

SmartPA Criteria Proposal

Drug/Drug Class:	Proton Pump Inhibitors (PPIs) PDL Edit
First Implementation Date:	October 14, 2004
Proposed Date:	September 16, 2021
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), 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"> Nexium® Rx Packet Omeprazole Rx Pantoprazole Tabs Protonix® Susp 	<ul style="list-style-type: none"> Aciphex® Aciphex® Sprinkle™ Dexilant Esomeprazole Lansoprazole Nexium® Rx Caps Omeprazole OTC Omeprazole/Sodium Bicarbonate Pantoprazole Susp Prevacid® Prilosec® Protonix® Tabs Rabeprazole Zegerid®

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.