

# 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).

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#### 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

**Data Source:** 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.

<u>Cohort Eligibility Criteria:</u> 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)<sup>1</sup> 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.



### Overview for Request: cder\_mpl1r\_wp089

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

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



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## 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.



**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 - i**ndicator 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



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+ 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 (Da | iys)    |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |
| 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+ \   | 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 | iys)   |         |        |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |
| 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 | 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  | 12,380 | 100.0   | 17,596 | 100.0   | 23,216 | 100.0   | 25,666 | 100.0   | 24,834 | 100.0   | 33 <i>,</i> 654 | 100.0   | 30,344 | 100.0   | 23,685 | 100.0   | 29,923      | 100.0   |
| Duration (Da | iys)   |         |        |         |        |         |        |         |        |         |                 |         |        |         |        |         |             |         |
| 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         | -       |
|              |        |         |        |         |        |         |        |         |        |         |                 |         |        |         |        |         | and 12 of 7 |         |



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   |
| <b>Duration Gro</b> | 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+ <b>\</b> | /ears   |
| 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   |
| <b>Duration Gro</b> | 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   | 80+ \  | 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   |
| <b>Duration Gro</b> | 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+ <b>\</b> | fears   |
| 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   |
| <b>Duration Gr</b> | oups (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       | ı (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   | 80+ \   | 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   |
| <b>Duration Gr</b> | oups (Days | )       |        |         |        |         |        |         |        |         |         |         |         |         |        |         |         |         |
| 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       | (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   | 80+ \  | fears   |
| 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   |
| <b>Duration G</b> | roups (Days | ;)      |        |         |        |         |        |         |        |         |        |         |        |         |        |         |        |         |
| 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  | -       |

cder\_mpatawp069 presented in these cells due to a small sample size or to assure a small cell cannot be recalculated through the cells presented.



 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+ <b>\</b> | <b>fears</b> |
| 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        |
| <b>Duration Gr</b> | oups (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       | ı (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+ \   | /ears   |
| 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   |
| <b>Duration Gr</b> | oups (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       | (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   | 80+`   | 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   |
| <b>Duration Gr</b> | 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  | -       |



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+ \   | 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   |
| <b>Duration Group</b> | 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      | 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       | -       | 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   | 80+`   | 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   |
| <b>Duration Group</b> | 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      | iys)     |         |        |         |        |         |        |         |        |         |        |         |        |         |        |         |        |         |
| 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   | 80+`   | 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   |
| <b>Duration Group</b> | 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      | iys)     |         |        |         |        |         |        |         |        |         |        |         |        |         |        |         |        |         |
| 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+ \   | 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   |
| <b>Duration Group</b> | 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      | iys)     |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |         |
| 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   | 80+`   | 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   |
| <b>Duration Group</b> | 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      | iys)     |         |        |         |        |         |        |         |        |         |        |         |        |         |        |         |        |         |
| 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   | 80+    | 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   |
| <b>Duration Group</b> | os (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+ Y   | 'ears   |
| 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   |
| <b>Duration Group</b> | 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    | 0.8     | 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    | 0.8     | 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 (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                  | 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   | 80+ \  | 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   |
| <b>Duration Group</b> | 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      | 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                  | 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   | 80+ \  | 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   |
| <b>Duration Group</b> | 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      | 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      | -       | 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   | 80+ <b>\</b> | 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   |
| <b>Duration Group</b> | 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+ \  | 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   |
| <b>Duration Group</b> | 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+ `  | 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   |
| <b>Duration Group</b> | 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      | 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      | -       | 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+ \  | 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   |
| <b>Duration Group</b> | 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      | iys)     |         |        |         |        |         |        |         |        |         |         |         |        |         |        |         |        |         |
| 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   | 80+ \  | 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   |
| <b>Duration Group</b> | 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   | 80+ `  | 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   |
| <b>Duration Group</b> | 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   |
| <b>Duration Group</b> | 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      | iys)     |         |        |         |         |         |         |         |        |         |         |         |         |         |         |         |         |         |
| 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   | 80+ \  | 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   |
| <b>Duration Group</b> | os (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      | 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      | -       | 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+ \  | 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   |
| <b>Duration Group</b> | 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 <i>,</i> 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      | iys)     |         |        |         |                |         |        |         |        |         |        |         |        |         |        |         |        |         |
| 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   | 80+ `  | 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   |
| <b>Duration Group</b> | 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+ `  | 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   |
| <b>Duration Group</b> | 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   | 80+`   | 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 Group  | os (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  | -       |

