Health Net

Prior Authorization Protocol

ACIPHEX/ACIPHEX SPRINKLE® (rabeprazole), DEXILANT® (dexlansoprazole), esomeprazole strontium, NEXIUM®(esomeprazole), PRILOSEC® POWDER (omeprazole), PREVACID[R] SOLUTABS (lansopraozle), *ZEGERID® (omeprazole/ sodium bicarbonate)*

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Coverage of drugs is first determined by the member's pharmacy or medical benefit. Please consult with or refer to the Evidence of Coverage document.

I. FDA Approved Indications:

Indication	Aciphex	Dexilant	Nexium	Prilosec Powder	Prevacid	Zegerid	Aciphex Sprinkle	esomeprazole strontium
Duodenal ulcers	X		*	X	X	X		
Duodenal ulcer, maintenance				*	X			
Duodenal ulcer, Giant				*				
Erosive esophagitis	X	X	X	X	X	X		X
Erosive esophagitis, maintenance	X	X	X	X	X	X		X
Gastric ulcers	*			X	X	X		
Nonsteroidal anti-inflammatory drug (NSAID)-associated gastric ulcer, risk reduction			X	*	X			X
NSAID-associated gastric ulcer, healing of				*	X			
Helicobacter pylori Triple Therapy	X		X	X	X			X
Helicobacter pylori Dual Therapy				X	X			
Helicobacter pylori Quadruple Therapy	*			*	*			
Pathological hypersecretory conditions, including	X		X	X	X			X

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Indication	Aciphex	Dexilant	Nexium	Prilosec Powder	Prevacid	Zegerid	Aciphex Sprinkle	esomeprazole strontium
Zollinger-Ellison Syndrome								
Symptomatic gastroesophageal reflux disease (GERD) (Erosive/Ulcerative)	X		X (Pediatric Only)	X	X (Pediatric Only)	X	X (Pediatric only)	X
Symptomatic GERD, maintenance (Erosive/Ulcerative)	X							
Symptomatic GERD (Non-erosive)		X	X		X			X
Indigestion	*			*				
Drug-induced GI disturbance				*				
Esophageal stricture				*				
Heartburn					*			
Reduction of risk of upper GI bleed in critically ill patients				*		X		

*Clinical trials have demonstrated the efficacy and safety for these indications, although not currently FDA-approved.

II. Health Net Approved Indications and Usage Guidelines:

- Patient with ONE of the following:
  - Symptomatic GERD
  - Esophageal- Schatzki's ring, erosive esophagitis (EE), esophageal stricture
  - Extra-esophageal: vocal cord damage/nodules, asthma, laryngitis and pharyngitis
  - Barrett's esophagus, Laryngopharyngeal reflux (LPR), or Zollinger-Ellison Syndrome (automatically qualifies for BID dosing if requested)
  - Gastric ulcer (GU) or duodenal ulcer (DU)
  - *H. pylori*

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- High-risk individuals on NSAIDs defined as ONE of the following:
  - History of complicated Peptic Ulcer Disease (PUD)
  - Age > 60 years
  - Concurrent anticoagulant, platelet inhibitors (e.g. warfarin, aspirin, Plavix®) or oral corticosteroid (e.g. prednisone) therapy

AND

- Dexilant, esomeprazole, omeprazole/sodium bicarbonate, Prevacid Solutabs, rabeprazole: Failure or clinically significant adverse effects of a minimum 4 week trial of each preferred generic PPI: omeprazole capsules, pantoprazole tablets, and lansoprazole capsules
- For members on Plavix and requesting Dexilant, failure or clinically significant adverse effects of a minimum 4 week trial of pantoprazole tablets only is required.

AND

- For pediatric members, Prevacid SoluTabs, and Aciphex Sprinkles can be approved as requested

  OR
- For pediatric patients, omeprazole 2 mg/mL suspension can be approved
- For patients with a g-tube or significant dysphagia, Prevacid SoluTabs, omeprazole/sodium can be approved after a trial of Protonix Packets (chart note documentation may be required)

AND

- For two per day dosing requests of non-preferred agents, must be titrated up from one per day.

III. Coverage is Not Authorized For:

- Prevacid SoluTabs or Aciphex Sprinkle for patients less than 1 year of age
- Non-FDA approved indications, which are not listed in the Health Net Approved Indications and Usage Guidelines section unless there is sufficient documentation of efficacy and safety in the published literature.

