Proton Pump Inhibitors (PPIs) Step Therapy and Quantity Limit Program Summary

For the **GenRx Closed** formulary, step therapy will target Nexium suspension packets. Any generic PPI except omeprazole/sodium bicarbonate can serve as a prerequisite.

For the **GenRx Open, Health Insurance Marketplace & KeyRx** formularies, step therapy will target ALL brand PPIs and generic omeprazole/sodium bicarbonate. Any generic PPI except omeprazole/sodium bicarbonate can serve as a prerequisite.

For the **FlexRx Closed** formulary, step therapy will target Nexium suspension packets. Any generic PPI except omeprazole/sodium bicarbonate can serve as a prerequisite.

For the **FlexRx Open** formulary, step therapy will target ALL brand PPIs and generic omeprazole/sodium bicarbonate. Any generic PPI except omeprazole/sodium bicarbonate can serve as a prerequisite.

This program is a GenRx Standard and FlexRx Standard program.

The BCBS MN Step Therapy Supplement also applies to this program for all Commercial/HIM lines of business.

FDA APPROVED INDICATIONS AND DOSAGE[1-9, 16, 18]

Agent(s)	Indication(s)
Aciphex® (rabeprazole) Tablet[a]	Healing of erosive or ulcerative GERD in adults
	Maintenance of healing of erosive or ulcerative GERD in adults
	Treatment of symptomatic GERD in adults and adolescents 12 years of age and older
	Healing of duodenal ulcers in adults
	Helicobacter pylori eradication to reduce the risk of duodenal ulcer recurrence in adults
	Treatment of pathological hypersecretory conditions, including Zollinger-Ellison syndrome in adults
Aciphex® Sprinkle™, Rabeprazole Sprinkle[b] Capsule	Treatment of GERD in pediatric patients 1 to 11 years of age for up to 12 weeks
Dexilant®, Dexlansoprazole[a] (dexlansoprazole) Capsule	Healing of erosive esophagitis in patients 12 years of age and older
	Maintenance of healed erosive esophagitis and relief of heartburn in patients 12 years of age and older
	Treatment of symptomatic non-erosive GERD in patients 12 years of age and older
Esomeprazole Strontium Capsule[b]	Treatment of gastroesophageal reflux disease (GERD) in adults
	Risk reduction of NSAID-associated gastric ulcer in adults
	H. pylori eradication to reduce the risk of duodenal ulcer recurrence in adults
	Pathological hypersecretory conditions, including Zollinger-Ellison syndrome in adults
Konvomep™ (omeprazole/sodium bicarbonate) Oral suspension	Treatment of active benign gastric ulcer
	Reduction of risk of upper gastrointestinal (GI) bleeding in critically ill patients
	Treatment of GERD

Agent(s)	Indication(s)
Nexium® (esomeprazole magnesium) Capsule[a], Suspension packet[a]	Risk reduction of NSAID-associated gastric ulcer
	H. pylori eradication to reduce the risk of duodenal ulcer recurrence
	Pathological hypersecretory conditions, including Zollinger-Ellison syndrome
Prevacid® **Prevacid**® **SoluTab**™ (lansoprazole) Capsule[a], ODT[a]	Short-term treatment of active duodenal ulcer in adults
	H. pylori eradication to reduce the risk of duodenal ulcer Recurrence in adults
	Maintenance of healed duodenal ulcers in adults
	Short-term treatment of active benign gastric ulcer in adults
	Healing of NSAID-associated gastric ulcer
	Risk reduction of NSAID-associated gastric ulcer in adults
	Treatment of symptomatic GERD
	Treatment of erosive esophagitis
	Maintenance of healing of erosive esophagitis in adults
	Pathological hypersecretory conditions including Zollinger-Ellison syndrome in adults
Prilosec® (omeprazole) Capsule[a], Suspension packet	Treatment of active duodenal ulcer in adults
	Eradication of *Helicobacter pylori* to reduce the risk of duodenal ulcer recurrence in adults
	Treatment of active benign gastric ulcer in adults
	Treatment of symptomatic GERD in patients 1 year of age and older
	Treatment of erosive esophagitis due to acid-mediated GERD in patients 1 month of age and older
	Maintenance of healing of erosive esophagitis due to acid-mediated GERD in patients 1 year of age and older
	Pathological hypersecretory conditions in adults
Protonix® (pantoprazole) Tablet[a], Suspension packet[a]	Short-term treatment of erosive esophagitis associated with GERD in patients 5 years of age and older
	Maintenance of healing of erosive esophagitis in adults
	Pathological hypersecretory conditions including Zollinger-Ellison syndrome in adults
Voquezna® (vonoprazan) Tablet	Healing of erosive esophagitis
	Maintenance of healed erosive esophagitis
	Treatment of H. pylori infection
Zegerid® (omeprazole/sodium bicarbonate) Capsule[a], Suspension packet[a]	Short-term treatment of active duodenal ulcer in adults
	Short-term treatment of active benign gastric ulcer in adults
	Treatment of heartburn and other symptoms associated with GERD in adults
	Treatment of erosive esophagitis due to acid-mediated GERD which has been diagnosed by endoscopy in adults
	Maintenance of healing of erosive esophagitis due to acid-mediated GERD in adults
	Reduction of risk of upper GI bleeding in critically ill adult patients (oral suspension only)