<sup>\*\*\*\*\*</sup>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   | 80+ `  | 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   |
| <b>Duration Group</b> | 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   | 80+ '  | 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   |
| <b>Duration Group</b> | os (Days) <sup>1</sup> |         |        |         |        |         |        |         |        |         |        |         |        |         |        |         |        |         |
| 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 Memberswith 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 <sup>1</sup> | 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              |
| 5                       | 3,227   | 1.6     | 40     | 80.6  | 126.2              |
| 6                       | 2,299   | 1.2     | 37     | 76.6  | 123.0              |



Table 13a. Descriptive Statistics for Gaps (in Days) between Treatment Episodes of Metoclopramide among Female Memberswith 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 <sup>1</sup> | 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              |

<sup>1</sup>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.



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 <sup>1</sup> | Number | Percent | Median | Mean  | Standard Deviation |
|-------------------------|--------|---------|--------|-------|--------------------|
| Age Group: 40-44 years  |        |         |        |       |                    |
| 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  | 1.8     | 42     | 89.4  | 145.1              |
| Age Group: 50-54 years  |        |         |        |       |                    |
| Fotal 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                       | 1,276  | 1.5     | 40     | 72.9  | 102.0              |



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 <sup>1</sup> | 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               |

<sup>1</sup>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.



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

| Gap Number <sup>1</sup> | Number | Percent | Median | Mean  | Standard Deviation |
|-------------------------|--------|---------|--------|-------|--------------------|
| Age Group: 40-44 years  |        |         |        |       |                    |
| 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                       | 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 | 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              |
|                         |        |         |        |       |                    |



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 <sup>1</sup> | 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               |  |

<sup>1</sup> 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.



Table 14a. Descriptive Statistics for Gaps (in Days) between Treatment Episodes of Metoclopramide among Female Memberswith 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 <sup>1</sup> | 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  |         |         |        |       |                    |
| Fotal 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               |



Table 14a. Descriptive Statistics for Gaps (in Days) between Treatment Episodes of Metoclopramide among Female Memberswith 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 <sup>1</sup> | 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               |

<sup>1</sup>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.



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

| Age Group: 40-44 years |         |       | Median | Mean  | Standard Deviation |
|------------------------|---------|-------|--------|-------|--------------------|
|                        |         |       |        |       |                    |
| 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 |         |       |        |       |                    |
| Fotal 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 |         |       |        |       |                    |
| Fotal 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              |
|                        |         | 2.4   | 21     | 50.3  | 93.4               |



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 <sup>1</sup> | 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               |

<sup>1</sup>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.



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 <sup>1</sup> | 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              |
| 5                       | 755    | 4.5     | 21     | 58.4  | 113.8              |
| 6                       | 583    | 3.4     | 22     | 53.7  | 98.7               |



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 <sup>1</sup> | 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               |

<sup>1</sup>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.



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

|   | Female Members with No<br>Evidence of a Liveborn Delivery |         | Female Members with<br>Type 2 Diabetes, and No<br>Evidence of a Liveborn<br>Delivery |         | Female Members with<br>Gastroparesis and Type 2<br>Diabetes, and No Evidence<br>of a Liveborn Delivery |         |
|---|---|---------|--|---------|--|---------|
|   | 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.



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

|   | Female Members with No<br>Evidence of a Liveborn<br>Delivery |         | Female Members with<br>Type 2 Diabetes, and No<br>Evidence of a Liveborn<br>Delivery |         | Female Members with<br>Gastroparesis and Type 2<br>Diabetes, and No Evidence<br>of a Liveborn 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.



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

| DP ID | DP Start Date <sup>1</sup> | 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   |

<sup>1</sup>The 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.



