# Real-world demographic and clinical characteristics of vonoprazan-treated patients in the United States diagnosed with gastroesophageal reflux disease (GERD): a descriptive analysis of non-erosive vs. erosive GERD

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## Background

- GERD comprises non-erosive and erosive phenotypes *(ie.*, non-erosive and erosive GERD).[1]
- The potassium-competitive acid blocker (PCAB), vonoprazan, is first-in-class and, currently, the only FDA-approved treatment of its kind for healing and maintenance of healing of erosive GERD (erosive esophagitis) and relief of heartburn in both non-erosive and erosive GERD.[2]

## Objective

- **To provide a descriptive analysis of real-world data characterizing vonoprazan patient demographics and treatment characteristics within the US.**

## Methods

- Retrospective database analysis of adult patients who initiated vonoprazan in the US
- We identified patients in IQVIA's Anonymous Patient Longitudinal Database (APLD), a US administrative claims database which receives over 4 billion prescription claims per year.
- Most longitudinal prescription information is collected weekly or monthly from pharmacies and long-term care facilities.
- For inclusion in the descriptive analysis, patients must have had:
  - continuous eligibility criteria of medical and pharmacy benefits over the 12 month pre-index vonoprazan (baseline period)
  - ≥1 GERD diagnosis code (K210, K2100, K2101, K219)
  - continuous eligibility criteria post-index vonoprazan until the most recent data cutoff in February 2025 (follow-up period)
- We assessed demographic, clinical, and treatment characteristics and comorbidities for the 3-year observation study period (February 21, 2022, to February 21, 2025).
- Vonoprazan dose switching patterns were defined as a change in dose after 30 days of index date.

## Acknowledgements & Disclosures

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- EDS consulted for Phathom. IA and MG are employees of Phathom Pharmaceuticals. CWH is a consultant for Phathom Pharmaceuticals and Sebela.

## Results

- 23,546 patients treated with vonoprazan met the eligibility criteria (**Table 1**).
- We excluded 7468 who did not have evidence of a GERD diagnosis code in the study observation period.
- The remaining patients were categorized based on their GERD phenotype (10,150 non-erosive, 5916 erosive). Most were female (non-erosive, 72.6%; erosive, 70.7%) (**Table 1**).
- The regional distribution of vonoprazan uptake was highest in the Southern US (non-erosive, 48.4%; erosive, 45.7%) (**Table 1**).
- Commercial insurance was the most common payer type (non-erosive, 49.8%; erosive, 50.0%) (**Table 1**).

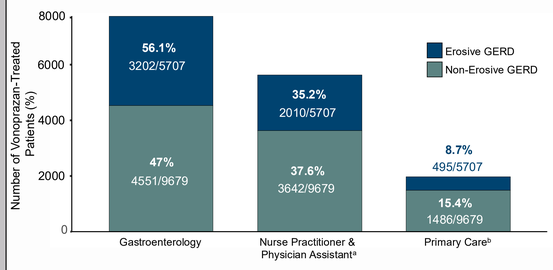
**Table 1.** Patient demographics

| | Non-Erosive GERD n=10,150 | Erosive GERD[a] n=5916 |
|---|---|---|
| Age (years) | | |
| Mean (range) | 60.5 (18-85) | 60.4 (18-85) |
| Sex, n (%) | | |
| Female | 7370 (72.6) | 4183 (70.7) |
| Male | 2780 (27.4) | 1734 (29.3) |
| Region, n (%)[b] | | |
| South | 4938 (48.4) | 2752 (45.7) |
| Northeast | 2437 (23.7) | 1399 (24.0) |
| West | 1424 (14.0) | 1009 (17.3) |
| Midwest | 1294 (12.6) | 726 (11.9) |
| Other | 137 (1.3) | 70 (1.2) |
| Payment channel, n (%)[c] | | |
| Commercial | 5192 (49.8) | 3059 (50.0) |
| Medicare Part D | 4275 (41.0) | 2489 (40.8) |
| Medicaid | 531 (5.1) | 361 (5.9) |
| Cash | 421 (4.0) | 198 (3.2) |
| Medicare[d] | 1 (0.01) | 1 (0.02) |

[a] A patient with diagnostic codes for both non-erosive and erosive GERD was included in the erosive GERD group. [b] Duplicates may have occurred if some patients mapped to multiple regions. [c] Duplicates may have occurred for patients who had more than one payment type. [d] Includes payment channel outside of Medicare Part D, such as a hospital.

- Gastroenterologists were the most frequent prescribers (non-erosive, 47%; erosive, 56.1%) (**Figure 1**).

