4
4	5,103	2.6	35	106.2	190.0
5	3,662	1.8	31	90.0	166.4
6	2,762	1.4	28	74.9	138.1
Age Group: 45-49 years					
Total Episodes	225,068	100.0	238	489.8	597.7
1	33,437	14.9	102	279.9	398.2
2	15,475	6.9	52	173.7	290.0
3	9,398	4.2	37	117.7	206.9
4	6,381	2.8	32	94.9	173.2
5	4,697	2.1	29	83.6	165.6
6	3,575	1.6	26	71.8	136.7
Age Group: 50-54 years					
Total Episodes	259,434	100.0	218	478.4	596.3
1	37,646	14.5	83	261.1	393.6
2	17,750	6.8	43	151.0	266.0
3	11,082	4.3	33	107.3	204.4
4	7,806	3.0	29	85.9	164.0
5	5,828	2.2	28	75.3	145.8
6	4,536	1.7	26	68.0	139.8
Age Group: 55-59 years					
Total Episodes	252,088	100.0	182	447.7	578.5
1	37,255	14.8	67	237.5	373.2
2	18,310	7.3	37	135.1	248.1
3	11,613	4.6	31	99.5	196.2
4	8,112	3.2	27	76.9	155.2
5	6,086	2.4	26	67.4	137.7
6	4,739	1.9	24	59.0	120.5
Age Group: 60-64 years					
Total Episodes	224,608	100.0	158	403.8	531.9
1	33,148	14.8	53	206.1	335.6
2	16,552	7.4	32	119.3	222.2
3	10,473	4.7	27	86.9	170.1
4	7,340	3.3	25	70.7	142.7
5	5,390	2.4	23	59.5	119.7
6	4,147	1.8	21	51.4	96.9

cder_mpl1r_wp089 Page 52 of 79



Table 14a. Descriptive Statistics for Gaps (in Days) between Treatment Episodes of Metoclopramide among Female Members with No Evidence of a Live Birth Delivery in the Sentinel Distributed Database between January 1, 2008 and September 30, 2015, by Age Group, for Episodes with Allowable Gaps of 0 Days

Gap Number ¹	Number	Percent	Median	Mean	Standard Deviation
Age Group: 65-69 years					
Total Episodes	352,427	100.0	196	438.8	536.4
1	51,428	14.6	55	214.1	338.7
2	24,634	7.0	31	119.0	223.6
3	15,497	4.4	26	84.7	171.9
4	10,720	3.0	25	70.5	142.5
5	7,999	2.3	24	60.7	123.1
6	6,074	1.7	22	53.7	104.1
Age Group: 70-74 years					
Total Episodes	324,379	100.0	196	442.4	536.9
1	47,184	14.5	49	206.5	329.5
2	22,630	7.0	29	113.6	216.4
3	14,183	4.4	25	79.0	156.1
4	10,040	3.1	23	65.4	130.0
5	7,523	2.3	21	58.2	122.0
6	5,690	1.8	20	51.4	108.2
Age Group: 75-79 years					
Total Episodes	249,219	100.0	163	424.4	535.8
1	36,775	14.8	40	181.9	306.6
2	18,466	7.4	27	103.0	198.3
3	11,606	4.7	22	74.9	156.8
4	8,178	3.3	21	60.9	122.9
5	6,117	2.5	19	52.1	111.6
6	4,640	1.9	18	46.3	96.3
Age Group: 80+ years					
Total Episodes	364,401	100.0	84	344.3	487.9
1	55,231	15.2	25	132.0	250.4
2	29,058	8.0	19	74.8	159.6
3	18,715	5.1	17	57.9	128.9
4	13,150	3.6	15	48.1	107.4
5	9,720	2.7	15	43.3	96.9
6	7,427	2.0	13	38.5	86.5

¹ Gap number indicates the sequential number of the gaps identified between episodes. The number of episodes with a gap of 1, represents members with at least two episodes. Note only the first 6 episodes are presented in this table.

cder_mpl1r_wp089 Page 53 of 79



Table 14b. Descriptive Statistics for Gaps (in Days) between Treatment Episodes of Metoclopramide among Female Members with Type 2 Diabetes and No Evidence of a Live Birth Delivery in the Sentinel Distributed Database between January 1, 2008 and September 30, 2015, by Age Group, for Episodes with Allowable Gaps of 0 Days