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

Generic NameBrand NameMetoclopramideMetoclopramide HClMetoclopramideReglanMetoclopramideMetozolv ODT



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     |



|        |   |           | Code      |
|--------|---|-----------|-----------|
| Code   | Description   | Code Type | Category  |
| 59400  | Routine obstetric care including antepartum care, vaginal delivery (with or without   | CPT-4     | Procedure |
|        | episiotomy, and/or forceps) and postpartum care   |           |           |
| 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 episiotomy, and/or forceps) and postpartum care, after previous cesarean delivery | CPT-4     | Procedure |
| 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;<br>including postpartum care   |           | Procedure |
| 541.01 | 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 |
| 542.11 | 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 |
| 542.21 | Other pre-existing hypertension, with delivery  | ICD-9-CM  | Diagnosis |
| 542.22 | Other pre-existing hypertension, with delivery, with current postpartum complication  | ICD-9-CM  | Diagnosis |
| 542.31 | Transient hypertension of pregnancy, with delivery  | ICD-9-CM  | Diagnosis |
| 542.32 | Transient hypertension of pregnancy, with delivery, with current postpartum complication  | ICD-9-CM  | Diagnosis |
| 542.41 | Mild or unspecified pre-eclampsia, with delivery  | ICD-9-CM  | Diagnosis |
| 542.42 | Mild or unspecified pre-eclampsia, with delivery, with current postpartum complication  | ICD-9-CM  | Diagnosis |
| 542.51 | Severe pre-eclampsia, with delivery   | ICD-9-CM  | Diagnosis |
| 542.52 | Severe pre-eclampsia, with delivery, with current postpartum complication   | ICD-9-CM  | Diagnosis |
| 542.61 | 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 |



|        |  |           | 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<br>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 |



|        |  |           | 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 |



|        |   |           | Code      |
|--------|---|-----------|-----------|
| Code   | Description   | Code Type | Category  |
| 649.32 | Coagulation defects complicating pregnancy, childbirth, or the puerperium, delivered, with mention of postpartum complication   | ICD-9-CM  | Diagnosis |
| 649.41 | Epilepsy complicating pregnancy, childbirth, or the puerperium, delivered, with or without mention of antepartum condition  | ICD-9-CM  | Diagnosis |
| 649.42 | Epilepsy complicating pregnancy, childbirth, or the puerperium, delivered, with mention of postpartum complication  | ICD-9-CM  | Diagnosis |
| 649.51 | Spotting complicating pregnancy, delivered, with or without mention of antepartum condition   | ICD-9-CM  | Diagnosis |
| 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 |
| 549.71 | 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 completed weeks gestation, with delivery by (planned) cesarean section, delivered, with or without mention of antepartum condition | ICD-9-CM  | Diagnosis |
| 649.82 | Onset (spontaneous) of labor after 37 completed weeks of gestation but before 39 completed weeks gestation, with delivery by (planned) cesarean section, delivered, with mention of postpartum complication         | ICD-9-CM  | Diagnosis |
| 650    | Normal delivery   | ICD-9-CM  | Diagnosis |
| 551.01 | Twin pregnancy, delivered   | ICD-9-CM  | Diagnosis |
| 551.11 | Triplet pregnancy, delivered  | ICD-9-CM  | Diagnosis |
| 551.21 | Quadruplet pregnancy, delivered   | ICD-9-CM  | Diagnosis |
| 551.31 | Twin pregnancy with fetal loss and retention of one fetus, delivered  | ICD-9-CM  | Diagnosis |
| 551.41 | Triplet pregnancy with fetal loss and retention of one or more, delivered   | ICD-9-CM  | Diagnosis |
| 551.51 | Quadruplet pregnancy with fetal loss and retention of one or more, delivered  | ICD-9-CM  | Diagnosis |
| 551.61 | 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 |
| 551.81 | Other specified multiple gestation, delivered   | ICD-9-CM  | Diagnosis |
| 51.91  | Unspecified multiple gestation, delivered   | ICD-9-CM  | Diagnosis |
| 52.01  | Unstable lie of fetus, delivered  | ICD-9-CM  | Diagnosis |
| 52.11  | Breech or other malpresentation successfully converted to cephalic presentation, delivered  | ICD-9-CM  | Diagnosis |
| 52.21  | Breech presentation without mention of version, delivered   | ICD-9-CM  | Diagnosis |
| 52.31  | Transverse or oblique fetal presentation, delivered   | ICD-9-CM  | Diagnosis |
| 52.41  | Fetal face or brow presentation, delivered  | ICD-9-CM  | Diagnosis |
| 52.51  | High fetal head at term, delivered  | ICD-9-CM  | Diagnosis |
| 52.61  | Multiple gestation with malpresentation of one fetus or more, delivered   | ICD-9-CM  | Diagnosis |
| 52.71  | Prolapsed arm of fetus, delivered   | ICD-9-CM  | Diagnosis |
| 52.81  | Other specified malposition or malpresentation of fetus, delivered  | ICD-9-CM  | Diagnosis |
| 552.91 | Unspecified malposition or malpresentation of fetus, delivered  | ICD-9-CM  | Diagnosis |
| 553.01 | Major abnormality of bony pelvis, not further specified, delivered  | ICD-9-CM  | Diagnosis |
| 553.11 | 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 |



