Washington State Health Care Authority

Proton Pump Inhibitors (PPI)

Medical policy no. 49.27.00 Effective July 1, 2018

Note:

- *For non-preferred agents in this class/category, patients must have had an inadequate response or have had a documented intolerance due to severe adverse reaction or contraindication to at least TWO* preferred agents.*
  **If there is only one preferred agent in the class/category documentation of inadequate response to ONE preferred agent is needed*
- *If a new-to-market drug falls into an existing class/category, the drug will be considered non-preferred and subject to this class/category prior authorization (PA) criteria*

Background:

Stomach acid is natural and a valuable contributor to digestion by breaking down food and releasing its micronutrients. In excess, it can cause many problems such as inflammation and irritation to the esophagus or the development of other serious stomach conditions. There are several types of medications that can reduce the amount of acid in the stomach, including histamine 2-receptor antagonist (H2RA) and proton pump inhibitors (PPI). PPIs work by irreversibly blocking the proton pumps that release acid into the stomach. They are generally well tolerated but adverse outcomes have been associated with long-term use of PPIs.

Medical necessity

Drug	Medical Necessity
dexlansoprazole (DEXILANT) esomeprazole magnesium (NEXIUM) esomeprazole strontium lansoprazole (PREVACID) omeprazole (PRILOSEC) pantoprazole (PROTONIX) rabeprazole (ACIPHEX)	Proton pump inhibitors (PPI) may be considered medically necessary when used concurrently with certain medication or to treat certain medical conditions *All non-preferred products require a trial of two (2) preferred products

Clinical policy:

Clinical Criteria	
SHORT-TERM USE	Proton pump inhibitors (PPIs) for 1 tablet or capsule per day do not require prior authorization for short-term relief from gastric acid production. PPIs are limited to a maximum 2-month supply during any 12-month period. A third month can be approved upon request for tapering and discontinuation purposes.
LONG-TERM USE WITH CERTAIN CONCURRENT THERAPIES	Long-term use of PPIs will require prior authorization to determine medical necessity for patients currently receiving concurrent pharmacotherapies. For each prior authorization request, a transaction history documenting claims may be required. One additional month can be approved upon request for tapering purposes following discontinuation of the other pharmacotherapies.

	For long-term PPI use to be considered medically necessary, the following criteria must be met:
	
	• A chronic NSAID (including aspirin greater than or equal to (≥) 325 mg per day) was filled within the last 30 days.
	
	• Chronic low-dose aspirin was filled within the last 30 days and an EGD report from within the last 10 years showing a history of a GI bleed.
	
	• A chronic high-dose systemic steroid was filled within the last 30 days.
	
	• An antiplatelet or anticoagulant was filled within the last 30 days.
	
	• A bisphosphonate was filled within the last 30 days AND
	  ○ Risedronate has been tried/failed (risedronate GI safety similar to placebo); AND
	  ○ Symptoms persist despite swallowing the bisphosphonate with a full glass of water and remaining upright after swallowing the bisphosphonate; AND
	  ○ There are pre-existing esophageal disorders.
	
	• A pancreatic enzyme was filled within the last 30 days.
	
	• Concurrent cancer therapy, if PPI prescribed by or in consultation with an oncologist.

LONG-TERM USE WITH CERTAIN MEDICAL CONDITIONS	Long-term use of PPIs will require prior authorization to determine medical necessity for the treatment for the treatment of specific GI conditions.
	
	For long-term PPI use to be considered medically necessary, for the following criteria must be met:
	
	• Diagnosis of pathological gastric acid hypersecretion, such as Zollinger-Ellison syndrome. Documentation must include consultation note from gastroenterologist documenting diagnosis of pathological gastric acid hypersecretion.
	
	• Diagnosis of Barrett's esophagus. Documentation must include:
	  ○ Most current EGD report from within last 5 years with clinical diagnosis; AND
	  ○ Corresponding pathology report showing histological confirmation of intestinal metaplasia in esophageal biopsies.

