

UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2021 P 3035-11
Program	Step Therapy-Proton Pump Inhibitors (PPI)
Medication	Nexium for suspension (esomeprazole), Prevacid SoluTab (lansoprazole), Zegerid **for suspension (omeprazole and sodium bicarbonate)
P&T Approval Date	8/2014, 8/2015, 1/2016, 3/2016, 4/2017, 5/2018, 3/2019, 1/2020, 3/2021
Effective Date	6/1/2021; Oxford: N/A

1. Background:

Proton Pump Inhibitors (PPIs) are FDA approved to treat a variety of conditions, including duodenal ulcers, duodenal ulcers associated with *Helicobacter pylori*, gastric ulcers, erosive esophagitis, Gastroesophageal reflux disease (GERD) in adults and children, hypersecretory conditions such as Zollinger-Ellison syndrome, GERD-related laryngitis and to improve pancreatic enzyme absorption in CF patients (not FDA approved indication). In addition, they are frequently used to treat conditions such as heartburn and other gastric ailments for which the over the counter product is sufficient. Multiple solid oral dosage forms of PPIs are available over the counter.

Step Therapy programs are utilized to encourage the use of lower cost alternatives for certain therapeutic classes. This program requires a member to try the lower cost PPIs before coverage will be provided for Nexium suspension, Prevacid SoluTab and Zegerid** suspension. Claims for Nexium suspension and Prevacid SoluTabs will process automatically for patients under the age of 6.

2. Coverage Criteria^a:

A. Authorization

1. **Nexium suspension and Prevacid SoluTabs** will be approved based on **ONE** of the following criteria:

a. History of failure, contraindication, or intolerance to **ALL** of the following (list reason for therapeutic failure, contraindication, or intolerance):

- (1) A prescription formulation of omeprazole
- (2) pantoprazole (generic Protonix: Non-Camber pantoprazole products)
- (3) rabeprazole

-OR-

b. Patient is unable to swallow a tablet or capsule dosage form due to one of the following:

- (1) age
- (2) oral/motor difficulties
- (3) dysphagia

-OR-

c. Patient utilizes a feeding tube for medication administration

2. **Zegerid suspension**** will be approved based on the following criterion:

a. History of failure, contraindication, or intolerance to **BOTH** of the following:

- (1) Nexium Suspension
- (2) Prevacid SoluTabs

Authorization will be issued for 12 months

^a State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

**Typically excluded from coverage.

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. Nexium [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP.; November 2020.
2. Prevacid SoluTab [package insert]. Deerfield, IL: Takeda Pharmaceuticals America; November 2020.
3. Zegerid [package insert]. Bridgewater, NJ: Salix Pharmaceuticals, Inc.; November 2020.

Program	Step Therapy – PPI
Change Control	
Date	Change
8/2014	New program.
8/2015	Annual Review. Removed the requirement one must try an OTC PPI since those are not covered agents. Added Maryland Continuation of Care.
1/2016	Added Zegerid suspension to criteria. Updated criteria to allow coverage when patient has a feeding tube.
3/2016	Updated step one medications for Zegerid. Updated background section to remove Zegerid from statement that claims will process automatically for patients under the age of six.
7/2016	Added Indiana and West Virginia coverage information.
11/2016	Administrative change. Added California coverage information.
4/2017	Annual review. References updated. State mandate reference language updated.
5/2018	Annual review. References updated.
3/2019	Annual review. References updated.
1/2020	Updated to clarify pantoprazole alternatives.
3/2021	Annual review. References updated.