

# MEDICATION COVERAGE POLICY

## PHARMACY AND THERAPEUTICS ADVISORY COMMITTEE

<b>POLICY</b>	Digestive Disorders	<b>P&amp;T DATE</b>	12/8/2020
<b>THERAPEUTIC CLASS</b>	Gastrointestinal Disorders	<b>REVIEW HISTORY</b> (MONTH/YEAR)	12/19, 12/18, 5/17, 12/16, 5/15, 9/14, 9/11, 2/10
<b>LOB AFFECTED</b>	Medi-Cal		

*This policy has been developed through review of medical literature, consideration of medical necessity, generally accepted medical practice standards, and approved by the HPSJ Pharmacy and Therapeutic Advisory Committee.*

## OVERVIEW

Proton-pump inhibitors (PPIs) is the mainstay class for management of gastroesophageal reflux disease (GERD) and peptic ulcer disease (PUD). Patients with mild or intermittent symptoms of GERD are initially managed by lifestyle and dietary changes. Antacids and histamine-2 receptor antagonists (H2RAs) may be initiated for temporarily relief. However, if GERD symptoms persist, PPI is recommended for longer periods of time. In patients with advanced PUD (presence of stomach ulcer >2 cm, failure to eradicate H. pylori infection, recurrent peptic ulcers, continued NSAID use),<sup>1</sup> continual maintenance therapy is recommended. That being said, PPIs should be discontinued when no longer necessary. In general, for non-steroidal anti-inflammatory drug (NSAID)-induced ulcer, patients should be managed with a PPI for at least 8 weeks. In patients with duodenal and gastric disorders, therapy usually lasts 4-12 weeks or until ulcer has healed. Patients with GERD should be managed for 8-12 weeks then trial off the PPI to be managed by lifestyle changes. The below criteria, limits, and requirements for certain agents are in place to ensure appropriate use of those agents.

**Table 1: Available GERD/PUD Agents (Current as of 10/2019)**

Single Agents					
Therapeutic Class	Generic Name (Brand Name)	Available Strengths	Formulary Limits	Average Cost per 30 days	Notes
Histamine-2 Receptor Antagonist (H2RA)	Cimetidine (Tagamet)	200mg, 300mg, 400mg, 800mg, 300mg/5ml	--	\$18.92	
			--	\$77.72	
	Famotidine (Pepcid)	10mg	NF	--	
		20mg, 40mg	--	\$4.20	
		40mg/mL	--	\$129.22	
	Ranitidine (Zantac)	75mg, 150mg, 300mg tablets	--	\$3.38	
		150mg, 300mg capsules	PA	\$28.52	Reserved for treatment failure to Ranitidine tablets.
15mg/ml		--	\$5.78		
Nizatidine (Axid)	150mg, 300mg, 15mg/mL	NF	\$71.89		
Proton-Pump Inhibitor (PPI)	Dexlansoprazole (Dexilant)	30mg, 60mg	PA	\$291.85	Reserved for treatment failure to Rabeprazole.
	Esomeprazole (Nexium OTC)	20mg capsules	ST	\$32.51	Reserved for treatment failure to 2 first-line agents.
		20mg tablets	NF	--	Non-formulary. Alternative = Nexium OTC capsules.
	Esomeprazole (Nexium Rx)	20mg capsules, 40mg	NF	--	
	Esomeprazole magnesium Granules (Nexium Packet)	2.5mg, 5mg, 10mg, 20mg, 40mg	NF	\$264.15	
	Esomeprazole strontium	49.3mg	NF	--	
	First-Lansoprazole	3mg/ml	NF	--	Non-formulary. Alternative = Prevacid Solutab
Lansoprazole (Prevacid)	15mg, 30mg	--	\$10.39		