|        |   |           | 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 complication   | ICD-9-CM  | Diagnosis |
| 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, delivered  | ICD-9-CM  | Diagnosis |
| 654.42 | Other abnormalities in shape or position of gravid uterus and of neighboring structures, delivered, with mention of postpartum complication | ICD-9-CM  | Diagnosis |
| 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 complication                                      | ICD-9-CM  | Diagnosis |
| 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 mention of postpartum complication                  | ICD-9-CM  | Diagnosis |
| 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 of mother, delivery                              | ICD-9-CM  | Diagnosis |
| 655.91 | Unspecified fetal abnormality affecting management of mother, delivery  | ICD-9-CM  | Diagnosis |



|        |   |           | 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 |
|        |   |           | -         |



|        |   |           | 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     | ICD-9-CM  | Diagnosis |
|        | delivery, delivered   |           | 0         |
| 663.31 | Other and unspecified cord entanglement, without mention of compression, complicating | ICD-9-CM  | Diagnosis |
|        | labor and delivery, delivered   |           | 0         |
| 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 |



|        |   |           | 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<br>in labor and delivery, delivered, with mention of postpartum complication | ICD-9-CM  | Diagnosis |
| 568.81 | 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 |
| 569.41 | 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 |



|        |   |           | Code      |
|--------|---|-----------|-----------|
| Code   | Description   | Code Type | Category  |
| 669.61 | Breech extraction, without mention of indication, delivered, with or without mention of<br>antepartum condition | ICD-9-CM  | Diagnosis |
| 569.71 | Cesarean delivery, without mention of indication, delivered, with or without mention of antepartum condition    | ICD-9-CM  | Diagnosis |
| 69.81  | Other complication of labor and delivery, delivered, with or without mention of antepartum condition            | ICD-9-CM  | Diagnosis |
| 69.82  | Other complication of labor and delivery, delivered, with mention of postpartum                                 | ICD-9-CM  | Diagnosis |
| 69.91  | Unspecified complication of labor and delivery, with delivery, with or without mention of antepartum condition  | ICD-9-CM  | Diagnosis |
| 69.92  | Unspecified complication of labor and delivery, with delivery, with mention of postpartum complication          | ICD-9-CM  | Diagnosis |
| 570.02 | Major puerperal infection, unspecified, delivered, with mention of postpartum complication                      | ICD-9-CM  | Diagnosis |
| 570.12 | Puerperal endometritis, delivered, with mention of postpartum complication                                      | ICD-9-CM  | Diagnosis |
| 570.22 | Puerperal sepsis, delivered, with mention of postpartum complication  | ICD-9-CM  | Diagnosis |
| 570.32 | Puerperal septic thrombophlebitis, delivered, with mention of postpartum complication                           | ICD-9-CM  | Diagnosis |
