

Proton Pump Inhibitors (PPIs)

Policy # 00356

Original Effective Date: 07/17/2013

Current Effective Date: 05/01/2025

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the “Company”), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member’s contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

For Patients With “Step Therapy” (generic before brand) ONLY:

Based on review of available data, the Company may consider brand name proton pump inhibitors (PPIs), (including, but not limited to Aciphex[®] [rabeprazole], Dexilant[®] [dexlansoprazole], Prevacid[®] [lansoprazole], Prilosec[®] [omeprazole], Zegerid[®] [omeprazole/sodium bicarbonate], and Protonix[®] [pantoprazole])[‡] to be **eligible for coverage**** when the below patient selection criteria are met:

Patient Selection Criteria

Coverage eligibility will be considered for brand name PPIs when the below criteria for the selected drug is met:

- Requested drug is ANY brand name PPI: There is clinical evidence or patient history that suggests the generically available products will be ineffective or cause an adverse reaction to the patient; OR
- Requested drug is ANY brand name PPI: Patient has tried and failed (e.g., intolerance or inadequate response) one of the following:
 - Prescription generic PPI (e.g., rabeprazole, pantoprazole, lansoprazole, omeprazole, omeprazole/sodium bicarbonate); OR
 - Over the counter Prilosec (omeprazole) at a dose of at least 20 mg per day for at least 14 days under the supervision of a physician; OR
 - Over the counter Prevacid (lansoprazole) at a dose of at least 15 mg per day for at least 14 days under the supervision of a physician; OR
 - Over the counter Zegerid (omeprazole/sodium bicarbonate) at a dose of at least 20 mg of omeprazole per day for at least 14 days under the supervision of a physician; OR
 - Over the counter Nexium (esomeprazole) at a dose of at least 20 mg per day for at least 14 days under the supervision of a physician; OR

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- Requested drug is Prilosec delayed-release oral suspension: Patient meets one of the following criteria:
 - Patient is less than 2 years of age; OR
 - Patient has difficulty swallowing tablets/capsules or cannot swallow tablets/capsules; OR
 - Patient has a feeding tube (e.g. nasogastric tube, gastric tube).

When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of brand name PPIs when patient selection criteria are not met or for usage not included in the above patient selection criteria to be **not medically necessary.****

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

For Patients With "Prior Authorization" ONLY:

Based on review of available data, the Company may consider Prilosec delayed release oral suspension and to be **eligible for coverage**** when the patient selection criterion for the requested drug is met:

Patient Selection Criteria

Coverage eligibility will be considered for Prilosec delayed release oral suspension when the below criterion is met:

- Patient has tried and failed (e.g., intolerance or inadequate response) generic esomeprazole delayed release oral suspension (granules) OR Nexium^{®‡} delayed release oral suspension (granules) where no generic equivalent for Nexium delayed release oral suspension (granules) exists unless there is clinical evidence or patient history that suggests the use of these alternatives will be ineffective or cause an adverse reaction to the patient.

When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of Prilosec delayed release oral suspension when the patient selection criterion is not met to be **not medically necessary.****

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When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

For Patients With BOTH "Prior Authorization" AND "Step Therapy":

Based on review of available data, the Company may consider brand name proton pump inhibitors (PPIs), (including, but not limited to Aciphex [rabeprazole], Dexilant [dexlansoprazole], Prevacid [lansoprazole], Prilosec [omeprazole], Zegerid [omeprazole/sodium bicarbonate], and Protonix [pantoprazole]) to be **eligible for coverage**** when the below patient selection criteria are met:

Patient Selection Criteria

Coverage eligibility will be considered for brand name proton pump inhibitors (PPIs) when the below criteria for the selected drug is met:

- Requested drug is ANY brand name PPI EXCEPT Prilosec delayed-release oral suspension: There is clinical evidence or patient history that suggests the generically available products will be ineffective or cause an adverse reaction to the patient; OR
- Requested drug is ANY brand name PPI EXCEPT Prilosec delayed-release oral suspension: Patient has tried and failed (e.g., intolerance or inadequate response) one of the following:
 - Prescription generic PPI (e.g., rabeprazole, pantoprazole, lansoprazole, omeprazole, omeprazole/sodium bicarbonate); OR
 - Over the counter Prilosec (omeprazole) at a dose of at least 20 mg per day for at least 14 days under the supervision of a physician; OR
 - Over the counter Prevacid (lansoprazole) at a dose of at least 15 mg per day for at least 14 days under the supervision of a physician; OR
 - Over the counter Zegerid (omeprazole/sodium bicarbonate) at a dose of at least 20 mg of omeprazole per day for at least 14 days under the supervision of a physician; OR
 - Over the counter Nexium (esomeprazole) at a dose of at least 20 mg per day for at least 14 days under the supervision of a physician; OR
- Requested drug is Prilosec delayed-release oral suspension:
 - Patient has tried and failed (e.g., intolerance or inadequate response) generic esomeprazole delayed release oral suspension (granules) OR Nexium delayed release oral suspension (granules) where no generic equivalent for Nexium delayed release oral suspension (granules) exists unless there is clinical evidence or patient history that suggests the use of these alternatives will be ineffective or cause an adverse reaction to the patient.

