BlueCross BlueShield of Louisiana

An independent licensee of the Blue Cross and Blue Shield Association.

Proton Pump Inhibitors (PPIs) and Proton Pump Inhibitor/Non-Steroidal Anti-Inflammatory Drug (NSAID) Combination Products

Policy # 00356
Original Effective Date: 07/17/2013
Current Effective Date: 07/16/2014

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.*

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], Nexium® [esomeprazole], Prevacid® [lansoprazole], Prilosec® [omeprazole], Zegerid® [omeprazole/sodium bicarbonate], and Protonix® [pantoprazole])‡ OR brand name proton pump inhibitor/non-steroidal anti-inflammatory drug (NSAID) combination products (including, but not limited to Vimovo® [naproxen/esomeprazole])‡ 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) OR brand name proton pump inhibitor/non-steroidal anti-inflammatory drug (PPI/NSAID) combination products when the below criteria for the selected drug is met:

- Requested drug is ANY brand name non-combination proton pump inhibitor (PPI) or brand name proton pump inhibitor/non-steroidal anti-inflammatory drug (PPI/NSAID) combination product: There is clinical evidence or patient history that suggests the generically available products will be ineffective or cause an adverse reaction to the patient.
- Requested drug is ANY brand name non-combination PPI: Patient has tried and failed one of the following:
    - Prescription generic PPI (e.g. rabeprazole, pantroprazole, lansoprazole, omeprazole, omeprazole/sodium bicarbonate); OR
    - Over the counter Prilosec (omeprazole) at a dose of at least 20mg 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 15mg 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 20mg 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 20mg per day for at least 14 days under the supervision of a physician.
- Requested drug is Prevacid Solutab OR Prilosec delayed-release oral suspension (granules): Patient meets one of the following criteria:
    - Patient is less than 2 years of age; OR

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- Patient has difficulty swallowing tablets/capsules or cannot swallow tablets/capsules; OR
- Patient has a feeding tube (e.g. nasogastric tube, gastric tube)

- Requested drug is a brand name proton pump inhibitor/non-steroidal anti-inflammatory drug (PPI/NSAID) combination product: Patient has tried and failed BOTH:
  - Prescription generic rabeprazole, omeprazole, pantoprazole, or lansoprazole; AND
  - Prescription brand or generic naproxen at a dose of 250mg, 375mg, or 500mg twice daily.

When Services Are Considered Not Medically Necessary
Based on review of available data, the Company considers the use of brand name proton pump inhibitors (PPIs) OR brand name proton pump inhibitor/non-steroidal anti-inflammatory drug (PPI/NSAID) combination products 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. In some instances, PPIs are combined with NSAIDs in order to serve as a protective mechanism against the possible adverse gastrointestinal effects of NSAIDs.

Rationale/Source

The patient selection criteria presented in this policy takes into consideration clinical evidence or patient history that suggests the available generic PPIs OR generic components of a brand name PPI/NSAID combination product 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 OR using a brand name PPI/NSAID combination drug over the available separate generic PPI or NSAID products. Generic drugs are considered to have equal bioavailability and efficacy in comparison to brand name drugs.

References

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10. Aciphex® [package insert]. Titusville, NJ; Janssen Pharmaceutica Inc., October 2012.
11. Nexium® [package insert]. Willmington, DE: AstraZeneca LP; November 2012.

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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/DrugSafetyInformationforHeathcareProfessionals/ucm190787.htm. Created November 17, 2009.

Policy History

Original Effective Date: 07/17/2013
Current Effective Date: 07/16/2014
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.
Next Scheduled Review Date: 07/2015

*****Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
    1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
    2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
    3. Reference to federal regulations.

**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.

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.

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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.