IV. General Information:

- Dexilant 60 mg vs. Prevacid 30 mg in EE was evaluated in two studies. Non-inferiority was demonstrated in both studies, but superiority was demonstrated in only one study.
- Dexilant 90 mg was studied and did not provide additional clinical benefit over Dexilant 60 mg in EE.
- Patients with a platelet reactivity index (PRI) >50% is linked to sub-acute stent thrombosis.
- In a study by Siller-Matula JM, et al., The PRI was similar in patients on Protonix or Nexium (mean 51%; 95% CI 48-54%) and for patients on Plavix and Protonix the mean was PRI = 50% and for Plavix and Nexium the mean PRI was 54%.
- Over 90% of gastric and duodenal ulcers heal within 8 weeks of proton pump inhibitor (PPI) therapy.
- There have been models constructed to evaluate both the efficacy and cost-effectiveness of “step-up” therapy (starting with H2 antagonists and titrating to symptom control) and “step-down therapy” (starting with PPI therapy and decreasing therapy to the lowest form of acid suppression that controls symptoms). Neither method has been proven superior.
- Patients with PUD (DU or GU) should be tested for *H. pylori* and treated, if positive.

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- For Laryngopharyngeal reflux (LPR), the American Academy of Otolaryngology recommends twice-daily dosing with PPIs for a minimum period of 6 months with the possibility of chronic treatment. BID dosing of PPIs has been shown to be superior to QD dosing in LPR.
- Zegerid is contraindicated in patients with metabolic alkalosis and hypocalcemia because of its sodium bicarbonate content.
- 2 capsules of Zegerid 20 mg are not interchangeable with 1 capsule of Zegerid 40 mg because each capsule or packet contains the same amount of sodium bicarbonate.
- Pediatric patients: The safety and efficacy of Dexilant, Zegerid and Protonix in children have not been established. The safety and efficacy of Prevacid have been established in pediatric patients 1 to 17 years of age. The safety and efficacy of omeprazole have been established in pediatric patients 1 to 16 years of age. The safety and efficacy of Nexium have been established in pediatric patients 1 to 17 years of age for up to 8 weeks. The safety and efficacy of Aciphex have been established in pediatric patients 1 year and older for up to 36 weeks.
- Safety and efficacy of proton pump inhibitors have not been established in patients less than 1 year of age. Lansoprazole was no more effective than placebo in patients 1 month to less than 1 year of age with symptomatic GERD in a multi-center, double-blind, placebo controlled study (Orenstein et al, 2009). Studies with Aciphex Sprinkle do not support its use for the treatment of GERD in pediatric patients younger than 1 year of age.
- Prevacid has a non FDA-approved, Class IIa strength recommendation for giant duodenal ulcer per Micromedex. Of 27 study patients with giant duodenal ulcer placed on Prilosec, 20 (71.4%) did not require operative intervention, and 8 (28.6%) required operation for ulcer complications.
- Prevacid has a non FDA-approved, Class IIa strength recommendation for heartburn and H. pylori quadruple therapy per Micromedex.
- Aciphex has a non FDA-approved, Class II a strength recommendation for gastric ulcers, H. pylori quadruple therapy and indigestion per Micromedex.
- Several published observational studies suggest that high-dose, defined as multiple daily doses, and long-term PPI therapy (a year or longer) may be associated with an increased risk for osteoporosis related fractures. Patients should use the lowest dose and shortest duration of PPI therapy appropriate to the condition being treated. Patients at risk for osteoporosis-related fractures should be managed according to established treatment guidelines.
- Hypomagnesemia has been reported rarely in patients treated with PPIs for $\geq$ 3 months that can lead to serious adverse events including tetany, arrhythmias, and seizures. For patients expected to be on prolonged treatment or who take PPIs with medications such as digoxin or drugs that may cause hypomagnesemia (e.g.,diuretics), consider monitoring magnesium levels prior to initiation of PPI treatment and periodically.
- According to their respective package inserts, concomitant administration of either pantoprazole or dexlansoprazole with clopidogrel in healthy subjects had no clinically important effect on exposure to the active metabolite of clopidogrel or clopidogrel-induced platelet inhibition. No dose adjustment of clopidogrel is necessary when administered with an approved dose of Protonix or Dexilant. American Hospital Formulary Service Drug Information further states, “If concomitant proton-pump inhibitor therapy [with clopidogrel] is considered necessary, some clinicians suggest the use of pantoprazole, which appears to be the weakest inhibitor of cytochrome P450 2C19 (CYP2C19) among proton-pump inhibitors.”
- Long term daily use (longer than 3 years) of PPIs may lead to malabsorption of cyanocobalamin (vitamin B-12). PPIs can cause acute interstitial nephritis.

