



# Reducing Real-world Healthcare Resource Utilization for Patients with Diabetic Gastroparesis (DGP) Treated with Metoclopramide Nasal Spray versus Oral Metoclopramide

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David C. Kunkel, MD, AGAF  
GI Motility & Physiology Program  
University of California, San Diego

UC San Diego  
HEALTH SCIENCES

# Disclosures

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# Background



**Diabetic Gastroparesis (DGP)** is a chronic disorder of the stomach characterized by delayed gastric emptying which results in nausea, vomiting, early satiety, bloating, and severe abdominal pain.<sup>1</sup>

- In 2022 the prevalence of GP was 267.7 per 100,000 US adults with 57.4% of cases among individuals with Type 1/2 diabetes mellitus.<sup>2</sup>
- Symptoms of DGP lead to poorly controlled diabetes impacting quality of life and increasing the risk of mortality.<sup>3</sup>
- Symptom management includes dietary restrictions, antiemetics, treatment with the only approved medication, metoclopramide (MCP) and surgery.<sup>4</sup>
- In a survey of 1,423 GP patients conducted in 2017, 60% of patients said they were dissatisfied or somewhat dissatisfied with available treatment options.<sup>5</sup>
- DGP patients experience 3x greater emergency department (ED) costs, 3x greater inpatient admission costs, and 2x greater outpatient costs compared to non-GP patients.<sup>6</sup>

# Rationale & Objective

- In June 2020, MCP nasal spray (NMCP) became the first non-oral, outpatient treatment FDA approved for patients with acute and recurrent DGP.<sup>1</sup>
- Moderate to severe NMCP patients in the phase 3 double-blind, placebo-controlled trial experienced a significant reduction in nausea and upper abdominal pain ( $P<0.05$ ) compared to placebo.<sup>2</sup>
- Given the high burden DGP places on patients and payers, we hypothesized that better symptom control in patients treated with NMCP may result in lower healthcare resource utilization (HCRU) compared to patients treated with oral MCP (OMCP).

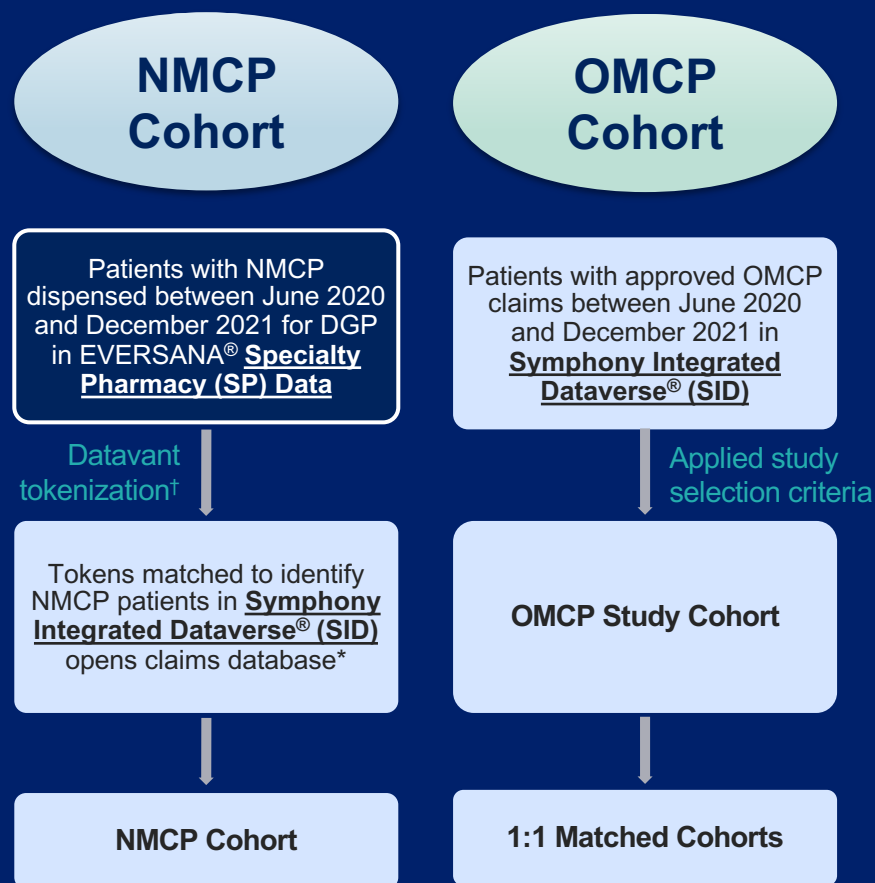


## Research Objective

To compare the frequency of physician office, outpatient facility, ED, and inpatient hospital visits for patients with DGP treated with NMCP versus OMCP.