Total Episodes 46,944 100.0 138 356.5 484.8 1 8,175 17.4 95 252.1 358.1 2 4,376 9.3 54 161.6 260.7 3 2,760 5.9 39 119.9 210.5 4 1,913 4.1 32 97.8 180.5 5 1,409 3.0 31 85.4 159.4 6 1,091 2.3 29 69.6 118.0 Age Group: 45-49 years Total Episodes 64,774 100.0 125 360.5 497.4 1 10,942 16.9 87 245.8 356.0 2 5,930 9.2 45 155.3 259.6 3 3,842 5.9 34 107.6 188.2 4 2,719 4.2 30 86.4 165.4 5 2,034 3.1 28 74.5 136.0 6 1,577 2.4 25 69.1 135.6 Age Group: 50-54 years Total Episodes 87,591 100.0 113 353.7 499.5 1 14,324 16.4 69 225.2 341.5 2 7,753 8.9 40 137.7 243.6 3 5,133 5.9 32 96.3 177.7 4 3,736 4.3 29 79.0 146.2 5 2,840 3.3,736 4.3 29 79.0 146.2 5 2,840 3.7 29 79.0 146.2 6 2,235 2.6 25 63.0 177.6 Age Group: 55-59 years Total Episodes 102,500 100.0 104 348.2 494.7 1 1 6,667 16.3 61 209.3 329.0 2 9,104 8.9 35 123.1 225.6 3 6,024 5.9 29 91.8 177.8 4 4 4,297 4.2 26 75.3 151.0 5 3,240 3.2 25 63.6 122.3 6 2,529 2.5 22 56.6 115.0	Gap Number ¹	Number	Percent	Median	Mean	Standard Deviation
1 8,175 17.4 95 252.1 358.1 2 4,376 9.3 54 161.6 260.7 3 2,760 5.9 39 119.9 210.5 4 1,913 4.1 32 97.8 180.5 5 1,409 3.0 31 85.4 159.4 6 1,091 2.3 29 69.6 118.0 Age Group: 45-49 years Total Episodes 64,774 100.0 125 360.5 497.4 1 10,942 16.9 87 245.8 356.0 2 5,930 9.2 45 155.3 259.6 3 3,842 5.9 34 107.6 188.2 4 2,719 4.2 30 86.4 165.4 5 2,034 3.1 28 74.5 136.0 6 1,577 2.4 25 69.1 135.6 Age Group: 50-54 years Total Episodes 87,591 100.0 113 353.7 499.5 1 14,324 16.4 69 225.2 341.5 2 7,753 8.9 40 137.7 243.6 3 5,133 5.9 32 96.3 177.7 4 3,736 4.3 29 79.0 146.2 2 7,755 8.9 40 137.7 243.6 6 2,235 2.6 25 63.0 117.6 Age Group: 50-559 years Total Episodes 102,500 100.0 104 348.2 494.7 1 1 16,677 16.3 61 209.3 329.0 2 9,104 8.9 35 123.1 225.6 3 6,024 5.9 29 91.8 177.8 4 4,27 4,2 26 75.3 151.0 2 9,104 8.9 35 123.1 225.6 3 6,024 5.9 29 91.8 177.8 4 4,27 4,2 26 75.3 151.0 5 3,240 3.2 25 56.6 115.0 Age Group: 50-54 years Total Episodes 102,500 100.0 104 348.2 494.7 5 3 2.9 9,104 8.9 35 123.1 225.6 3 6,024 5.9 29 91.8 177.8 4 4,27 4,2 26 75.3 151.0 5 3,240 3.2 25 56.6 115.0 Age Group: 60-64 years Total Episodes 101,718 100.0 99 336.1 477.2 3 15.0 486.6 115.0 4 4,4175 4.1 25 70.3 138.3 5 3,130 5,874 8.8 31 115.0 215.7 3 5,874 4,41,775 4.1 25 70.3 138.3 5 5,3120 3.1 22 59.6 120.1	Age Group: 40-44 years					
2 4,376 9.3 54 161.6 260.7 3 2,760 5.9 39 119.9 210.5 4 1,913 4.1 32 97.8 180.5 5 1,409 3.0 31 85.4 159.4 6 1,091 2.3 29 69.6 118.0 Age Group: 45-49 years Total Episodes 64,774 100.0 125 360.5 497.4 5 1 10,942 16.9 87 24.8 356.0 2 5,930 9.2 45 155.3 259.6 3 3,842 5.9 34 107.6 188.2 4 2,719 4.2 30 86.4 165.4 5 2,034 3.1 28 74.5 136.0 6 1,577 2.4 25 69.1 135.6 Age Group: 50-54 years 100.0 113 353.7 499.5 <	Total Episodes	46,944	100.0	138	356.5	484.8
3 2,760 5.9 39 119.9 210.5 4 1,913 4.1 32 97.8 180.5 5 1,409 3.0 31 85.4 159.4 6 1,091 2.3 29 69.6 118.0 Age Group: 45-49 years Total Episodes 64,774 100.0 125 360.5 497.4 1 10,942 16.9 87 245.8 356.0 2 5,930 9.2 45 155.3 259.6 3 3,842 5.9 34 107.6 188.2 4 2,719 4.2 30 86.4 165.4 5 2,034 3.1 28 74.5 136.0 6 1,577 2.4 25 69.1 135.6 Age Group: 50-54 years Total Episodes 87,591 100.0 113 353.7 499.5 1 1,43,24 16.4 <td>1</td> <td>8,175</td> <td>17.4</td> <td>95</td> <td>252.1</td> <td>358.1</td>	1	8,175	17.4	95	252.1	358.1
4 1,913 4.1 32 97.8 180.5 5 1,409 3.0 31 85.4 159.4 6 1,091 2.3 29 69.6 118.0 Aspectroup: 45-49 years Total Episodes 64,774 100.0 125 360.5 497.4 1 10,942 16.9 87 245.8 356.0 2 5,930 9.2 45 155.3 259.6 3 3,842 5.9 34 107.6 188.2 4 2,719 4.2 30 86.4 165.4 5 2,034 3.1 28 74.5 136.0 6 1,577 2.4 25 69.1 135.6 6 2,034 3.1 28 74.5 136.0 6 17,77 2.4 25 69.1 135.6 Age Group: 50-54 years 101.4 69 225.2 341.5 2 <td>2</td> <td>4,376</td> <td>9.3</td> <td>54</td> <td>161.6</td> <td>260.7</td>	2	4,376	9.3	54	161.6	260.7
5 1,409 3.0 31 85.4 159.4 6 1,091 2.3 29 69.6 118.0 Age Group: 45-49 years 36.0 497.4 Total Episodes 64,774 100.0 125 360.5 497.4 Total Episodes 6,9774 100.0 125 360.5 497.4 2 5,930 9.2 45 155.3 259.6 3 3,842 5.9 34 107.6 188.2 4 2,719 4.2 30 86.4 165.4 5 2,034 3.1 28 74.5 136.0 6 1,577 2.4 25 69.1 135.6 Age Group: 50-54 years 101.0 113 353.7 499.5 10tal Episodes 87,591 100.0 113 353.7 499.5 11 14,324 16.4 69 225.2 341.5 2 7,753 8.9 40 137.7	3	2,760	5.9	39	119.9	210.5
6 1,091 2.3 29 69.6 118.0 Age Group: 45-49 years Total Episodes 64,774 100.0 125 360.5 497.4 1 10,942 16.9 87 245.8 356.0 2 5,930 9.2 45 155.3 259.6 3 3,842 5.9 34 107.6 188.2 4 2,719 4.2 30 86.4 165.4 5 2,034 3.1 28 74.5 136.0 6 1,577 2.4 25 69.1 135.6 Age Group: 50-54 years 1 14,324 16.4 69 225.2 341.5 1 14,324 16.4 69 225.2 341.5 2 2 7,753 8.9 40 137.7 243.6 3 5,133 5.9 32 96.3 177.7 4 3,736 4.3 29 79.0 146.2	4	1,913	4.1	32	97.8	180.5
Age Group: 45-49 years Total Episodes 64,774 100.0 125 360.5 497.4 1 10,942 16.9 87 245.8 356.0 2 5,930 9.2 45 155.3 259.6 3 3,842 5.9 34 107.6 188.2 4 2,719 4.2 30 86.4 165.4 5 2,034 3.1 28 74.5 136.0 6 1,577 2.4 25 69.1 135.6 Age Group: 50-54 years Total Episodes 87,591 100.0 113 353.7 499.5 1 14,324 16.4 69 225.2 341.5 2 7,753 8.9 40 137.7 243.6 3 5,133 5.9 32 96.3 177.7 4 3,736 4.3 29 79.0 146.2 5 2,840 3.2 27 72.6 137.9 6 2,235 2.6 25 63.0 17.6 Age Group: 55-59 years Total Episodes 102,500 100.0 104 348.2 494.7 1 1 16,677 16.3 61 293.3 329.0 2 9,104 8.9 35 123.1 225.6 3 6,024 5.9 29 91.8 177.8 4 4 4,297 4.2 26 75.3 151.0 5 3,240 3.2 25 63.6 122.3 6 2,529 2.5 22 56.6 115.0 Age Group: 60-64 years Total Episodes 101,718 100.0 99 336.1 477.2 1 1 16,376 16.1 49 191.7 315.0 Age Group: 60-64 years Total Episodes 101,718 100.0 99 336.1 477.2 1 16,376 16.1 49 191.7 315.0 2 8,944 8.8 31 115.0 215.7 3 5,874 5.8 27 88.0 16.1 4 4,175 4.1 25 70.3 138.3 5 9.8 27 88.0 16.17 4 4,175 4.1 25 70.3 138.3	5	1,409	3.0	31	85.4	159.4
Total Episodes 64,774 100.0 125 360.5 497.4 1 10,942 16.9 87 245.8 356.0 2 5,930 9.2 45 155.3 259.6 3 3,842 5.9 34 107.6 188.2 4 2,719 4.2 30 86.4 165.4 5 2,034 3.1 28 74.5 136.0 6 1,577 2.4 25 69.1 135.6 Age Group: 50-54 years 7 7 2.4 25 69.1 135.6 Age Group: 50-54 years 7 100.0 113 353.7 499.5 20 7,753 8.9 40 137.7 243.6 3 5,133 5.9 32 96.3 177.7 4 3,736 4.3 29 79.0 146.2 5 2,840 3.2 27 72.6 137.9 6 2,235	6	1,091	2.3	29	69.6	118.0
1 10,942 16.9 87 245.8 356.0 2 5,930 9.2 45 155.3 259.6 3 3,842 5.9 34 107.6 188.2 4 2,719 4.2 30 86.4 165.4 5 2,034 3.1 28 74.5 136.0 6 1,577 2.4 25 69.1 135.6 Age Group: 50-54 years Total Episodes 87,591 100.0 113 353.7 499.5 1 14,324 16.4 69 225.2 341.5 2 7,753 8.9 40 137.7 24.6 3 5,133 5.9 32 96.3 177.7 4 3,736 4.3 29 79.0 146.2 5 2,840 3.2 27 72.6 137.9 6 2,235 2.6 25 63.0 117.6 Age Group: 55-59 years Total Episodes 102,500 100.0 104 348.2 494.7 1 16,677 16.3 61 209.3 329.0 2 9,104 8.9 35 123.1 225.6 3 6,024 5.9 29 91.8 177.8 4 4,297 4.2 26 75.3 151.0 5 3,240 3.2 25 63.6 122.3 6 2,529 2.5 22 56.6 115.0 Age Group: 66-64 years Total Episodes 101,718 100.0 99 336.1 477.2 1 16,376 16.1 49 191.7 315.0 Age Group: 66-64 years Total Episodes 101,718 100.0 99 336.1 477.2 1 16,376 16.1 49 191.7 315.0 2 8,944 8.8 31 115.0 215.7 3 5,874 5.8 27 84.0 16.7 4 4,175 4.1 25 70.3 138.3 5 38 5,874 5.8 27 84.0 16.7	Age Group: 45-49 years					
2 5,930 9.2 45 155.3 259.6 3 3,842 5.9 34 107.6 188.2 4 2,719 4.2 30 86.4 165.4 5 2,034 3.1 28 74.5 136.0 6 1,577 2.4 25 69.1 135.6 Age Group: 50-54 years Total Episodes 87,591 100.0 113 353.7 499.5 1 14,324 16.4 69 225.2 341.5 2 7,753 8.9 40 137.7 243.6 3 5,133 5.9 32 96.3 177.7 4 3,736 4.3 29 79.0 146.2 5 2,840 3.2 27 72.6 137.9 6 2,235 2.6 25 63.0 117.6 Age Group: 55-59 years Total Episodes 102,500 100.0	Total Episodes	64,774	100.0	125	360.5	497.4
3 3,842 5.9 34 107.6 188.2 4 2,719 4.2 30 86.4 165.4 5 2,034 3.1 28 74.5 136.0 6 1,577 2.4 25 69.1 135.6 Age Group: 50-54 years Total Episodes 87,591 100.0 113 353.7 499.5 1 14,324 16.4 69 225.2 341.5 2 7,753 8.9 40 137.7 243.6 3 5,133 5.9 32 96.3 177.7 4 3,736 4.3 29 79.0 146.2 5 2,840 3.2 27 72.6 137.9 6 2,235 2.6 25 63.0 117.6 Age Group: 55-59 years Total Episodes 102,500 100.0 104 348.2 494.7 1 16,677 16.3 <t< td=""><td>1</td><td>10,942</td><td>16.9</td><td>87</td><td>245.8</td><td>356.0</td></t<>	1	10,942	16.9	87	245.8	356.0
4 2,719 4.2 30 86.4 165.4 165.4 5 2,034 3.1 28 74.5 136.0 6 1,577 2.4 25 69.1 135.6 Age Group: 50-54 years Total Episodes 87,591 100.0 113 353.7 499.5 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	2	5,930	9.2	45	155.3	259.6
5 2,034 3.1 28 74.5 136.0 6 1,577 2.4 25 69.1 135.6 Age Group: 50-54 years Total Episodes 87,591 100.0 113 353.7 499.5 1 14,324 16.4 69 225.2 341.5 2 7,753 8.9 40 137.7 243.6 3 5,133 5.9 32 96.3 177.7 4 3,736 4.3 29 79.0 146.2 5 2,840 3.2 27 72.6 137.9 6 2,235 2.6 25 63.0 117.6 Age Group: 55-59 years Total Episodes 102,500 100.0 104 348.2 494.7 1 16,677 16.3 61 20.9 329.0 2 9,104 8.9 35 123.1 225.6 3 6,024 5.9 29	3	3,842	5.9	34	107.6	188.2
6 1,577 2.4 25 69.1 135.6 Age Group: 50-54 years Total Episodes 87,591 100.0 113 353.7 499.5 1 14,324 16.4 69 225.2 341.5 2 7,753 8.9 40 137.7 243.6 3 5,133 5.9 32 96.3 177.7 4 3,736 4.3 29 79.0 146.2 5 2,840 3.2 27 72.6 137.9 6 2,235 2.6 25 63.0 117.6 Age Group: 55-59 years Total Episodes 102,500 100.0 104 348.2 494.7 1 16,677 16.3 61 209.3 329.0 2 9,104 8.9 35 123.1 225.6 3 6,024 5.9 29 91.8 177.8 4 4,297 4.2 26 75.3 <td>4</td> <td>2,719</td> <td>4.2</td> <td>30</td> <td>86.4</td> <td>165.4</td>	4	2,719	4.2	30	86.4	165.4
Age Group: 50-54 years Total Episodes 87,591 100.0 113 353.7 499.5 1 14,324 16.4 69 225.2 341.5 2 7,753 8.9 40 137.7 243.6 3 5,133 5.9 32 96.3 177.7 4 3,736 4.3 29 79.0 146.2 5 2,840 3.2 27 72.6 137.9 6 2,235 2.6 25 63.0 117.6 Age Group: 55-59 years Total Episodes 102,500 100.0 104 348.2 494.7 1 16,677 16.3 61 209.3 329.0 2 9,104 8.9 35 123.1 225.6 3 6,024 5.9 29 91.8 177.8 4 4,297 4.2 2.6 75.3 151.0 5 3,240 3.2 25 63.6 122.3 6 2,529 2.5 22 56.6 115.0 Age Group: 60-64 years Total Episodes 101,718 100.0 99 336.1 477.2 1 16,376 16.1 49 191.7 315.0 2 8,944 8.8 31 115.0 215.7 3 5,874 5.8 27 84.0 161.7 4 4,175 4.1 25 70.3 138.3 5 3,120 3.1 22 59.6 120.1	5	2,034	3.1	28	74.5	136.0
Total Episodes 87,591 100.0 113 353.7 499.5 1 14,324 16.4 69 225.2 341.5 2 7,753 8.9 40 137.7 243.6 3 5,133 5.9 32 96.3 177.7 4 3,736 4.3 29 79.0 146.2 5 2,840 3.2 27 72.6 137.9 6 2,235 2.6 25 63.0 117.6 Ase Group: 55-59 years Total Episodes 102,500 100.0 104 348.2 494.7 1 16,677 16.3 61 209.3 329.0 2 9,104 8.9 35 123.1 225.6 3 6,024 5.9 29 91.8 177.8 4 4,297 4.2 26 75.3 151.0 5 3,240 3.2 25 6.6 115.0 <	6	1,577	2.4	25	69.1	135.6
1 14,324 16.4 69 225.2 341.5 2 7,753 8.9 40 137.7 243.6 3 5,133 5.9 32 96.3 177.7 4 3,736 4.3 29 79.0 146.2 5 2,840 3.2 27 72.6 137.9 6 2,235 2.6 25 63.0 117.6 Age Group: 55-59 years Total Episodes 102,500 100.0 104 348.2 494.7 1 16,677 16.3 61 209.3 329.0 2 9,104 8.9 35 123.1 225.6 3 6,024 5.9 29 91.8 177.8 4 4,297 4.2 26 75.3 151.0 5 3,240 3.2 25 63.6 122.3 6 2,529 2.5 22 56.6 115.0 Age Group: 60-64 years Total Episodes 101,718 100.0 99	Age Group: 50-54 years					
2 7,753 8.9 40 137.7 243.6 3 5,133 5.9 32 96.3 177.7 4 3,736 4.3 29 79.0 146.2 5 2,840 3.2 27 72.6 137.9 6 2,235 2.6 25 63.0 117.6 Age Group: 55-59 years Total Episodes 102,500 100.0 104 348.2 494.7 1 16,677 16.3 61 209.3 329.0 2 9,104 8.9 35 123.1 225.6 3 6,024 5.9 29 91.8 177.8 4 4,297 4.2 26 75.3 151.0 5 3,240 3.2 25 63.6 122.3 6 2,529 2.5 22 56.6 115.0 Age Group: 60-64 years Total Episodes 101,718 100.0 99 336.1 477.2 1 16,376 16.1 49 191	Total Episodes	87,591	100.0	113	353.7	499.5
3 5,133 5.9 32 96.3 177.7 4 3,736 4.3 29 79.0 146.2 5 2,840 3.2 27 72.6 137.9 6 2,235 2.6 25 63.0 117.6 Ase Group: 55-59 years Total Episodes 102,500 100.0 104 348.2 494.7 1 16,677 16.3 61 209.3 329.0 2 9,104 8.9 35 123.1 225.6 3 6,024 5.9 29 91.8 177.8 4 4,297 4.2 26 75.3 151.0 5 3,240 3.2 25 63.6 122.3 6 2,529 2.5 22 56.6 115.0 Ase Group: 60-64 years Total Episodes 101,718 100.0 99 336.1 477.2 1 16,376 16.1 49 191.7 315.0 2 8,944 8.8 <	1	14,324	16.4	69	225.2	341.5
4 3,736 4.3 29 79.0 146.2 5 2,840 3.2 27 72.6 137.9 6 2,235 2.6 25 63.0 117.6 Ase Group: 55-59 years Total Episodes 102,500 100.0 104 348.2 494.7 1 16,677 16.3 61 209.3 329.0 2 9,104 8.9 35 123.1 225.6 3 6,024 5.9 29 91.8 177.8 4 4,297 4.2 26 75.3 151.0 5 3,240 3.2 25 63.6 122.3 6 2,529 2.5 22 56.6 115.0 Ase Group: 60-64 years Total Episodes 101,718 100.0 99 336.1 477.2 1 16,376 16.1 49 191.7 315.0 2 8,944 8.8 31 115.0 215.7 3 5,874 5.8 27	2	7,753	8.9	40	137.7	243.6
5 2,840 3.2 27 72.6 137.9 6 2,235 2.6 25 63.0 117.6 Age Group: 55-59 years Total Episodes 102,500 100.0 104 348.2 494.7 1 16,677 16.3 61 209.3 329.0 2 9,104 8.9 35 123.1 225.6 3 6,024 5.9 29 91.8 177.8 4 4,297 4.2 26 75.3 151.0 5 3,240 3.2 25 63.6 122.3 6 2,529 2.5 22 56.6 115.0 Age Group: 60-64 years Total Episodes 101,718 100.0 99 336.1 477.2 1 16,376 16.1 49 191.7 315.0 2 8,944 8.8 31 115.0 215.7 3 5,874 5.8 27 84.0 161.7 4 4,175 4.1 25 70.3 138.3 5 3,120 3.1 22 59.6 120.1	3	5,133	5.9	32	96.3	177.7
6 2,235 2.6 25 63.0 117.6 Age Group: 55-59 years Total Episodes 102,500 100.0 104 348.2 494.7 1 16,677 16.3 61 209.3 329.0 2 9,104 8.9 35 123.1 225.6 3 6,024 5.9 29 91.8 177.8 4 4,297 4.2 26 75.3 151.0 5 3,240 3.2 25 63.6 122.3 6 2,529 2.5 22 56.6 115.0 Age Group: 60-64 years Total Episodes 101,718 100.0 99 336.1 477.2 1 16,376 16.1 49 191.7 315.0 2 8,944 8.8 31 115.0 215.7 3 5,874 5.8 27 84.0 161.7 4 4,175 4.1 25	4	3,736	4.3	29	79.0	146.2
Age Group: 55-59 years Total Episodes 102,500 100.0 104 348.2 494.7 1 16,677 16.3 61 209.3 329.0 2 9,104 8.9 35 123.1 225.6 3 6,024 5.9 29 91.8 177.8 4 4,297 4.2 26 75.3 151.0 5 3,240 3.2 25 63.6 122.3 6 2,529 2.5 22 56.6 115.0 Age Group: 60-64 years Total Episodes 101,718 100.0 99 336.1 477.2 1 16,376 16.1 49 191.7 315.0 2 8,944 8.8 31 115.0 215.7 3 5,874 5.8 27 84.0 161.7 4 4,175 4.1 25 70.3 138.3 5 3,120 3.1 22 59.6 <t< td=""><td>5</td><td>2,840</td><td>3.2</td><td>27</td><td>72.6</td><td>137.9</td></t<>	5	2,840	3.2	27	72.6	137.9
Total Episodes 102,500 100.0 104 348.2 494.7 1 16,677 16.3 61 209.3 329.0 2 9,104 8.9 35 123.1 225.6 3 6,024 5.9 29 91.8 177.8 4 4,297 4.2 26 75.3 151.0 5 3,240 3.2 25 63.6 122.3 6 2,529 2.5 22 56.6 115.0 Age Group: 60-64 years Total Episodes 101,718 100.0 99 336.1 477.2 1 16,376 16.1 49 191.7 315.0 2 8,944 8.8 31 115.0 215.7 3 5,874 5.8 27 84.0 161.7 4 4,175 4.1 25 70.3 138.3 5 3,120 3.1 22 59.6 120.1	6	2,235	2.6	25	63.0	117.6
1 16,677 16.3 61 209.3 329.0 2 9,104 8.9 35 123.1 225.6 3 6,024 5.9 29 91.8 177.8 4 4,297 4.2 26 75.3 151.0 5 3,240 3.2 25 63.6 122.3 6 2,529 2.5 22 56.6 115.0 Age Group: 60-64 years Total Episodes 101,718 100.0 99 336.1 477.2 1 16,376 16.1 49 191.7 315.0 2 8,944 8.8 31 115.0 215.7 3 5,874 5.8 27 84.0 161.7 4 4,175 4.1 25 70.3 138.3 5 3,120 3.1 22 59.6 120.1	Age Group: 55-59 years					
2 9,104 8.9 35 123.1 225.6 3 6,024 5.9 29 91.8 177.8 4 4,297 4.2 26 75.3 151.0 5 3,240 3.2 25 63.6 122.3 6 2,529 2.5 22 56.6 115.0 Age Group: 60-64 years Total Episodes 101,718 100.0 99 336.1 477.2 1 16,376 16.1 49 191.7 315.0 2 8,944 8.8 31 115.0 215.7 3 5,874 5.8 27 84.0 161.7 4 4,175 4.1 25 70.3 138.3 5 3,120 3.1 22 59.6 120.1	Total Episodes	102,500	100.0	104	348.2	494.7
3 6,024 5.9 29 91.8 177.8 4 4,297 4.2 26 75.3 151.0 5 3,240 3.2 25 63.6 122.3 6 2,529 2.5 22 56.6 115.0 Age Group: 60-64 years Total Episodes 101,718 100.0 99 336.1 477.2 1 16,376 16.1 49 191.7 315.0 2 8,944 8.8 31 115.0 215.7 3 5,874 5.8 27 84.0 161.7 4 4,175 4.1 25 70.3 138.3 5 3,120 3.1 22 59.6 120.1	1	16,677	16.3	61	209.3	329.0
4 4,297 4.2 26 75.3 151.0 5 3,240 3.2 25 63.6 122.3 6 2,529 2.5 22 56.6 115.0 Age Group: 60-64 years Total Episodes 101,718 100.0 99 336.1 477.2 1 16,376 16.1 49 191.7 315.0 2 8,944 8.8 31 115.0 215.7 3 5,874 5.8 27 84.0 161.7 4 4,175 4.1 25 70.3 138.3 5 3,120 3.1 22 59.6 120.1	2	9,104	8.9	35	123.1	225.6
5 3,240 3.2 25 63.6 122.3 6 2,529 2.5 22 56.6 115.0 Age Group: 60-64 years Total Episodes 101,718 100.0 99 336.1 477.2 1 16,376 16.1 49 191.7 315.0 2 8,944 8.8 31 115.0 215.7 3 5,874 5.8 27 84.0 161.7 4 4,175 4.1 25 70.3 138.3 5 3,120 3.1 22 59.6 120.1	3	6,024	5.9	29	91.8	177.8
6 2,529 2.5 22 56.6 115.0 Age Group: 60-64 years Total Episodes 101,718 100.0 99 336.1 477.2 1 16,376 16.1 49 191.7 315.0 2 8,944 8.8 31 115.0 215.7 3 5,874 5.8 27 84.0 161.7 4 4,175 4.1 25 70.3 138.3 5 3,120 3.1 22 59.6 120.1	4	4,297	4.2	26	75.3	151.0
Age Group: 60-64 years Total Episodes 101,718 100.0 99 336.1 477.2 1 16,376 16.1 49 191.7 315.0 2 8,944 8.8 31 115.0 215.7 3 5,874 5.8 27 84.0 161.7 4 4,175 4.1 25 70.3 138.3 5 3,120 3.1 22 59.6 120.1	5	3,240	3.2	25	63.6	122.3
Total Episodes 101,718 100.0 99 336.1 477.2 1 16,376 16.1 49 191.7 315.0 2 8,944 8.8 31 115.0 215.7 3 5,874 5.8 27 84.0 161.7 4 4,175 4.1 25 70.3 138.3 5 3,120 3.1 22 59.6 120.1	6	2,529	2.5	22	56.6	115.0
1 16,376 16.1 49 191.7 315.0 2 8,944 8.8 31 115.0 215.7 3 5,874 5.8 27 84.0 161.7 4 4,175 4.1 25 70.3 138.3 5 3,120 3.1 22 59.6 120.1	Age Group: 60-64 years					
2 8,944 8.8 31 115.0 215.7 3 5,874 5.8 27 84.0 161.7 4 4,175 4.1 25 70.3 138.3 5 3,120 3.1 22 59.6 120.1	Total Episodes	101,718	100.0	99	336.1	477.2
3 5,874 5.8 27 84.0 161.7 4 4,175 4.1 25 70.3 138.3 5 3,120 3.1 22 59.6 120.1	1	16,376	16.1	49	191.7	315.0
4 4,175 4.1 25 70.3 138.3 5 3,120 3.1 22 59.6 120.1	2	8,944	8.8	31	115.0	215.7
5 3,120 3.1 22 59.6 120.1	3	5,874	5.8	27	84.0	161.7
	4	4,175	4.1	25	70.3	138.3
6 2,405 2.4 21 50.3 93.4	5	3,120	3.1	22	59.6	120.1
	6	2,405	2.4	21	50.3	93.4

