Clinical Policy: Gastrointestinal Agents: Proton Pump Inhibitors

Reference Number: OH.PHAR.PPA.59
Effective Date: 01/01/2020
Last Review Date: N/A
Line of Business: Medicaid

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description:

GASTROINTESTINAL AGENTS: PPIs

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
LANSOPRAZOLE capsules (generic of Prevacid®) OMEPRAZOLE capsules (generic of Prilosec®) NEXIUM® packets (esomeprazole) PANTOPRAZOLE (generic of Protonix®) PROTONIX® suspension (No PA required for age 6 or under)	ACIPHEX® sprinkle capsule (rabeprazole) DEXILANT® (dexlansoprazole) ESOMEPRAZOLE STRONTIUM ESOMEPRAZOLE capsules (generic of Nexium®) OMEPRAZOLE tablets (generic of Prilosec OTC®) OMEPRAZOLE/SODIUM BICARBONATE PREVACID SOLUTAB® (lansoprazole ODT) PRILOSEC® suspension (omeprazole) PROTONIX® suspension (PA required for age over 6) RABEPRAZOLE (generic of Aciphex®)

FDA Approved Indication(s)
Proton Pump Inhibitors are indicated for the treatment of:

- duodenal ulcer
- dyspepsia
- esophagitis
- gastric ulcer
- gastroesophageal reflux disease (GERD)
- Helicobacter pylori (H. pylori) eradication
- multiple endocrine adenoma syndrome
- NSAID-induced ulcer prophylaxis
- pyrosis (heartburn)
- systemic mastocytosis
- Zollinger-Ellison syndrome

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of Buckeye Health Plan, an affiliate of Centene Corporation®, that Aciphex, Dexilant, esomeprazole strontium, Nexium capsules, omeprazole tablets, Zegerid, Prevacid SoluTab, Prilosec suspension, and Protonix suspension (PA required for age over 6) are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Once Daily Dosing (must meet all)**:**

1. FDA-approved or supported by standard pharmacopeias;
2. Member must meet labeled age requirements for the medication;
3. The member meets one of the following (a or b):
   a. Documentation that there have been therapeutic failures to trials of no less than 30 days each of at least two medications that are preferred UNLESS there is a reason the member cannot be changed to a preferred medication. Acceptable reasons include:
      - Allergies to all medications not requiring prior approval.
      - Contraindication to or drug-to-drug interaction with medications not requiring prior approval.
      - History of unacceptable/toxic side effects to medications not requiring prior approval.
      - Presence of a gastrostomy and/or jejunostomy tube (G-tube, GJ-tube, J-tube).
   b. Documentation that the member was initiated on a medication requiring prior approval in the hospital for the treatment of a condition such as GI bleed.

**NOTE: No PA is required for preferred PPI's at any dose for age under 21 UNLESS the request is for Protonix suspension (PA required for age over 6).

Approval duration: 180 days.

B. Twice Daily Dosing (must meet all)**:**

1. FDA-approved or supported by standard pharmacopeias;
2. Member must meet labeled age requirements for the medication;
3. Documented diagnosis of ONE of the following (a or b):
   a. Helicobacter pylori (H. pylori)
   b. Chronic Obstructive Pulmonary Disease (COPD), Dyspepsia, Gastritis, Gastroparesis, Symptomatic Uncomplicated Barrett's Esophagus, Carcinoma of GI tract, Crest Syndrome, Esophageal Varices, Scleroderma, Systemic Mastocytosis, OR Zollinger-Ellison Syndrome
4. For a diagnosis of COPD, Dyspepsia, Gastritis, Gastroparesis, Symptomatic Uncomplicated Barrett's Esophagus, Carcinoma of GI tract, Crest Syndrome, Esophageal Varices, Scleroderma, Systemic Mastocytosis, or Zollinger-Ellison Syndrome:
   - Must have failed once daily dosing.
5. The member meets one of the following (a or b):
   a. Documentation that there have been therapeutic failures to trials of no less than 30 days each of at least two medications that are preferred UNLESS there is a reason the member cannot be changed to a preferred medication. Acceptable reasons include:
      - Allergies to all medications not requiring prior approval.
      - Contraindication to or drug-to-drug interaction with medications not requiring prior approval.
      - History of unacceptable/toxic side effects to medications not requiring prior approval.
      - Presence of a gastrostomy and/or jejunostomy tube (G-tube, GJ-tube, J-tube).

b. Documentation that the member was initiated on a medication requiring prior approval in the hospital for the treatment of a condition such as GI bleed.

**NOTE: No PA is required for preferred PPI's at any dose for age under 21 UNLESS the request is for Protonix suspension (PA required for age over 6).

Approval duration: 30 days for H. pylori; **12 months** for COPD, Dyspepsia, Gastritis, Gastroparesis, Symptomatic Uncomplicated Barrett's Esophagus, Carcinoma of GI tract, Crest Syndrome, Esophageal Varices, Scleroderma, Systemic Mastocytosis, or Zollinger-Ellison Syndrome.

II. Diagnoses/Indications for which coverage is NOT authorized:

Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – CP.PMN.53 for Medicaid or evidence of coverage documents.

III. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

COPD: Chronic Obstructive Pulmonary Disease
DR: Delayed Release
ER: Extended Release
FDA: Food and Drug Administration
GERD: Gastroesophageal Reflux Disease
H. Pylori: Helicobacter pylori
NSAID: Nonsteroidal Anti-inflammatory Drug
ODT: Orally Disintegrating Tablet
OTC: Over the Counter
PA: Prior Authorization
PPI: Proton Pump Inhibitor

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

*****See above tables for preferred alternatives***** *Dosing varies by drug product. See FDA approved dosing and administration.*

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

- *See package insert; clinical pharmacology or other appropriate clinical reference*

IV. Dosage and Administration:

varies by drug product. See package insert; clinical pharmacology or other appropriate clinical reference for FDA approved dosing and administration

V. Product Availability: See package insert; clinical pharmacology or other appropriate clinical reference for product availability

VI. References. Refer to package insert.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
New policy created.	10.19	N/A

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.