# Study Design



## OMCP Selection Criteria

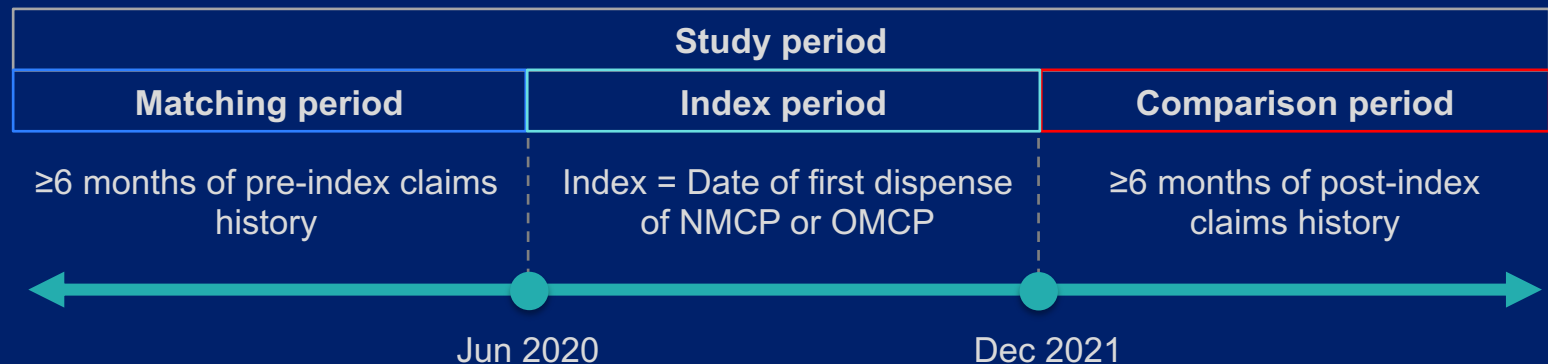
- $\geq 2$  insurance claims with a diagnosis for GP (ICD-10: K31.84)  $>30$  days apart
- $>1$  insurance claim for diabetes with gastroparesis (E8.43, E9.43, E10.43, E11.43)
- $\geq 6$  months of pre-index claims history (date OMCP/ NMCP claim) and  $\geq 6$  months post-index claims history
- $\geq 18$  years of age at index date

† Datavant tokenization is a HIPAA-compliant process to maintain de-identification

\* The SID is a US insurance claims database including pharmacy and medical claims data for  $>300M$  individuals in the US

# Statistical Analysis

- OMCP patients were matched to NMCP patients using propensity score (PS) matching.
- HCRU categories of physician office, hospital outpatient, inpatient hospitalization, and ED visits were captured by examining place of service and CPT codes for evaluation and management on each medical claim.
- Mean number of each type of HCRU (all-cause and DGP-related<sup>a</sup>, respectively), and number of visits avoided, were compared between NMCP and matched OMCP for the 6-month follow-up period using Mann-Whitney test.
- Incidence rate ratio, likelihood of utilizing service by category was also calculated.



