UnitedHealthcare®

Clinical Pharmacy Program Guidelines for Proton Pump Inhibitors

Program	Prior Authorization
Medication	Proton Pump Inhibitors
Markets in Scope	Arizona, California, Hawaii, Maryland, Nevada, New Jersey, New York, New York EPP, Pennsylvania-CHIP, Rhode Island, South Carolina
Issue Date	9/2009
Pharmacy and Therapeutics Approval Date	7/2020
Effective Date	9/2020

1. Background:

Product Name	PDL Status
Lansoprazole capsule (Prevacid)	Preferred
Omeprazole capsule (Prilosec)	Preferred
Pantoprazole sodium tablet (Protonix)	Preferred
Esomeprazole magnesium OTC capsule (Nexium) 24 HR - OTC]	Preferred w/PA
Esomeprazole magnesium granule (Nexium Granule Suspension)	Preferred w/ Age Edit
Lansoprazole solutab (Prevacid Solutab)	Preferred w/ Age Edit
Dexlansoprazole capsule (Dexilant)	Non-Preferred
Esomeprazole strontium capsule	Non-Preferred
Esomeprazole magnesium capsule (Nexium)	Non-Preferred
Omeprazole magnesium OTC tablet (Prilosec OTC)	Non-Preferred
Omeprazole magnesium powder packet (Prilosec Powder for Suspension)	Non-Preferred
Omeprazole tablet	Non-Preferred
Pantoprazole sodium packet (Protonix Suspension Packet)	Non-Preferred
Rabeprazole sodium tablet (Aciphex Tab)	Non-Preferred
Rabeprazole sodium sprinkle capsule (Aciphex Sprinkle)	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

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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 • United States Pharmacopoeia-National Formulary (USP-NF)

2. Coverage Criteria:

A. <u>Lansoprazole Solutab (Prevacid Solutab) and Esomeprazole Magnesium Granule (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

Authorization will be issued for 12 months.

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

1. Initial Therapy to Exceed Quantity Limits

   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 within the quantity limit

      -OR-

      (2) The patient has documented erosive disease

      -OR-

      (3) The patient has documented symptoms of complicated

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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 will be issued for 8 weeks for circumstances (1), (2), and (3). Authorization of therapy will be issued for 12 months 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 12 months.

C. Esomeprazole magnesium OTC capsule (Nexium 24 HR OTC)- Prior Authorization

1. History of failure to at least a 30 day trial, or contraindication or intolerance to **two** of the following:

- Omeprazole capsule
- Pantoprazole tablet
- Lansoprazole DR capsule

Authorization will be issued for 12 months.

D. Solid Oral Dosage Form: Non-Preferred Criteria

1. History of failure to at least a 30 day trial, or contraindication or intolerance to **three** of the following:

- Omeprazole capsule
- Pantoprazole tablet
- Lansoprazole DR capsule

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- Esomeprazole magnesium OTC capsule (Prior authorization required)

Authorization will be issued for 12 months.

E. **Non-Solid Oral Dosage Form: Non-Preferred Criteria**
This section applies to the following products: Rabeprazole sodium sprinkle capsule (Aciphex Sprinkle), Omeprazole magnesium powder packet (Prilosec Powder for Suspension), Pantoprazole sodium packet (Protonix Suspension Packet)

1. Patient has a history of failure to at least a 30 day trial, or contraindication or intolerance to **all** of the following products:
   - Lansoprazole capsule as sprinkle administration
   - Lansoprazole Solutab (Prior authorization required)
   - Esomeprazole magnesium granule pack (Prior authorization required)

Authorization will be issued for 12 months.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Prevacid/Prevacid Solutab [package insert]. Deerfield, IL: Takeda Pharmaceuticals America, Inc.; June 2018.
2. Protonix [package insert]. Philadelphia, PA: Pfizer Inc.; April 2019.
3. Prilosec [package insert]. Zug, Switzerland: Covis Pharma; August 2018.
4. Nexium [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; June 2018.
5. Aciphex tablet [package insert]. Woodcliff Lake, NJ: Eisai Inc.; September 2019.
6. Aciphex Sprinkle [package insert]. Research triangle Park, NC: Cerecor, Inc,; June 2018.
7. Dexilant [package insert]. Deerfield, IL: Takeda Pharmaceuticals America, Inc.; June 2018.
8. Esomeprazole strontium [package insert]. Glasgow, KY: Amneal Pharmaceuticals; December 2019.
9. Wolfe MM. Proton pump inhibitors: Overview of use and adverse effects in the treatment of acid related disorders. Feldman M, ed. UpToDate. Waltham, MA: UpToDate Inc. https://www.uptodate.com (Accessed on June 10, 2020).

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10. Kahrilas PJ. Medical management of gastroesophageal reflux disease in adults. Talley NJ, ed. UpToDate. Waltham, MA: UpToDate Inc. http://www.uptodate.com (Accessed on June 10, 2020).

Program	Prior Authorization- Proton Pump Inhibitors
Change Control	
Date	Change
9/2009	Policy was reformatted.
12/2009	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.
5/2010	Replaced "Kapidex" with new name "Dexilant."
9/2010	Removed Dexilant from criteria. Dexilant added to nonpreferred drug product list table.
12/2010	Annual Review
3/2011	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.
8/2011	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"
3/2012	Annual Review
3/2013	Annual Review
6/2014	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

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	Limits" instead of "Lansoprazole twice daily 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.
9/2014	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.
6/2016	Updated policy template. Removed prior authorization criteria for Prevacid (lansoprazole) capsules.
4/2017	Added non-preferred criteria. Updated policy template.
5/2017	Added non-solid oral dosage form, non-preferred product criteria. Clarified that the existing non-preferred section is for solid oral dosage forms.
5/2018	Changed all 1 year authorization durations to 12 months for consistency. Updated references.
6/2019	Revised Nexium OTC step therapy. Removed language about administration of lansoprazole as a sprinkle. Updated references.
7/2020	Updated background and references. Revised step therapy language.

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