



Proton Pump Inhibitors (PPI) Policy Criteria

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February 22, 2017

Overview

- Current PPI Policy
- Proposed New PPI Policy
 - Concurrent Medications
 - Gastrointestinal Conditions
 - Other Chronic Medical Conditions

Current PPI Policy

Proton Pump Inhibitors (PPIs)

Ingredient	Label Name	Generic Available	Current PDL Status as of 06/17/2015
Dexlansoprazole	Dexilant	No	Non-Preferred
Esomeprazole Magnesium	Nexium capsule	Yes	Non-Preferred
	Nexium granules	No	Preferred (only for <18yo)
Esomeprazole Strontium	Esomeprazole Strontium		<i>Not Reviewed</i>
Lansoprazole	Prevacid, Prevacid Solutab	Yes	Non-Preferred
Omeprazole	Prilosec capsules	Yes	Generic Preferred
Omeprazole Magnesium	Prilosec OTC tablets	Yes	Generic Preferred
Omeprazole-Sodium Bicarbonate	Zegerid, Zegerid OTC	Yes	Non-Preferred
Pantoprazole Sodium	Protonix	Yes	Generic Preferred
	Protonix Pack	No	Preferred (EA inability to swallow)
Rabeprazole Sodium	Aciphex	Yes	Non-Preferred

Current PPI Policy

- Must step through at least one preferred product before a non-preferred product will be authorized
- Limited to 90-days allowed without authorization
- Continued treatment requires trial & failure of ranitidine **OR** documentation of **ONE** the following:
 - GI ulcer or esophagitis
 - Pathological hypersecretory conditions
 - Barrett's esophagitis
 - Laryngospasms or respiratory diseases (asthma/COPD)
 - H. pylori eradication
 - Gastroparesis
 - Pyloric stenosis
 - Esophageal stenosis/stricture or Schatzki's ring
 - Cystic fibrosis
 - Cerebral palsy
 - Concurrent medication with NSAID, bisphosphonate, pancreatic enzyme, anticoagulant, or unable to tolerate chemotherapy

Management of GERD

The American College of Gastroenterology recommends:

- Weight loss
- Head of bed elevation
- Avoidance of meals 2-3 hours before bedtime
- PPI for 8 weeks

Katz, P O. "Diagnosis and Management of Gastroesophageal Reflux Disease". *Am J Gastroenterol* 2013; 108-328

Proposed New PPI Policy

Proposed New Policy

- Limit 1 tablet or capsule per day
- Cover without prior authorization for 2 months during 12-month period from start date of PPI therapy for gastric acid relief
 - If a taper plan is requested, an additional 1 month may be approved
- Cover through prior authorization for patients with certain concurrent medications, gastrointestinal conditions, or other chronic medical conditions as described on slides 9-26
- Must step through all preferred products before a non-preferred product will be authorized

Concurrent Medications

- NSAIDs, antiplatelets & anticoagulants
- Aspirin 81 mg
- Bisphosphonates
- Pancreatic enzyme replacement therapy
- Chemotherapy

Concurrent NSAIDs, antiplatelets & anticoagulants

- Cover without prior authorization for prophylaxis of ulcers and GI bleeds with NSAID, antiplatelet, or anticoagulant fill within last 30 days

Concurrent aspirin 81 mg

REQUIREMENTS

- Transaction history from the pharmacy showing aspirin claims
- EGD report showing past GI bleed within 10 years

Tran-Duy, F. "Should Patients Prescribed Long-term Low-Dose Aspirin Receive Proton Pump Inhibitors? A Systematic Review and Meta-analysis". *Int J Clin Pract.* 2015;69(10):1088-1011

- The practice of co-prescribing PPIs in patients taking low-dose aspirin is supported by some data, but the evidence is rather weak. It currently remains unclear whether the benefits of co-administration of PPIs in users of low-dose aspirin outweigh their potential harms.

Concurrent bisphosphonates

REQUIREMENTS

- Transaction history from the pharmacy showing bisphosphonate claims
- Previous trial & failure of risedronate

de Groen, P C et al. "Esophagitis Associated with the Use of Alendronate." *N Engl J Med.* 1996;335(14):1016

- In patients for whom adequate information was available, esophagitis seemed to be associated with swallowing alendronate with little or no water, lying down during or after ingestion of the tablet, continuing to take alendronate after the onset of symptoms, and having preexisting esophageal disorders.

Harris, S T et al. "Effects of Risedronate Treatment on Vertebral and Nonvertebral Fractures in Women With Postmenopausal Osteoporosis. A Randomized Controlled Trial." *JAMA.* 1999;282(14):1344

- The overall safety profile of risedronate, including gastrointestinal safety, was similar to that of placebo.

Concurrent pancreatic enzyme replacement therapy

REQUIREMENTS

- Consultation notes from gastroenterologist showing an incomplete response to pancreatic enzyme extracts to improve fat digestion

Domínguez-Muñoz, J E et al. "Optimising the Therapy of Exocrine Pancreatic Insufficiency by the Association of a Proton Pump Inhibitor to Enteric Coated Pancreatic Extracts." *Gut* 55.7 (2006): 1056–1057. *PMC*. Web. 13 Feb. 2017.

