UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Proton Pump Inhibitors

Program	Prior Authorization
Medication	Proton Pump Inhibitors
Issue Date	9/2009
Pharmacy and Therapeutics Approval Date	5/2017
Effective Date	7/2017

1. Background:

Product Name	PDL Status
OMEPRAZOLE CAP [Prilosec]	Preferred
OMEPRAZOLE MAGNESIUM CAP	Preferred
PANTOPRAZOLE SODIUM TAB	Preferred
LANSOPRAZOLE CAP [Prevacid]	Preferred
ESOMEPRAZOLE MAGNESIUM OTC CAP [Nexium 24 HR - OTC]	Preferred w/PA
ESOMEPRAZOLE MAGNESIUM GRA PACK [Nexium Granule Suspension]	Preferred w/ Age Edit
LANSOPRAZOLE SOLUTAB [Prevacid Solutab]	Preferred w/ Age Edit
OMEPRAZOLE TAB	Non-Preferred
RABEPRAZOLE SODIUM TAB [Aciphex Tab]	Non-Preferred
RABEPRAZOLE SODIUM SPRINKLE CAP [Aciphex Sprinkle]	Non-Preferred
DEXLANSOPRAZOLE CAP [Dexilant]	Non-Preferred
ESOMEPRAZOLE STRONTIUM CAP	Non-Preferred
ESOMEPRAZOLE MAGNESIUM CAP [Nexium]	Non-Preferred
OMEPRAZOLE MAGNESIUM POW PACK [Prilosec Powder for Suspension]	Non-Preferred
OMEPRAZOLE MAGNESIUM OTC TAB [Prilosec OTC]	Non-Preferred
PANTOPRAZOLE SODIUM PACK [Protonix Suspension Packet]	Non-Preferred

Off-labeled Use:
Drug therapies must be utilized in accordance with FDA approved indications OR the uses found within the compendia of literature† AND the drug is being prescribed for a medically accepted indication that is recognized as a covered benefit by the applicable health plans' program. Authorization for off-labeled use of medication will be evaluated on an individual basis. Review of an off-labeled request by the UnitedHealthcare Community & State Medical Staff will be predicated on the appropriateness of treatment, scientific evidence and full consideration of medical necessity.

†-compendia of current literature: • American Hospital Formulary Service Drug Information • National Comprehensive Cancer Network Drugs and Biologics Compendium • Thomson Micromedex DrugDex • Clinical Pharmacology

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2. Coverage Criteria:

A. <u>Lansoprazole Solutab [Prevacid Solutab] and Esomeprazole Magnesium Granule Pack [Nexium Granule Suspension] – Age Edit</u>

1. One of the following:

   a. The patient is less than 2 years of age

   -OR-

   b. History of failure, contraindication or intolerance to lansoprazole capsule as sprinkle administration*

*Alternative Administration Methods of Lansoprazole Capsules:

- For patients who have difficulty swallowing capsules lansoprazole delayed-Release capsules can be opened and administered as follows:
  - Sprinkle intact granules on one tablespoon of either applesauce, ENSURE pudding, cottage cheese, yogurt or strained pears
  - Sprinkle intact granules into a small volume of either apple juice, orange juice or tomato juice (60 mL – approximately 2 ounces)
- Nasogastric Tube (≥16 French) Administration:
  - Mix intact granules into 40 mL of apple juice. DO NOT USE OTHER LIQUIDS. Inject through the nasogastric tube into the stomach. Flush with additional apple juice to clear the tube.

Authorization of therapy will be issued for 1 year

B. <u>Requests to Exceed Proton Pump Inhibitor Quantity Limits</u>

1. Initial Therapy to Exceed Once Daily Dosing

   a. **Proton Pump Inhibitor exceeding quantity limit** will be approved when **<u>one</u>** of the following circumstances is met:

      (1) The patient did not exhibit an adequate response to treatment with once a day dosing.

      -OR-

      (2) The patient has documented erosive disease.

      -OR-

      (3) The patient has documented symptoms of complicated disease (e.g. dysphagia, bleeding, weight loss, choking,

chest pain).

-OR-

(4) The patient has a pathological hypersecretory condition such as Zollinger-Ellison syndrome, Barrett's Esophagus, multiple endocrine adenomas, or systemic mastocytosis.