| 70.82  | Other major puerperal infection, delivered, with mention of postpartum complication                             | ICD-9-CM  | Diagnosis |
| 71.01  | Varicose veins of legs, with delivery, with or without mention of antepartum condition                          | ICD-9-CM  | Diagnosis |
| 71.02  | Varicose veins of legs, with delivery, with mention of postpartum complication                                  | ICD-9-CM  | Diagnosis |
| 71.11  | Varicose veins of vulva and perineum, with delivery, with or without mention of antepartum condition            | ICD-9-CM  | Diagnosis |
| 71.12  | Varicose veins of vulva and perineum, with delivery, with mention of postpartum                                 | ICD-9-CM  | Diagnosis |
| 71.21  | Superficial thrombophlebitis with delivery, with or without mention of antepartum condition                     | ICD-9-CM  | Diagnosis |
| 71.22  | Superficial thrombophlebitis with delivery, with mention of postpartum complication                             | ICD-9-CM  | Diagnosis |
| 71.31  | Deep phlebothrombosis, antepartum, with delivery  | ICD-9-CM  | Diagnosis |
| 71.42  | Deep phlebothrombosis, postpartum, with delivery  | ICD-9-CM  | Diagnosis |
| 71.51  | Other phlebitis and thrombosis with delivery, with or without mention of antepartum condition                   | ICD-9-CM  | Diagnosis |
| 71.52  | Other phlebitis and thrombosis with delivery, with mention of postpartum complication                           | ICD-9-CM  | Diagnosis |
| 71.81  | Other venous complication, with delivery, with or without mention of antepartum condition                       | ICD-9-CM  | Diagnosis |
| 71.82  | Other venous complication, with delivery, with mention of postpartum complication                               | ICD-9-CM  | Diagnosis |
| 71.91  | Unspecified venous complication, with delivery, with or without mention of antepartum condition                 | ICD-9-CM  | Diagnosis |
| 71.92  | Unspecified venous complication, with delivery, with mention of postpartum complication                         | ICD-9-CM  | Diagnosis |
| 72.02  | Puerperal pyrexia of unknown origin, delivered, with mention of postpartum complication                         | ICD-9-CM  | Diagnosis |
| 73.01  | Obstetrical air embolism, with delivery, with or without mention of antepartum condition                        | ICD-9-CM  | Diagnosis |
| 73.02  | Obstetrical air embolism, with delivery, with mention of postpartum complication                                | ICD-9-CM  | Diagnosis |
| 73.11  | Amniotic fluid embolism, with delivery, with or without mention of antepartum condition                         | ICD-9-CM  | Diagnosis |
| 73.12  | Amniotic fluid embolism, with delivery, with mention of postpartum complication                                 | ICD-9-CM  | Diagnosis |
| 73.21  | Obstetrical blood-clot embolism, with delivery, with or without mention of antepartum condition                 | ICD-9-CM  | Diagnosis |
| 573.22 | Obstetrical blood-clot embolism, with mention of postpartum complication  | ICD-9-CM  | Diagnosis |
| 573.31 | Obstetrical pyemic and septic embolism, with delivery, with or without mention of<br>antepartum condition       | ICD-9-CM  | Diagnosis |



