Clinical Policy: Proton Pump Inhibitors

Reference Number: CP.CPA.209
Effective Date: 11.16.16
Last Review Date: 11.19
Line of Business: Commercial

Revision Log

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

Description

The following are proton pump inhibitors (PPIs) requiring prior authorization: rabeprazole (AcipHex®, AcipHex® Sprinkle), dexlansoprazole (Dexilant®), esomeprazole strontium (ES), esomeprazole (Nexium®, Nexium® 24HR, Nexium® 24HR ClearMinis™), omeprazole (Prilosec® Packets), lansoprazole (Prevacid® SoluTabs™), omeprazole/sodium bicarbonate (Zegerid®, Zegerid® OTC).

FDA Approved Indication(s)

Indication	AcipHex	Dexilant	Nexium	Prilosec	Prevacid	Zegerid	Aciphex Sprinkle	ES
Duodenal ulcers	X		*	X	X	X		
Duodenal ulcers, maintenance				*	X			
Duodenal ulcers, 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 (*H.* pylori) Triple Therapy	X		X	X	X			X
H. pylori Dual Therapy				X	X			
H. pylori Quadruple therapy	*		*	*	*			
Pathological hypersecretory conditions, including Zollinger-Ellison Syndrome	X		X	X	X			X
Symptomatic gastroesophageal reflux disease (GERD) (erosive/ulcerative)	X		X^	X	X^	X	X^p^	X

Indication	AcipHex	Dexilant	Nexium	Prilosec	Prevacid	Zegerid	Aciphex Sprinkle	ES
Symptomatic GERD, maintenance (erosive/ulcerative)	X							
Symptomatic GERD (non-erosive)		X	X		X			X
Indigestion	*		*	*				
Drug-induced gastrointestinal (GI) disturbance				*				
Esophageal stricture				*				
Heartburn			X		*			
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.*
^ Includes adults and pediatrics
[P] Pediatrics only

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 health plans affiliated with Centene Corporation® that Aciphex/Aciphex Sprinkle, Dexilant, esomeprazole strontium, Nexium/Nexium 24HR/Nexium 24HR ClearMinis, Prilosec Packets, Prevacid SoluTabs, and Zegerid/Zegerid OTC are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. All Indications (must meet all)**:**

1. Prescribed for one of the following uses (a – e):
   a. Symptomatic GERD, including heartburn or laryngopharyngeal reflux;
   b. Esophageal complications of GERD (e.g., erosive esophagitis, esophageal stricture, Barrett's esophagus, and Schatzki's ring);
   c. Extra-esophageal complications (e.g., laryngopharyngeal reflux, vocal cord damage/nodules, asthma, laryngitis and pharyngitis);
   d. Peptic ulcer disease (e.g., gastric ulcers, duodenal ulcers, *H. pylori* and Zollinger-Ellison Syndrome);
   e. Gastrointestinal bleed prophylaxis for NSAID use and member meets at least one of the following (i, ii, or iii):
      i. History of peptic ulcer disease;
      ii. Age ≥ 60 years;
      iii. Concurrent therapy with anticoagulants (e.g., warfarin, aspirin, clopidogrel) or oral corticosteroids (e.g., prednisone);
2. For lansoprazole disintegrating tablets or AcipHex Sprinkle: age ≥ 1 year old;
3. Member meets any of the following (a, b, c, or d):

a. Age < 12 years and request is for lansoprazole disintegrating tablets, AcipHex Sprinkle, or Prilosec packets;
b. Presence of G-tube or significant dysphagia and request is for Prevacid SoluTabs, Prilosec packets, or omeprazole/sodium bicarbonate: failure of a ≥ 4-week trial of Protonix® packets at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced (chart note documentation may be required);
c. Currently on clopidogrel and request is for Dexilant: Failure of a ≥ 4-week trial of pantoprazole tablets at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
d. Request is for Dexilant, esomeprazole, lansoprazole disintegrating tablets, omeprazole suspension, omeprazole/sodium bicarbonate, rabeprazole: failure of a ≥ 4-week trial of ALL of the following preferred generic PPIs at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced: omeprazole capsules, pantoprazole tablets, and lansoprazole capsules;

4. For BID dosing requests of non-preferred agents for conditions other than *H. pylori* or pathological hypersecretory conditions, including Zollinger-Ellison Syndrome: member must be titrated up from once daily dosing;
5. Dose does not exceed the FDA-approved maximum recommended dose (refer to Section V).

Approval duration: Length of Benefit

B. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial.

II. Continued Therapy

A. All Indications in Section I (must meet all)**:**

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed the FDA-approved maximum recommended dose (refer to Section V).

Approval duration: Length of Benefit

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial.

