Proton Pump Inhibitors (PPIs)

Dexlansoprazole (Dexilant), Esomeprazole (Nexium), Lansoprazole (Prevacid, Prevacid SoluTabs, First-Lansoprazole), Omeprazole (First-Omeprazole, Prilosec Powder Packet), Pantoprazole (Protonix Suspension), Rabeprazole (Aciphex, Aciphex Sprinkles)

Effective: 4/14/15

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**OVERVIEW**

**FDA-APPROVED INDICATIONS**

Proton Pump Inhibitors are indicated for the following conditions:

- Gastroesophageal reflux disease (GERD): For the relief of heartburn and other symptoms associated with GERD (dexlansoprazole, esomeprazole, lansoprazole, omeprazole, pantoprazole, rabeprazole)
- Duodenal Ulcer: For short-term treatment of active duodenal ulcers (lansoprazole, omeprazole, rabeprazole), and to maintain healing (lansoprazole)
- Duodenal ulcer associated with H. pylori infection: Dual therapy in combination with clarithromycin (omeprazole) or amoxicillin (lansoprazole) or triple therapy in combination with clarithromycin and amoxicillin (esomeprazole, lansoprazole, omeprazole, rabeprazole)
- Erosive esophagitis: For short-term treatment and maintenance of healing of erosive esophagitis (dexlansoprazole, esomeprazole, lansoprazole, omeprazole, pantoprazole, rabeprazole)
- Gastric Ulcer: For the short-term treatment of active benign gastric ulcers (esomeprazole, lansoprazole, omeprazole)
- Helicobacter pylori eradication in combination with antimicrobial agents
- Pathological hypersecretory conditions, e.g., Zollinger-Ellison syndrome, multiple endocrine adenomas, mastocytosis: For the long-term treatment of pathological hypersecretory conditions (esomeprazole, lansoprazole, omeprazole, pantoprazole, rabeprazole)
- Risk reduction of nonsteroidal anti-inflammatory drug-associated gastric ulcer: Reduction in the occurrence of gastric ulcers associated with continuous NSIAD therapy in patients at risk (esomeprazole, lansoprazole)

Prescription omeprazole in 10 mg, 20 mg, and 40 mg capsules and pantoprazole 20 mg and 40 mg tablets are the preferred proton pump inhibitors (PPI). They are covered without prior authorization.

A trial with esomeprazole (Nexium OTC) should be tried before the use of other non-preferred PPIs.

For members who are unable to swallow oral tablets or capsules, lansoprazole suspension (First-Lansoprazole) and omeprazole suspension (First-Omeprazole) are preferred PPIs. They are covered without prior authorization for members 13 years of age and younger.

**PHARMACY COVERAGE GUIDELINES**

Tufts Health Plan – Network Health may authorize coverage of a non-preferred proton pump inhibitor for members when the following criteria for a particular PPI are met and limitations do not apply:

Dexlansoprazole (Dexilant), lansoprazole capsules (Prevacid), rabeprazole (Aciphex)

- The member tried and failed therapy, or the provider indicates clinical inappropriateness of therapy with omeprazole, pantoprazole, and esomeprazole

Esomeprazole capsules (Nexium) prescription,

- The member tried and failed therapy, or the provider indicates clinical inappropriateness of therapy with omeprazole, pantoprazole, and esomeprazole (OTC)
Esomeprazole capsules over-the-counter (Nexium OTC)
- The member tried and failed therapy, or the provider indicates clinical inappropriateness of therapy with omeprazole

Lansoprazole dispersible tablets (Prevacid SoluTabs), omeprazole granules for suspension (Prilosec Suspension), pantoprazole suspension (Protonix Suspension), rabeprazole (Aciphex Sprinkles)
- The member is 13 years of age or younger or the member is unable to swallow oral tablets/capsules
- The member tried and failed therapy, or the provider indicates clinical inappropriateness of therapy with both omeprazole suspension (First-Omeprazole) and lansoprazole suspension (First-Lansoprazole)

Upon renewal,
- The member has had an office visit and has been re-assessed for this condition within the past year, and continued therapy with this medication is considered medically necessary

LIMITATIONS
- The length of approval will be for 2 years; subsequent approval will require a new authorization.
- Requests for brand-name products, which have AB-rated generics, will be reviewed according to Brand Name criteria.

CODES
None

REFERENCES
1. Nexium (Esomeprazole) [prescribing information]. Wilmington, DE: AstraZeneca; February 2014.
2. Prilosec (omeprazole) [prescribing information]. Wilmington, DE: AstraZeneca; March 2014.
3. Prevacid (lansoprazole) [prescribing information]. East Hanover, NJ: Takeda Pharmaceuticals Inc; May 2012.
5. Aciphex (rabeprazole) [prescribing information]. Charlotte, NC: Eisai; December 2014.

APPROVAL HISTORY
- 04/14/15: Reviewed by the Pharmacy and Therapeutics Committee; incorporated criteria for Aciphex Sprinkles; modified approval duration to two years.
- 2/10/15: Reviewed by the Pharmacy and Therapeutics Committee; approval will be limited to one year; esomeprazole OTC is a preferred agent.
- 3/14/13: Reviewed by the Pharmacy and Therapeutics Committee.

BACKGROUND, PRODUCT, AND DISCLAIMER INFORMATION
Pharmacy Medication Request Guidelines have been developed for determining coverage for Tufts Health Plan – Network Health benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. They are used in conjunction with the applicable Member Handbook and in coordination with the member’s physician(s). Pharmacy Medication Request Guidelines are developed for selected therapeutic classes or drugs found to be safe but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the Tufts Health Plan – Network Health service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. Tufts Health Plan – Network Health reviews Pharmacy Medication Request Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

Pharmacy Medication Request Guidelines apply to all insured offerings unless otherwise noted in this policy or the applicable Member Handbook. Check the applicable Preferred Drug List (formulary) in the pharmacy section of our website to determine if the drug requires you to get prior authorization.

For Tufts Health Unify (Medicare-Medicaid One Care for people ages 21 – 64), please refer to the Tufts Health Unify Prior Authorization Medical Necessity Guidelines.
Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines, when applicable, and adherence to plan policies and procedures and claims editing logic.