<sup>a</sup> A DGP-related event was determined by the presence of a diagnosis code for nausea, vomiting, or GP on the billing claim

# Cohort Selection

## NMCP Cohort Selection Criteria

**1,569** Number of DGP patients with a record of a prescription for NMCP from EVERSANA® Specialty Pharmacy\*

**879** Any patients with matching Datavant Token between EVERSANA® Specialty Pharmacy and SID database

**602** Number of patients who filled NMCP prescription<sup>‡</sup>

**257<sup>‡</sup>** ≥6 months of pre-index claims history (date of first nasal or oral MCP claim) and ≥6 months post-index claims history

## OMCP Cohort Selection Criteria

**1** **2,919,392** Adult with a record of prescription fill for OMCP from SID

**2** **244,532** >1 insurance claim for diabetes (ICD-10: E8.43, E9.43, E10.43, E11.43)

**3** **15,627** ≥2 insurance claims with a diagnosis for GP (ICD-10: K31.84) >30 days apart

**4** **7,797** ≥6 months of pre-index claims history (date of first nasal or oral MCP claim) and ≥6 months post-index claims history

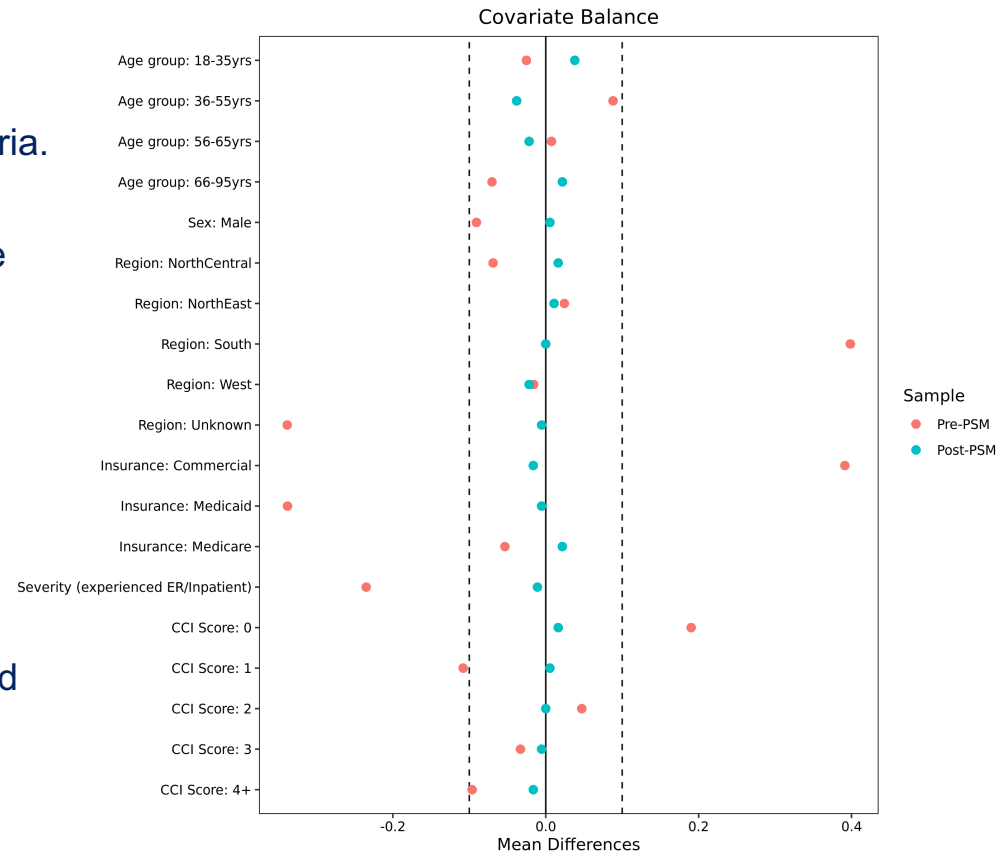
**5** **257** 1:1 Match to NMCP Cohort

\*A written prescription does not indicate the patient received NMCP. Patients may not receive NMCP do plan denials or other factors.

‡ All patients additional met the criteria of having a diagnosis for GP and gastroparesis based on SP records or SID claims.

# Selection of Matched OMCP Cohort

- 7,797 OMCP patients met initial selection criteria.
- A 1–1 match using “nearest neighbor” PS matching approach was used based on the following variables:
  - Age Category
  - Sex
  - Region
  - Payer
  - CCI score
  - DGP Severity
- This resulted in 257 OMCP patients for analysis.
- SMDs < 0.10 show balance Post-PS matching between the two cohorts regarding the included covariates.



