

Document ID#: 2111796
Subject: Proton Pump Inhibitors
Effective Date: November 15, 2011

Clinical Documentation and Prior Authorization Required	√	Type of Review — Case Management	
Not Covered		Type of Review — Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	RX	Administrative Process (Internal Use Only)	LPN

Note: This pharmacy medical necessity guideline applies to commercial products. For Tufts Health Plan Medicare Preferred members, please refer to the Tufts Medicare Preferred Step Therapy Criteria. Background, applicable product and disclaimer information can be found on the last page.

Overview

Proton pump inhibitors (PPIs) are used in the management of peptic ulcers (duodenal and gastric), symptoms of gastroesophageal reflux disease (GERD), erosive esophagitis, drug-induced ulcers and hypersecretory syndromes like Zollinger-Ellison, and Helicobacter pylori (H.pylori) infection.

Currently available PPIs are substituted benzimidazoles that inhibit gastric acid secretion by covalently binding to cysteine residues of the proton pump. There are differences at the cellular level with respect to the rates with which the individual PPIs bind to – and dissociate from – H⁺/K⁺-ATPase, and the specific cysteines with which they bind. However, these observations have not been translated into clinically significant differences underscoring the impression that currently available PPIs are essentially interchangeable in clinical practice.

The FDA has approved five proton pump inhibitors for the treatment of acid-related disorders (esomeprazole, lansoprazole, omeprazole, pantoprazole and rabeprazole). Each of these commercially available PPIs has unique pharmacokinetic properties and pharmacodynamic activity, however, these pharmacological differences are relevant only if they equate to clinically significant differences in efficacy, tolerability or safety of the compounds.

A review of the clinical efficacy and safety for all five PPIs indicates that there is very little evidence of any significant differences in the general population, or in relevant subgroups. There are minor pharmacokinetic differences between the agents; however, these differences appear not to be clinically meaningful based on clinical evidence. Each PPI possesses different FDA-labeled indications yet they can all be used for acid suppression and H.pylori eradication. The PPIs also differ with regard to their drug interaction profiles; however, the only clinically significant interaction with all of the PPIs is with omeprazole and warfarin. This interaction is manageable with increased INR (International Normalized Ratio) monitoring.

Pharmacy Coverage Guidelines

Note: Prescriptions that meet the initial step therapy requirements will adjudicate at the point of service. If the Member does not meet the initial step therapy criteria, the prescription will deny at the point of service with a message indicating that prior authorization (PA) is required. Refer to the Coverage Criteria below and submit prior authorization requests to Tufts Health Plan using the Universal Pharmacy Medical Review Request Form for Members who do not meet the step therapy criteria at the point of service.

Please refer to the table below for formularies and medications subject to this policy:

Drug	Tufts Health Plan Commercial Massachusetts Formulary	Tufts Health Plan Generic Focused Formulary	Tufts Health Plan Commercial R.I. Formulary
Step-1			
omeprazole	Covered	Covered	Covered
Step-2			
lansoprazole	Requires prior use of a Step-1 drug	Requires prior use of a Step-1 drug	Requires prior use of a Step-1 drug
omeprazole / sodium bicarbonate			
pantoprazole			
Not Covered			
Aciphex®	Tufts Health Plan may cover if the following criteria are met: <ul style="list-style-type: none"> A formulary exception request is submitted and approved by Tufts Health Plan. Please refer to the Pharmacy Medical Necessity Guidelines for Non-Covered Drugs. <p style="text-align: center;">AND</p> <ul style="list-style-type: none"> The Member has had either an adequate trial of or intolerance to TWO proton pump inhibitors as evidenced by: <ol style="list-style-type: none"> Previous paid claims under the prescription benefit administered by Tufts Health Plan (within the previous 180 days) <li style="text-align: center;">OR Physician documented use (within the last 2 years) 		
Dexilant™ (formerly known as Kapidex™)			
lansoprazole soluble tablet			
Nexium®			
Prevacid®			
Prevacid® Solutab™			
Prilosec®			
Protonix®			
Zegerid®			

Automated Step Therapy Coverage Criteria

Step 1: Medications on Step-1 are covered without prior authorization

Step 2: Tufts Health Plan may cover Step 2 medications if the following criteria are met:

- The member has had a 30-day trial of a Step-1 or Step-2 medication within the previous 180 days as evidenced by a previous paid claim under the prescription benefit administered by Tufts Health Plan.