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When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of brand name PPIs when patient selection criteria are not met or for usage not included in the above patient selection criteria to be **not medically necessary.****

Background/Overview

Proton pump inhibitors are commonly used anti-secretory agents that are highly effective at suppressing gastric acid and subsequently treating associated conditions, including gastroesophageal reflux disease. Of note, Prilosec suspension and Nexium granules for suspension are both indicated down to 1 month of age.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

The patient selection criteria presented in this policy takes into consideration clinical evidence or patient history that suggests the available generic PPIs will be ineffective or cause an adverse reaction to the patient. This policy also takes into consideration whether or not a patient is able to swallow or whether or not they have a feeding tube as well as the age of the patient. Based on a review of the data, in the absence of the above mentioned caveats, there is no advantage of using a brand name PPI over the available generic PPIs. Generic drugs are considered to have equal bioavailability and efficacy in comparison to brand name drugs. There is also no advantage of using Prilosec suspension over generic esomeprazole granules for suspension (or Nexium granules for suspension when the generic equivalent to Nexium granules is not available).

References

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2013. Available at <http://www.clinicalpharmacology-ip.com/Default.aspx>.
2. DeVault KR, Castell DO, The Practice Parameters Committee of the American College of Gastroenterology. Updated guidelines for the diagnosis and treatment of gastroesophageal reflux disease. *Am J Gastroenterol*. 2005;100:190-200.
3. AGA Institute. American Gastroenterological Association medical position statement on the management of gastroesophageal reflux disease. *Gastroenterology*. 2008;135:1383-1391.
4. Prilosec OTC[‡] product label. Available at: <http://www.prilosecotc.com>. Accessed December 14, 2012.

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6. Zegerid OTC™‡ [package insert]. Available at: <http://www.zegeridotc.com/zegeridotc/home/index.jspa>.
7. Prilosec [package insert]. Wilmington, DE: AstraZeneca, Inc; October 2012.
8. Prevacid [package insert]. Lake Forest, IL: TAP Pharmaceuticals, Inc; September 2012.
9. Protonix [package insert]. Philadelphia, PA: Wyeth Laboratories; October 2012.
10. Aciphex [package insert]. Titusville, NJ; Janssen Pharmaceutica Inc., October 2012.
11. Nexium [package insert]. Wilmington, DE: AstraZeneca LP; November 2012.
12. Zegerid [package insert]. San Diego, CA: Santarus, Inc.; November 2012.
13. Dexilant [package insert]. Deerfield, IL: Takeda Pharmaceuticals America, Inc.; September 2012.
14. Information for healthcare professionals: update to the labeling of clopidogrel bisulfate (marketed as Plavix) to alert healthcare professionals about a drug interaction with omeprazole (marketed as Prilosec and Prilosec OTC). U.S. Food and Drug Administration Web site. Available at: <http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/DrugSafetyInformationforHealthcareProfessionals/ucm190787.htm>. Created November 17, 2009.
15. Dexlansoprazole [package insert]. TWI Pharmaceuticals. Paramus, New Jersey. Updated January 2022.

Policy History

Original Effective Date: 07/17/2013

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| 06/27/2013 | Medical Policy Committee review |
| 07/17/2013 | Medical Policy Implementation Committee approval. New policy. |
| 07/10/2014 | Medical Policy Committee review |
| 07/16/2014 | Medical Policy Implementation Committee approval. Added rabeprazole as a new generic option. Also added option for use of new OTC Nexium under the supervision of a physician. |
| 06/04/2015 | Medical Policy Committee review |
| 06/17/2015 | Medical Policy Implementation Committee approval. Defined that generic PPI and generic naproxen need to be tried for 6 months. |
| 06/02/2016 | Medical Policy Committee review |
| 06/20/2016 | Medical Policy Implementation Committee approval. No change to coverage. |
| 09/07/2017 | Medical Policy Committee review |
| 09/20/2017 | Medical Policy Implementation Committee approval. Split into Step, PA, PA/Step: Added PA to Prilosec Suspension to use Nexium Granules. Changed title to PPIs only. |

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09/06/2018 Medical Policy Committee review
09/19/2018 Medical Policy Implementation Committee approval. No change to coverage.
09/05/2019 Medical Policy Committee review
09/11/2019 Medical Policy Implementation Committee approval. No change to coverage.
09/03/2020 Medical Policy Committee review
09/09/2020 Medical Policy Implementation Committee approval. Removed the criteria for Prevacid Solutab from step and step/PA now that it is available in generic form. Updated the Prilosec suspension criteria to use the generic esomeprazole granules first OR Nexium granules if the generic equivalent to Nexium granules does not exist.
09/02/2021 Medical Policy Committee review
09/08/2021 Medical Policy Implementation Committee approval. No change to coverage
04/07/2022 Medical Policy Committee review
04/13/2022 Medical Policy Implementation Committee approval. Added the newly released branded Dextansoprazole capsules to the policy with associated criteria.
04/06/2023 Medical Policy Committee review
04/12/2023 Medical Policy Implementation Committee approval. Removed the criteria for branded Dextansoprazole capsules from step and step/PA now that it is available in generic form.
04/04/2024 Medical Policy Committee review
04/10/2024 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
04/03/2025 Medical Policy Committee review
04/09/2025 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 04/2026

****Medically Necessary (or “Medical Necessity”)** - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

- A. In accordance with nationally accepted standards of medical practice;
- B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
- C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

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For these purposes, “nationally accepted standards of medical practice” means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: If the Patient’s health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.