

# 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 16, 2021
<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), a highly prescribed class of drugs, are used to treat a variety of conditions including ulcers, heartburn, gastro-esophageal reflux disease (GERD), and ulcers, including those caused by medications such as aspirin or non-steroidal anti-inflammatory drugs (NSAIDs). They may also be given alongside antibiotics in cases of ulcers caused by *Helicobacter pylori* (*H. pylori*) infections. PPIs reduce stomach acid production by blocking the enzyme system (H+/K+ ATPase) responsible for pumping acid into the stomach. Due to their widespread use, emerging evidence indicating the potential for long-term adverse effects has come to light. While short-term PPI use is effective and generally considered to be safe (most available products have OTC formulations), the current guidance suggests caution with long-term use. Providers should continue to evaluate the risk versus benefit for extended therapy.

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>• Esomeprazole</li> <li>• Lansoprazole</li> <li>• Nexium® Rx Caps</li> <li>• Omeprazole OTC</li> <li>• Omeprazole/Sodium Bicarbonate</li> <li>• Pantoprazole Susp</li> <li>• Prevacid®</li> <li>• Prilosec®</li> <li>• Protonix® Tabs</li> <li>• Rabeprazole</li> <li>• Zegerid®</li> </ul>

Type of Criteria:  Increased risk of ADE  
 Appropriate Indications

Preferred Drug List  
 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. Evidence-Based Medicine and Fiscal Analysis: "Proton Pump Inhibitor Agents – Therapeutic Class Review", Conduent Business Services, L.L.C., Richmond, VA; July 2021.
2. Evidence-Based Medicine Analysis: "Proton Pump Inhibitors", UMKC-DIC; July 2021.
3. 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.
4. 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.
5. USPDI, Micromedex; 2021.
6. Facts and Comparisons eAnswers (online); 2021 Clinical Drug Information, LLC.