- Addition of a PPI leads to a significant improvement and even normalization of fat digestion in patients with exocrine pancreatic insufficiency and an incomplete response to enzyme substitution therapy
- Patients with an adequate response to enzyme substitution therapy do not profit from additional PPI

Concurrent chemotherapy

REQUIREMENTS

- Indicated from oncologist:
 - that a PPI is needed to tolerate chemotherapy
 - anticipated duration of chemotherapy

Uwagawa, T et al. "Proton-Pump Inhibitor as Palliative Care for Chemotherapy-Induced Gastroesophageal Reflux Disease in Pancreatic Cancer Patients." *J Palliat Med.* 2010 Jul;13(7):815-8

- Rabeprazole significantly improved chemotherapy-induced GERD symptoms

Gastrointestinal conditions

- Pathological gastric acid hypersecretion
- GERD with endoscopically identifiable lesions
 - Barrett's esophagus
 - Esophageal stenosis/stricture or Schatzki ring
 - Erosive / Ulcerative esophagitis
- Duodenal ulcer
- Gastric ulcer

Pathological gastric acid hypersecretion

e.g., Zollinger-Ellison Syndrome

APPROVAL

- 1 year & renewable

REQUIREMENTS

- Consultation notes from gastroenterologist documenting diagnosis of pathological gastric acid hypersecretion

Barrett's esophagus

APPROVAL

- 1 year & renewable

REQUIREMENTS

- Most current EGD report from within last 5 years showing impression of Barrett's esophagus
- Corresponding pathology report showing histological confirmation of intestinal metaplasia in esophageal biopsies

ACG Clinical Guideline

- Patients with nondysplastic Barrett's esophagus should undergo endoscopic surveillance every 3-5 years

Esophageal stenosis/stricture or Schatzki ring

APPROVAL

- 1 year & renewable

REQUIREMENTS

- EGD report showing stenosis, stricture, or ring

Smith PM, Kerr GD, Cockel R. 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

- Omeprazole 20 mg QD was superior to ranitidine 150 mg BID in preventing stricture recurrence

Erosive / Ulcerative esophagitis

APPROVAL

- Up to 12 months, renewal requires additional EGD documenting medical necessity for continued treatment

REQUIREMENTS

- EGD report of less than 12 months showing LA classification AND negative H. pylori breath test, stool test, or biopsy

Prevacid (lansoprazole) [prescribing information]. Deerfield, IL: Takeda Pharmaceuticals America; October 2016.

Prilosec & Prevacid clinical trials did not extend past 12 months for maintenance of erosive esophagitis

Duodenal ulcer

APPROVAL

- Up to 12 months, renewal requires additional EGD documenting medical necessity for continued treatment
 - If *H. pylori* positive upon approval, then request to treat for eradication of *H. pylori* infection is initiated

REQUIREMENTS

- EGD report of less than 12 months showing duodenal ulcer AND one of the following:
 - *H. pylori* breath test; OR
 - *H. pylori* stool test; OR
 - Biopsy

Gastric ulcer

APPROVAL

- Up to 2 months, renewal requires additional EGD documenting medical necessity for continued treatment
 - If *H. pylori* positive upon approval, then request to treat for eradication of *H. pylori* infection is initiated

REQUIREMENTS

- EGD report of less than 2 months showing gastric ulcer AND one of the following:
 - *H. pylori* breath test; OR
 - *H. pylori* stool test; OR
 - Biopsy

Other chronic medical conditions

- Cystic fibrosis
- Cerebral palsy
- Asthma or other respiratory disorder
- Laryngospasm

Cystic fibrosis

APPROVAL

- 1 year & renewable

REQUIREMENTS

- Progress notes from pulmonologist or gastroenterologist showing GERD or steatorrhea

Tran, TM et al. "Effects of a Proton-Pump Inhibitor in Cystic Fibrosis". *Acta Paediatr.* 1998 May;87(5):553-8

- Most children with cystic fibrosis show persisting steatorrhea even when treated with pancreatic enzyme
- Low duodenal pH could be responsible for persisting fat loss
- Lansoprazole adjuvant therapy significantly improves both steatorrhea & nutritional status (fat mass & bone mineral content)

Cerebral palsy

APPROVAL

- 1 year & renewable

REQUIREMENTS

- Progress notes showing gastrointestinal problems; AND one of the following:
 - trial and failure of ranitidine; **OR**
 - difficulty communicating

CEREBRALPALSY.ORG

- Children with cerebral palsy are prone to digestive problems that could interfere with their ability to digest food & absorb nutrients.
- Because they often have difficulty communicating, parents may not realize the serious health risks that these otherwise common childhood conditions present to their child with cerebral palsy

Asthma or other respiratory disorder

APPROVAL

- 1 year & renewable

REQUIREMENTS

- Laryngoscopy from pulmonologist or gastroenterologist showing aspiration of stomach acid is exacerbating respiratory disorder

The American Lung Association Asthma Clinical Research Centers. “Efficacy of Esomeprazole for Treatment of Poorly Controlled Asthma”. *N Engl J Med* 2009; 360:1487-1499

- After following 402 patients for 6 months, we were not able to show any treatment benefit with respect to the primary outcome — the rate of episodes of poor asthma control — or with respect to secondary outcomes, including asthma symptoms, nocturnal awakening, quality of life, and lung function. Moreover, there was no significant difference in asthma-related outcomes between patients in whom reflux was documented and those in whom it was not.

Laryngospasm

APPROVAL

- 1 year & renewable

REQUIREMENTS

- Laryngoscopy from ear nose throat specialist showing that aspiration of stomach acid is the cause of laryngospasm

Qadeer, M A. "Proton Pump Inhibitor Therapy for Suspected GERD-Related Chronic Laryngitis: A Meta-Analysis of Randomized Controlled Trials". *Am J Gastroenterol* 2006 Nov;101(11):2646-54

- PPI therapy may offer a modest, but nonsignificant, clinical benefit over placebo in suspected GERD-related CL. Validated diagnostic guidelines may facilitate the recognition of those patients most likely to respond favorably to PPI treatment.

Stakeholder Comments?

- Motion: “I move the Medicaid Fee-For-Service Program implement the limitations for the Proton Pump Inhibitor drug class listed on slide 8 as recommended”