CVS Caremark®

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| Reference number(s) |
| 169-J, 918-J |

# Post Limit Prior Authorization Proton Pump Inhibitors

## Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

| Brand Name | Generic Name |
| --- | --- |
| AcipHex | rabeprazole |
| AcipHex Sprinkles | rabeprazole |
| Dexilant | dexlansoprazole |
| Konvomep | omeprazole/sodium bicarbonate |
| Nexium | esomeprazole |
| Prevacid | lansoprazole |
| Prilosec | lansoprazole |
| Protonix | pantoprazole |
| Zegerid | omeprazole/sodium bicarbonate |

## Indications

### FDA-approved Indications

For Helicobacter pylori eradication to reduce the risk of ulcer recurrence, the PPI is used in conjunction with antibiotics.

| Indication | AcipHex  (rabeprazole) | AcipHex Sprinkles (rabeprazole) | Dexilant  (dexlansoprazole) | Konvomep  (omeprazole/ sodium bicarbonate) | Nexium  (esomeprazole) | Prevacid (lansoprazole) | Prilosec (omeprazole) | Protonix (pantoprazole) | Zegerid  (omeprazole/ sodium bicarbonate) |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Short-term treatment of active duodenal ulcer | ✓ |  |  |  |  | ✓ | ✓ |  | ✓ |
| Helicobacter pylori eradication to reduce the risk of ulcer recurrence | ✓ |  |  |  | ✓ | ✓ | ✓ |  |  |
| Maintenance of healing of duodenal ulcers |  |  |  |  |  | ✓ |  |  |  |
| Short-term treatment of gastric ulcer |  |  |  | ✓ |  | ✓ | ✓ |  | ✓ |
| Short-term treatment of symptoms associated with GERD | ✓ | ✓ | ✓ |  | ✓ | ✓ | ✓ | ✓ | ✓ |
| Short-term treatment of erosive esophagitis / GERD | ✓ |  | ✓ |  | ✓ | ✓ | ✓ | ✓ | ✓ |
| Maintenance healing of erosive esophagitis | ✓ |  | ✓ |  | ✓ | ✓ | ✓ | ✓ | ✓ |
| Pathological hypersecretory conditions | ✓ |  |  |  | ✓ | ✓ | ✓ | ✓ |  |
| Short-term treatment of NSAID-associated gastric ulcer |  |  |  |  |  | ✓ |  |  |  |
| Risk reduction of NSAID-associated gastric ulcer |  |  |  |  | ✓ | ✓ |  |  |  |
| Risk reduction of upper GI bleeding in critically ill patients |  |  |  | ✓ |  |  |  |  | ✓  Suspension |

## Coverage Criteria

Authorization may be granted for the requested drug when ONE of the following criteria are met:

* The requested drug is being prescribed for ANY of the following
  + Barrett’s esophagus as confirmed by biopsy.
  + Hypersecretory syndrome, such as Zollinger-Ellison, confirmed with a diagnostic test
  + Endoscopically verified peptic ulcer disease.
  + Frequent and severe symptoms of chronic gastroesophageal reflux disease (GERD).
  + Atypical symptoms or complications of GERD (i.e., maintenance of healing of erosive esophagitis, maintenance of healing of duodenal ulcers).
* The patient is at high risk for gastrointestinal (GI) adverse events. [NOTE: Risk factors for serious GI adverse events include, but are not limited to, the following: eosinophilic esophagitis, chronic nonsteroidal anti-inflammatory drug (NSAID) therapy, history of peptic ulcer disease and/or GI bleeding, treatment with oral corticosteroids, treatment with anticoagulants, poor general health status, or advanced age.]

## Duration of Approval (DOA)

* 169-J:
  + Barrett’s esophagus as confirmed by biopsy OR Hypersecretory syndrome, such as Zollinger-Ellison, confirmed with a diagnostic test: DOA: Indefinite/Lifetime
  + Endoscopically verified peptic ulcer disease, Frequent and severe symptoms of chronic gastroesophageal reflux disease (GERD), Atypical symptoms or complications of GERD, Eosinophilic esophagitis, High risk for GI adverse events: DOA: 36 months
* MMT 918-J:
  + Barrett’s esophagus as confirmed by biopsy OR Hypersecretory syndrome, such as Zollinger-Ellison, confirmed with a diagnostic test: DOA: Indefinite/Lifetime
  + Endoscopically verified peptic ulcer disease, Frequent and severe symptoms of chronic gastroesophageal reflux disease (GERD), Atypical symptoms or complications of GERD, Eosinophilic esophagitis, High risk for GI adverse events: DOA: 12 months

## References

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2. Aciphex Sprinkles [package insert]. Rockville, MD: Atyu Therapeutics, LLC/Cerecor, Inc.; December 2020.
3. Dexilant [package insert]. Lexington, MA: Takeda Pharmaceuticals America, Inc.; July 2023.
4. Konvomep [package insert]. Woburn, MA: Azurity Pharmaceuticals, Inc.; April 2024.
5. Nexium [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; July 2023.
6. Omeprazole Capsules [package insert]. East Windsor, NJ: Aurobindo Pharma USA, Inc.; April 2023.
7. Prevacid, Prevacid SoluTab [package insert]. Lexington, MA: Takeda Pharmaceuticals America, Inc.; August 2023.
8. Prilosec Granules [package insert]. Zug, Switzerland: Covis Pharma; March 2024.
9. Protonix [package insert]. Philadelphia, PA: Wyeth Pharmaceuticals LLC; June 2023.
10. Zegerid [package insert]. Bridgewater, NJ: Salix Pharmaceuticals; July 2023.
11. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2025. https://online.lexi.com. Accessed February 19, 2025.
12. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: https://www.micromedexsolutions.com/ (cited: 02/19/2025).
13. Shaheen N, Falk G, Iyer P, et al. Diagnosis and Management of Barrett’s Esophagus: An Updated ACG Guideline. Am J Gastroenterol. 2022; 117:559-587.
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15. Falconi M, Eriksson B, Kaltsas G, et al. Consensus guidelines update for the management of functional p-NETs (F-p-NETs) and non-functional p-NETs (NF-p-NETs). Neuroendocrinology. 2016; 103(2): 153–171.
16. Kavitt R, Lipowska A, Anyane-Yeboa A, et al. Diagnosis and Treatment of Peptic Ulcer Disease. The American Journal of Medicine (2019) 132:447−456
17. Lanza FL, Chan F, Quigley E, et al. Guidelines for Prevention of NSAID-Related Ulcer Complications. Am J Gastroenterol 2009; 104: 728-738.