	<b>Lansoprazole ODT (Prevacid Solutabs)</b>	15mg, 30mg	PA	\$398.40	Prevacid Solutab: Step therapy to ranitidine syrup for children <10 years old OR documented inability to swallow tablets/capsules
	<b>First-Omeprazole</b>	2mg/ml	NF	--	Non-formulary. Alternative = Prevacid Solutab
	<b>Omeprazole (Prilosec)</b>	20mg (Rx) capsules, 40mg	--	\$1.66	
		10mg capsules, 20mg (OTC) tablets, 20mg ODT	NF	--	
	<b>Omeprazole magnesium (Prilosec)</b>	20mg tablets, 20.6mg capsules	NF	--	
	<b>Omeprazole (Prilosec Suspension Packets)</b>	2.5mg, 10mg	PA, QL, AL	--	Step therapy to ranitidine syrup for children <6 years old. 2.5mg - Limited to 60 packets per month. 10mg - Limited to 30 packets per month.
	<b>Pantoprazole (Protonix)</b>	20mg, 40mg tablets	--	\$2.31	
		40mg suspension	NF	--	
	<b>Rabeprazole (Aciphex)</b>	5mg, 10mg capsules	NF	--	
		20mg tablets	ST	\$13.13	Reserved for treatment failure to Nexium OTC capsules.
<b>Miscellaneous</b>	<b>Bismuth Subsalicylate</b>	262mg, 262mg/15ml, 525mg/ml15ml	-	\$4.69	
	<b>Mag Hydrox/Al Hydrox/Simeth (Maalox)</b>	200mg-200mg-20mg/5ml, 400mg-400mg-40mg/5ml	-	\$1.98	
<b>Combination Agents</b>					
<b>Therapeutic Class</b>	<b>Generic Name (Brand Name)</b>	<b>Available Strengths</b>	<b>Formulary Limits</b>	<b>Average Cost per 30 days</b>	<b>Notes</b>
<b>H2RA</b>	<b>Famotidine/Calcium Carbonate/Magnesium Hydroxide</b>	10-800-165mg	NF	--	
<b>PPI</b>	<b>Esomeprazole/Naproxen</b>	20mg-375mg, 20mg-500mg	NF	--	
	<b>Omeprazole/Sodium Bicarbonate (Zegerid, Zegerid OTC)</b>	20mg-1100mg, 40mg-1100mg, 20mg-1680mg pkt, 40mg-1680mg pkt	NF	\$5,949.45	*Strength available as Rx only
<b>H. Pylori Pre-packaged Regimens</b>	<b>Bismuth Subcitrate/ Metronidazole/ Tetracycline (Pylera)</b>	140mg-125mg-125mg	NF	\$360.60	Individual agents are available on formulary. Use individual agents separately.
	<b>Bismuth Subsalicylate/ Metronidazole/ Tetracycline (Helidac)</b>	See packaging for details on how supplied.	NF	--	
	<b>Lansoprazole/ Amoxicillin/ Clarithromycin (Prevpac)</b>		NF	--	
	<b>Omeprazole/Amoxicillin/ Clarithromycin (Omeclamox-Pak)</b>		NF	--	
ST = Step therapy; QL = Quantity Limit; PA = Prior Authorization Required; NF = Non-Formulary; ODT = Orally Disintegrating Tablet					

## ✚ EVALUATION CRITERIA FOR APPROVAL/EXCEPTION CONSIDERATION

Below are the coverage criteria and required information for each agent. These coverage criteria have been reviewed approved by the HPSJ Pharmacy & Therapeutics (P&T) Advisory Committee. For conditions not covered under this Coverage Policy, HPSJ will make the determination based on Medical Necessity as described in HPSJ Medical Review Guidelines (UM06).

### **Histamine-2 Receptor Antagonist (H2RA) Single-Agent Products**

*Cimetidine, Famotidine (Pepcid), Ranitidine (Zantac)*

- Coverage Criteria:** Ranitidine capsules are reserved for patients who have tried and failed treatment with Ranitidine tablets.
- Limits:** None
- Required Information for Approval:** N/A
- Other Notes:** None

### **Proton Pump Inhibitor (PPI) Single-Agent Products**

*1<sup>st</sup> line—Lansoprazole (Prevacid, Prevacid Solutab), Omeprazole (Prilosec), Pantoprazole (Protonix); 2<sup>nd</sup> line—Esomeprazole (Nexium OTC capsules); 3<sup>rd</sup> line—rabeprazole (Aciphex); 4<sup>th</sup>—line dexlansoprazole (Dexilant)*

#### **1<sup>st</sup> line—Lansoprazole (Prevacid, Prevacid Solutab), Omeprazole (Prilosec), Pantoprazole (Protonix)**

- Coverage Criteria:** None
- Limits:**
  - Prilosec suspension 2.5mg packets: 60 packets per 30 days
  - Prilosec suspension 10mg packets: 30 packets per 30 days
- Required Information for Approval:** N/A
- Other Notes:**
  - Prevacid Solutab Coverage Criteria: Step therapy to ranitidine syrup for children <10 years old OR documented inability to swallow tablets/capsules.
  - Prilosec suspension packets- Step therapy to ranitidine syrup for children <6 years old.
- Non-Formulary:** First-Omeprazole/Lansoprazole, Omeprazole 10mg capsules/20mg ODT/20mg tablets/20.6mg capsules, Pantoprazole suspension