cder_mpl1r_wp089 Page 54 of 79



Table 14b. Descriptive Statistics for Gaps (in Days) between Treatment Episodes of Metoclopramide among Female Members with Type 2 Diabetes and No Evidence of a Live Birth Delivery in the Sentinel Distributed Database between January 1, 2008 and September 30, 2015, by Age Group, for Episodes with Allowable Gaps of 0 Days

Gap Number ¹	Number	Percent	Median	Mean	Standard Deviation
Age Group: 65-69 years					
Total Episodes	158,799	100.0	126	368.6	489.3
1	25,262	15.9	47	189.8	309.3
2	13,117	8.3	30	111.9	211.0
3	8,477	5.3	26	83.4	168.7
4	5,929	3.7	24	67.6	138.6
5	4,425	2.8	23	59.4	124.1
6	3,354	2.1	22	52.1	96.2
Age Group: 70-74 years					
Total Episodes	150,509	100.0	121	371.0	492.4
1	23,687	15.7	44	183.8	302.4
2	12,391	8.2	28	107.4	204.4
3	7,997	5.3	25	77.3	152.2
4	5,694	3.8	23	64.0	125.9
5	4,279	2.8	21	57.0	119.1
6	3,244	2.2	19	52.4	112.7
Age Group: 75-79 years					
Total Episodes	118,624	100.0	102	356.2	487.3
1	18,861	15.9	36	162.9	280.0
2	10,053	8.5	25	94.7	184.8
3	6,397	5.4	21	70.4	146.5
4	4,551	3.8	20	57.3	113.1
5	3,391	2.9	18	49.1	103.0
6	2,576	2.2	17	45.1	91.7
Age Group: 80+ years					
Total Episodes	158,776	100.0	59	296.4	447.5
1	25,546	16.1	24	123.0	236.4
2	13,969	8.8	18	74.2	158.3
3	9,039	5.7	16	58.2	128.3
4	6,383	4.0	15	45.8	99.7
5	4,690	3.0	14	41.7	93.0
6	3,542	2.2	13	38.5	86.3

¹ Gap number indicates the sequential number of the gaps identified between episodes. The number of episodes with a gap of 1, represents members with at least two episodes. Note only the first 6 episodes are presented in this table.

cder_mpl1r_wp089 Page 55 of 79



Table 14c. Descriptive Statistics for Gaps (in Days) between Treatment Episodes of Metoclopramide among Female Members with Gastroparesis, Type 2 Diabetes, and No Evidence of a Live Birth Delivery in the Sentinel Distributed Database between January 1, 2008 and September 30, 2015, by Age Group, for Episodes with Allowable Gaps of 0 Days

Gap Number ¹	Number	Percent	Median	Mean	Standard Deviation
Age Group: 40-44 years					
Total Episodes	9,181	100.0	57	210.4	348.5
1	1,675	18.2	54	170.1	271.5
2	1,089	11.9	42	129.7	217.7
3	747	8.1	36	105.3	173.2
4	539	5.9	30	94.4	175.0
5	427	4.7	32	75.4	122.1
6	346	3.8	30	71.3	116.2
Age Group: 45-49 years					
Total Episodes	12,825	100.0	52	210.7	358.4
1	2,288	17.8	55	172.8	274.5
2	1,477	11.5	36	120.0	209.0
3	1,028	8.0	33	94.7	162.6
4	761	5.9	28	80.9	173.2
5	597	4.7	30	66.8	108.1
6	471	3.7	25	62.9	109.6
Age Group: 50-54 years					
Total Episodes	16,679	100.0	44	202.8	360.1
1	2,893	17.3	43	154.1	264.3
2	1,854	11.1	36	111.4	211.2
3	1,343	8.1	31	82.1	159.0
4	1,009	6.0	30	78.1	133.6
5	784	4.7	26	70.0	136.0
6	623	3.7	25	60.8	112.4
Age Group: 55-59 years					
Total Episodes	18,058	100.0	42	201.6	356.9
1	3,254	18.0	38	136.8	237.8
2	2,136	11.8	34	97.7	176.1
3	1,494	8.3	28	76.6	150.0
4	1,068	5.9	23	67.7	128.4
5	814	4.5	24	63.5	135.7
6	643	3.6	21	54.5	105.0
Age Group: 60-64 years					
Total Episodes	16,962	100.0	41	203.1	356.6
1	3,046	18.0	33	132.4	239.7
2	1,912	11.3	28	91.7	184.5
3	1,340	7.9	26	72.2	126.7
4	996	5.9	26	79.3	157.6
-		4 =	24	FO 4	112.0
5	755	4.5	21	58.4	113.8

cder_mpl1r_wp089 Page 56 of 79



Table 14c. Descriptive Statistics for Gaps (in Days) between Treatment Episodes of Metoclopramide among Female Members with Gastroparesis, Type 2 Diabetes, and No Evidence of a Live Birth Delivery in the Sentinel Distributed Database between January 1, 2008 and September 30, 2015, by Age Group, for Episodes with Allowable Gaps of 0 Days

Gap Number ¹	Number	Percent	Median	Mean	Standard Deviation
Age Group: 65-69 years					
Total Episodes	23,058	100.0	39	212.3	374.0
1	4,200	18.2	29	123.2	234.7
2	2,561	11.1	26	88.8	183.0
3	1,788	7.8	24	70.9	147.6
4	1,288	5.6	22	63.4	138.8
5	986	4.3	22	55.0	98.3
6	764	3.3	22	52.6	99.6
Age Group: 70-74 years					
Total Episodes	20,471	100.0	39	214.3	373.0
1	3,691	18.0	29	118.9	219.7
2	2,277	11.1	28	92.4	183.0
3	1,548	7.6	25	68.6	134.4
4	1,129	5.5	21	55.7	105.8
5	863	4.2	19	47.9	91.2
6	680	3.3	20	56.3	123.7
Age Group: 75-79 years					
Total Episodes	15,120	100.0	38	221.9	382.7
1	2,787	18.4	25	115.6	224.4
2	1,723	11.4	23	76.2	156.0
3	1,145	7.6	19	60.8	120.2
4	835	5.5	19	48.4	96.8
5	607	4.0	20	46.5	94.0
6	455	3.0	17	43.9	83.5
Age Group: 80+ years					
Total Episodes	17,302	100.0	28	196.1	364.3
1	3,161	18.3	19	85.2	184.1
2	1,874	10.8	18	68.2	156.9
3	1,284	7.4	16	55.4	120.6
4	918	5.3	15	43.7	94.6
5	672	3.9	12	37.9	86.9
6	520	3.0	12	33.9	61.6