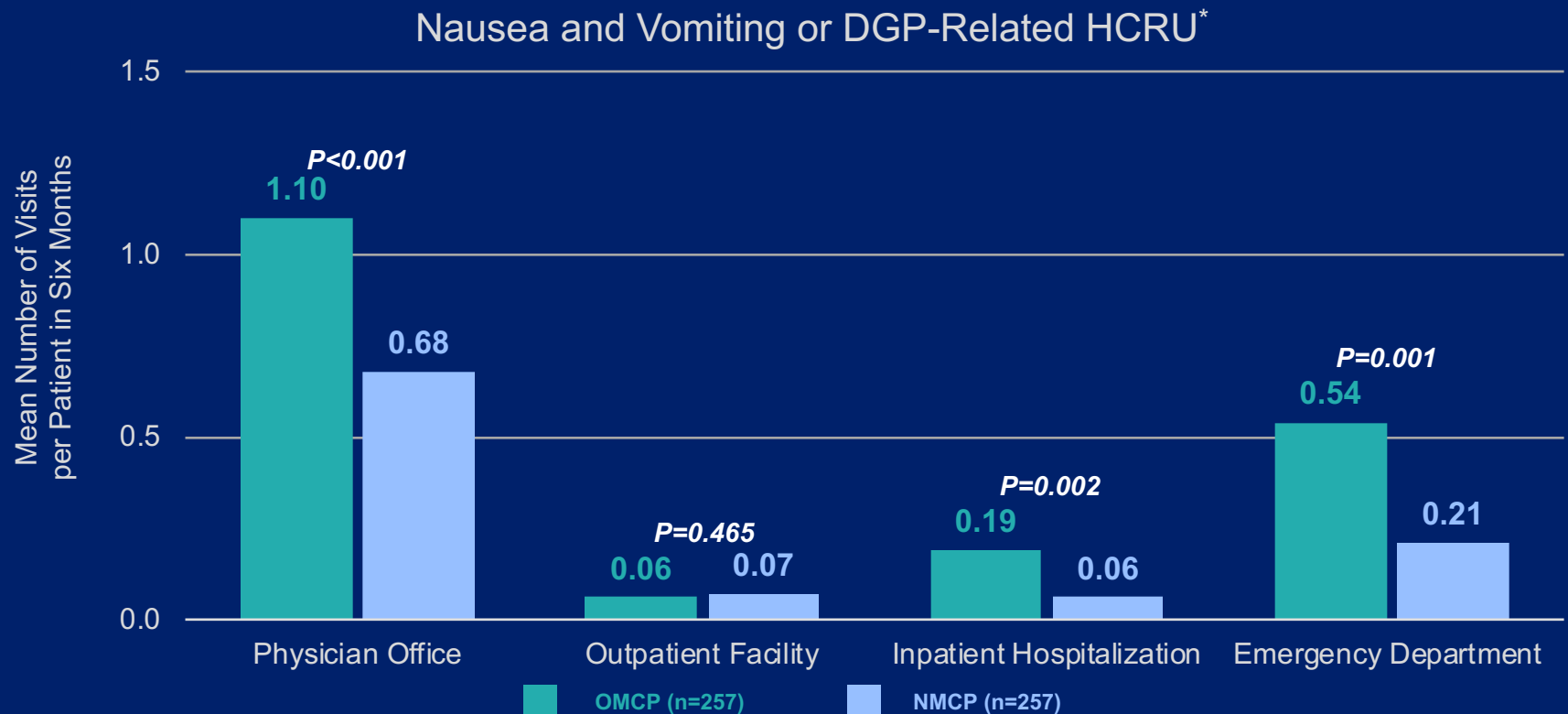
# Demographics and Clinical Characteristics Post Match

- Mean (SD) age at index was 53.5 (14.3) for NMCP and 52.7 (13.8) for OMCP.
- 77.0% of patients in both cohorts were female.
- Mean CCI (SD) score was 2.2 in both cohorts.
- 31.1% of both cohorts experienced an ED visit or inpatient hospitalization in the 6-months prior to index.

