

Market Applicability						
Market	GA	KY	MD	NJ	NY	WA
Applicable	X	X	X	X	X	X

## Proton Pump Inhibitors

Override(s)	Approval Duration	
Prior Authorization Quantity Limit**	<u>Preferred PPI:</u> No Prior Authorization required	
	<u>Preferred PPI quantity override:</u> h. pylori diagnosis	1 year 14 days
	<u>Non-Preferred PPI:</u> h. pylori diagnosis	1 year 14 days
	<u>Non-Preferred PPI quantity override:</u> h. pylori diagnosis	1 year 14 days
	<p>**Quantity Supply Overrides (listed in the Quantity Limit Override section below)</p> <p>If Prior Authorization of Benefits criteria for non-preferred agent are met, the following criteria will apply for quantity supply:</p> <ul style="list-style-type: none"> <li>• If the individual was on a preferred agent, at a dose of 2 per day, then the quantity limit may be overridden on the non-preferred agent to 2 per day</li> <li>• If the individual was on a preferred agent at a dose of 1 per day, then they must first try once daily dosing of the non-preferred agent prior to going to BID dosing</li> </ul>	

Quantity Limit Override Criteria
<p><b>For prescription PPI's and Zegerid OTC:</b> Quantity limit = 1 dose/day</p> <p><b>For over-the-counter PPI's (except Zegerid OTC):</b> Quantity limit = 2 doses per day</p> <p>Quantity Limit <i>does not apply</i> to generic Prilosec (omeprazole) Rx, generic Prilosec (omeprazole, omeprazole magneisum) OTC, and generic Protonix (pantoprazole) Rx.</p> <p>Requests for a greater quantity of proton pump inhibitors (PPIs) may be approved if the following criteria are met:</p>

Market Applicability						
Market	GA	KY	MD	NJ	NY	WA
Applicable	X	X	X	X	X	X

- I. Increased dosing of 4 per day for 14 days for esomeprazole DR 20mg OTC capsules, Nexium 24HR 20mg OTC capsules/tablets, Prilosec OTC, lansoprazole OTC, Prevacid 24HR OTC  
OR  
Increased dosing of 2 per day for 14 days for all other PPIs may be approved a diagnosis of: *Helicobacter pylori*, for eradication;

**OR**

- II. Increased dosing beyond 4 doses/day for esomeprazole DR 20mg OTC capsules, Nexium 24HR 20mg OTC capsules/tablets, Prilosec OTC, lansoprazole OTC, Prevacid 24HR OTC  
OR  
Increased dosing beyond 2 doses/day for all other PPIs is approvable for:
- A. Hypersecretory syndromes (Zollinger-Ellison syndrome, multiple endocrine adenomas, or systemic mastocytosis); **OR**
  - B. Barrett's Esophagus; **OR**
  - C. Laryngeal, esophageal or gastric cancer; **OR**
  - D. Scleroderma or limited scleroderma (CREST syndrome);

**OR**

- III. Increased dosing up to 4 doses/day for esomeprazole DR 20mg OTC capsules, Nexium 24HR 20mg OTC capsules/tablets, Prilosec OTC, lansoprazole OTC, Prevacid 24 HR OTC  
OR  
Increased Dosing up to 2 doses/day for all other PPIs is approvable for the following:
- A. Individual does not respond after a 30-day trial of stated dosing limit with the requested PPI; **OR**
  - B. Individual has been diagnosed with eosinophilic esophagitis.

Medications	Comments
Omeprazole Rx <sup>^</sup> (for individuals less than 6 years old only)	Preferred
Prevacid 24HR OTC (lansoprazole) brand and generic	
Prilosec OTC (omeprazole, omeprazole magnesium) brand and generic	

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

Market Applicability						
Market	GA	KY	MD	NJ	NY	WA
Applicable	X	X	X	X	X	X

<p>Nexium 24HR OTC –tablets</p> <p>Nexium 24HR OTC – capsules (esomeprazole DR OTC) brand and generic</p> <p>Zegerid OTC (omeprazole/sodium bicarbonate) brand and generic</p>	
<p>AcipHex (rabeprazole) brand and generic</p> <p>AcipHex Sprinkle (rabeprazole DR)</p> <p>Dexilant (dexlansoprazole)</p> <p>esomeprazole strontium</p> <p>Nexium (esomeprazole) brand and generic</p> <p>Nexium DR packet (esomeprazole) brand and generic</p> <p>Nexium Suspension (esomeprazole) brand and generic</p> <p>Prilosec Oral Suspension (omeprazole magnesium) brand and generic</p> <p>Prilosec (omeprazole) brand and generic</p> <p>Prevacid (lansoprazole) brand and generic</p> <p>Prevacid Solutab (lansoprazole ODT) brand and generic</p> <p>Protonix (pantoprazole) brand and generic</p>	<p>Non-Preferred</p>

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

Market Applicability						
Market	GA	KY	MD	NJ	NY	WA
Applicable	X	X	X	X	X	X

Protonix Oral Suspension (pantoprazole) brand and generic  Brand Rabeprazole DR Sprinkle  Zegerid (omeprazole/sodium bicarbonate) brand and generic (including Omeppi)  Zegerid Oral Suspension (omeprazole/sodium bicarbonate) brand and generic	
---	--

Non-preferred agents are prescription (Rx)

^Preferred agents are over-the-counter (OTC), except where noted.