¹ Gap number indicates the sequential number of the gaps identified between episodes. The number of episodes with a gap of 1, represents members with at least two episodes. Note only the first 6 episodes are presented in this table.

cder_mpl1r_wp089 Page 57 of 79



Table 15a. Cohort Attrition Table, for Episodes with Allowable Gaps of 50% of the Prior Dispensing

		mbers with No iveborn Delivery	Female Me Type 2 Diabe Evidence of Deli	etes, and No a Liveborn	Female Me Gastroparesi Diabetes, and of a Livebo	s and Type 2 I No Evidence
	Number	Percent	Number	Percent	Number	Percent
Total Episodes	2,163,033	100.0	839,609	100.0	116,829	100.0
Episodes censored due to disenrollment	****	<1	7,554	0.9	1,470	1.3
Episodes censored due to evidence of death	23,792	1.1	12,552	1.5	1,977	1.7
First episode censored due to Data Partner end date	****	<1	0	0.0	0	0.0
Episodes censored due to query end date	34,681	1.6	18,514	2.2	4,431	3.8
Episodes censored due to episode end date	2,108,680	97.5	810,436	96.5	110,725	94.8
Total Patients	1,436,794	100.0	502,877	100.0	52,937	100.0
First episode censored due to disenrollment	****	<1	3,565	0.7	642	1.2
First episode censored due to evidence of death	15,490	1.1	7,852	1.6	1,102	2.1
First episode censored due to Data Partner end date	****	<1	0	0.0	0	0.0
First episode censored due to query end date	12,924	0.9	6,463	1.3	1,501	2.8
First episode censored due to episode end date	1,410,977	98.2	489,662	97.4	50,475	95.3

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

cder_mpl1r_wp089 Page 58 of 79



Table 15b. Cohort Attrition Table, for Episodes with Allowable Gaps of 0 Days

	Female Mem Evidence of Deliv			etes, and No a Liveborn	Gastroparesi Diabetes, and	mbers with is and Type 2 I No Evidence rn Delivery
	Number	Percent	Number	Percent	Number	Percent
Total Episodes	2,450,284	100.0	990,235	100.0	149,656	100.0
Episodes censored due to disenrollment	****	<1	7,554	0.8	1,470	1.0
Episodes censored due to evidence of death	23,783	1.0	12,549	1.3	1,976	1.3
First episode censored due to Data Partner end date	****	<1	0	0.0	0	0.0
Episodes censored due to query end date	33,625	1.4	17,936	1.8	4,281	2.9
Episodes censored due to episode end date	2,397,178	97.8	961,730	97.1	143,721	96.0
Total Patients	1,436,794	100.0	502,877	100.0	52,937	100.0
First episode censored due to disenrollment	****	<1	2,674	0.5	474	0.9
First episode censored due to evidence of death	12,733	0.9	6,331	1.3	873	1.6
First episode censored due to Data Partner end date	****	<1	0	0.0	0	0.0
First episode censored due to query end date	8,839	0.6	4,300	0.9	982	1.9
First episode censored due to episode end date	1,417,533	98.7	493,193	98.1	51,200	96.7

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

cder_mpl1r_wp089 Page 59 of 79



Appendix A. Dates of Available Data for Each Data Partner (DP) until Request End Date (September 30, 2015)

DP ID	DP Start Date ¹	DP End Date
DP01	1/1/2008	9/30/2015
DP02	1/1/2012	9/30/2015
DP03	1/1/2006	9/30/2015
DP04	1/1/2000	9/30/2015
DP05	1/1/2000	9/30/2015
DP06	1/2/2000	5/31/2015
DP07	1/1/2000	9/30/2015
DP08	6/1/2007	9/30/2015
DP09	1/1/2000	9/30/2015
DP10	1/1/2000	9/30/2015
DP11	1/1/2005	9/30/2015
DP12	1/1/2000	9/30/2015
DP13	1/1/2000	9/30/2015
DP14	1/1/2004	9/30/2015
DP15	1/1/2008	9/30/2015
DP16	1/1/2000	9/30/2015
DP17	1/1/2010	9/30/2015

¹The start and end dates are based on the minimum and maximum dates within each DP. The month with the maximum date must have at least 80% of the number of records in the previous month.

cder_mpl1r_wp089 Page 60 of 79



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

Generic Name	Brand Name
Metoclopramide	Metoclopramide HCl
Metoclopramide	Reglan
Metoclopramide	Metozolv ODT

cder_mpl1r_wp089 Page 61 of 79



Appendix C. List of Healthcare Common Procedure Coding System (HCPCS) Procedure Codes Used to Define the Exposure in this Request

Code	Description	Code Type
J2765	Injection, metoclopramide HCl, up to 10 mg	HCPCS

cder_mpl1r_wp089 Page 62 of 79



Code	Description	Code Type	Code Category
59400	Routine obstetric care including antepartum care, vaginal delivery (with or without	CPT-4	Procedure
33400	episiotomy, and/or forceps) and postpartum care	City	rroccaure
59409	Vaginal delivery only (with or without episiotomy and/or forceps);	CPT-4	Procedure
59410	Vaginal delivery only (with or without episiotomy and/or forceps); including postpartum care	CPT-4	Procedure
59510	Routine obstetric care including antepartum care, cesarean delivery, and postpartum care	CPT-4	Procedure
59514	Cesarean delivery only;	CPT-4	Procedure
59515	Cesarean delivery only; including postpartum care	CPT-4	Procedure
59610	Routine obstetric care including antepartum care, vaginal delivery (with or without	CPT-4	Procedure
	episiotomy, and/or forceps) and postpartum care, after previous cesarean delivery		
59612	Vaginal delivery only, after previous cesarean delivery (with or without episiotomy and/or forceps);	CPT-4	Procedure
59614	Vaginal delivery only, after previous cesarean delivery (with or without episiotomy and/or forceps); including postpartum care	CPT-4	Procedure
59618	Routine obstetric care including antepartum care, cesarean delivery, and postpartum care, following attempted vaginal delivery after previous cesarean delivery	CPT-4	Procedure
59620	Cesarean delivery only, following attempted vaginal delivery after previous cesarean delivery;	CPT-4	Procedure
59622	Cesarean delivery only, following attempted vaginal delivery after previous cesarean delivery; including postpartum care	CPT-4	Procedure
641.01	Placenta previa without hemorrhage, with delivery	ICD-9-CM	Diagnosis
641.11	Hemorrhage from placenta previa, with delivery	ICD-9-CM	Diagnosis
641.21	Premature separation of placenta, with delivery	ICD-9-CM	Diagnosis
641.31	Antepartum hemorrhage associated with coagulation defects, with delivery	ICD-9-CM	Diagnosis
641.81	Other antepartum hemorrhage, with delivery	ICD-9-CM	Diagnosis
641.91	Unspecified antepartum hemorrhage, with delivery	ICD-9-CM	Diagnosis
642.01	Benign essential hypertension with delivery	ICD-9-CM	Diagnosis
642.02	Benign essential hypertension, with delivery, with current postpartum complication	ICD-9-CM	Diagnosis
642.11	Hypertension secondary to renal disease, with delivery	ICD-9-CM	Diagnosis
642.12	Hypertension secondary to renal disease, with delivery, with current postpartum complication	ICD-9-CM	Diagnosis
642.21	Other pre-existing hypertension, with delivery	ICD-9-CM	Diagnosis
642.22	Other pre-existing hypertension, with delivery, with current postpartum complication	ICD-9-CM	Diagnosis
642.31	Transient hypertension of pregnancy, with delivery	ICD-9-CM	Diagnosis
642.32	Transient hypertension of pregnancy, with delivery, with current postpartum complication	ICD-9-CM	Diagnosis
642.41	Mild or unspecified pre-eclampsia, with delivery	ICD-9-CM	Diagnosis
642.42	Mild or unspecified pre-eclampsia, with delivery, with current postpartum complication	ICD-9-CM	Diagnosis
642.51	Severe pre-eclampsia, with delivery	ICD-9-CM	Diagnosis
642.52	Severe pre-eclampsia, with delivery, with current postpartum complication	ICD-9-CM	Diagnosis
642.61	Eclampsia, with delivery	ICD-9-CM	Diagnosis
642.62	Eclampsia, with delivery, with current postpartum complication	ICD-9-CM	Diagnosis
642.71	Pre-eclampsia or eclampsia superimposed on pre-existing hypertension, with delivery	ICD-9-CM	Diagnosis
642.72	Pre-eclampsia or eclampsia superimposed on pre-existing hypertension, with delivery, with current postpartum complication	ICD-9-CM	Diagnosis
642.91	Unspecified hypertension, with delivery	ICD-9-CM	Diagnosis

cder_mpl1r_wp089 Page 63 of 79



			Code
Code	Description	Code Type	Category
642.92	Unspecified hypertension, with delivery, with current postpartum complication	ICD-9-CM	Diagnosis
643.01	Mild hyperemesis gravidarum, delivered	ICD-9-CM	Diagnosis
643.11	Hyperemesis gravidarum with metabolic disturbance, delivered	ICD-9-CM	Diagnosis
643.21	Late vomiting of pregnancy, delivered	ICD-9-CM	Diagnosis
643.81	Other vomiting complicating pregnancy, delivered	ICD-9-CM	Diagnosis
643.91	Unspecified vomiting of pregnancy, delivered	ICD-9-CM	Diagnosis
644.21	Early onset of delivery, delivered, with or without mention of antepartum condition	ICD-9-CM	Diagnosis
645.01	Prolonged pregnancy, with delivery	ICD-9-CM	Diagnosis
645.11	Post term pregnancy, delivered, with or without mention of antepartum condition	ICD-9-CM	Diagnosis
645.21	Non-specific live birth delivery code	ICD-9-CM	Diagnosis
645.22	Prolonged pregnancy, delivered, with or without mention of antepartum condition	ICD-9-CM	Diagnosis
646.01	Papyraceous fetus, delivered, with or without mention of antepartum condition	ICD-9-CM	Diagnosis
646.11	Edema or excessive weight gain in pregnancy, with delivery, with or without mention of antepartum complication	ICD-9-CM	Diagnosis
646.12	Edema or excessive weight gain in pregnancy, with delivery, with current postpartum complication	ICD-9-CM	Diagnosis
646.21	Unspecified renal disease in pregnancy, with delivery	ICD-9-CM	Diagnosis
646.22	Unspecified renal disease in pregnancy, with delivery, with current postpartum complication	ICD-9-CM	Diagnosis
646.31	Pregnancy complication, recurrent pregnancy loss, with or without mention of antepartum condition	ICD-9-CM	Diagnosis
646.41	Peripheral neuritis in pregnancy, with delivery	ICD-9-CM	Diagnosis
646.42	Peripheral neuritis in pregnancy, with delivery, with current postpartum complication	ICD-9-CM	Diagnosis
646.51	Asymptomatic bacteriuria in pregnancy, with delivery	ICD-9-CM	Diagnosis
646.52	Asymptomatic bacteriuria in pregnancy, with delivery, with current postpartum complication	ICD-9-CM	Diagnosis
646.61	Infections of genitourinary tract in pregnancy, with delivery	ICD-9-CM	Diagnosis
646.62	Infections of genitourinary tract in pregnancy, with delivery, with current postpartum	ICD-9-CM	Diagnosis
646.71	Liver and biliary tract disorders in pregnancy, delivered, with or without mention of antepartum condition	ICD-9-CM	Diagnosis
646.81	Other specified complication of pregnancy, with delivery	ICD-9-CM	Diagnosis
646.82	Other specified complications of pregnancy, with delivery, with current postpartum	ICD-9-CM	Diagnosis
646.91	Unspecified complication of pregnancy, with delivery	ICD-9-CM	Diagnosis
647.01	Maternal syphilis, complicating pregnancy, with delivery	ICD-9-CM	Diagnosis
647.02	Maternal syphilis, complicating pregnancy, with delivery, with current postpartum	ICD-9-CM	Diagnosis
647.11	Maternal gonorrhea with delivery	ICD-9-CM	Diagnosis
647.12	Maternal gonorrhea, with delivery, with current postpartum complication	ICD-9-CM	Diagnosis
647.21	Other maternal venereal diseases with delivery	ICD-9-CM	Diagnosis
647.22	Other maternal venereal diseases with delivery, with current postpartum complication	ICD-9-CM	Diagnosis
647.31	Maternal tuberculosis with delivery	ICD-9-CM	Diagnosis
647.32	Maternal tuberculosis with delivery, with current postpartum complication	ICD-9-CM	Diagnosis
647.41	Maternal malaria with delivery	ICD-9-CM	Diagnosis
647.42	Maternal malaria with delivery, with current postpartum complication	ICD-9-CM	Diagnosis
647.51	Maternal rubella with delivery	ICD-9-CM	Diagnosis
647.52	Maternal rubella with delivery, with current postpartum complication	ICD-9-CM	Diagnosis