		NMCP N = 257	OMCP N = 257
<b>Age, years</b>	Mean (SD)	53.5 (14.3)	52.7 (13.8)
<b>Age groups, n (%)</b>	18-35	35 (13.6%)	28 (10.9%)
	36 – 55	106 (41.2%)	115 (44.7%)
	56 – 65	57 (22.2%)	62 (24.1%)
	66 +	59 (23.0%)	52 (20.2%)
<b>Sex, n (%)</b>	Female	198 (77.0%)	198 (77.0%)
	Male	59 (23.0%)	59 (23.0%)
<b>US Region of Primary Residence, n (%)</b>	Midwest	20 (7.8%)	24 (9.3%)
	Northeast	61 (23.7%)	52 (20.2%)
	South	166 (64.6%)	172 (66.9%)
	West	10 (3.9%)	9 (3.5%)
<b>Payer type, n (%)</b>	Commercial	170 (66.1%)	158 (61.5%)
	Medicaid	20 (7.8%)	25 (9.7%)
	Medicare	67 (26.1%)	74 (28.8%)
<b>CCI Score</b>	Mean (SD)	2.2 (2.2)	2.2 (2.4)
<b>CCI Score categories, n (%)</b>	0	55 (21.4%)	57 (22.2%)
	1	67 (26.1%)	67 (26.1%)
	2	49 (19.1%)	53 (20.6%)
	3	36 (14.0%)	33 (12.8%)
	4+	50 (19.5%)	47 (18.3%)
<b>Severity, n (%)</b>	No	177 (68.9%)	177 (68.9%)
	Yes	80 (31.1%)	80 (31.1%)
<b>Prior OMCP Treatment, n (%)</b>	No	99 (38.5%)	N/A
	Yes	158 (61.5%)	N/A



# Patients Treated with Nasal Metoclopramide (NMCP) Showed Significant Reduction in Number of Healthcare Visits vs. Oral (OMCP) Patients



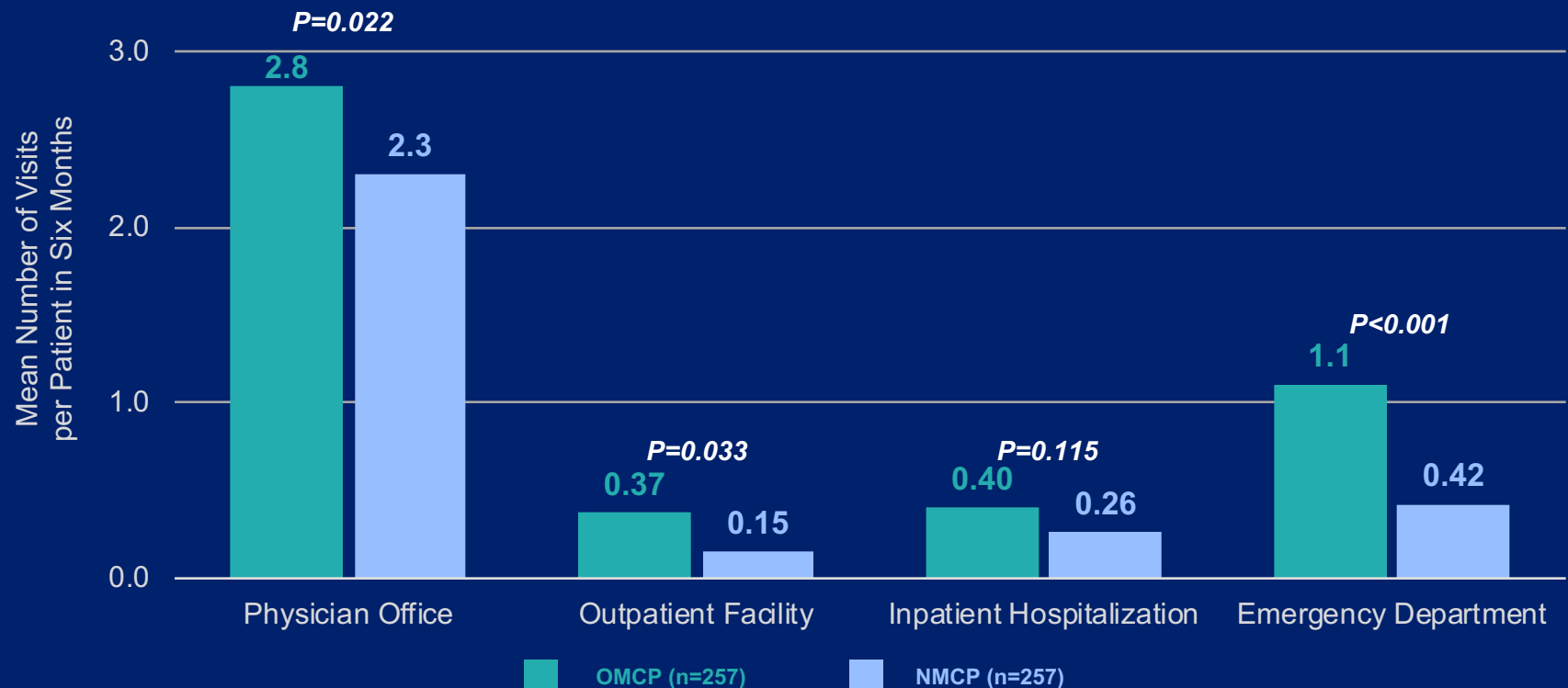
**NMCP-treated patients had 99 fewer physician office visits, 1 additional outpatient facility visit, 34 fewer inpatient hospitalizations, and 84 fewer ED visits for DGP in the 6-month follow-up period.**