GERD = gastroesophageal reflux disease
GI = gastrointestinal
NSAID = non-steroidal anti-inflammatory drugs
ODT = orally disintegrating tablet
a – generic available
b – branded generic available

See package insert for FDA prescribing information: https://dailymed.nlm.nih.gov/dailymed/index.cfm

CLINICAL RATIONALE

Current guidelines recognize the proton pump inhibitors (PPIs) as first-line therapy for the management of dyspepsia, gastroesophageal reflux disease (GERD), peptic ulcer disease (PUD), eradication of Helicobacter pylori (H. pylori), and Zollinger Ellison syndrome (ZES).[10-15, 17]

In studies comparing PPIs to one another, while some differences have been reported, the magnitude of differences (safety/efficacy) has been small and of uncertain clinical importance. The degree to which any differences would justify the selection of one vs. another PPI, particularly when considering cost-effectiveness, is unclear. Data suggests the similar efficacy of PPIs that has been observed in controlled clinical trials may not necessarily translate into equivalent effectiveness when these drugs are substituted for one another.[16] Differences in dosage formulations and drug interactions may occasionally influence choice of PPI in individual cases.[10-13]

Safety[1-9, 16, 18]

Aciphex is contraindicated in the following:
- Patients with known hypersensitivity to substituted benzimidazoles or to any component of the formulation
- Patients receiving rilpivirine-containing products

Dexilant is contraindicated in the following:
- Patients with known hypersensitivity to any component of the formulation
- Patients receiving rilpivirine-containing products

Esomeprazole Strontium is contraindicated the following:
- Known hypersensitivity to proton pump inhibitors (PPIs) (angioedema and anaphylaxis have occurred)

Konvomep is contraindicated in the following:
- Known hypersensitivity to any components of the formulation
- Patients receiving rilpivirine-containing products

Nexium is contraindicated in patients with known hypersensitivity substituted benzimidazoles or any component of the formulation.

Prevacid is contraindicated in the following:
- Patients with known severe hypersensitivity to any component of the formulation
- Patients receiving rilpivirine-containing products

Prilosec is contraindicated in the following:
- Patients with known hypersensitivity to substituted benzimidazoles or any component of the formulation
- Patients receiving rilpivirine-containing products

Protonix is contraindicated in the following:
- Patients with known hypersensitivity to substituted benzimidazoles or to any component of the formulation
- Patients receiving rilpivirine-containing products

Voquezna is contraindicated in the following:
- Known hypersensitivity to vonoprazan or any component of Voquezna
- Rilpivirine-containing products

Zegerid is contraindicated in the following:

- Patients with known hypersensitivity to substituted benzimidazoles or to any components of the formulation
- Patients receiving rilpivirine-containing products

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Proton Pump Inhibitors (PPIs) Step Therapy

TARGET AGENT(S)[a]
Aciphex® (rabeprazole)
Aciphex® Sprinkle™ (rabeprazole)
Dexilant® (dexlansoprazole)
Dexlansoprazole
Esomeprazole Strontium
Konvomep™ (Omeprazole/sodium bicarbonate)
Nexium® (esomeprazole)
Prevacid® (lansoprazole)
Prevacid® SoluTab™ (lansoprazole)
Prilosec® (omeprazole)
Protonix® (pantoprazole)
Rabeprazole Sprinkle
Voquezna® (vonoprazan)
Zegerid® (omeprazole/sodium bicarbonate)
a - see formulary specific information

PRIOR AUTHORIZATION CRITERIA FOR APPROVAL
Target Agent(s) will be approved when ONE of the following is met:

1. The patient's medication history includes use of a prescription strength prerequisite agent
   OR
2. The patient has an intolerance or hypersensitivity to a prescription strength prerequisite agent
   OR
3. The patient has an FDA labeled contraindication to ALL prescription strength prerequisite agent
   OR
4. BOTH of the following:
   A. The prescriber has stated that the patient has tried a prescription strength prerequisite agent
      AND
   B. The prescription strength prerequisite agent was discontinued due to lack of effectiveness or an adverse event

   OR
5. The patient is currently being treated with the requested agent as indicated by ALL of the following:
   A. A statement by the prescriber that the patient is currently taking the requested agent
      AND
   B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent
      AND
   C. The prescriber states that a change in therapy is expected to be ineffective or cause harm

   OR
6. The prescriber has provided documentation that ALL prescription strength prerequisite agents cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm

Length of Approval: 12 months

NOTE: If Quantity Limit applies, please refer to Quantity Limit document.