

# 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 15, 2022
<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<sup>+</sup>/K<sup>+</sup> 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® Sprinkle™</li> <li>Dexilant</li> <li><b>Dexlansoprazole</b></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

- Failure to achieve desired therapeutic outcomes with trial on 2 or more preferred agents:
  - Documented trial period for preferred agents **OR**
  - Documented ADE/ADR to preferred agents
- **For dexlansoprazole: Clinical Consultant Review required for medical necessity**

## 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
ACIPHEX DR 20 MG TAB	RABEPRAZOLE	2 tablets per day
ACIPHEX SPRINKLE DR 5 MG CAP	RABEPRAZOLE	2 capsules per day
ACIPHEX SPRINKLE DR 10 MG CAP	RABEPRAZOLE	2 capsules per day
DEXILANT DR 30 MG CAP	DEXLANSOPRAZOLE	2 capsules per day
DEXILANT DR 60 MG CAP	DEXLANSOPRAZOLE	1 capsule per day
ESOMEPRAZOLE 20 MG TAB	ESOMEPRAZOLE	2 tablets per day
ESOMEPRAZOLE DR 49.3 MG CAP	ESOMEPRAZOLE	1 capsule per day
NEXIUM DR 2.5 MG PACKET	ESOMEPRAZOLE	2 packets per day
NEXIUM DR 5 MG PACKET	ESOMEPRAZOLE	2 packets per day
NEXIUM DR 10 MG PACKET	ESOMEPRAZOLE	2 packets per day
NEXIUM DR 20 MG CAP	ESOMEPRAZOLE	2 capsules per day
NEXIUM DR 20 MG PACKET	ESOMEPRAZOLE	2 packets per day
NEXIUM DR 40 MG CAP	ESOMEPRAZOLE	2 capsules per day
NEXIUM DR 40 MG PACKET	ESOMEPRAZOLE	2 packets per day
OMEPRAZOLE DR 20 MG CAP	OMEPRAZOLE	2 capsules per day
OMEPRAZOLE DR 20 MG ODT	OMEPRAZOLE	2 tablets per day
OMEPRAZOLE DR 20 MG TAB	OMEPRAZOLE	2 tablets per day
OMEPRAZOLE MAG DR 20.6 MG CAP	OMEPRAZOLE	2 capsules per day
PREVACID 15 MG SOLUTAB	LANSOPRAZOLE	2 tablets per day
PREVACID 30 MG SOLUTAB	LANSOPRAZOLE	2 tablets per day
PREVACID DR 15 MG CAP	LANSOPRAZOLE	2 tablets per day
PREVACID DR 30 MG CAPS	LANSOPRAZOLE	2 tablets per day
PRILOSEC 20 MG OTC TAB	OMEPRAZOLE	2 tablets per day
PRILOSEC DR 2.5 MG SUS	OMEPRAZOLE	4 packets per day
PRILOSEC DR 10 MG CAP	OMEPRAZOLE	2 tablets per day
PRILOSEC DR 10 MG SUSP	OMEPRAZOLE	4 packets per day

PRILOSEC DR 40 MG CAP	OMEPRAZOLE	2 tablets per day
PROTONIX DR 20 MG TAB	PANTOPRAZOLE	2 tablets per day
PROTONIX 40 MG SUSP	PANTOPRAZOLE	2 packets per day
PROTONIX DR 40 MG TAB	PANTOPRAZOLE	2 tablets per day
ZEGERID 20 MG CAP	OMEPRAZOLE/SODIUM BICARB	1 capsule per day
ZEGERID 20 MG PACKET	OMEPRAZOLE/SODIUM BICARB	1 packet per day
ZEGERID 40 MG CAP	OMEPRAZOLE/SODIUM BICARB	1 capsule per day
ZEGERID 40 MG PACKET	OMEPRAZOLE/SODIUM BICARB	1 packet 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

- Evidence-Based Medicine Analysis: "Proton Pump Inhibitors", UMKC-DIC; July 2022.
- Evidence-Based Medicine and Fiscal Analysis: "Proton Pump Inhibitor Agents – Therapeutic Class Review", Conduent Business Services, L.L.C., Richmond, VA; July 2021.
- 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.
- 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.
- USPDI, Micromedex; 2022.
- Facts and Comparisons eAnswers (online); 2022 Clinical Drug Information, LLC.