

# SmartPA Criteria Proposal

<b>Drug/Drug Class:</b>	Proton Pump Inhibitors (PPIs) PDL Edit
<b>First Implementation Date:</b>	October 14, 2004
<b>Proposed Date:</b>	September 17, 2020
<b>Prepared For:</b>	MO HealthNet
<b>Prepared By:</b>	MO HealthNet/Conduent
<b>Criteria Status:</b>	<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"> <li>• Nexium® Rx Packet</li> <li>• Omeprazole Rx</li> <li>• Pantoprazole Tabs</li> <li>• Protonix® Susp</li> </ul>	<ul style="list-style-type: none"> <li>• Aciphex®</li> <li>• Aciphex® Sprinkle</li> <li>• Dexilant™</li> <li>• Esomep-EZS™ Kit</li> <li>• Esomeprazole</li> <li>• Lansoprazole</li> <li>• Nexium® OTC</li> <li>• Nexium® Rx Caps</li> <li>• Omeprazole OTC</li> <li>• Omeprazole/Bicarb OTC/Rx</li> <li>• <b>Pantoprazole Susp</b></li> <li>• Prevacid®</li> <li>• Prilosec®</li> <li>• Protonix®</li> <li>• Rabeprazole</li> <li>• Zegerid®</li> </ul>

- 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

## 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.

### SmartPA PDL Proposal Form

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