

UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

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| 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:

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| <p>A. Authorization</p> <p>1. Nexium suspension and Prevacid SoluTabs will be approved based on <u>ONE</u> of the following criteria:</p> <p>a. History of failure, contraindication, or intolerance to <u>ALL</u> of the following (list reason for therapeutic failure, contraindication, or intolerance):</p> <p style="margin-left: 40px;">(1) A prescription formulation of omeprazole (2) pantoprazole (generic Protonix: Non-Camber pantoprazole products) (3) rabeprazole</p> <p style="text-align: center;">-OR-</p> |
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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 |
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| 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. |