Abbreviations: DGP=Diabetic Gastroparesis; MCP=metoclopramide

\* Nausea, vomiting, and gastroparesis related HCRU were assessed by examining only insurance claims with ICD-10 diagnosis codes specific to each condition.

# Patients Treated with Nasal Metoclopramide (NMCP) Showed Significant Reduction in Number of Healthcare Visits vs. Oral (OMCP) Patients

All-Cause HCRU\*



**NMCP-treated patients had 124 fewer physician office visits, 55 fewer outpatient facility visits, 37 fewer inpatient hospitalizations, and 167 fewer ED visits for any cause in the 6-month follow-up period.**

\* Includes any claim regardless of diagnosis code present on claim; includes claims for nausea and vomiting or DGP-related

# Patients Treated with Nasal Metoclopramide (NMCP) Showed Significant Reduction in the Incidence Rate of Healthcare Visits vs. Oral (OMCP) Patients

## Likelihood of Utilizing Resource in NMCP Cohort Compared to OMCP Cohort<sup>2</sup>

	Nausea and Vomiting or DGP-related HCRU		All Cause HCRU	
	IRR (95% CI)	<i>P</i> -value	IRR (95% CI)	<i>P</i> -value
Physician Office	0.64 (0.47, 0.87)	0.005	0.83 (0.67, 1.02)	0.077
Outpatient Facility	0.22 (0.03, 1.16)	0.098	0.41 (0.17, 1.02)	0.053
Inpatient Hospitalization	0.32 (0.14, 0.7)	0.005	0.64 (0.36, 1.13)	0.128
Emergency Department	0.40 (0.2, 0.78)	0.007	0.39 (0.25, 0.61)	<0.001

**The likelihood of a patient treated having a DGP-related physician office visit was 36% lower in the NMPC cohort. Similarly, for inpatient hospitalizations and ED visits the likelihood was 68% and 60% lower, respectively, for NMCP-treated patients versus OMCP.**

# Conclusions



**In a matched comparison of Health Care Resource Utilization (HCRU) in 6 months post initiation of therapy:**

## Conclusions

- Nasal Metoclopramide-treated patients (NMCP) had significantly fewer nausea and vomiting or Diabetic Gastroparesis (DGP)-related office, Emergency Department (ED), and inpatient hospital visits than Oral Metoclopramide-treated patients (OMCP).
- The reduction in DGP-related HCRU equated to an avoidance of 99 physician office, 84 fewer ED, and 34 fewer inpatient hospital visits for NMCP patients versus OMCP patients.
- The likelihood of a DGP patient treated with NMCP visiting the ED or being admitted to the hospital was less than half that of patients treated with OMCP during the same period.