Coverage Criteria for Members not meeting the Automated Step Therapy Coverage Criteria at the Point of Sale

The following stepped approach applies to proton pump inhibitors covered by Tufts Health Plan:

Step 2: Tufts Health Plan may cover medications on Step-2 if the following criteria are met:

- The Member has had a 30-day trial of a Step-1 proton pump inhibitor as evidenced by physician's documented use within the last 2 years, excluding the use of samples.
- OR**
- The Member has had a 30-day trial of a Step-2 proton pump inhibitor as evidenced by physician's documented use within the last 2 years, excluding the use of samples.
- OR**
- Physician documented use of an adequate trial of at least 14 days of Prilosec OTC[®] within the previous 180 days.

Note: For children below 13 years of age, Tufts Health Plan covers lansoprazole soluble tablets, Nexium oral suspension, Prevacid Solutabs and Protonix oral suspension without prior authorization. Dispensing limitations may apply.

Limitations

1. Medications on Step-2 are not covered unless the above step therapy criteria are met.
2. The following quantity limitations apply for any strength and combination of the following proton pump inhibitors (see below). Please refer to the Pharmacy Medical Necessity Guidelines for Drugs with Quantity Limitations and submit a formulary exception request for those Members requiring higher quantities.
 - Omeprazole - 90 capsules per 90 days
 - Omeprazole/sodium bicarbonate - 90 capsules per 90 days
 - lansoprazole - 90 capsules per 90 days
 - lansoprazole soluble tablet - 90 tablets per 90 days
 - pantoprazole - 90 tablets per 90 days
 - Aciphex - 90 tablets per 90 days
 - Dexilant (formerly known as Kapidex) - 90 capsules per 90 days
 - Nexium - 90 capsules/packets per 90 days
 - Prevacid - 90 capsules per 90 days
 - Prevacid Solutab - 90 tablets per 90 days
 - Prilosec* - 90 capsules/packets per 90 days
 - Protonix - 90 tablets/packets per 90 days
 - Zegerid - 90 capsules/packets per 90 days

Codes

None.

References

1. Aciphex® (rabeprazole) [package insert]. Teaneck, NJ: Esai Inc.; August 2003.
2. Horn J. The proton-pump inhibitors: similarities and differences. Clin Ther 2000; 22: 266-80.
3. Kapidex™ (dexlansoprazole) [package insert]. Deerfield, IL: Takeda Pharmaceuticals America, Inc.; January 2009.
4. McDonagh MS, Carson S. Drug Class Review on Proton Pump Inhibitors. 2006. Accessed: 9 March 2007. Available at: <http://www.ohsu.edu/drugeffectiveness/reports/final.cfm>.
5. Nexium® (esomeprazole) [package insert]. Wilmington, DE: AstraZeneca LP.; October 2006.
6. Prevacid® (lansoprazole) [package insert]. Lake Forest, IL: TAP Pharmaceuticals Inc.; September 2006.
7. Prilosec® (omeprazole) [package insert]. Wilmington, DE: AstraZeneca LP.; September 2006.
8. Protonix® (pantoprazole) [package insert]. Philadelphia, PA: Wyeth Pharmaceuticals Inc.; December 2005.
9. Sachs G, Shin JM, Howden CW. Review article: the clinical pharmacology of proton pump inhibitors. Alimentary Pharmacol Ther 2006; 23 (s2), 2–8.
10. Welage LS, Berardi RR. Evaluation of omeprazole, lansoprazole, pantoprazole, and rabeprazole in the treatment of acid-related diseases. J Am Pharm Assoc 2000; 40:52-62.
11. Zegerid® (omeprazole) [package insert]. San Diego, CA: Santarus, Inc.; February 2006.