cder_mpl1r_wp089 Page 64 of 79



	Description	Codo Timo	Code
Code	Description	Code Type	Category
647.61	Other maternal viral disease with delivery	ICD-9-CM	Diagnosis
647.62	Other maternal viral disease with delivery, with current postpartum complication	ICD-9-CM	Diagnosis
647.81	Other specified maternal infectious and parasitic disease with delivery	ICD-9-CM	Diagnosis
647.82	Other specified maternal infectious and parasitic disease with delivery, with current postpartum complication	ICD-9-CM	Diagnosis
647.91	Unspecified maternal infection or infestation with delivery	ICD-9-CM	Diagnosis
647.92	Unspecified maternal infection or infestation with delivery, with current postpartum	ICD-9-CM	Diagnosis
648.01	Maternal diabetes mellitus with delivery	ICD-9-CM	Diagnosis
648.02	Maternal diabetes mellitus with delivery, with current postpartum complication	ICD-9-CM	Diagnosis
648.11	Maternal thyroid dysfunction with delivery, with or without mention of antepartum	ICD-9-CM	Diagnosis
648.12	Maternal thyroid dysfunction with delivery, with current postpartum complication	ICD-9-CM	Diagnosis
648.21	Maternal anemia, with delivery	ICD-9-CM	Diagnosis
648.22	Maternal anemia with delivery, with current postpartum complication	ICD-9-CM	Diagnosis
648.31	Maternal drug dependence, with delivery	ICD-9-CM	Diagnosis
648.32	Maternal drug dependence, with delivery, with current postpartum complication	ICD-9-CM	Diagnosis
648.41	Maternal mental disorders, with delivery	ICD-9-CM	Diagnosis
648.42	Maternal mental disorders, with delivery, with current postpartum complication	ICD-9-CM	Diagnosis
648.51	Maternal congenital cardiovascular disorders, with delivery	ICD-9-CM	Diagnosis
648.52	Maternal congenital cardiovascular disorders, with delivery, with current postpartum	ICD-9-CM	Diagnosis
648.61	Other maternal cardiovascular diseases, with delivery	ICD-9-CM	Diagnosis
648.62	Other maternal cardiovascular diseases, with delivery, with current postpartum complication	ICD-9-CM	Diagnosis
648.71	Bone and joint disorders of maternal back, pelvis, and lower limbs, with delivery	ICD-9-CM	Diagnosis
648.72	Bone and joint disorders of maternal back, pelvis, and lower limbs, with delivery, with current postpartum complication	ICD-9-CM	Diagnosis
648.81	Abnormal maternal glucose tolerance, with delivery	ICD-9-CM	Diagnosis
648.82	Abnormal maternal glucose tolerance, with delivery, with current postpartum complication	ICD-9-CM	Diagnosis
648.91	Other current maternal conditions classifiable elsewhere, with delivery	ICD-9-CM	Diagnosis
648.92	Other current maternal conditions classifiable elsewhere, with delivery, with current postpartum complication	ICD-9-CM	Diagnosis
649.01	Tobacco use disorder complicating pregnancy, childbirth, or the puerperium, delivered, with or without mention of antepartum condition	ICD-9-CM	Diagnosis
649.02	Tobacco use disorder complicating pregnancy, childbirth, or the puerperium, delivered, with mention of postpartum complication	ICD-9-CM	Diagnosis
649.11	Obesity complicating pregnancy, childbirth, or the puerperium, delivered, with or without mention of antepartum condition	ICD-9-CM	Diagnosis
649.12	Obesity complicating pregnancy, childbirth, or the puerperium, delivered, with mention of postpartum complication	ICD-9-CM	Diagnosis
649.21	Bariatric surgery status complicating pregnancy, childbirth, or the puerperium, delivered, with or without mention of antepartum condition	ICD-9-CM	Diagnosis
649.22	Bariatric surgery status complicating pregnancy, childbirth, or the puerperium, delivered, with mention of postpartum complication	ICD-9-CM	Diagnosis
649.31	Coagulation defects complicating pregnancy, childbirth, or the puerperium, delivered, with or without mention of antepartum condition	ICD-9-CM	Diagnosis

cder_mpl1r_wp089 Page 65 of 79



Cada	Description	Code Type	Code Category
Code 649.32	Description Congression defeats complicating programs, shildhigh or the programs delivered with	ICD-9-CM	
049.32	Coagulation defects complicating pregnancy, childbirth, or the puerperium, delivered, with mention of postpartum complication	ICD-9-CIVI	Diagnosis
649.41	Epilepsy complicating pregnancy, childbirth, or the puerperium, delivered, with or without	ICD-9-CM	Diagnosis
045.41	mention of antepartum condition	ICD-J-CIVI	Diagnosis
649.42	Epilepsy complicating pregnancy, childbirth, or the puerperium, delivered, with mention of	ICD-9-CM	Diagnosis
043.42	postpartum complication	ICD 5 CIVI	Diagnosis
649.51	Spotting complicating pregnancy, delivered, with or without mention of antepartum	ICD-9-CM	Diagnosis
	condition		
649.61	Uterine size date discrepancy, delivered, with or without mention of antepartum condition	ICD-9-CM	Diagnosis
649.62	Uterine size date discrepancy, delivered, with mention of postpartum complication	ICD-9-CM	Diagnosis
649.71	Cervical shortening, delivered, with or without mention of antepartum condition	ICD-9-CM	Diagnosis
649.81	Onset (spontaneous) of labor after 37 completed weeks of gestation but before 39	ICD-9-CM	Diagnosis
	completed weeks gestation, with delivery by (planned) cesarean section, delivered, with or		
	without mention of antepartum condition		
649.82	Onset (spontaneous) of labor after 37 completed weeks of gestation but before 39	ICD-9-CM	Diagnosis
	completed weeks gestation, with delivery by (planned) cesarean section, delivered, with		
	mention of postpartum complication		
650	Normal delivery	ICD-9-CM	Diagnosis
651.01	Twin pregnancy, delivered	ICD-9-CM	Diagnosis
651.11	Triplet pregnancy, delivered	ICD-9-CM	Diagnosis
651.21	Quadruplet pregnancy, delivered	ICD-9-CM	Diagnosis
651.31	Twin pregnancy with fetal loss and retention of one fetus, delivered	ICD-9-CM	Diagnosis
651.41	Triplet pregnancy with fetal loss and retention of one or more, delivered	ICD-9-CM	Diagnosis
651.51	Quadruplet pregnancy with fetal loss and retention of one or more, delivered	ICD-9-CM	Diagnosis
651.61	Other multiple pregnancy with fetal loss and retention of one or more fetus(es), delivered	ICD-9-CM	Diagnosis
651.71	Multiple gestation following (elective) fetal reduction, delivered, with or without mention of antepartum condition	ICD-9-CM	Diagnosis
651.81	Other specified multiple gestation, delivered	ICD-9-CM	Diagnosis
651.91	Unspecified multiple gestation, delivered	ICD-9-CM	Diagnosis
652.01	Unstable lie of fetus, delivered	ICD-9-CM	Diagnosis
652.11	Breech or other malpresentation successfully converted to cephalic presentation, delivered	ICD-9-CM	Diagnosis
652.21	Breech presentation without mention of version, delivered	ICD-9-CM	Diagnosis
652.31	Transverse or oblique fetal presentation, delivered	ICD-9-CM	Diagnosis
652.41	Fetal face or brow presentation, delivered	ICD-9-CM	Diagnosis
652.51	High fetal head at term, delivered	ICD-9-CM	Diagnosis
652.61	Multiple gestation with malpresentation of one fetus or more, delivered	ICD-9-CM	Diagnosis
652.71	Prolapsed arm of fetus, delivered	ICD-9-CM	Diagnosis
652.81	Other specified malposition or malpresentation of fetus, delivered	ICD-9-CM	Diagnosis
652.91	Unspecified malposition or malpresentation of fetus, delivered	ICD-9-CM	Diagnosis
653.01	Major abnormality of bony pelvis, not further specified, delivered	ICD-9-CM	Diagnosis
653.11	Generally contracted pelvis in pregnancy, delivered	ICD-9-CM	Diagnosis
653.21	Inlet contraction of pelvis in pregnancy, delivered	ICD-9-CM	Diagnosis
653.31	Outlet contraction of pelvis in pregnancy, delivered	ICD-9-CM	Diagnosis

cder_mpl1r_wp089 Page 66 of 79



			Code
Code	Description	Code Type	Category
653.41	Fetopelvic disproportion, delivered	ICD-9-CM	Diagnosis
653.51	Unusually large fetus causing disproportion, delivered	ICD-9-CM	Diagnosis
653.61	Hydrocephalic fetus causing disproportion, delivered	ICD-9-CM	Diagnosis
653.71	Other fetal abnormality causing disproportion, delivered	ICD-9-CM	Diagnosis
653.81	Fetal disproportion of other origin, delivered	ICD-9-CM	Diagnosis
653.91	Unspecified fetal disproportion, delivered	ICD-9-CM	Diagnosis
654.01	Congenital abnormalities of pregnant uterus, delivered	ICD-9-CM	Diagnosis
654.02	Congenital abnormalities of pregnant uterus, delivered, with mention of postpartum	ICD-9-CM	Diagnosis
	complication		
654.11	Tumors of body of uterus, delivered	ICD-9-CM	Diagnosis
654.12	Tumors of body of uterus, delivered, with mention of postpartum complication	ICD-9-CM	Diagnosis
654.21	Previous cesarean delivery, delivered, with or without mention of antepartum condition	ICD-9-CM	Diagnosis
654.31	Retroverted and incarcerated gravid uterus, delivered	ICD-9-CM	Diagnosis
654.32	Retroverted and incarcerated gravid uterus, delivered, with mention of postpartum	ICD-9-CM	Diagnosis
654.41	Other abnormalities in shape or position of gravid uterus and of neighboring structures,	ICD-9-CM	Diagnosis
	delivered		
654.42	Other abnormalities in shape or position of gravid uterus and of neighboring structures,	ICD-9-CM	Diagnosis
	delivered, with mention of postpartum complication		
654.51	Cervical incompetence, delivered	ICD-9-CM	Diagnosis
654.52	Cervical incompetence, delivered, with mention of postpartum complication	ICD-9-CM	Diagnosis
654.61	Other congenital or acquired abnormality of cervix, with delivery	ICD-9-CM	Diagnosis
654.62	Other congenital or acquired abnormality of cervix, delivered, with mention of postpartum	ICD-9-CM	Diagnosis
	complication		
654.71	Congenital or acquired abnormality of vagina, with delivery	ICD-9-CM	Diagnosis
654.72	Congenital or acquired abnormality of vagina, delivered, with mention of postpartum	ICD-9-CM	Diagnosis
654.81	Congenital or acquired abnormality of vulva, with delivery	ICD-9-CM	Diagnosis
654.82	Congenital or acquired abnormality of vulva, delivered, with mention of postpartum	ICD-9-CM	Diagnosis
654.91	Other and unspecified abnormality of organs and soft tissues of pelvis, with delivery	ICD-9-CM	Diagnosis
654.92	Other and unspecified abnormality of organs and soft tissues of pelvis, delivered, with	ICD-9-CM	Diagnosis
	mention of postpartum complication		
655.01	Central nervous system malformation in fetus, with delivery	ICD-9-CM	Diagnosis
655.11	Chromosomal abnormality in fetus, affecting management of mother, with delivery	ICD-9-CM	Diagnosis
655.21	Hereditary disease in family possibly affecting fetus, affecting management of mother, with	ICD-9-CM	Diagnosis
655.31	Suspected damage to fetus from viral disease in mother, affecting management of mother, with delivery	ICD-9-CM	Diagnosis
655.41	Suspected damage to fetus from other disease in mother, affecting management of mother, with delivery	ICD-9-CM	Diagnosis
655.51	Suspected damage to fetus from drugs, affecting management of mother, delivered	ICD-9-CM	Diagnosis
655.61	Suspected damage to fetus from radiation, affecting management of mother, delivered	ICD-9-CM	Diagnosis
655.71	Decreased fetal movements, affecting management of mother, delivered	ICD-9-CM	Diagnosis
655.81	Other known or suspected fetal abnormality, not elsewhere classified, affecting management	ICD-9-CM	Diagnosis
	of mother, delivery		
655.91	Unspecified fetal abnormality affecting management of mother, delivery	ICD-9-CM	Diagnosis