|        |   |           | Code      |
|--------|---|-----------|-----------|
| Code   | Description   | Code Type | Category  |
| 573.32 | Obstetrical pyemic and septic embolism, with delivery, with mention of postpartum   | ICD-9-CM  | Diagnosis |
| 573.81 | Other obstetrical pulmonary embolism, with delivery, with or without mention of antepartum condition                                      | ICD-9-CM  | Diagnosis |
| 573.82 | Other obstetrical pulmonary embolism, with delivery, with mention of postpartum complication  | ICD-9-CM  | Diagnosis |
| 74.01  | Cerebrovascular disorder, with delivery, with or without mention of antepartum condition  | ICD-9-CM  | Diagnosis |
| 74.02  | Cerebrovascular disorder, with delivery, with mention of postpartum complication  | ICD-9-CM  | Diagnosis |
| 74.12  | Disruption of cesarean wound, with delivery, with mention of postpartum complication  | ICD-9-CM  | Diagnosis |
| 74.22  | Disruption of perineal wound, with delivery, with mention of postpartum complication  | ICD-9-CM  | Diagnosis |
| 574.32 | Other complication of obstetrical surgical wounds, with delivery, with mention of postpartum complication                                 | ICD-9-CM  | Diagnosis |
| 74.42  | Placental polyp, with delivery, with mention of postpartum complication   | ICD-9-CM  | Diagnosis |
| 74.51  | Peripartum cardiomyopathy, delivered, with or without mention of antepartum condition   | ICD-9-CM  | Diagnosis |
| 74.52  | Peripartum cardiomyopathy, delivered, with mention of postpartum condition  | ICD-9-CM  | Diagnosis |
| 74.82  | Other complication of puerperium, with delivery, with mention of postpartum complication  | ICD-9-CM  | Diagnosis |
| 74.92  | Unspecified complications of puerperium, with delivery, with mention of postpartum complication   | ICD-9-CM  | Diagnosis |
| 75.01  | Infection of nipple associated with childbirth, delivered, with or without mention of antepartum condition                                | ICD-9-CM  | Diagnosis |
| 75.02  | Infection of nipple associated with childbirth, delivered with mention of postpartum complication   | ICD-9-CM  | Diagnosi  |
| 75.11  | Abscess of breast associated with childbirth, delivered, with or without mention of antepartum condition                                  | ICD-9-CM  | Diagnosis |
| 75.12  | Abscess of breast associated with childbirth, delivered, with mention of postpartum complication  | ICD-9-CM  | Diagnosis |
| 75.21  | Nonpurulent mastitis, delivered, with or without mention of antepartum condition  | ICD-9-CM  | Diagnosis |
| 75.22  | Nonpurulent mastitis, delivered, with mention of postpartum complication  | ICD-9-CM  | Diagnosis |
| 75.81  | Other specified infection of the breast and nipple associated with childbirth, delivered, with or without mention of antepartum condition | ICD-9-CM  | Diagnosis |
| 75.82  | Other specified infection of the breast and nipple associated with childbirth, delivered, with mention of postpartum complication         | ICD-9-CM  | Diagnosis |
| 75.91  | Unspecified infection of the breast and nipple, delivered, with or without mention of antepartum condition                                | ICD-9-CM  | Diagnosis |
| 75.92  | Unspecified infection of the breast and nipple, delivered, with mention of postpartum complication  | ICD-9-CM  | Diagnosis |
| 76.01  | Retracted nipple, delivered, with or without mention of antepartum condition  | ICD-9-CM  | Diagnosis |
| 76.02  | Retracted nipple, delivered, with mention of postpartum complication  | ICD-9-CM  | Diagnosi  |
| 76.11  | Cracked nipple, delivered, with or without mention of antepartum condition  | ICD-9-CM  | Diagnosi  |
| 76.12  | Cracked nipple, delivered, with mention of postpartum complication  | ICD-9-CM  | Diagnosi  |
| 76.21  | Engorgement of breasts, delivered, with or without mention of antepartum condition  | ICD-9-CM  | Diagnosi  |
| 76.22  | Engorgement of breasts, delivered, with mention of postpartum complication  | ICD-9-CM  | Diagnosi  |
| 76.31  | Other and unspecified disorder of breast associated with childbirth, delivered, with or without mention of antepartum condition           | ICD-9-CM  | Diagnosi  |



|        |   |           | Code      |
|--------|---|-----------|-----------|
| Code   | Description   | Code Type | Category  |
| 676.32 | Other and unspecified disorder of breast associated with childbirth, delivered, with mention                                  | ICD-9-CM  | Diagnosis |
|        | of postpartum complication  |           |           |
| 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   | ICD-9-CM  | Diagnosis |
| 679.02 | antepartum condition<br>Maternal complications from in utero procedure, delivered, with mention of postpartum<br>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 |