	• Diagnosis of esophageal stenosis/stricture or Schatzki ring. Documentation must include EGD report with clinical diagnosis. • Diagnosis of eosinophilic esophagitis. Documentation must include: ○ Initial Criteria: EGD report with esophageal biopsy showing clinical diagnosis within last 12 months **Initial approval will be for up to 4 months** ○ Reauthorization Criteria: PPIs for eosinophilic esophagitis may be reauthorized when ALL of the following are met: a. Patient shows an improvement in symptoms b. Reduction in inflammation and positive histological response shown by a reduction in eosinophilis (< 15 eosinophils/hpf) on follow-up endoscopy with biopsies **Reauthorization approval will be for up to 12 months** • Diagnosis of recent erosive/ulcerative esophagitis. Documentation must include: ○ All EGD reports from within the last 16 months with LA classification; AND ○ All H. pylori biopsy or breath/stool tests (negative test, or positive test then subsequent negative test after triple/quadruple therapy). **Approval will be for up to 16 months (up to 4 months for acute healing and up to 1 year for maintenance).** • Diagnosis of recent gastric ulcer. Documentation must include: ○ EGD report with clinical diagnosis of less than 60 days, AND ○ All H. pylori biopsy or breath/stool tests (negative test, or positive then subsequent negative test after triple/quadruple therapy). **Approval will be for up to 2 months** • Diagnosis of recent duodenal ulcer. Documentation must include: ○ EGD report with clinical diagnosis of less than 1 year, AND ○ All H. pylori biopsy or breath/stool tests (negative test, or positive then subsequent negative test after triple/quadruple therapy). **Approval will be for up to 1 year.** • For all other diagnosis, documentation must include progress notes.
EXCLUDED CONDITIONS:	Use of PPIs will not be approved for the following conditions: • GERD without workup

	• Respiratory disorder or laryngospasm without evidence of aspiration
PRIOR AUTHORIZATION APPROVAL DURATION AND LIMITS	• Patients meeting the medically necessary criteria above will be approved for proton pump inhibitor therapy for up to 1 year (unless mentioned otherwise), if PPIs remain the most appropriate intervention to treat their conditions. • Patients must begin PPI treatment with a preferred product. Non-preferred products will not be approved unless the patient has failed two (2) preferred products or the prescription is signed "Dispense as Written" by an endorsing prescriber. • Authorization is limited to one (1) tablet or capsule per day. For larger quantities, the provider will need to submit additional documentation to demonstrate medical necessity for prescribing above the limit. • Patients not meeting criteria will may receive a maximum 2-month supply per 12-month period from the date of the first claim. An additional month for tapering and discontinuation purposes may be approved. • A slow taper is recommended to prevent an increase in rebound acid secretion. In general, the longer the PPI history or the higher the dose, the longer the taper should take. See Tables 1 and 2 for sample taper schedules.

Table 1. Sample PPI taper schedule for QD dosing

	Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
Current	PPI	PPI	PPI	PPI	PPI	PPI	PPI
Week 1	H2B	PPI	PPI	PPI	PPI	PPI	PPI
Week 2	H2B	PPI	PPI	PPI	PPI	PPI	H2B
Week 3	PPI	PPI	PPI	PPI	H2B	PPI	PPI
Week 4	PPI	H2B	PPI	PPI	H2B	PPI	H2B
Week 5	H2B	H2B	H2B	H2B	H2B	H2B	H2B

H2B = H2 blocker, e.g. ranitidine

Table 2. Sample PPI taper schedule for BID dosing

	Sunday		Monday		Tuesday		Wednesday		Thursday		Friday		Saturday	
	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM
Current	PPI	PPI	PPI	PPI	PPI	PPI	PPI	PPI	PPI	PPI	PPI	PPI	PPI	PPI