cder_mpl1r_wp089 Page 67 of 79



			Code
Code	Description	Code Type	Category
656.01	Fetal-maternal hemorrhage, with delivery	ICD-9-CM	Diagnosis
656.11	Rhesus isoimmunization affecting management of mother, delivered	ICD-9-CM	Diagnosis
656.21	Isoimmunization from other and unspecified blood-group incompatibility, affecting	ICD-9-CM	Diagnosis
	management of mother, delivered		
656.31	Fetal distress affecting management of mother, delivered	ICD-9-CM	Diagnosis
656.41	Intrauterine death affecting management of mother, delivered	ICD-9-CM	Diagnosis
656.51	Poor fetal growth, affecting management of mother, delivered	ICD-9-CM	Diagnosis
656.61	Excessive fetal growth affecting management of mother, delivered	ICD-9-CM	Diagnosis
656.71	Other placental conditions affecting management of mother, delivered	ICD-9-CM	Diagnosis
656.81	Other specified fetal and placental problems affecting management of mother, delivered	ICD-9-CM	Diagnosis
656.91	Unspecified fetal and placental problem affecting management of mother, delivered	ICD-9-CM	Diagnosis
657.01	Polyhydramnios, with delivery	ICD-9-CM	Diagnosis
658.01	Oligohydramnios, delivered	ICD-9-CM	Diagnosis
658.11	Premature rupture of membranes in pregnancy, delivered	ICD-9-CM	Diagnosis
658.21	Delayed delivery after spontaneous or unspecified rupture of membranes, delivered	ICD-9-CM	Diagnosis
658.31	Delayed delivery after artificial rupture of membranes, delivered	ICD-9-CM	Diagnosis
658.41	Infection of amniotic cavity, delivered	ICD-9-CM	Diagnosis
658.81	Other problem associated with amniotic cavity and membranes, delivered	ICD-9-CM	Diagnosis
658.91	Unspecified problem associated with amniotic cavity and membranes, delivered	ICD-9-CM	Diagnosis
659.01	Failed mechanical induction of labor, delivered	ICD-9-CM	Diagnosis
659.11	Failed medical or unspecified induction of labor, delivered	ICD-9-CM	Diagnosis
659.21	Unspecified maternal pyrexia during labor, delivered	ICD-9-CM	Diagnosis
659.31	Generalized infection during labor, delivered	ICD-9-CM	Diagnosis
659.41	Grand multiparity, delivered, with or without mention of antepartum condition	ICD-9-CM	Diagnosis
659.51	Elderly primigravida, delivered	ICD-9-CM	Diagnosis
659.61	Elderly multigravida, delivered, with mention of antepartum condition	ICD-9-CM	Diagnosis
659.71	Abnormality in fetal heart rate or rhythm, delivered, with or without mention of antepartum condition	ICD-9-CM	Diagnosis
659.81	Other specified indication for care or intervention related to labor and delivery, delivered	ICD-9-CM	Diagnosis
659.91	Unspecified indication for care or intervention related to labor and delivery, delivered	ICD-9-CM	Diagnosis
660.01	Obstruction caused by malposition of fetus at onset of labor, delivered	ICD-9-CM	Diagnosis
660.11	Obstruction by bony pelvis during labor and delivery, delivered	ICD-9-CM	Diagnosis
660.21	Obstruction by abnormal pelvic soft tissues during labor and delivery, delivered	ICD-9-CM	Diagnosis
660.31	Deep transverse arrest and persistent occipitoposterior position during labor and deliver, delivered	ICD-9-CM	Diagnosis
660.41	Shoulder (girdle) dystocia during labor and deliver, delivered	ICD-9-CM	Diagnosis
660.51	Locked twins, delivered	ICD-9-CM	Diagnosis
660.61	Unspecified failed trial of labor, delivered	ICD-9-CM	Diagnosis
660.71	Unspecified failed forceps or vacuum extractor, delivered	ICD-9-CM	Diagnosis
660.81	Other causes of obstructed labor, delivered	ICD-9-CM	Diagnosis
660.91	Unspecified obstructed labor, with delivery	ICD-9-CM	Diagnosis
661.01	Primary uterine inertia, with delivery	ICD-9-CM	Diagnosis
661.11	Secondary uterine inertia, with delivery	ICD-9-CM	Diagnosis

cder_mpl1r_wp089 Page 68 of 79



			Code
Code	Description	Code Type	Category
661.21	Other and unspecified uterine inertia, with delivery	ICD-9-CM	Diagnosis
661.31	Precipitate labor, with delivery	ICD-9-CM	Diagnosis
661.41	Hypertonic, incoordinate, or prolonged uterine contractions, with delivery	ICD-9-CM	Diagnosis
661.91	Unspecified abnormality of labor, with delivery	ICD-9-CM	Diagnosis
662.01	Prolonged first stage of labor, delivered	ICD-9-CM	Diagnosis
662.11	Unspecified prolonged labor, delivered	ICD-9-CM	Diagnosis
662.21	Prolonged second stage of labor, delivered	ICD-9-CM	Diagnosis
662.31	Delayed delivery of second twin, triplet, etc., delivered	ICD-9-CM	Diagnosis
663.01	Prolapse of cord, complicating labor and delivery, delivered	ICD-9-CM	Diagnosis
663.11	Cord around neck, with compression, complicating labor and delivery, delivered	ICD-9-CM	Diagnosis
6632.1	Other and unspecified cord entanglement, with compression, complicating labor and delivery, delivered	ICD-9-CM	Diagnosis
663.31	Other and unspecified cord entanglement, without mention of compression, complicating	ICD-9-CM	Diagnosis
	labor and delivery, delivered		J
663.41	Short cord complicating labor and delivery, delivered	ICD-9-CM	Diagnosis
663.51	Vasa previa complicating labor and delivery, delivered	ICD-9-CM	Diagnosis
663.61	Vascular lesions of cord complicating labor and delivery, delivered	ICD-9-CM	Diagnosis
663.81	Other umbilical cord complications during labor and delivery, delivered	ICD-9-CM	Diagnosis
663.91	Unspecified umbilical cord complication during labor and delivery, delivered	ICD-9-CM	Diagnosis
664.01	First-degree perineal laceration, with delivery	ICD-9-CM	Diagnosis
664.11	Second-degree perineal laceration, with delivery	ICD-9-CM	Diagnosis
664.21	Third-degree perineal laceration, with delivery	ICD-9-CM	Diagnosis
664.31	Fourth-degree perineal laceration, with delivery	ICD-9-CM	Diagnosis
664.41	Unspecified perineal laceration, with delivery	ICD-9-CM	Diagnosis
664.51	Vulvar and perineal hematoma, with delivery	ICD-9-CM	Diagnosis
664.61	Anal sphincter tear complicating delivery, not associated with third-degree perineal	ICD-9-CM	Diagnosis
	laceration, delivered, with or without mention of antepartum condition		
664.81	Other specified trauma to perineum and vulva, with delivery	ICD-9-CM	Diagnosis
664.91	Unspecified trauma to perineum and vulva, with delivery	ICD-9-CM	Diagnosis
665.01	Rupture of uterus before onset of labor, with delivery	ICD-9-CM	Diagnosis
665.11	Rupture of uterus during labor, with delivery	ICD-9-CM	Diagnosis
665.22	Inversion of uterus, delivered with postpartum complication	ICD-9-CM	Diagnosis
665.31	Laceration of cervix, with delivery	ICD-9-CM	Diagnosis
665.41	High vaginal laceration, with delivery	ICD-9-CM	Diagnosis
665.51	Other injury to pelvic organs, with delivery	ICD-9-CM	Diagnosis
665.61	Damage to pelvic joints and ligaments, with delivery	ICD-9-CM	Diagnosis
665.71	Pelvic hematoma, with delivery	ICD-9-CM	Diagnosis
665.72	Pelvic hematoma, delivered with postpartum complication	ICD-9-CM	Diagnosis
665.81	Other specified obstetrical trauma, with delivery	ICD-9-CM	Diagnosis
665.82	Other specified obstetrical trauma, delivered, with postpartum	ICD-9-CM	Diagnosis
665.91	Unspecified obstetrical trauma, with delivery	ICD-9-CM	Diagnosis
665.92	Unspecified obstetrical trauma, delivered, with postpartum complication	ICD-9-CM	Diagnosis
666.02	Third-stage postpartum hemorrhage, with delivery	ICD-9-CM	Diagnosis

cder_mpl1r_wp089 Page 69 of 79



			Code
Code	Description	Code Type	Category
666.12	Other immediate postpartum hemorrhage, with delivery	ICD-9-CM	Diagnosis
666.22	Delayed and secondary postpartum hemorrhage, with delivery	ICD-9-CM	Diagnosis
666.32	Postpartum coagulation defects, with delivery	ICD-9-CM	Diagnosis
667.02	Retained placenta without hemorrhage, with delivery, with mention of postpartum	ICD-9-CM	Diagnosis
667.12	Retained portions of placenta or membranes, without hemorrhage, delivered, with mention of postpartum complication	ICD-9-CM	Diagnosis
668.01	Pulmonary complications of the administration of anesthesia or other sedation in labor and delivery, delivered	ICD-9-CM	Diagnosis
668.02	Pulmonary complications of the administration of anesthesia or other sedation in labor and delivery, delivered, with mention of postpartum complication	ICD-9-CM	Diagnosis
668.11	Cardiac complications of the administration of anesthesia or other sedation in labor and delivery, delivered	ICD-9-CM	Diagnosis
668.12	Cardiac complications of the administration of anesthesia or other sedation in labor and delivery, delivered, with mention of postpartum complication	ICD-9-CM	Diagnosis
668.21	Central nervous system complications of the administration of anesthesia or other sedation in labor and delivery, delivered	ICD-9-CM	Diagnosis
668.22	Central nervous system complications of the administration of anesthesia or other sedation in labor and delivery, delivered, with mention of postpartum complication	ICD-9-CM	Diagnosis
668.81	Other complications of the administration of anesthesia or other sedation in labor and delivery, delivered	ICD-9-CM	Diagnosis
668.82	Other complications of the administration of anesthesia or other sedation in labor and delivery, delivered, with mention of postpartum complication	ICD-9-CM	Diagnosis
668.91	Unspecified complication of the administration of anesthesia or other sedation in labor and delivery, delivered	ICD-9-CM	Diagnosis
668.92	Unspecified complication of the administration of anesthesia or other sedation in labor and delivery, delivered, with mention of postpartum complication	ICD-9-CM	Diagnosis
669.01	Maternal distress, with delivery, with or without mention of antepartum condition	ICD-9-CM	Diagnosis
669.02	Maternal distress, with delivery, with mention of postpartum complication	ICD-9-CM	Diagnosis
669.11	Shock during or following labor and delivery, with delivery, with or without mention of antepartum condition	ICD-9-CM	Diagnosis
669.12	Shock during or following labor and delivery, with delivery, with mention of postpartum complication	ICD-9-CM	Diagnosis
669.21	Maternal hypotension syndrome, with delivery, with or without mention of antepartum condition	ICD-9-CM	Diagnosis
669.22	Maternal hypotension syndrome, with delivery, with mention of postpartum complication	ICD-9-CM	Diagnosis
669.32	Acute kidney failure following labor and delivery, delivered, with mention of postpartum complication	ICD-9-CM	Diagnosis
669.41	Other complications of obstetrical surgery and procedures, with delivery, with or without mention of antepartum condition	ICD-9-CM	Diagnosis
669.42	Other complications of obstetrical surgery and procedures, with delivery, with mention of postpartum complication	ICD-9-CM	Diagnosis
669.51	Forceps or vacuum extractor delivery without mention of indication, delivered, with or without mention of antepartum condition	ICD-9-CM	Diagnosis

cder_mpl1r_wp089 Page 70 of 79



Code	Description	Code Type	Code Category
669.61	Breech extraction, without mention of indication, delivered, with or without mention of	ICD-9-CM	Diagnosis
	antepartum condition		
669.71	Cesarean delivery, without mention of indication, delivered, with or without mention of antepartum condition	ICD-9-CM	Diagnosis
669.81	Other complication of labor and delivery, delivered, with or without mention of antepartum condition	ICD-9-CM	Diagnosis
669.82	Other complication of labor and delivery, delivered, with mention of postpartum	ICD-9-CM	Diagnosis
669.91	Unspecified complication of labor and delivery, with delivery, with or without mention of antepartum condition	ICD-9-CM	Diagnosis
669.92	Unspecified complication of labor and delivery, with delivery, with mention of postpartum complication	ICD-9-CM	Diagnosis
670.02	Major puerperal infection, unspecified, delivered, with mention of postpartum complication	ICD-9-CM	Diagnosis
670.12	Puerperal endometritis, delivered, with mention of postpartum complication	ICD-9-CM	Diagnosis
670.22	Puerperal sepsis, delivered, with mention of postpartum complication	ICD-9-CM	Diagnosis
670.32	Puerperal septic thrombophlebitis, delivered, with mention of postpartum complication	ICD-9-CM	Diagnosis
670.82	Other major puerperal infection, delivered, with mention of postpartum complication	ICD-9-CM	Diagnosis
671.01	Varicose veins of legs, with delivery, with or without mention of antepartum condition	ICD-9-CM	Diagnosis
671.02	Varicose veins of legs, with delivery, with mention of postpartum complication	ICD-9-CM	Diagnosis
671.11	Varicose veins of vulva and perineum, with delivery, with or without mention of antepartum condition	ICD-9-CM	Diagnosis
671.12	Varicose veins of vulva and perineum, with delivery, with mention of postpartum	ICD-9-CM	Diagnosis
671.21	Superficial thrombophlebitis with delivery, with or without mention of antepartum condition	ICD-9-CM	Diagnosis
671.22	Superficial thrombophlebitis with delivery, with mention of postpartum complication	ICD-9-CM	Diagnosis
671.31	Deep phlebothrombosis, antepartum, with delivery	ICD-9-CM	Diagnosis
671.42	Deep phlebothrombosis, postpartum, with delivery	ICD-9-CM	Diagnosis
671.51	Other phlebitis and thrombosis with delivery, with or without mention of antepartum condition	ICD-9-CM	Diagnosis
671.52	Other phlebitis and thrombosis with delivery, with mention of postpartum complication	ICD-9-CM	Diagnosis
671.81	Other venous complication, with delivery, with or without mention of antepartum condition	ICD-9-CM	Diagnosis
671.82	Other venous complication, with delivery, with mention of postpartum complication	ICD-9-CM	Diagnosis
671.91	Unspecified venous complication, with delivery, with or without mention of antepartum condition	ICD-9-CM	Diagnosis
671.92	Unspecified venous complication, with delivery, with mention of postpartum complication	ICD-9-CM	Diagnosis
672.02	Puerperal pyrexia of unknown origin, delivered, with mention of postpartum complication	ICD-9-CM	Diagnosis
673.01	Obstetrical air embolism, with delivery, with or without mention of antepartum condition	ICD-9-CM	Diagnosis
673.02	Obstetrical air embolism, with delivery, with mention of postpartum complication	ICD-9-CM	Diagnosis
673.11	Amniotic fluid embolism, with delivery, with or without mention of antepartum condition	ICD-9-CM	Diagnosis
673.12	Amniotic fluid embolism, with delivery, with mention of postpartum complication	ICD-9-CM	Diagnosis
673.21	Obstetrical blood-clot embolism, with delivery, with or without mention of antepartum condition	ICD-9-CM	Diagnosis
673.22	Obstetrical blood-clot embolism, with mention of postpartum complication	ICD-9-CM	Diagnosis
673.31	Obstetrical pyemic and septic embolism, with delivery, with or without mention of antepartum condition	ICD-9-CM	Diagnosis

