



SmartPA Criteria Proposal

Drug/Drug Class:	Proton Pump Inhibitors (PPIs) PDL Edit
First Implementation Date:	October 14, 2004
Proposed Date:	September 17, 2020
Prepared For:	MO HealthNet
Prepared By:	MO HealthNet/Conduent
Criteria Status:	<input type="checkbox"/> Existing Criteria <input checked="" type="checkbox"/> Revision of Existing Criteria <input type="checkbox"/> New Criteria

Executive Summary

Purpose: The MO HealthNet Pharmacy Program will implement a state-specific preferred drug list.

Why Issue Selected: Proton pump inhibitors (PPIs) are used to treat ulcers, heartburn, gastro-esophageal reflux disease (GERD), and ulcers caused by drugs, such as aspirin or non-steroidal anti-inflammatory drugs (NSAIDs). PPIs reduce stomach acid by blocking the enzyme system responsible for pumping acid into the stomach. PPIs are also given with antibiotics to eliminate *H. pylori*, which often causes ulcers. PPIs are among the most commonly prescribed classes of drugs, and their use is increasing, in particular for long-term treatment, often being over-prescribed and used for inappropriate conditions. In recent years, considerable attention has been directed towards a wide range of adverse effects; several long-term side effects have been investigated. While short-term PPI therapy is effective and generally considered to be safe (most available products have OTC formulations), the current guidance suggests caution with long-term uses of PPIs. MO HealthNet wants to ensure that long-term therapy with PPIs is reserved for appropriate indications.

Total program savings for the PDL classes will be regularly reviewed.

Program-Specific Information:	Preferred Agents	Non-Preferred Agents
	<ul style="list-style-type: none"> • Nexium® Rx Packet • Omeprazole Rx • Pantoprazole Tabs • Protonix® Susp 	<ul style="list-style-type: none"> • Aciphex® • Aciphex® Sprinkle • Dexilant™ • Esomep-EZS™ Kit • Esomeprazole • Lansoprazole • Nexium® OTC • Nexium® Rx Caps • Omeprazole OTC • Omeprazole/Bicarb OTC/Rx • Pantoprazole Susp • Prevacid® • Prilosec® • Protonix® • Rabeprazole • Zegerid®

- Type of Criteria: Increased risk of ADE Preferred Drug List
- Appropriate Indications Clinical Edit
- Data Sources: Only Administrative Databases Databases + Prescriber-Supplied

Setting & Population

- Drug class for review: Proton Pump Inhibitors (PPIs)
- Age range: All appropriate MO HealthNet participants

Approval Criteria

- Short-term therapy (< 180 days of therapy in the past 12 months) **OR**
- Documented diagnosis of one of the following in the past 2 years required for long-term therapy (≥ 180 days of therapy in the past 12 months):
 - Barrett's Esophagus
 - Drug-Induced Ulcer
 - Zollinger Ellison Syndrome
 - Mastocytosis
 - Erosive Esophagus
 - Endocrine Neoplasm
 - Peptic Ulcer Disease
 - GERD (symptomatic)
 - Hiatal Hernia
 - Upper GI Bleed
 - Pancreatic Insufficiency
 - Cystic Fibrosis
 - Other diagnoses – clinical consultant review required
- Failure to achieve desired therapeutic outcomes with trial on 2 or more preferred agents:
 - Documented trial period for preferred agents **OR**
 - Participant is currently pregnant **OR**
 - Documented ADE/ADR to preferred agents

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Denial Criteria

- Therapy will be denied if all approval criteria are not met
- Lack of adequate trial on required preferred agents
- Claim exceeds maximum dosing limitation for the following:

Drug Description	Generic Equivalent	Max Dosing Limitation
NEXIUM 20 MG	ESOMEPRAZOLE	4 tablets per day
NEXIUM 40 MG	ESOMEPRAZOLE	4 tablets per day
PREVACID 15 MG	LANSOPRAZOLE	4 tablets per day
PREVACID 30 MG	LANSOPRAZOLE	4 tablets per day
PRILOSEC 20 MG	OMEPRAZOLE	4 tablets per day
PRILOSEC 20 MG OTC	OMEPRAZOLE	4 tablets per day
OMEPRAZOLE 20 MG DR TAB	OMEPRAZOLE	4 tablets per day
PRILOSEC 10 MG	OMEPRAZOLE	4 tablets per day
PRILOSEC 40 MG	OMEPRAZOLE	4 tablets per day
PROTONIX 40 MG	PANTOPRAZOLE	4 tablets per day
PROTONIX 20 MG	PANTOPRAZOLE	4 tablets per day
ACIPHEX 20 MG	RABEPRAZOLE	4 tablets per day

Required Documentation

Laboratory Results:
MedWatch Form:

Progress Notes:
Other:

Disposition of Edit

Denial: Exception Code "0160" (Preferred Drug List)
Rule Type: PDL

Default Approval Period

1 year

References

1. Drug Effectiveness Review Project – Drug Class Review on “Proton Pump Inhibitors”. Center for Evidence-Based Policy, Oregon Health & Science University; March 2010; Updated Evidence Scan February 2015.
2. Evidence-Based Medicine and Fiscal Analysis: “Proton Pump Inhibitor Agents – Therapeutic Class Review”, Conduent Business Services, L.L.C., Richmond, VA; July 2020.
3. Evidence-Based Medicine Analysis: “Proton Pump Inhibitors”, UMKC-DIC; June 2020.
4. Freedberg DE, Kim, LS, Yang, YX. The Risks and Benefits of Long-term Use of Proton Pump Inhibitors: Expert Review and Best Practice Advice from the American Gastroenterological Association. *Gastroenterology*. 2017 Mar;152 (4):706-715.
5. Artesiani ML, Bazzoli F, Eusebi LE, Gelli D, Montagnani M, Rabitti S, Zagari RM. Proton Pump Inhibitors: Risks of long-term use. *J Gastroenterol Hepatol*. 2017 Jul;32(7):1295-1302.
6. Lippincott, Williams, Wilkins. PDR Electronic Library, Montvale NJ; 2020.
7. USPDI, Micromedex; 2020.
8. Facts and Comparisons eAnswers (online); 2020 Clinical Drug Information, LLC.

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