Authorization of therapy will be issued for 8 weeks for circumstances (1), (2), and (3) Authorization of therapy will be issued for 1 year for circumstance (4)

2. Renewals to Exceed Quantity Limits

a. **Proton Pump Inhibitor exceeding quantity limit** will be approved when **one** of the following circumstances is met:

(1) The patient is continuing therapy for a pathological hypersecretory condition such as Zollinger-Ellison syndrome, Barrett's Esophagus, multiple adenomas, or systemic mastocytosis.

Authorization will be issued for 1 year.

C. Nexium 24 HR OTC- Prior Authorization

1. History of failure, contraindication or intolerance to a 30 day trial of omeprazole at a minimum dose of 40mg daily and pantoprazole at a minimum dose of 40mg daily.

Authorization will be issued for 12 months.

D. Solid Oral Dosage Form: Non-Preferred Criteria

1. Patient has a history of failure, contraindication, or intolerance to a trial of at least **three** of the following products:
   - Omeprazole capsule
   - Pantoprazole tablet
   - Lansoprazole DR capsule
   - Nexium 20mg OTC capsule

Authorization will be issued for 1 year.

D. Non-Solid Oral Dosage Form: Non-Preferred Criteria

This section applies to the following products: RABEPRAZOLE SODIUM SPRINKLE CAP [Aciphex Sprinkle], OMEPRAZOLE MAGNESIUM POWDER PACK [Prilosec Powder for Suspension], PANTOPRAZOLE SODIUM PACK [Protonix Suspension Packet]

1. **BOTH** of the following:

   a. The patient has a history of failure, contraindication or intolerance to Lansoprazole Solutab [Prevacid Solutab] AND Esomeprazole Magnesium Granule Pack [Nexium Granule Suspension]

   -AND

   b. History of failure, contraindication or intolerance to lansoprazole capsule as sprinkle administration*

*Alternative Administration Methods of Lansoprazole Capsules:

- For patients who have difficulty swallowing capsules lansoprazole delayed-Release capsules can be opened and administered as follows:
  - Sprinkle intact granules on one tablespoon of either applesauce, ENSURE pudding, cottage cheese, yogurt or strained pears
  - Sprinkle intact granules into a small volume of either apple juice, orange juice or tomato juice (60 mL – approximately 2 ounces)
- Nasogastric Tube (≥16 French) Administration:
  - Mix intact granules into 40 mL of apple juice. DO NOT USE OTHER LIQUIDS. Inject through the nasogastric tube into the stomach. Flush with additional apple juice to clear the tube.

Authorization of therapy will be issued for 1 year

3. References:

1. Prevacid® Prescribing Information. Takeda, September 2012.
2. Protonix® Prescribing Information. Wyeth, December 2013.
3. Prilosec® Prescribing Information. AstraZeneca, March 2014.
4. Nexium® Prescribing Information. AstraZeneca, March 2014.
5. Clinical Pharmacology Gold Standard. 2014.
6. US Food and Drug Administration Non Prescription Drugs Advisory Committee with Gastrointestinal Drugs Advisory Committee. http://www.fda.gov/ohrms/dockets/ac/02/transcripts/3861T1.htm
7. Williams D. Gastroesophageal Reflux Disease: In: Pharmacotherapy, A Pathophysiologic Approach. Ed. diPiro et. al. 1997. 4th Edition. 532-47.
8. DeVault KR, Castell DO (for the Practice Parameters Committee of the American College Of Gastroenterology). Guidelines for the diagnosis and treatment of gastroesophageal reflux disease. Arch Intern Med 1995; 155: 2165-73.