cder_mpl1r_wp089 Page 71 of 79



			Code
Code	Description	Code Type	Category
673.32	Obstetrical pyemic and septic embolism, with delivery, with mention of postpartum	ICD-9-CM	Diagnosis
673.81	Other obstetrical pulmonary embolism, with delivery, with or without mention of	ICD-9-CM	Diagnosis
	antepartum condition		
673.82	Other obstetrical pulmonary embolism, with delivery, with mention of postpartum	ICD-9-CM	Diagnosis
	complication		
674.01	Cerebrovascular disorder, with delivery, with or without mention of antepartum condition	ICD-9-CM	Diagnosis
674.02	Cerebrovascular disorder, with delivery, with mention of postpartum complication	ICD-9-CM	Diagnosis
674.12	Disruption of cesarean wound, with delivery, with mention of postpartum complication	ICD-9-CM	Diagnosis
674.22	Disruption of perineal wound, with delivery, with mention of postpartum complication	ICD-9-CM	Diagnosis
674.32	Other complication of obstetrical surgical wounds, with delivery, with mention of postpartum complication	ICD-9-CM	Diagnosis
674.42	Placental polyp, with delivery, with mention of postpartum complication	ICD-9-CM	Diagnosis
674.51	Peripartum cardiomyopathy, delivered, with or without mention of antepartum condition	ICD-9-CM	Diagnosis
674.52	Peripartum cardiomyopathy, delivered, with mention of postpartum condition	ICD-9-CM	Diagnosis
674.82	Other complication of puerperium, with delivery, with mention of postpartum complication	ICD-9-CM	Diagnosis
674.92	Unspecified complications of puerperium, with delivery, with mention of postpartum complication	ICD-9-CM	Diagnosis
675.01	Infection of nipple associated with childbirth, delivered, with or without mention of antepartum condition	ICD-9-CM	Diagnosis
675.02	Infection of nipple associated with childbirth, delivered with mention of postpartum complication	ICD-9-CM	Diagnosis
675.11	Abscess of breast associated with childbirth, delivered, with or without mention of	ICD-9-CM	Diagnosis
0,0.22	antepartum condition		2.00
675.12	Abscess of breast associated with childbirth, delivered, with mention of postpartum	ICD-9-CM	Diagnosis
	complication		J
675.21	Nonpurulent mastitis, delivered, with or without mention of antepartum condition	ICD-9-CM	Diagnosis
675.22	Nonpurulent mastitis, delivered, with mention of postpartum complication	ICD-9-CM	Diagnosis
675.81	Other specified infection of the breast and nipple associated with childbirth, delivered, with or without mention of antepartum condition	ICD-9-CM	Diagnosis
675.82	Other specified infection of the breast and nipple associated with childbirth, delivered, with mention of postpartum complication	ICD-9-CM	Diagnosis
675.91	Unspecified infection of the breast and nipple, delivered, with or without mention of antepartum condition	ICD-9-CM	Diagnosis
675.92	Unspecified infection of the breast and nipple, delivered, with mention of postpartum complication	ICD-9-CM	Diagnosis
676.01	Retracted nipple, delivered, with or without mention of antepartum condition	ICD-9-CM	Diagnosis
676.02	Retracted nipple, delivered, with mention of postpartum complication	ICD-9-CM	Diagnosis
676.11	Cracked nipple, delivered, with or without mention of antepartum condition	ICD-9-CM	Diagnosis
676.12	Cracked nipple, delivered, with mention of postpartum complication	ICD-9-CM	Diagnosis
676.21	Engorgement of breasts, delivered, with or without mention of antepartum condition	ICD-9-CM	Diagnosis
676.22	Engorgement of breasts, delivered, with mention of postpartum complication	ICD-9-CM	Diagnosis
676.31	Other and unspecified disorder of breast associated with childbirth, delivered, with or without mention of antepartum condition	ICD-9-CM	Diagnosis

cder_mpl1r_wp089 Page 72 of 79



Code	Description	Code Type	Code Category
676.32	Other and unspecified disorder of breast associated with childbirth, delivered, with mention	ICD-9-CM	Diagnosis
070.32	of postpartum complication	ICD-3-CIVI	Diagnosis
676.41	Failure of lactation, with delivery, with or without mention of antepartum condition	ICD-9-CM	Diagnosis
676.42	Failure of lactation, with delivery, with mention of postpartum complication	ICD-9-CM	Diagnosis
676.51	Suppressed lactation, with delivery, with or without mention of antepartum condition	ICD-9-CM	Diagnosis
676.52	Suppressed lactation, with delivery, with mention of postpartum complication	ICD-9-CM	Diagnosis
676.61	Galactorrhea, with delivery, with or without mention of antepartum condition	ICD-9-CM	Diagnosis
676.62	Galactorrhea, with delivery, with mention of postpartum complication	ICD-9-CM	Diagnosis
676.81	Other disorder of lactation, with delivery, with or without mention of antepartum condition	ICD-9-CM	Diagnosis
676.82	Other disorder of lactation, with delivery, with mention of postpartum complication	ICD-9-CM	Diagnosis
676.91	Unspecified disorder of lactation, with delivery, with or without mention of antepartum condition	ICD-9-CM	Diagnosis
676.92	Unspecified disorder of lactation, with delivery, with mention of postpartum complication	ICD-9-CM	Diagnosis
678.01	Fetal hematologic conditions, delivered, with or without mention of antepartum condition	ICD-9-CM	Diagnosis
678.11	Fetal conjoined twins, delivered, with or without mention of antepartum condition	ICD-9-CM	Diagnosis
679.01	Maternal complications from in utero procedure, delivered, with or without mention of antepartum condition	ICD-9-CM	Diagnosis
679.02	Maternal complications from in utero procedure, delivered, with mention of postpartum complication	ICD-9-CM	Diagnosis
679.11	Fetal complications from in utero procedure, delivered, with or without mention of antepartum condition	ICD-9-CM	Diagnosis
679.12	Fetal complications from in utero procedure, delivered, with mention of postpartum	ICD-9-CM	Diagnosis
72	Forceps, vacuum, and breech delivery	ICD-9-CM	Procedure
720	Low forceps operation	ICD-9-CM	Procedure
721	Low forceps operation with episiotomy	ICD-9-CM	Procedure
722	Mid forceps operation	ICD-9-CM	Procedure
722.1	Mid forceps operation with episiotomy	ICD-9-CM	Procedure
722.9	Other mid forceps operation	ICD-9-CM	Procedure
723	High forceps operation	ICD-9-CM	Procedure
723.1	High forceps operation with episiotomy	ICD-9-CM	Procedure
723.9	Other high forceps operation	ICD-9-CM	Procedure
724	Forceps rotation of fetal head	ICD-9-CM	Procedure
725	Breech extraction	ICD-9-CM	Procedure
725.1	Partial breech extraction with forceps to aftercoming head	ICD-9-CM	Procedure
725.2	Other partial breech extraction	ICD-9-CM	Procedure
725.3	Total breech extraction with forceps to aftercoming head	ICD-9-CM	Procedure
725.4	Other total breech extraction	ICD-9-CM	Procedure
726	Forceps application to aftercoming head	ICD-9-CM	Procedure
727	Vacuum extraction	ICD-9-CM	Procedure
727.1	Vacuum extraction with episiotomy	ICD-9-CM	Procedure
727.9	Other vacuum extraction	ICD-9-CM	Procedure
728	Other specified instrumental delivery	ICD-9-CM	Procedure
729	Unspecified instrumental delivery	ICD-9-CM	Procedure

cder_mpl1r_wp089 Page 73 of 79



			Code
Code	Description	Code Type	Category
73	Other procedures inducing or assisting delivery	ICD-9-CM	Procedure
730	Artificial rupture of membranes	ICD-9-CM	Procedure
730.1	Induction of labor by artificial rupture of membranes	ICD-9-CM	Procedure
730.9	Other artificial rupture of membranes	ICD-9-CM	Procedure
731	Other surgical induction of labor	ICD-9-CM	Procedure
732	Internal and combined version and extraction	ICD-9-CM	Procedure
732.1	Internal and combined version without extraction	ICD-9-CM	Procedure
732.2	Internal and combined version with extraction	ICD-9-CM	Procedure
733	Failed forceps	ICD-9-CM	Procedure
734	Medical induction of labor	ICD-9-CM	Procedure
735	Manually assisted delivery	ICD-9-CM	Procedure
735.1	Manual rotation of fetal head	ICD-9-CM	Procedure
735.9	Other manually assisted delivery	ICD-9-CM	Procedure
736	Episiotomy	ICD-9-CM	Procedure
738	Operations on fetus to facilitate delivery	ICD-9-CM	Procedure
739	Other operations assisting delivery	ICD-9-CM	Procedure
739.1	External version to assist delivery	ICD-9-CM	Procedure
739.2	Replacement of prolapsed umbilical cord	ICD-9-CM	Procedure
739.3	Incision of cervix to assist delivery	ICD-9-CM	Procedure
739.4	Pubiotomy to assist delivery	ICD-9-CM	Procedure
739.9	Other operations to assist delivery	ICD-9-CM	Procedure
740	Classical cesarean section	ICD-9-CM	Procedure
741	Low cervical cesarean section	ICD-9-CM	Procedure
742	Extraperitoneal cesarean section	ICD-9-CM	Procedure
744	Cesarean section of other specified type	ICD-9-CM	Procedure
749	Cesarean section of unspecified type	ICD-9-CM	Procedure
749.9	Other cesarean section of unspecified type	ICD-9-CM	Procedure
763.0	Fetus or newborn affected by breech delivery and extraction	ICD-9-CM	Diagnosis
763.2	Fetus or newborn affected by forceps delivery	ICD-9-CM	Diagnosis
763.3	Fetus or newborn affected by delivery by vacuum extractor	ICD-9-CM	Diagnosis
763.4	Fetus or newborn affected by cesarean delivery	ICD-9-CM	Diagnosis
763.6	Fetus or newborn affected by precipitate delivery	ICD-9-CM	Diagnosis
768.0	Fetal death from asphyxia or anoxia before onset of labor or at unspecified time	ICD-9-CM	Diagnosis
768.1	Fetal death from asphyxia or anoxia during labor	ICD-9-CM	Diagnosis
V27	Outcome of delivery	ICD-9-CM	Diagnosis
V27.0	Outcome of delivery, single liveborn	ICD-9-CM	Diagnosis
V27.1	Outcome of delivery, single stillborn	ICD-9-CM	Diagnosis
V27.2	Outcome of delivery, twins, both liveborn	ICD-9-CM	Diagnosis
V27.3	Outcome of delivery, twins, one liveborn and one stillborn	ICD-9-CM	Diagnosis
V27.4	Outcome of delivery, twins, both stillborn	ICD-9-CM	Diagnosis
V27.5	Outcome of delivery, other multiple birth, all liveborn	ICD-9-CM	Diagnosis
V27.6	Outcome of delivery, other multiple birth, some liveborn	ICD-9-CM	Diagnosis
V27.7	Outcome of delivery, other multiple birth, all stillborn	ICD-9-CM	Diagnosis

