

## Proton Pump Inhibitors Policy Number: C4714-A

**CRITERIA EFFECTIVE DATES:**

ORIGINAL EFFECTIVE DATE	LAST REVIEWED DATE	NEXT REVIEW DATE
3/1/2012	4/1/2020	4/1/2021
J CODE	TYPE OF CRITERIA	LAST P&T APPROVAL
NA	RxPA	Q2 2020

**PRODUCTS AFFECTED:**

ACIPHEX (rabeprazole), ACIPHEX SPRINKLES (rabeprazole), DEXILANT (dexlansoprazole), esomeprazole strontium, NEXIUM (esomeprazole), PREVACID (lansoprazole), PREVICID SOLUTAB (lansoprazole ODT), PRILOSEC (omeprazole), PROTONIX (pantoprazole), ZEGERID (omeprazole/sodium bicarbonate)

**DRUG CLASS:**

Proton Pump Inhibitors

**ROUTE OF ADMINISTRATION:**

Oral

**PLACE OF SERVICE:**

Retail Pharmacy

**AVAILABLE DOSAGE FORMS:**

Esomep-EZS KIT 20MG	NexIUM 24HR CPDR 20MG	EQL Lansoprazole CPDR 15MG
First-Lansoprazole SUSP 3MG/ML	NexIUM CPDR 20MG	GNP Lansoprazole CPDR 15MG
First-Omeprazole SUSP 2MG/ML	RA Esomeprazole Magnesium CPDR 20MG	GoodSense Lansoprazole CPDR 15MG
Omeprazole+Syrspend SF Alka SUSP 2MG/ML	SM Esomeprazole Magnesium CPDR 20MG	Heartburn Treatment 24 Hour CPDR 15MG
Dexilant CPDR 30MG	esomeprazole Magnesium CPDR 40MG	HM Lansoprazole CPDR 15MG
Dexilant CPDR 60MG	NexIUM CPDR 40MG	KLS Lansoprazole CPDR 15MG
CVS Esomeprazole Magnesium CPDR 20MG	NexIUM PACK 2.5MG	Lansoprazole CPDR 15MG
Esomeprazole Magnesium CPDR 20MG	NexIUM PACK 10MG	Prevacid 24HR CPDR 15MG
GNP Esomeprazole Magnesium CPDR 20MG	NexIUM PACK 20MG	Prevacid CPDR 15MG
GoodSense Esomeprazole CPDR 20MG	NexIUM PACK 40MG	RA Lansoprazole CPDR 15MG
Heartburn Treatment 24 Hour CPDR 20MG	NexIUM PACK 5MG	SM Lansoprazole CPDR 15MG
HM Esomeprazole Magnesium DR CPDR 20MG	NexIUM 24HR TBEC 20MG	Lansoprazole CPDR 30MG
KLS Esomeprazole Magnesium CPDR 20MG	esomeprazole Sodium SOLR 20MG	Prevacid CPDR 30MG
NexIUM 24HR Clear Minis CPDR 20MG	esomeprazole Sodium SOLR 40MG	Lansoprazole TBDP 15MG
	NexIUM I.V. SOLR 40MG	Prevacid SoluTab TBDP 15MG
	esomeprazole Strontium CPDR 49.3MG	Lansoprazole TBDP 30MG
	CVS Lansoprazole CPDR 15MG	
	EQ Lansoprazole CPDR 15MG	

Prevacid SoluTab TBDP 30MG	CVS Omeprazole CPDR 20.6 (20 Base) MG	Omeprazole-Sodium Bicarbonate CAPS 40- 1100MG
Omeprazole CPDR 10MG	EQ Omeprazole Magnesium CPDR 20MG	Zegerid CAPS 40-1100MG
Omeprazole CPDR 20MG	KP Omeprazole Magnesium CPDR 20.6 (20 Base) MG	Omeprazole-Sodium Bicarbonate PACK 20- 1680MG
Omeprazole CPDR 40MG	Omeprazole Magnesium CPDR 20.6 (20 Base) MG	Zegerid PACK 20-1680MG
CVS Omeprazole TBEC 20MG	QC Omeprazole Magnesium CPDR 20.6 (20 Base) MG	Omeprazole-Sodium Bicarbonate PACK 40- 1680MG
EQ Omeprazole TBEC 20MG	PriLOSEC OTC TBEC 20MG	Zegerid PACK 40-1680MG
EQL Omeprazole TBEC 20MG	PriLOSEC PACK 10MG	Pantoprazole Sodium TBEC 20MG
GNP Omeprazole TBEC 20MG	PriLOSEC PACK 2.5MG	Protonix TBEC 20MG
HM Omeprazole TBEC 20MG	EQ Omeprazole TBDD 20MG	Pantoprazole Sodium TBEC 40MG
KLS Omeprazole TBEC 20MG	Omeprazole TBDD 20MG	Protonix TBEC 40MG
Omeprazole TBEC 20MG	CVS Omeprazole-Sod Bicarbonate CAPS 20- 1100MG	Protonix PACK 40MG
PX Omeprazole TBEC 20MG	OmePPI CAPS 20-1100MG	Pantoprazole Sodium SOLR 40MG
RA Omeprazole TBEC 20MG	Omeprazole-Sodium Bicarbonate CAPS 20- 1100MG	Protonix SOLR 40MG
SB Omeprazole TBEC 20MG	RA Omeprazole-Sodium Bicarb CAPS 20-1100MG	AcipHex Sprinkle CPSP 10MG
SM Omeprazole TBEC 20MG	Zegerid CAPS 20-1100MG	AcipHex Sprinkle CPSP 5MG
TGT Omeprazole TBEC 20MG	Zegerid OTC CAPS 20- 1100MG	AcipHex TBEC 20MG
Acid Reducer CPDR 20.6 (20 Base) MG	OmePPI CAPS 40-1100MG	RABEprazole Sodium TBEC 20MG