|       |  |            | 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 |
| '32.1 | Internal and combined version without extraction                                 | ICD-9-CM   | Procedure |
| 32.2  | Internal and combined version with extraction                                    | ICD-9-CM   | Procedure |
| 33    | Failed forceps   | ICD-9-CM   | Procedure |
| '34   | Medical induction of labor   | ICD-9-CM   | Procedure |
| '35   | 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 |
| '36   | Episiotomy   | ICD-9-CM   | Procedure |
| '38   | Operations on fetus to facilitate delivery                                       | ICD-9-CM   | Procedure |
| '39   | Other operations assisting delivery  | ICD-9-CM   | Procedure |
| '39.1 | External version to assist delivery  | ICD-9-CM   | Procedure |
| 39.2  | Replacement of prolapsed umbilical cord  | ICD-9-CM   | Procedure |
| 39.3  | Incision of cervix to assist delivery  | ICD-9-CM   | Procedure |
| 39.4  | Pubiotomy to assist delivery   | ICD-9-CM   | Procedure |
| 39.9  | Other operations to assist delivery  | ICD-9-CM   | Procedure |
| 40    | Classical cesarean section   | ICD-9-CM   | Procedure |
| 41    | Low cervical cesarean section  | ICD-9-CM   | Procedure |
| 42    | Extraperitoneal cesarean section   | ICD-9-CM   | Procedure |
| 44    | Cesarean section of other specified type   | ICD-9-CM   | Procedure |
| 49    | Cesarean section of unspecified type   | ICD-9-CM   | Procedure |
| 49.9  | Other cesarean section of unspecified type                                       | ICD-9-CM   | Procedure |
| 63.0  | Fetus or newborn affected by breech delivery and extraction                      | ICD-9-CM   | Diagnosis |
| 63.2  | Fetus or newborn affected by forceps delivery                                    | ICD-9-CM   | Diagnosis |
| /63.3 | Fetus or newborn affected by delivery by vacuum extractor                        | ICD-9-CM   | Diagnosis |
| 63.4  | Fetus or newborn affected by cesarean delivery                                   | ICD-9-CM   | Diagnosis |
| 63.6  | Fetus or newborn affected by precipitate delivery                                | ICD-9-CM   | Diagnosis |
| 68.0  | Fetal death from asphyxia or anoxia before onset of labor or at unspecified time | ICD-9-CM   | Diagnosis |
| '68.1 | Fetal death from asphyxia or anoxia during labor                                 | ICD-9-CM   | Diagnosis |
| /27   | Outcome of delivery  | ICD-9-CM   | Diagnosis |
| /27.0 | Outcome of delivery, single liveborn   | ICD-9-CM   | Diagnosis |
| /27.1 | Outcome of delivery, single stillborn  | ICD-9-CM   | Diagnosis |
| 27.2  | Outcome of delivery, twins, both liveborn  | ICD-9-CM   | Diagnosis |
| /27.3 | Outcome of delivery, twins, one liveborn and one stillborn                       | ICD-9-CM   | Diagnosis |
| /27.4 | Outcome of delivery, twins, both stillborn                                       | ICD-9-CM   | Diagnosis |
| /27.5 | Outcome of delivery, other multiple birth, all liveborn                          | ICD-9-CM   | Diagnosis |
| /27.6 | Outcome of delivery, other multiple birth, some liveborn                         | ICD-9-CM   | -         |
| 21.0  | Succome of denvery, other multiple birth, some investorin                        | 100-3-0101 | Diagnosis |



|        |  |           | 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 mention of cesarean delivery | ICD-9-CM  | Diagnosis |
| V33.01 | Twin, unspecified whether mate stillborn or liveborn, born in hospital, delivered by cesarean delivery                 | ICD-9-CM  | Diagnosis |
| 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 hospitalized                 | ICD-9-CM  | Diagnosis |
| 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 delivery                   | ICD-9-CM  | Diagnosis |
| 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 delivery                  | ICD-9-CM  | Diagnosis |
| 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 hospitalized               | ICD-9-CM  | Diagnosis |



|        |   |           | 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 |



## 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 uncontrolled | ICD-9-CM    |  |  |  |  |  |  |  |
| 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    |  |  |  |  |  |  |  |
| 50.72           | 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  |             |  |  |  |  |  |  |  |
| 36.3            | Gastroparesis  | ICD-9-CM    |  |  |  |  |  |  |  |
|                 |  |             |  |  |  |  |  |  |  |