cder_mpl1r_wp089 Page 74 of 79



			Code
Code	Description	Code Type	Category
V27.9	Outcome of delivery, unspecified	ICD-9-CM	Diagnosis
V30	Single liveborn	ICD-9-CM	Diagnosis
V30.0	Single liveborn, born in hospital	ICD-9-CM	Diagnosis
V30.00	Single liveborn, born in hospital, delivered without mention of cesarean delivery	ICD-9-CM	Diagnosis
V30.01	Single liveborn, born in hospital, delivered by cesarean delivery	ICD-9-CM	Diagnosis
V30.1	Single liveborn, born before admission to hospital	ICD-9-CM	Diagnosis
V30.2	Single liveborn, born outside hospital and not hospitalized	ICD-9-CM	Diagnosis
V31	Twin birth, mate liveborn	ICD-9-CM	Diagnosis
V31.0	Twin, mate liveborn, born in hospital	ICD-9-CM	Diagnosis
V31.00	Twin, mate liveborn, born in hospital, delivered without mention of cesarean delivery	ICD-9-CM	Diagnosis
V31.01	Twin, mate liveborn, born in hospital, delivered by cesarean delivery	ICD-9-CM	Diagnosis
V31.1	Twin birth, mate liveborn, born before admission to hospital	ICD-9-CM	Diagnosis
V31.2	Twin birth, mate liveborn, born outside hospital and not hospitalized	ICD-9-CM	Diagnosis
V32	Twin birth, mate stillborn	ICD-9-CM	Diagnosis
V32.0	Twin, mate stillborn, born in hospital	ICD-9-CM	Diagnosis
V32.00	Twin, mate stillborn, born in hospital, delivered without mention of cesarean delivery	ICD-9-CM	Diagnosis
V32.01	Twin, mate stillborn, born in hospital, delivered by cesarean delivery	ICD-9-CM	Diagnosis
V32.1	Twin birth, mate stillborn, born before admission to hospital	ICD-9-CM	Diagnosis
V32.2	Twin birth, mate stillborn, born outside hospital and not hospitalized	ICD-9-CM	Diagnosis
V33	Twin birth, unspecified whether mate liveborn or stillborn	ICD-9-CM	Diagnosis
V33.0	Twin, unspecified, born in hospital	ICD-9-CM	Diagnosis
V33.00	Twin, unspecified whether mate stillborn or liveborn, born in hospital, delivered without	ICD-9-CM	Diagnosis
	mention of cesarean delivery		
V33.01	Twin, unspecified whether mate stillborn or liveborn, born in hospital, delivered by cesarean	ICD-9-CM	Diagnosis
	delivery		
V33.1	Twin birth, unspecified whether mate liveborn or stillborn, born before admission to hospital	ICD-9-CM	Diagnosis
V33.2	Twin birth, unspecified whether mate liveborn or stillborn, born outside hospital and not	ICD-9-CM	Diagnosis
	hospitalized		
V34	Other multiple birth (three or more), mates all liveborn	ICD-9-CM	Diagnosis
V34.0	Other multiple, mates all liveborn, born in hospital	ICD-9-CM	Diagnosis
V34.00	Other multiple, mates all liveborn, born in hospital, delivered without mention of cesarean	ICD-9-CM	Diagnosis
	delivery		
V34.01	Other multiple, mates all liveborn, born in hospital, delivered by cesarean delivery	ICD-9-CM	Diagnosis
V34.1	Other multiple birth (three or more), mates all liveborn, born before admission to hospital	ICD-9-CM	Diagnosis
V34.2	Other multiple birth (three or more), mates all liveborn, born outside hospital and not	ICD-9-CM	Diagnosis
V35	Other multiple birth (three or more), mates all stillborn	ICD-9-CM	Diagnosis
V35.0	Other multiple, mates all stillborn, born in hospital	ICD-9-CM	Diagnosis
V35.00	Other multiple, mates all stillborn, born in hospital, delivered without mention of cesarean	ICD-9-CM	Diagnosis
	delivery		
V35.01	Other multiple, mates all stillborn, born in hospital, delivered by cesarean delivery	ICD-9-CM	Diagnosis
V35.1	Other multiple birth (three or more), mates all stillborn, born before admission to hospital	ICD-9-CM	Diagnosis
V35.2	Other multiple birth (three or more), mates all stillborn, born outside of hospital and not	ICD-9-CM	Diagnosis
	hospitalized		

cder_mpl1r_wp089 Page 75 of 79



			Code
Code	Description	Code Type	Category
V36	Other multiple birth (three or more), mates liveborn and stillborn	ICD-9-CM	Diagnosis
V36.0	Other multiple, mates liveborn and stillborn, born in hospital	ICD-9-CM	Diagnosis
V36.00	Other multiple, mates liveborn and stillborn, born in hospital, delivered without mention of cesarean delivery	ICD-9-CM	Diagnosis
V36.01	Other multiple, mates liveborn and stillborn, born in hospital, delivered by cesarean delivery	ICD-9-CM	Diagnosis
V36.1	Other multiple birth (three or more), mates liveborn and stillborn, born before admission to hospital	ICD-9-CM	Diagnosis
V36.2	Other multiple birth (three or more), mates liveborn and stillborn, born outside hospital and not hospitalized	ICD-9-CM	Diagnosis
V37	Other multiple birth (three or more), unspecified whether mates liveborn or stillborn	ICD-9-CM	Diagnosis
V37.0	Other multiple, unspecified whether mates stillborn or liveborn, born in hospital	ICD-9-CM	Diagnosis
V37.00	Other multiple, unspecified whether mates stillborn or liveborn, born in hospital, delivered without mention of cesarean delivery	ICD-9-CM	Diagnosis
V37.01	Other multiple, unspecified whether mates stillborn or liveborn, born in hospital, delivered by cesarean delivery	ICD-9-CM	Diagnosis
V37.1	Other multiple birth (three or more), unspecified whether mates liveborn or stillborn, born before admission to hospital	ICD-9-CM	Diagnosis
V37.2	Other multiple birth (three or more), unspecified whether mates liveborn or stillborn, born outside of hospital	ICD-9-CM	Diagnosis
V39	Liveborn, unspecified whether single, twin, or multiple	ICD-9-CM	Diagnosis
V39.0	Other liveborn, unspecified whether single, twin, or multiple, born in hospital	ICD-9-CM	Diagnosis
V39.00	Liveborn infant, unspecified whether single, twin, or multiple, born in hospital, delivered without mention of cesarean delivery	ICD-9-CM	Diagnosis
V39.01	Liveborn infant, unspecified whether single, twin, or multiple, born in hospital, delivered by cesarean	ICD-9-CM	Diagnosis
V39.1	Liveborn, unspecified whether single, twin or multiple, born before admission to hospital	ICD-9-CM	Diagnosis
V39.2	Liveborn, unspecified whether single, twin or multiple, born outside hospital and not hospitalized	ICD-9-CM	Diagnosis

cder_mpl1r_wp089 Page 76 of 79



Appendix E. List of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) Diagnosis Codes Used to Define Inclusion Criteria for Index-Defining Events

Code	Code Type	Description
	Type 2 Diabetes	
250.00	Diabetes mellitus without mention of complication, type II or unspecified type, not stated as	ICD-9-CM
	uncontrolled	
250.10	Diabetes with ketoacidosis, type II or unspecified type, not stated as uncontrolled	ICD-9-CM
250.20	Diabetes with hyperosmolarity, type II or unspecified type, not stated as uncontrolled	ICD-9-CM
250.30	Diabetes with other coma, type II or unspecified type, not stated as uncontrolled	ICD-9-CM
250.40	Diabetes with renal manifestations, type II or unspecified type, not stated as uncontrolled	ICD-9-CM
250.50	Diabetes with ophthalmic manifestations, type II or unspecified type, not stated as uncontrolled	ICD-9-CM
250.60	Diabetes with neurological manifestations, type II or unspecified type, not stated as uncontrolled	ICD-9-CM
250.70	Diabetes with peripheral circulatory disorders, type II or unspecified type, not stated as uncontrolled	ICD-9-CM
250.80	Diabetes with other specified manifestations, type II or unspecified type, not stated as uncontrolled	ICD-9-CM
250.90	Diabetes with unspecified complication, type II or unspecified type, not stated as uncontrolled	ICD-9-CM
250.02	Diabetes mellitus without mention of complication, type II or unspecified type, uncontrolled	ICD-9-CM
250.12	Diabetes with ketoacidosis, type II or unspecified type, uncontrolled	ICD-9-CM
250.22	Diabetes with hyperosmolarity, type II or unspecified type, uncontrolled	ICD-9-CM
250.32	Diabetes with other coma, type II or unspecified type, uncontrolled	ICD-9-CM
250.42	Diabetes with renal manifestations, type II or unspecified type, uncontrolled	ICD-9-CM
250.52	Diabetes with ophthalmic manifestations, type II or unspecified type, uncontrolled	ICD-9-CM
250.62	Diabetes with neurological manifestations, type II or unspecified type, uncontrolled	ICD-9-CM
250.72	Diabetes with peripheral circulatory disorders, type II or unspecified type, uncontrolled	ICD-9-CM
250.82	Diabetes with other specified manifestations, type II or unspecified type, uncontrolled	ICD-9-CM
250.92	Diabetes with unspecified complication, type II or unspecified type, uncontrolled	ICD-9-CM
	Gastroparesis	
536.3	Gastroparesis	ICD-9-CM

cder_mpl1r_wp089 Page 77 of 79



Appendix F. Specifications Defining Parameters in this Request

This request used the Cohort Identification and Descriptive Analysis (CIDA) module, version 5.3.1, to understand real world use of metoclopramide, including the duration, number, frequency (including length of time between episodes), and cumulative dose of metoclopramide exposure episodes in patients with a general diabetes diagnosis and in patients with a combination of diagnosis of gastroparesis and diagnosis of diabetes.

Query Period: January 1, 2008 - September 30, 2015

Coverage Requirement: Medical and Drug

Enrollment Requirement: 365 days **Enrollment Gap:** 45 days

Age Groups: 40-44, 45-49, 50-54, 55-59, 60-64, 65-69, 70-74, 75-79, 80+ years

Sex: Female

Stratifications: Age

	Exposure										Inclusion/Exclusion Criteria			
Scenar	io Exposure	Care Setting	Washout (Days)	Incidence Criteria	Incidence Care Setting	Episode Gap Type	Episode Gap	Same Day Dispensings	Censoring	Туре	Criteria	Care Setting	Look Period	
1	Metoclopramide (oral or injectable)	Any	365	Metoclopramide (oral or injectable)	Any	Percentage	50%	Maximum amount and days supplied	Death, Drop of Enrollment, Query End, Data Partner (DP) End Date	Exclusion	Live Birth	Inpatient	(0, 301)	
	Metoclopramide (oral or		365	Metoclopramide (oral or	Any	Percentage	50%	Maximum amount and	Death, Drop of Enrollment,	Exclusion	Live Birth	Inpatient	(0, 301)	
2	injectable)	Ally	303	injectable)	Ally	rercentage	3070	days supplied	Query End, DP End Date	Inclusion	Type 2 Diabetes (T2DM)	Any	(-365, 0)	
	Metoclopramide			Metoclopramide				Maximum amount and	Death, Drop of Enrollment,	Exclusion	Live Birth	Inpatient	(0, 301)	
3	(oral or injectable)	Any	365	(oral or injectable)	Any	Percentage	50%	days supplied	Query End, DP End Date	Inclusion	Gastroparesis AND T2DM	Any	(-365, 0)	



Appendix F. Specifications Defining Parameters in this Request

This request used the Cohort Identification and Descriptive Analysis (CIDA) module, version 5.3.1, to understand real world use of metoclopramide, including the duration, number, frequency (including length of time between episodes), and cumulative dose of metoclopramide exposure episodes in patients with a general diabetes diagnosis and in patients with a combination of diagnosis of gastroparesis and diagnosis of diabetes.

l .	Exposure										clusion/Exclusio	n Criteria	
Scenario	Exposure	Care Setting	Washout (Days)	Incidence Criteria	Incidence Care Setting	Episode Gap Type	Episode Gap	Same Day Dispensings	Censoring	Туре	Criteria	Care Setting	Look Period
4	Metoclopramide (oral or injectable)	Any	365	Metoclopramide (oral or injectable)	Any	Fixed	0	Maximum amount and days supplied	Death, Drop of Enrollment, Query End, DP End Date	Exclusion	Live Birth	Inpatient	(0, 301)
	Metoclopramide (oral or injectable)	de Any 365	265	Metoclopramide (oral or injectable)	Any	Fixed	0	Maximum amount and	Death, Drop of Enrollment,	Exclusion	Live Birth	Inpatient	(0, 301)
5			303					days supplied	Query End, DP End Date	Inclusion	T2DM	Any	(-365, 0)
6	Metoclopramide (oral or	Any	365	Metoclopramide (oral or	Any	Fixed	0	Maximum amount and	Death, Drop of Enrollment,	Exclusion	Live Birth	Inpatient	(0, 301)
	injectable)	, uly	303	injectable)	, uty	Tixeu	Ü	days supplied	Query End, DP End Date	Inclusion	Gastroparesis AND T2DM	Any	(-365, 0)

International Classification of Diseases, Ninth and Tenth Revisions, Clinical Modification (ICD-9-CM and ICD-10-CM), International Classification of Diseases, Tenth Revision, Procedure Coding System (ICD-10-PCS), and Current Procedural Terminology, Fourth Edition (CPT-4) codes are provided by Optum360. National Drug Codes (NDCs) are checked against First Data Bank's "National Drug Data File (NDDF®) Plus."