Week 1	PPI	H2B	PPI	PPI	PPI	PPI	PPI	PPI	PPI	PPI	PPI	PPI	PPI	PPI
Week 2	PPI	H2B	PPI	PPI	PPI	PPI	PPI	PPI	PPI	PPI	PPI	PPI	PPI	H2B
Week 3	PPI	PPI	PPI	PPI	PPI	PPI	PPI	PPI	PPI	H2B	PPI	PPI	PPI	PPI
Week 4	PPI	PPI	PPI	H2B	PPI	PPI	PPI	PPI	PPI	H2B	PPI	PPI	PPI	H2B
Week 5	PPI	H2B	PPI	H2B	PPI	H2B	PPI	H2B	PPI	H2B	PPI	H2B	PPI	H2B
Week 6	H2B	H2B	PPI	H2B	PPI	H2B	PPI	H2B	PPI	H2B	PPI	H2B	PPI	H2B
Week 7	H2B	H2B	PPI	H2B	PPI	H2B	PPI	H2B	PPI	H2B	PPI	H2B	H2B	H2B
Week 8	PPI	H2B	PPI	H2B	PPI	H2B	PPI	H2B	H2B	H2B	PPI	H2B	PPI	H2B
Week 9	PPI	H2B	H2B	H2B	PPI	H2B	PPI	H2B	H2B	H2B	PPI	H2B	H2B	H2B
Week 10	H2B	H2B	H2B	H2B	H2B	H2B	H2B	H2B	H2B	H2B	H2B	H2B	H2B	H2B

H2B = H2 blocker, e.g. ranitidine

References

1. Dellon, Evan S MD, MPH1, 6; Gonsalves, Nirmala MD2, 6; Hirano, Ikuo MD, FACG2, 6; Furuta, Glenn T MD3; Liacouras, Chris A MD4; Katzka, David A MD, FACG5 ACG Clinical Guideline: Evidenced Based Approach to the Diagnosis and Management of Esophageal Eosinophilia and Eosinophilic Esophagitis (EoE), American Journal of Gastroenterology: May 2013 - Volume 108 - Issue 5 - p 679-692doi: 10.1038/ajg.2013.71
2. Katz, P O. “Diagnosis and Management of Gastroesophageal Reflux Disease”. Am J Gastroenterol2013; 108-328
3. Tran-Duy, F. “Should Patients Prescribed Long-term Low-Dose Aspirin Receive Proton Pump Inhibitors? A Systematic Review and Meta-analysis”. IntJ ClinPract.2015;69(10):1088-1011
4. de Groen, P C et al. "Esophagitis Associated with the Use of Alendronate.“ N Engl J Med. 1996;335(14):1016
5. Harris, S T et al. “Effects of Risedronate Treatment on Vertebal and Nonvertebral Fractures in Women With Postmenopausal Osteoporosis. A Randomized Controlled Trial.” JAMA. 1999;282(14):1344
6. Domínguez-Muñoz, J E et al. “Optimisingthe Therapy of Exocrine Pancreatic Insufficiency by the Association of a Proton Pump Inhibitor to Enteric Coated Pancreatic Extracts.” Gut55.7 (2006): 1056–1057. PMC. Web. 13 Feb. 2017.
7. Uwagawa, T et al. “Proton-Pump Inhibitor as Palliative Care for Chemotherapy-Induced Gastroesophageal Reflux Disease in Pancreatic Cancer Patients.” J PalliatMed. 2010 Jul;13(7):815-8
8. ACG Clinical Guideline
9. Smith PM, Kerr GD, CockelR. A comparison of omeprazole and ranitidine in the prevention of recurrence of benign esophageal stricture. Restore Investigator Group. Gastroenterology. 1994 Nov. 107(5):1312-8
10. Prevacid(lansoprazole) [prescribing information]. Deerfield, IL: Takeda Pharmaceuticals America; October 2016.
11. Tran, TM et al. “Effects of a Proton-Pump Inhibitor in Cystic Fibrosis”. ActaPaediatr. 1998 May;87(5):553-8
12. CEREBRALPALSY.ORG
13. The American Lung Association Asthma Clinical Research Centers. “Efficacy of Esomeprazole for Treatment of Poorly Controlled Asthma”. N EnglJ Med 2009; 360:1487-1499

14. Qadeer, M A. “Proton Pump Inhibitor Therapy for Suspected GERD-Related Chronic Laryngitis: A Meta-Analysis of Randomized Controlled Trials”. Am J Gastroenterol2006 Nov;101(11):2646-54

History

Date	Action and Summary of Changes
08/31/2020	Added eosinophilic esophagitis indication and criteria
06/20/2018	No Change
02/22/2017	New Policy