#### **2<sup>nd</sup> line—Esomeprazole (Nexium OTC capsules)**

- Coverage Criteria:** Nexium OTC capsules are reserved for documentation of treatment failure of 2 (two) dose-optimized 1<sup>st</sup> line agents (Omeprazole 40mg or higher, Pantoprazole 40mg or higher, Lansoprazole 60mg or higher).
- Limits:** None
- Required Information for Approval:** Drug refill history showing fills of two 1<sup>st</sup> line agents at the doses indicated above
- Non-Formulary:** Nexium OTC tablets, Nexium Rx, Esomeprazole strontium, Nexium packets

#### **3<sup>rd</sup> line—Rabeprazole (Aciphex tablets)**

- Coverage Criteria:** Aciphex is reserved for documented treatment failure of 2 (two) dose-optimized first-line therapies (omeprazole, pantoprazole, lansoprazole) AND Nexium OTC capsules 40mg or higher.
- Limits:** None
- Required Information for Approval:** Drug refill history showing fills of two 1<sup>st</sup> line agents AND Esomeprazole (Nexium OTC capsules) at the doses indicated above
- Non-Formulary:** Rabeprazole capsules

#### **4<sup>th</sup> line—Dexlansoprazole (Dexilant)**

- Coverage Criteria:** Dexilant is reserved for documentation of treatment failure of 2 (two) dose-optimized first line agents (Omeprazole, Pantoprazole, Lansoprazole), Nexium OTC capsules (2<sup>nd</sup> line), AND Rabeprazole (3<sup>rd</sup> line).
- Limits:** None
- Required Information for Approval:** Drug refill history showing fills of two 1<sup>st</sup> line agents, Esomeprazole (Nexium OTC), AND Rabeprazole at the doses indicated above

## Miscellaneous

*Bismuth Subsalicylate (Stomach Relief, Peptif Relief, Kaopectate, Soothe), Mag Hydrox/Al Hydrox/Simeth (Maalox)*

- Coverage Criteria: None
- Limits: None
- Required Information for Approval: N/A
- Other notes: None

### Clinical Justification:

Currently, there are no guidelines that support the use of one PPI over another. All PPIs are shown to be equally effective and safe. Esomeprazole (Nexium, Nexium OTC) and Dexlansoprazole (Dexilant) are enantiomers of Omeprazole and Lansoprazole respectively. Esomeprazole is the racemic S-enantiomer of omeprazole (Prilosec), so each 20mg of omeprazole already naturally contains 10mg of Nexium within it. Therefore, the equivalent dose of Nexium 40mg is Omeprazole 80mg (divided as 40mg twice daily). Dexlansoprazole is the racemic R-enantiomer of lansoprazole (Prevacid), so each 30mg of lansoprazole already naturally contains 15mg of Dexilant in it. Therefore, the equivalent dose of Dexilant 60mg is lansoprazole 120mg (taken as 30mg caps - 2 caps BID).

## RECOMMENDATIONS

Review on an annual cycle

## REFERENCES

1. Dean L. Comparing proton pump inhibitors. *PubMed Clinical Q&A*. October 2010. Available from: <http://www.ncbi.nlm.nih.gov/pubmedhealth/PMH0004954>. (Accessed April 24, 2015).
2. Bhatt, DL, Cryer BL, Contact, CF, et al. Clopidogrel with or without omeprazole in coronary artery disease. *N Engl J Med*. 2010; 363: 1909-1917.
3. Katz P, Gerson L, Vela M. Guidelines for the Diagnosis and Management of Gastroesophageal Reflux Disease. *Am J Gastroenterol*. 2013;108(3):308-328. doi: 10.1038/ajg.2012.444
4. U.S. Food and Drug Administration. 2020. FDA Requests Removal Of All Ranitidine Products (Zantac) From The Market. [online] Available from: <https://www.fda.gov/news-events/press-announcements/fda-requests-removal-all-ranitidine-products-zantac-market>. (Accessed November 21, 2020).

## REVIEW & EDIT HISTORY

Document Changes	Reference	Date	P&T Chairman
Creation of Policy	GERD/PUD Coverage Policy.docx	4/2015	Jonathan Szkotak, PharmD
Update to Policy	HPSJ Coverage Policy – Gastrointestinal – Digestive Disorders 2015-9.docx	11/2015	Johnathan Yeh, PharmD
Update to Policy	HPSJ Coverage Policy - Gastrointestinal - Digestive Disorders 2017-5.docx	5/2017	Johnathan Yeh, PharmD
Update to Policy	HPSJ Coverage Policy - Gastrointestinal - Digestive Disorders 2018-12.docx	12/2018	Matthew Garrett, PharmD
Review Policy	Digestive Disorders	12/2019	Matthew Garrett, PharmD
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Note: All changes are approved by the HPSJ P&T Committee before incorporation into the utilization policy