10. Kitchin LI, Castell DO. Rationale and efficacy of conservative therapy for gastroesophageal reflux disease. Arch Intern Med 1991: 151: 448-54.
10. Inadomi JM, Jamal R, Hoffman RM, et. al. Step down management of gastroesophageal reflux disease. Gastroenterology. 2001. Nov, 121(5); 1095-100.
11. Naunton M, Peterson GM, Bleasel MD. Overuse of Proton Pump Inhibitors. J Clin Pharm Ther. 2000. Oct; 25(5): 333-40.
12. Storr M, Meining A, Allesher HD. Pharmacoeconomic issues of the treatment of gastroesophageal reflux disease. Expert Opin Pharmacother. 2001. Jul; 2(7): 1099-08.
13. Nathoo V. Managing gastro-oesophageal reflux disease in primary case. Int J Clin Pract. 2001. Sep; 55(7): 465-9.
14. Pharmacy Benefits Management Medical Advisory Panel. The Pharmacologic Management of Gastroesophageal Reflux Disease. VHA PBM-SHG Publication No. 98-0010 Hines, IL:
15. Pharmacy Benefits Management Strategic Healthcare Group, Veterans Health Administration, Department of Veterans Affairs. September 1998.
16. Kahrilas PJ. Gastroesophageal reflux disease. *JAMA* 1996;276:983-988.
17. Goldstein JL. Challenges in managing NSAID-associated gastrointestinal tract injury. Digestion. 2004;69:25-33.
18. Singh G, Triadafilopoulos G. Appropriate choice of proton pump inhibitor therapy in the prevention and management of NSAID-related gastrointestinal damage. Int J Clin Pract. 2005;59(10):1210-7.
19. Peura DA. Prevention of nonsteroidal anti-inflammatory drug-associated gastrointestinal symptoms and ulcer complications. Am J Med. 2004;117(5A):63S-71S.
20. DeVault KR, Castell DO. Updated Guidelines for the Diagnosis and Treatment of Gastroesophageal Reflux Disease. Am J Gastroenterol 2005;100:190-200.
21. American Gastroenterological Association (AGA) Medical position statement on the management of gastroesophageal reflux disease. *Gastroenterology*. 2008;135:1383-1391.
22. Gastroesophageal Reflux: Management Guidance for the Pediatrician. American Academy of Pediatrics 2013.
23. Pediatic Gastroesophageal Reflux clinical practice guidelines: joint recommendations of the NASPGHAN (North America Society for Pediatric Gastroenterology, Hepatology,and Nutrition) and ESPGHAN (the European Society for Pediatric Gastroenterology, Hepatology,and Nutrition). 2009
24. Eosinophilic esophagitis: Updated consensus recommendations for children and adults. Amercian Academy of Allergy, Asthman & Immunology. 2011.

Program	Prior Authorization- Proton Pump Inhibitors
Change Control	
Date	Change
Sept 2009	Policy was reformatted.
Dec 2009	Addition of Kapidex to the policy. Removal of pantoprazole from the criteria. Changed Prevacid listing to include Prevacid OTC. Added criteria for Prevacid Solutabs to be approved for members who have difficulty swallowing.

May 2010	Replaced "Kapidex" with new name "Dexilant."
Sept 2010	Removed Dexilant from criteria. Dexilant added to nonpreferred drug product list table.
Dec 2010	Annual Review
March 2011	Added pantoprazole to the lansoprazole step therapy requirements. Patients are required to try and fail separate trials of both omeprazole and pantoprazole. Previously, only omeprazole was required.
August 2011	Updated indication sections to only include Prevacid, the only drug affected by this step therapy guideline. Updated authorization period language from "authorization will remain as long as patient remains compliant with therapy" to "in the event that the member has had a 30 day lapse in medication utilization the request will be sent for medical necessity review"
March 2012	Annual Review
March 2013	Annual Review
June 2014	Rewrite policy. Full update to preferred drug list table. Lansoprazole capsule changed to prior authorization required. Nexium Granule added to PDL with age edit. Non-Preferred products added to product grid. Lansoprazole capsule criteria changed from step therapy criteria to prior authorization criteria due to recent PDL change. Same requirements (preferred alternatives) apply to lansoprazole capsule. Quantity limit exception criteria is now referred to as "Requests to Exceed Proton Pump Inhibitor Quantity Limits" instead of "Lansoprazole twice daly dosing." Clinical criteria to exceed quantity limits remains unchanged. Previous Prevacid Solutab criteria discontinued and replaced with new age edit clinical criteria applying to Nexium Granule and Prevacid Solutab. This criteria will be used to review cases for exceptions to the age edit on these products.
September 2014	Added Nexium 24 HR OTC product to preferred drug list as preferred with prior authorization. Added clinical criteria section III.D for Nexium 24 HR OTC.
June 2016	Updated policy template. Removed prior authorization criteria for Prevacid (lansoprazole) capsules.
April 2017	Added non-preferred criteria. Updated policy template.
May 2017	Added non-solid oral dosage form, non-preferred product criteria. Clarified that the existing non-preferred section is for solid oral dosage forms.