Approval History

Reviewed by the Pharmacy and Therapeutics Committee on May 8, 2007.

Subsequent Endorsement Date(s) and Changes Made:

1. May 13, 2008:
 - Added generic pantoprazole to Step 1 of Step Therapy Program
 - Added Protonix suspension to Step 2 of Step Therapy Program
 - Moved Protonix tablets from Step 2 to Not Covered status (Step 3)
 - Added pantoprazole and Protonix suspension dispensing limitations
2. March 10, 2009:

Effective 01/01/2010:

 - Moved pantoprazole from Step 1 to Step 2 of Step Therapy Program
 - Added lansoprazole to Step 2 of Step Therapy Program
 - Moved Nexium, Prevacid, Prevacid Solutab and Protonix suspension from Step 2 to Not Covered status (Step 3)
 - Added Kapidex to Medical Necessity Guidelines
 - Added Step Therapy Program to Tufts Health Plan Medicare Preferred formularies
3. September 8, 2009:

Effective 01/01/2010:

 - Added Step Therapy Program to Commercial and Rhode Island formularies
 - Removed Prevacid oral suspension (discontinued) from criteria.
4. November 10, 2009:
 - Added dispensing limitation for lansoprazole.
 - Added Prevacid Solutab and Protonix oral suspension to covered medications for children below the age of 13 years old.
 - Removed non-covered Prevacid® Naprapac™, drug has been discontinued.
5. January 1, 2010: Removal of Tufts Medicare Preferred language (separate criteria have been created specifically for Tufts Medicare Preferred).
6. May 11, 2010: Changed drug name change from Kapidex™ to Dexilant™

7. September 14, 2010:
 - Added omeprazole / sodium bicarbonate to Step-2 of the Proton Pump Inhibitor Step Therapy program.
 - Added limitation to omeprazole / sodium bicarbonate capsules of 90 capsules per 90 days.
8. November 9, 2010:
 - Added lansoprazole soluble tablet to Step-3 (not covered) of the Proton Pump Inhibitor Medical Necessity Guidelines.
 - Added the quantity limitation of 90 tablets per 90 days for lansoprazole soluble tablet.
 - Added lansoprazole soluble tablet to the Note: For children below 13 years of age, Tufts Health Plan covers lansoprazole soluble tablets, Nexium oral suspension, Prevacid Solutabs and Protonix oral suspension without prior authorization. Dispensing limitations may apply.
9. September 9, 2011: Added historical look back period of 2 years for physician documented use of Step Therapy pre-requisite drugs.
10. November 15, 2011: Removed the Step-3 wording as these drugs are not covered and therefore not subject to the automated step therapy.

Background, Product and Disclaimer Information

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for Tufts Health Plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. They are used in conjunction with a Member's benefit document and in coordination with the Member's physician(s). Tufts Health Plan makes coverage decisions on a case-by-case basis considering the individual Member's health care needs. Pharmacy Medical Necessity 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 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 revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

Pharmacy Medical Necessity Guidelines apply to all fully insured Tufts Health Plan offerings unless otherwise noted in this policy or the Member's benefit document. Check the applicable formulary in the Pharmacy section of our Website at www.tuftshealthplan.com to determine if the drug requires you to get prior authorization. This Pharmacy Medical Necessity Guideline does not apply to Uniformed Services Family Health Plan Members or to certain delegated service arrangements. Unless otherwise noted in the Member's benefit document or applicable Pharmacy Medical Necessity Guideline, Pharmacy Medical Necessity Guidelines do not apply to CareLinkSM Members. For self-insured plans, drug coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a coverage guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern. Applicable state or federal mandates will take precedence.

For Tufts Medicare Preferred, please refer to Tufts Medicare Preferred Step Therapy Criteria.

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.