### **APPROVAL CRITERIA**

Requests for a non-preferred proton pump inhibitor (PPI) may be approved for individuals who meet the following criteria:

- I. Individual has had trials (medication samples/coupons/discount cards are excluded from consideration as a trial) and inadequate response or intolerance to **two** preferred proton pump inhibitors (PPIs):
  - A. Esomeprazole DR 20mg OTC (esomeprazole DR OTC or Nexium 24HR OTC 20mg)\*
  - B. Lansoprazole OTC (lansoprazole OTC or Prevacid 24HR OTC);  
Omeprazole OTC (omeprazole OTC, omeprazole magnesium OTC or Prilosec OTC tablets)\*;
  - C. Omeprazole 20mg capsules Rx (for individuals less than 6 years old only)\*;
  - D. Omeprazole/sodium bicarbonate OTC (omeprazole/sodium bicarbonate OTC, Zegerid OTC)\*;

**AND**

- II. An equivalent preferred over-the-counter (OTC) agent has been tried prior to use of a non-preferred prescription agent (such as, Prilosec OTC versus Prilosec Rx; Nexium OTC versus Nexium Rx; Prevacid OTC versus Prevacid Rx; Zegerid OTC versus Zegerid 20 mg/1.1 g Rx);

**AND**

- III. The equivalent OTC agent has been utilized in an equivalent strength to the requested non-preferred prescription agent;

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

Market Applicability						
Market	GA	KY	MD	NJ	NY	WA
Applicable	X	X	X	X	X	X

OR

IV. The preferred PPI's are not FDA-approved for the prescribed indication and the non-preferred PPI is;

OR

V. Individual has the inability to swallow tablets/capsules;

OR

VI. \*Individuals concomitantly taking clopidogrel will only require a prior trial (medication samples/coupons/discount cards are excluded from consideration as a trial) with OTC lansoprazole;

OR

VII. Individual is less than one year of age.

#### Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2019. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: June 14, 2019.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2019; Updated periodically.
5. Katz PO, Gerson LB, Vela MF. Guidelines for the Diagnosis and Management of Gastroesophageal Reflux Disease. *Am J Gastroenterol*. 2013; 108:308-328. doi: 10.1038/ajg.2012.444. Available from: [https://journals.lww.com/ajg/Fulltext/2013/03000/Guidelines\\_for\\_the\\_Diagnosis\\_and\\_Management\\_of.6.aspx](https://journals.lww.com/ajg/Fulltext/2013/03000/Guidelines_for_the_Diagnosis_and_Management_of.6.aspx). Accessed May 24, 2019.
6. Chey WD, Leontiadis GI, Howden CW, Moss SF. ACG Clinical Guideline: Treatment of *Helicobacter pylori* infection. *Am J Gastroenterol*. 2017; 112:212-238. Doi:10.1038/ajg.2016.563. Available from: [https://journals.lww.com/ajg/Fulltext/2017/02000/ACG\\_Clinical\\_Guideline\\_Treatment\\_of\\_Helicobacter.12.aspx#pdf-link](https://journals.lww.com/ajg/Fulltext/2017/02000/ACG_Clinical_Guideline_Treatment_of_Helicobacter.12.aspx#pdf-link). Accessed May 24, 2019.
7. Shaheen NJ, Falk GW, Iyer PG, Gerson LB. ACG Clinical Guideline: Diagnosis and management of Barrett's Esophagus. *Am J Gastroenterol*. January 2016; 111(1): 30-50. Available from: [https://journals.lww.com/ajg/Fulltext/2016/01000/ACG\\_Clinical\\_Guideline\\_Diagnosis\\_and\\_Management.17.aspx](https://journals.lww.com/ajg/Fulltext/2016/01000/ACG_Clinical_Guideline_Diagnosis_and_Management.17.aspx). Accessed May 23, 2019.
8. Laine L, Jensen DM. Management of patients with ulcer bleeding. *Am J Gastroenterol*. March 2012; 107(3):345-360. Available from: [https://journals.lww.com/ajg/Fulltext/2012/03000/Management\\_of\\_Patients\\_With\\_Ulcer\\_Bleeding.6.aspx](https://journals.lww.com/ajg/Fulltext/2012/03000/Management_of_Patients_With_Ulcer_Bleeding.6.aspx). Accessed May 24, 2019.
9. Plavix [package insert]. Bridgewater, NJ: Bristol-Myers Squibb/Sanofi Pharmaceuticals Partnership; May 2019.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

<b>Market Applicability</b>						
<b>Market</b>	<b>GA</b>	<b>KY</b>	<b>MD</b>	<b>NJ</b>	<b>NY</b>	<b>WA</b>
<b>Applicable</b>	X	X	X	X	X	X

No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from the health plan.

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.