JOHNS HOPKINS MEDICINE / JOHNS HOPKINS HEALTHCARE	Johns Hopkins HealthCare LLC **Pharmacy Public** **Pharmacy Management Drug Policies**	*Policy Number*	MEDS048
		Effective Date	10/01/2008
		Review Date	03/01/2014
	Subject **High-Dose Proton Pump Inhibitors**	*Revision Date*	01/20/2021
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This document applies to the following Participating Organizations:

Priority Partners

Keywords: proton pump inhibitors

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I. POLICY

A. Proton Pump Inhibitors (PPIs) prescribed at doses greater than those approved by the FDA will require prior authorization for outpatient prescription drug benefit coverage to ensure high-dose PPIs are used only when clinically appropriate. The process for initiating a prior authorization request can be found in policy PHARM 20.
   1. PPMCO members are subject to the Priority Partners formulary, available at www.ppmco.org.
   2. USFHP members are subject to prior authorization criteria, step-edits and days-supply limits outlined in the Tricare Policy Manual. Tricare Policy supersedes JHHC Medical/Pharmacy Policies. Tricare limits may be accessed at: http://pec.ha.osd.mil/formulary_search.php?submenuheader=1

II. POLICY CRITERIA

A. Use of high-dose PPIs, up the maximum daily dose, may be approved in the following:
   1. Diagnosis of Zollinger-Ellison syndrome
   2. Diagnosis of Barrett's esophagus

B. Use of twice-daily PPIs may be approved in the following:
   1. Diagnosis of gastric hypersecretion
   2. Diagnosis of laryngopharyngeal reflux
   3. Use in combination with appropriate antibacterial agents in a H. pylori eradication regimen
   4. Patients with GERD who have severe esophageal dysmotility
   5. Patients with GERD, PUD, or erosive esophagitis, who continue to experience GI symptoms despite therapy with two different once-daily PPIs. An adequate therapy trial would consist of 8 weeks of usage for each PPI.

III. AUTHORIZATION PERIOD/LIMITATIONS

A. Approval for H. pylori eradication will be for one month.

B. Approval for Zollinger-Ellison syndrome or Barrett's esophagus will be for one year.

C. Initial approval for other indications will be restricted to 3 months of therapy, requiring follow-up approvals for future prescriptions.

D. Approval for continuation of therapy may be extended in 6-month intervals with clinical documentation showing a continued beneficial patient response to treatment.

IV. EXCLUSIONS

A. PPI doses higher than those approved by the FDA will not be approved for the following:
   1. Use as first-line therapy for the treatment of GERD, PUD, or erosive esophagitis

B. The use of physician samples, or manufacturer product discounts, does not guarantee coverage under the provisions of the medical and/or pharmacy benefit. All pertinent criteria must be met in order to be eligible for benefit coverage.

V. RECOMMENDED DOSE

A. Aciphex
- GERD: 20 mg once daily
- PUD: 20 mg once daily
- H. pylori eradication: 20 mg twice daily (in combination with antibacterial agents)
- Gastric hypersecretion: 60 mg once daily, may increase to 100 mg once daily or 60 mg twice daily

B. Nexium
- Erosive esophagitis: 20-40 mg once daily
- Gastric ulcer prophylaxis: 20-40 mg once daily
- GERD: 20 mg once daily
- H. pylori eradication: 40 mg once daily (in combination with antibacterial agents)
- Zollinger-Ellison syndrome: 40 mg twice daily

C. Prilosec/generic omeprazole
- Erosive esophagitis: 20 mg once daily
- Gastric hypersecretion: 60 mg once daily, may increase up to 120 mg three times daily if necessary GERD: 20 mg once daily
- H. pylori eradication: 20 mg twice daily (in combination with antibacterial agents)
- PUD: 20-40 mg daily
- Stress ulcer prophylaxis: 40 mg twice daily on the first day, then 40 mg once daily

D. Prevacid
- Erosive esophagitis: 15-30 mg once daily
- PUD: 15-30 mg once daily
- GERD: 15 mg once daily
- H. pylori eradication: 30 mg twice daily (in combination with antibacterial agents)
- Zollinger-Ellison syndrome: 60 mg once daily, increasing up to 90 mg twice daily if necessary

E. Protonix/generic pantoprazole
- Erosive esophagitis: 40 mg once daily
- Gastric hypersecretion: 40 mg twice daily
- H. pylori eradication: 40 mg twice daily (in combination with antibacterial agents)
- PUD: 40 – 80 mg once daily
- Zollinger-Ellison syndrome: 40 mg twice daily

F. Zegerid
   A. Note: dosing recommendations based on omeprazole component
      - Erosive esophagitis: 20 mg once daily
      - GERD: 20 mg once daily
      - PUD: 20-40 mg once daily
      - Upper GI hemorrhage: 40 mg once daily

VI. MAXIMUM DOSE

A. Aciphex: 60mg twice daily
B. Nexium: 240 mg/day
C. Prilosec (omeprazole): 120 mg three times daily
D. Prevacid: 90 mg twice daily
E. Protonix (pantoprazole): 240 mg/day
F. Zegerid: 40 mg daily (due to sodium bicarbonate component)

VII. REFERENCES

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3. Chey WD and Wong BC. American College of Gastroenterology Guidelines on the Management of *Helicobacter pylori* Infection. *Am J Gastroenterol* 2007; 102: 1808-25.
4. Wang KK and Sampliner RE. Updated Guidelines 2008 for the Diagnosis, Surveillance, and Therapy of Barrett's Esophagus. *Am J Gastroenterol* 2008; 103: 788-97.

VIII. APPROVALS

Signature on file at JHHC

DATE OF REVISION	SUMMARY OF CHANGE
04/20/2016	Removed background information/definitions, removed process of initiation of request
05/05/2017	Clarification of reauthorization criteria
07/27/2017	Updated Exclusions section regarding physician samples
07/01/2018	Removed EHP Line of Business
10/22/2019	Clarified criteria
01/20/2021	Clarified criteria

Review/Revision Dates: 7/16/2008, 10/1/2008, 1/14/2009, 3/1/2014, 4/20/2016, 5/5/2017, 7/27/2017, 07/01/2018, 10/22/2019, 01/20/2021