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V. Therapeutic Alternatives:

Drug	Dosing Regimen	Dose Limit/Maximum Dose
Prescription Proton Pump Inhibitors		
omeprazole (Prilosec®)	Adults: 20-40 mg PO QD - BID Children: (Age 1-16 yrs old) 5 to <10 kg: 5 mg PO QD 10 to <20 kg: 10 mg PO QD ≥20 kg: 20 mg PO QD	Doses up to 120 mg 3 times/day have been administered. Administer daily doses greater than 80 mg in divided doses.
lansoprazole (Prevacid®)	Adults: 15-30 mg PO QD - TID Pediatric: (1-11 yrs old) <30 kg: 15 mg PO QD >30 kg : 30 mg PO QD (12-17 yrs old) 15-60 mg PO QD	Doses up to 90 mg/day PO for eradication of *H.Pylori* ; up to 180 mg/day PO for Zollinger-Ellison syndrome.
pantoprazole (Protonix®)	Adults: 40 mg PO QD to BID Pediatric (5 years and older): ≥15 kg to <40 kg: 20 mg PO QD ≥40 kg: 40 mg PO QD	Doses up to 240 mg/day have been studied in pathological hypersecretory conditions (e.g. Zollinger-Ellison Syndrome)
High-Dose Prescription H_2 Blockers		
nizatidine (Axid®, Axid® AR)	Up to 150 mg PO BID (300 mg/day)	12 weeks
famotidine (Pepcid®)	Up to 40 mg PO BID	12 weeks
cimetidine (Tagamet®, Tagamet HB®)	Up to 800 mg PO BID or 400 mg PO QID	12 weeks
ranitidine (Zantac®)	Up to 300 mg PO BID	12 weeks
*Over-the-Counter (OTC) Proton Pump Inhibitors***		
Prevacid 24hr OTC® (lansoprazole) **OTC agents may not be covered	15 mg PO QD	15 mg/day for 14 days Consult MD if > 14 days
Prilosec OTC® (omeprazole)	20 mg PO QD	20 mg/day for 14 days Consult MD if > 14 days

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Drug	Dosing Regimen	Dose Limit/Maximum Dose
**OTC agents may not be covered		
Zegerid OTC® (omeprazole/sodium bicarbonate) **OTC agents may not be covered	20 mg/1100 mg PO QD	20 mg/1100 mg/day for 14 days Consult MD if > 14 days

*Requires Prior Authorization

VI. Recommended Dosing Regimen and Authorization Limit:

Drug	Dosing Regimen	Authorization Limit
rabeprazole (Aciphex®)	20-60 mg PO QD - BID	Length of Benefit
Aciphex Sprinkle (rabeprazole)	<15 kg: 5 -10 mg PO QD >=15 kg: 10 mg PO QD	Length of Benefit
esomeprazole (Nexium)	Adult: 20-40 mg PO QD to BID Pediatric: 1-11 yrs old: 10-20 mg PO QD 12-17 yrs old: 20-40 mg PO QD	Length of Benefit
Prilosec® Granules for suspension (omeprazole magnesium)	Adults: 20-60 mg PO QD - BID Children: (Age 1-16 yrs old) 5 to <10 kg: 5 mg PO QD 10 to <20 kg: 10 mg PO QD ≥20 kg: 20 mg PO QD	Length of Benefit
Prevacid SoluTab (lansoprazole)	Adults: 15-30 mg PO QD to TID or 60mg PO QD Pediatric: (1-11 yrs old) <30 kg: 15 mg PO QD >30 kg : 30 mg PO QD (12-17 yrs old) 15-30 mg PO QD	Length of Benefit
omeprazole/ sodium bicarbonate (Zegerid)	20-40 mg PO QD	Length of Benefit

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Drug	Dosing Regimen	Authorization Limit
Dexilant (dexlansoprazole)	30-60 mg PO QD	Length of Benefit
esomeprazole strontium	24.65-49.3 mg PO QD to BID	Length of Benefit

VII. Product Availability:

Aciphex Tablet, delayed release: 20 mg
Aciphex Sprinkle Delayed Release Capsule: 5 mg, 10 mg
Dexilant Capsule, delayed release: 30 mg, 60 mg
Nexium Capsule, delayed release: 20 mg, 40 mg
Nexium powder for oral suspension, packets: 2.5mg, 5mg, 10 mg, 20 mg, 40 mg
Prevacid SoluTab, delayed release: 15 mg, 30 mg
Prilosec powder for oral suspension, packets: 2.5 mg, 10 mg
Zegerid Capsule: 20 mg/1100 mg, 40 mg/1100 mg
Zegerid powder for oral suspension, packets: 20 mg/1680 mg, 40 mg/1680 mg
Esomeprazole strontium Capsule, delayed release: 24.65 mg (equivalent to 20 mg esomeprazole), 49.3 mg (equivalent to 40 mg esomeprazole)
Available OTC products:
Zegerid OTC Capsule: 20 mg/1100 mg
Prevacid 24hr OTC, delayed release: 15 mg

VIII. References:

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The materials provided to you are guidelines used by this health plan to authorize, modify, or determine coverage for persons with similar illnesses or conditions. Specific care and treatment may vary depending on individual needs and the benefits covered under your contract.

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