#### 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.

|          |   |                 |                   | Coverage F<br>Enrollment F<br>Enr         | Requirement:<br>Requirement:<br>ollment Gap:<br>Age Groups: | Medical and<br>365 days<br>45 days | Drug           | ember 30, 20:<br>5-59, 60-64, 6           | 15<br>55-69, 70-74, 75-79  | , 80+ γears               |                                  |                           |                |
|----------|---|-----------------|-------------------|---|---|------------------------------------|----------------|---|--|---------------------------|----------------------------------|---------------------------|----------------|
|          | Stratifications: Age Exposure             |                 |                   |   |   |                                    |                |   |  |                           | clusion/Exclusic                 | on Criteria               |                |
| Scenario | Exposure                                  | Care<br>Setting | Washout<br>(Days) | Incidence Criteria                        | Incidence<br>Care Setting                                   | Episode<br>Gap Type                | Episode<br>Gap | Same Day<br>Dispensings                   | Censoring  | Туре                      | Criteria                         | Care<br>Setting           | Look<br>Period |
| 1        | Metoclopramide<br>(oral or<br>injectable) | Any             | 365               | Metoclopramide<br>(oral or<br>injectable) | Any   | Percentage                         | 50%            | Maximum<br>amount and<br>days<br>supplied | Death, Drop of<br>Enrollment,<br>Query End, Data<br>Partner (DP) End<br>Date | Exclusion                 | Live Birth                       | Inpatient                 | (0, 301)       |
| 2        | Metoclopramide<br>(oral or<br>injectable) | Any             | 365               | Metoclopramide<br>(oral or<br>injectable) | Any   | Percentage                         | 50%            | Maximum<br>amount and<br>days<br>supplied | Death, Drop of<br>Enrollment,<br>Query End, DP<br>End Date                   | Exclusion                 | Live Birth<br>Type 2<br>Diabetes | Inpatient<br>Any          | (-365,         |
|          | Metoclopramide                            |                 |                   | Metoclopramide                            |   |                                    |                | Maximum<br>amount and<br>days<br>supplied | Death, Drop of<br>Enrollment,  | Exclusion                 | (T2DM)<br>Live Birth             | Inpatient                 | 0)<br>(0, 301) |
| 3        | (oral or<br>injectable)                   | Any             | 365               | (oral or<br>injectable)                   | Any   | Percentage                         | 50%            |   | 50% days   | Query End, DP<br>End Date | Inclusion                        | Gastroparesis<br>AND T2DM | Any            |



#### 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.

|         |   | Exposure        |                   |   |                           |                     |                |   |  |           | Inclusion/Exclusion Criteria |                 |  |           |            |           |         |
|---------|---|-----------------|-------------------|---|---------------------------|---------------------|----------------|---|--|-----------|------------------------------|-----------------|--|-----------|------------|-----------|---------|
| cenario | Exposure                                  | Care<br>Setting | Washout<br>(Days) | Incidence Criteria                        | Incidence<br>Care Setting | Episode<br>Gap Type | Episode<br>Gap | Same Day<br>Dispensings                   | Censoring  | Туре      | Criteria                     | Care<br>Setting | Look<br>Period                         |           |            |           |         |
| 4       | Metoclopramide<br>(oral or<br>injectable) | Any             | 365               | Metoclopramide<br>(oral or<br>injectable) | Any                       | Fixed               | 0              | Maximum<br>amount and<br>days<br>supplied | Death, Drop of<br>Enrollment,<br>Query End, DP<br>End Date | Exclusion | Live Birth                   | Inpatient       | (0, 301                                |           |            |           |         |
|         | Metoclopramide<br>(oral or An             | Any             | Any 365           | Metoclopramide<br>(oral or                | Any                       | Fixed               | 0              | Maximum<br>amount and                     | , 1  | Exclusion | Live Birth                   | Inpatient       | (0, 301                                |           |            |           |         |
| 5       | injectable)                               |                 | 303               | injectable)                               |                           | Tixed               | Ū              | days<br>supplied                          | Query End, DP<br>End Date                                  | Inclusion | T2DM                         | Any             | (-365,<br>0)                           |           |            |           |         |
| 6       | Metoclopramide<br>(oral or                | Any             | 365               | Metoclopramide<br>(oral or                | Any                       | <b>A</b> m <i>i</i> | 4.004          | Fixed                                     | 0  | 0         | Maximum<br>amount and        |                 | Death, Drop of Exclusio<br>Enrollment, | Exclusion | Live Birth | Inpatient | (0, 301 |
| 0       | injectable)                               | АЦУ             | 505               | injectable)                               | Any                       | Tixeu               | 0              | days<br>supplied                          | Query End, DP<br>End Date                                  | Inclusion | Gastroparesis<br>AND T2DM    | Any             | (-365 <i>,</i><br>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<sup>®</sup>) Plus."