**FDA-APPROVED USES:**

Barrett's Esophagus, Erosive Esophagitis, Gastric Bypass surgery, Gastroesophageal reflux disease (GERD), Hyperacidity in Cystic Fibrosis patients, Laryngophartngela Reflux disease (LPR), Zollinger-Ellison Syndrome, Reduction of risk for NSAID- associated gastric ulcer, Gastritis, Dyspepsia, Pyrosis (heartburn), Active GI Bleed, Helicobacter (H. Pylori) eradication, Duodenal ulcer(s), systemic mastocytosis, multiple endocrine adenoma syndrome

**COMPENDIAL APPROVED OFF-LABELED USES: None**

**COVERAGE CRITERIA: INITIAL AUTHORIZATION**

**DIAGNOSIS:**

Barrett's Esophagus, Erosive Esophagitis, Gastric Bypass surgery, Gastroesophageal reflux disease (GERD), Hyperacidity in Cystic Fibrosis patients, Laryngophartngela Reflux disease (LPR), Zollinger-Ellison Syndrome, Reduction of risk for NSAID- associated gastric ulcer, Gastritis, Dyspepsia, Pyrosis (heartburn), Active GI Bleed, Helicobacter (H. Pylori) eradication, Duodenal ulcer(s), systemic mastocytosis, multiple endocrine adenoma syndrome

**REQUIRED MEDICAL INFORMATION:****A. FOR ALL INDICATIONS:**

1. Documentation of FDA approved guideline based diagnosis and dosing is within recommended limits  
AND
2. Documentation of trial (at least 4 weeks) and failure, or contraindication to all preferred formulary proton pump inhibitors

NOTE: Long term care, hospice and end of life patients are exempt from prior authorization approval.

**DURATION OF APPROVAL:**

Initial authorization: 12 months, Continuation of therapy: 12 months

**QUANTITY:**

None

**PRESCRIBER REQUIREMENTS:**

None

**AGE RESTRICTIONS:**

None

**GENDER:**

Male and female

**CONTINUATION OF THERAPY:****A. ALL INDICATIONS:**

1. Adherence to therapy as verified by Prescriber and member's medication fill history (review Rx history for compliance), including: adherent to the prescribed medication regimen, tolerance to therapy and no severe adverse reactions or drug toxicity  
AND
2. Documentation therapy has resulted in clinical improvement from baseline or from the previous authorization

**CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:**

All other uses of Proton Pump Inhibitors are considered experimental/investigational and therefore, will follow Molina's Off-Label policy

**OTHER SPECIAL CONSIDERATIONS:**

None

**BACKGROUND:**

Proton pump inhibitors (PPIs) block the final step in gastric acid production through irreversible inhibition of the H<sup>+</sup>/K<sup>+</sup> ATPase enzyme system, also known as the acid (proton) pump, on the secretory surface of the gastric parietal cells. H<sup>+</sup>/K<sup>+</sup> ATPase enzyme system regulates intragastric pH through the exchange of intracellular hydrogen ions for extracellular potassium ions. Proton pump inhibitors are weak bases that require conversion in the acidic environment of stimulated parietal cells to the active sulfenamide metabolite. The active metabolite inhibits ATPase enzymes, which prevents secretion of hydrogen ions into the gastric lumen and reduces intragastric pH. Both

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basal and stimulus-induced acid production is inhibited. Only active ATPase enzymes are inhibited; approximately 75% are active at any given time.

PPIs are used in the treatment of many gastric-related disorder including gastric and duodenal ulcer disease, Helicobacter pylori eradication and gastroesophageal reflux disease (GERD); some of the drugs are also available over-the-counter for the self-treatment of dyspepsia and pyrosis. Efficacy and safety of the PPIs appear to be similar; however, esomeprazole and rabeprazole may provide slightly shorter time to symptom relief. Secondary to the widespread use of these medications, there

is concern regarding long-term adverse effects, such as vitamin B12 deficiency, hypomagnesemia, pneumonia, lupus-like symptoms, and enteric infections. All of the PPIs are substrates of the CYP2C19 isoenzymes and, with the exception of dexlansoprazole, have been found to exert some degree of CYP2C19 inhibition; pantoprazole has been found to be a weak CYP2C19 inhibitor.

**APPENDIX: None**

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## REFERENCES:

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2. Klok RM, Postma MJ, Van Hout BA, et al. Meta-analysis: comparing the efficacy of proton pump inhibitors in short-term use. *Aliment Pharmacol Ther* 2003;17:1237-45.
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