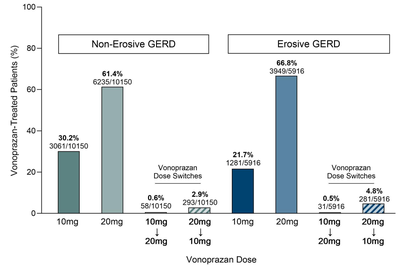
**Figure 1**. Top prescribers as reported by specialty




[a] Nurse practitioner and physician assistant specialties not listed in claims. [b] Includes internal medicine and family medicine.

- Vonoprazan 20 mg was the most frequent dose prescribed (non-erosive, 61.4%; erosive, 66.8%) (**Figure 2**). Most patients remained on their prescribed dose, and a few switched between doses (non-erosive, 3.5%; erosive, 5.3%).

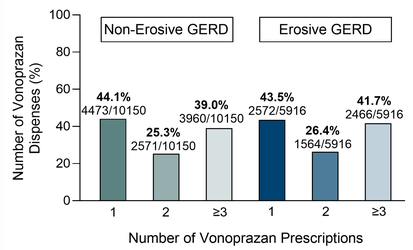
**Figure 2**. Prescribed vonoprazan dose (December 2023 - February 2025)




4.9% (351/10150) in non-erosive, 6.2% (312/5916) in erosive were dispensed both 10mg and 20mg vonoprazan doses within the 30-day period or during the follow-up observation period, which did not meet the defined switching criteria. Vonoprazan script index date varies within patient population.

- Over 35% of patients with non-erosive or erosive GERD had three or more refills since initiating vonoprazan (**Figure 3**).

**Figure 3**. Number of vonoprazan prescriptions (10 mg and 20 mg)




**Study limitations**

- Inherent to the use of claims data, which may not accurately reflect comprehensive management of a disease, there is the possibility of misclassification bias due to miscoding and missing data captured outside of the study observation period.
- Medication use was measured from pharmacy claims; patients may not have taken the medication as prescribed.

**Study strengths:**

- Large nationwide dataset
- Study inclusion criteria of continuous eligibility enrollment of medical and pharmacy benefits pre- and post-index vonoprazan to minimize data gaps within the study observation period

- GERD-related comorbidities or common complications of GERD (hiatal hernia – non-erosive, 16.0%; erosive, 33.9%; Barrett's esophagus – non-erosive, 5.9%; erosive, 11.7%) reflect real-world use. The most common general comorbidities may suggest that patients had established primary care follow-up (**Table 2**).

**Table 2.** Summary of patient comorbidities and possible extraesophageal manifestations of GERD

| | Non-Erosive GERD n=10,150 (%) | Erosive GERD[a] n=5916 (%) |
|---|---|---|
| General Comorbidities | | |
| Anxiety | 1417 (14.0) | 884 (15.0) |
| Cardiovascular disease | 3731 (36.8) | 2296 (38.8) |
| Chest pain | 2156 (21.2) | 1367 (23.1) |
| Chronic pain | 496 (4.9) | 344 (5.8) |
| Depression | 831 (8.2) | 530 (9.0) |
| Diabetes, type 2 | 1325 (13.1) | 773 (13.1) |
| Diabetes, type 1 | 50 (0.5) | 36 (0.6) |
| Hyperlipidemia | 2178 (21.5) | 1296 (21.9) |
| Obesity | 1475 (14.5) | 1037 (17.5) |
| Osteoarthritis | 703 (6.9) | 400 (6.8) |
| Gastrointestinal-Related Comorbidities | | |
| Aspiration pneumonia | 35 (0.3) | 33 (0.6) |
| Barrett's esophagus | 600 (5.9) | 690 (11.7) |
| Hiatal hernia | 1623 (16.0) | 2004 (33.9) |
| Gastroparesis | 445 (4.4) | 391 (6.6) |
| *H. pylori* infection | 127 (1.3) | 115 (1.94) |
| Peptic ulcer | 471 (4.6) | 544 (9.2) |
| Possible Extraesophageal Manifestations | | |
| Asthma | 825 (8.1) | 570 (9.6) |
| Chronic Cough | 253 (2.5) | 197 (3.3) |
| Chronic Laryngitis | 30 (0.3) | 19 (0.3) |

[a] A patient with diagnostic codes for both non-erosive and erosive GERD was included in the erosive GERD group.

## Conclusions

- **Most patients diagnosed with non-erosive GERD and treated with vonoprazan in this database are women.**
- **The most common general comorbidities suggest that these patients have primary care follow-up.**
- **Higher observed rates of Barrett's esophagus and hiatal hernia in patients with erosive GERD suggest validity in using administrative claims data to differentiate erosive and non-erosive subgroups among vonoprazan users.**

**References:** 1. Katz PO, *et al*. *Am J Gastroenterol.* 2022;117(1):27-56. 2. Howden CW, *et al*. *Aliment Pharmacol Ther* .2025;61(5):835-851.