Proton Pump Inhibitors

NOTICE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the Proton Pump Inhibitors (PPIs) Quantity Limit criteria is to encourage appropriate prescribing quantities as recommended by FDA-approved product labeling. The intent of the proton pump inhibitors (PPIs) step therapy is to ensure appropriate selection of patients for therapy based on product labeling, clinical guidelines and clinical studies. The criteria will encourage the use of the more cost-effective generic PPIs prior to the use of a brand or more costly generic when clinically appropriate while maintaining optimal therapeutic outcomes.

AcipHex (rabeprazole), Dexilant (dexlansoprazole), Esomeprazole Strontium, Nexium (esomeprazole), Prevacid (lansoprazole), Prilosec (omeprazole), and Protonix (pantoprazole) are all PPIs that suppress gastric acid secretion by specific inhibition of the H+/K+ ATPase enzyme system at the secretory surface of the gastric parietal cell. They reduce gastric acidity by acting specifically on the proton pump which is the final step in acid production.

POLICY

I. Prior authorization for Omeprazole 10mg & 40mg (generic Prilosec), Lansoprazole (generic Prevacid), or Pantoprazole (generic Protonix) is not required for quantities less than or equal to 2 dosage units per day. Additional quantities may be considered **medically necessary** if the patient has a diagnosis of Barrett's esophagus confirmed by biopsy or Zollinger-Ellison Syndrome confirmed by a diagnostic test.

II. Prior authorization for Omeprazole 20 mg (generic Prilosec) is not required for quantities less than or equal to 4 dosage units per day. Additional quantities may be considered **medically necessary**

if the patient has a diagnosis of Barrett's esophagus confirmed by biopsy or Zollinger-Ellison Syndrome confirmed by a diagnostic test.

III. Brand and generic AcipHex, Dexilant, Esomeprazole strontium, and brand or generic Nexium may be considered **medically necessary** if the following criteria is met:

- Patient must have tried and failed a therapeutic trial of at least **two** preferred PPIs (Prilosec (omeprazole), Prevacid (lansoprazole), and/or Protonix (pantoprazole).
- The requested amount does not exceed 2 dosage units per day for AcipHex, Esomeprazole strontium, and Nexium or 1 dosage unit per day for Dexilant unless the patient has a diagnosis of Barrett's esophagus confirmed by biopsy or Zollinger-Ellison Syndrome confirmed by a diagnostic test.

Approval will be **12 months**

IV. Brand and generic AcipHex Sprinkles may be considered **medically necessary** if the following criteria are met:

- Patient must be unable to swallow an intact capsule or tablet
- Patient must have tried and failed a therapeutic trial of BOTH lansoprazole AND omeprazole when the capsules are opened and the contents are sprinkled on soft food or liquid without crushing or chewing the capsules or the granules unless Step Therapy Exception Criteria for Approval is met .
- The requested amount does not exceed 1 dosage unit per day unless the patient has a diagnosis of Barrett's esophagus confirmed by biopsy or Zollinger-Ellison Syndrome confirmed by a diagnostic test.

Approval will be **12 months**

V. Prilosec packets, Protonix Packets, and Nexium Packets may be considered **medically necessary** if the following criteria are met:

- Patient must be unable to swallow an intact capsule or tablet
- Patient must have a contraindication to or tried and failed a therapeutic trial of BOTH lansoprazole AND omeprazole when the capsules are opened and the contents are sprinkled on soft food or liquid without crushing or chewing the capsules or the granules.
- The requested amount does not exceed 2 dosage units per day unless the patient has a diagnosis of Barrett's esophagus confirmed by biopsy or Zollinger-Ellison Syndrome confirmed by a diagnostic test.

Approval will be **12 months**

VI. Brand and generic Prevacid Solutabs may be considered **medically necessary** if the following criteria are met:

- Patient must be unable to swallow an intact capsule or tablet
- Patient must have a contraindication to or tried and failed a therapeutic trial of BOTH lansoprazole AND omeprazole when the capsules are opened and the contents are sprinkled on soft food or liquid without crushing or chewing the capsules or the granules; **OR** is unable to swallow capsules related to a medical condition or due to a nasogastric or gastrostomy tube.

- The requested amount does not exceed 2 dosage units per day unless the patient has a diagnosis of Barrett's esophagus confirmed by biopsy or Zollinger-Ellison Syndrome confirmed by a diagnostic test.

Approval will be **12 months**

VII. Medications included in this policy are considered **not medically necessary** for patients who do not meet the criteria set forth above.

Quantity limits apply:

Drug Name	Standard Benefit Allowance	Post-Limit PA Quantity Limit (up to)
Aciphex (rabeprazole)	60 tablets per 30 days	90 tablets per 30 days
Aciphex Sprinkles (rabeprazole)	30 capsules per 30 days	60 capsules per 30 days
Dexilant (dexlansoprazole)	30 capsules per 30 days	60 capsules per 30 days
Esomeprazole Strontium (esomeprazole strontium)	60 capsules per 30 days	90 capsules per 30 days
Nexium (esomeprazole)	60 capsules/packets per 30 days	90 capsules per 30 days
Prevacid (lansoprazole)	60 capsules/solutabs per 30 days	90 capsules/solutabs per 30 days
Prilosec (omeprazole)	60 capsules/packets per 30 days	90 capsules/packets per 30 days
Protonix (pantoprazole)	60 capsules/packets per 30 days	90 capsules/packets per 30 days

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

- Code(s), if applicable

REFERENCES

- AcipHex [package insert]. Woodcliff Lake, NJ: Eisai Inc., LTD.; June 2018.
- AcipHex Sprinkles [package insert]. Charlotte, NC: FSC Laboratories, Inc.; June 2018.
- Dexilant [package insert]. Deerfield, IL: Takeda Pharmaceuticals America, Inc.; June 2018.
- Esomeprazole Strontium [package insert]. Glasgow, KY: Amneal Pharmaceuticals: December 2014.
- Nexium [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; June 2018.
- Prevacid [package insert].Deerfield, IL: Takeda Pharmaceuticals America, Inc.; June 2018.
- Prilosec [package insert].Wilmington, DE: AstraZeneca Pharmaceuticals LP; December 2016.
- Protonix [package insert].Philadelphia, PA: Wyeth Pharmaceuticals Inc.; April 2019.
- Zegerid [package insert].San Diego, CA: Santarus, Inc June 2018.
- Ho, P. Michael; et.al. Risk of Adverse Outcomes Associated With Concomitant Use of Clopidogrel and Proton Pump Inhibitors Following Acute Coronary Syndrome, JAMA, March 4, 2009; 301: 937 - 944.
- Katz PO, Gerson LB, Vela MF. Guidelines for the diagnosis and management of gastroesophageal reflux disease. Am J Gastroenterol. 2013 Mar;108(3):308-28.

POLICY HISTORY

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