

MEDICATION COVERAGE POLICY

PHARMACY AND THERAPEUTICS ADVISORY COMMITTEE

POLICY	Digestive Disorders	P&T DATE	5/9/2017
THERAPEUTIC CLASS	Gastrointestinal Disorders	REVIEW HISTORY	12/16, 5/15, 9/14, 9/11,
LOB AFFECTED	Medi-Cal	(MONTH/YEAR)	2/10

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),¹ 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 5/2017)

Single Agents					
Therapeutic Class	Generic Name (Brand Name)	Available Strengths	Formulary Limits	Average Cost per 30 days	Notes
Histamine-2 Receptor Antagonist (H2RA)	Cimetidine	200mg, 300mg, 400mg, 800mg, 300mg/5ml	--	\$19.33	
	Famotidine (Pepcid)	20mg, 40mg	--	\$5.46	
	Ranitidine (Zantac)	75mg, 150mg, 300mg, 15mg/ml	--	\$11.72	
Proton-Pump Inhibitor (PPI)	Dexlansoprazole (Dexilant)	30mg, 60mg	ST; PA	\$240.65	Reserved for treatment failure to Rabeprazole.
	Esomeprazole (Nexium OTC)	20mg	ST; PA	\$33.23	Reserved for treatment failure to 2 first-line agents
	Esomeprazole (Nexium)	20mg, 40mg	NF	\$284.05	Removed from formulary. Substitute with Nexium OTC.
	Esomeprazole Granules (Nexium Packet)	10mg, 20mg, 40mg	NF	235.66	
	First-Lansoprazole	3mg/ml	NF	\$75.92	Removed from formulary. Substitute with Prevacid Solutab.
	Lansoprazole (Prevacid, Prevacid Solutabs)	15mg, 30mg	--*	\$22.64	Prevacid Solutab: Step therapy to ranitidine syrup for children <10 years old OR documented inability to swallow tablets/capsules
	First-Omeprazole	2mg/ml	NF	\$73.39	Removed from formulary. Substitute with Prevacid Solutab.
	Omeprazole (Prilosec)	20mg, 40mg	-	\$6.69	
	Omeprazole (Prilosec Suspension Packets)	2.5mg, 10mg	ST, QL, AL	--	Step therapy to ranitidine syrup for children <6 years old.
Pantoprazole (Protonix)	20mg 40mg	-	\$7.67		

	Rabeprazole (Aciphex)	20mg	ST; PA	\$28.52	Reserved for treatment failure to Nexium OTC.
Miscellaneous	Bismuth Subsalicylate	262mg, 262mg/15ml, 525mg/ml15ml	-	\$5.61	
	Mag Hydrox/Al Hydrox/Simeth (Maalox)	200mg-200mg- 20mg/5ml, 400mg-400mg- 40mg/5ml	-	\$4.97	
Combination Agents					
Therapeutic Class	Generic Name (Brand Name)	Available Strengths	Formulary Limits	Average Cost per 30 days	Notes
PPI	Esomeprazole/Naproxen	20mg-375mg, 20mg-500mg	NF	N/A	
	Omeprazole/Sodium Bicarbonate (Zegerid, Zegerid OTC)	20mg-1100mg, 40mg-1100mg*	NF	\$759.14	*Strength available as Rx only
H. Pylori Pre-packaged Regimens	Bismuth Subcitrate/Metronidazole / Tetracycline (Pylera)	140mg-125mg- 125mg	NF	\$360.60	Individual agents are available on formulary. Use individual agents separately.
	Bismuth Subsalicylate/ Metronidazole/Tetracycline (Helidac)	See packaging for details on how supplied.	NF	N/A	
	Lansoprazole/Amoxicillin / Clarithromycin (Prevpac)		NF	N/A	
	Omeprazole/Amoxicillin/ Clarithromycin (Omeclamox-Pak)		NF	N/A	
ST = Step therapy; QL = Quantity Limit; PA = Prior Authorization Required; NF = Non-Formulary; *PA required for Prevacid Solutab formulation only					

⊞ 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 HSPJ Medical Review Guidelines (UM06).

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

Cimetidine, Famotidine (Pepcid), Ranitidine (Zantac)

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

Proton Pump Inhibitor (PPI) Single-Agent Products

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

1st line—Lansoprazole (Prevacid, Prevacid Solutab), Omeprazole (Prilosec), Pantoprazole (Protonix)

- Coverage Criteria:** None
- Limits:** None
- 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. Quantity limit: 10mg - 30 packets per month; 2.5mg - 60 packets per month.

2nd line—Esomeprazole (Nexium OTC)

- Coverage Criteria:** Nexium OTC is reserved for documentation of treatment failure of 2 (two) dose-optimized 1st 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 1st line agents at the doses indicated above
- Other Notes:** None

3rd line—Rabeprazole (Aciphex)

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

4th 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 (2nd line), AND Rabeprazole (3rd line).
- Limits:** None
- Required Information for Approval:** Drug refill history showing fills of two 1st line agents, Esomeprazole (Nexium OTC), AND Rabeprazole at the doses indicated above
- Other Notes:** None

Miscellaneous
<i>Bismuth Subsalicylate (Stomach Relief, Peptif Relief, Kaopectate, Soothe), Mag Hydrox/Al Hydrox/Simeth (Maalox)</i>
<ul style="list-style-type: none"> <input type="checkbox"/> Coverage Criteria: None <input type="checkbox"/> Limits: None <input type="checkbox"/> Required Information for Approval: N/A <input type="checkbox"/> 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).

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.

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

Note: All changes are approved by the HPSJ P&T Committee before incorporation into the utilization policy