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

A. 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 policies – CP.CPA.09 for commercial.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

ES: esomeprazole strontium
FDA: Food and Drug Administration
GERD: gastroesophageal reflux disease
GI: gastrointestinal
H. pylori: *Helicobacter pylori*
NSAID: non-steroidal anti-inflammatory drug
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.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
pantoprazole tablets and suspension (Protonix)	**Short-term treatment of erosive esophagitis associated with GERD** Adult and pediatric (age ≥ 5 years and weight ≥ 40 kg): 40 mg PO QD Pediatric (age ≥ 5 years and weight ≥ 15 kg to < 40 kg): 20 mg PO QD **Maintenance of healing of erosive esophagitis** 40 mg PO QD **Pathological hypersecretory conditions, including Zollinger-Ellison Syndrome** 40 mg PO BID	40 mg/day (240 mg/day for pathological hypersecretory conditions)
omeprazole capsules (Prilosec)	**Duodenal ulcer** 20 mg PO QD **Symptomatic GERD; Erosive esophagitis (treatment and maintenance)** Adult: 20 mg PO QD Pediatric (age 1 to 16 years): Weight 5 kg to < 10 kg: 5 mg Weight 10 kg to < 20 kg: 10 mg Weight ≥ 20 kg: 20 mg Pediatric (age 1 month to < 1 year): Weight 5 kg to < 10 kg: 5 mg Weight ≥ 10 kg: 10 mg	40 mg/day (360 mg/day for pathological hypersecretory conditions)

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	H. pylori Triple therapy: 20 mg PO BID for 10 days, in combination with amoxicillin and clarithromycin Dual therapy: 40 mg PO QD for 14 days, in combination with clarithromycin 40 mg/day **Gastric ulcer** 40 mg PO QD **Pathological hypersecretory conditions, including Zollinger-Ellison Syndrome** 60 mg PO QD to 80 mg/day PO in divided doses	
lansoprazole capsules (Prevacid)	**Duodenal ulcers, risk reduction of NSAID-associated gastric ulcer, maintenance of healing of erosive esophagitis** 15 mg PO QD **Short-term treatment of symptomatic GERD and erosive esophagitis** Adult: 15 to 30 mg PO QD Pediatric (age 1 to 11 years): Weight > 30 kg: 30 mg PO QD Weight ≤ 30 kg: 15 mg PO QD Pediatric (age 12 to 17 years): Non-erosive GERD: 15 mg Erosive esophagitis: 30 mg ***H. pylori*** Triple therapy: 30 mg PO BID for 10 or 14 days in combination with amoxicillin and clarithromycin Dual therapy: 30 mg PO TID for 14 days in combination with amoxicillin **Benign gastric ulcer, healing of NSAID-associated gastric ulcer** 30 mg PO QD	30 mg/day (180 mg/day for pathological hypersecretory conditions)

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	Pathological hypersecretory conditions, including Zollinger-Ellison Syndrome 60 mg PO QD	

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

- Contraindication(s):
  - All agents: hypersensitivity (e.g., to drug or other PPIs, substituted benzimidazoles, or to any components of the formulation)
  - AcipHex/Aciphex Sprinkle, Dexilant, and Prevacid: coadministration with rilpivirine-containing products
- Boxed warning(s): none reported

Appendix D: 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 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.
- 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.
- Two capsules of Zegerid 20 mg are not interchangeable with one 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.
- 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.”

V. Dosage and Administration

Drug Name	Indication	Dosing Regimen	Maximum Dose
rabeprazole (Aciphex)	Duodenal ulcers; Erosive esophagitis; *H. pylori* triple therapy; Symptomatic GERD (erosive/ulcerative), healing and maintenance;	20 mg PO QD (treatment duration varies)	20 mg/day
	Pathological hypersecretory conditions, including Zollinger-Ellison Syndrome	60 mg PO QD to 60 mg PO BID	120 mg/day

Drug Name	Indication	Dosing Regimen	Maximum Dose
rabeprazole sodium delayed-release (Aciphex Sprinkle)	Symptomatic GERD (erosive/ulcerative)	**Pediatric** Age 1 to 11 years: Weight <15 kg: 5 to 10 mg PO QD Weight ≥15 kg: 10 mg PO QD	10 mg/day
dexlansoprazole (Dexilant)	Healing of erosive esophagitis	60 mg PO QD	60 mg/day
	Maintenance of healed erosive esophagitis and relief of heartburn; Symptomatic non-erosive GERD	30 mg PO QD	30 mg/day
esomeprazole (Nexium, Nexium 24HR, Nexium 24HR Clear Minis)	GERD (including erosive esophagitis, symptomatic GERD)	**Adult** 20 to 40 mg PO QD to BID **Pediatric** Age 1 to 11 years: 10 to 20 mg PO QD Age 12 to 17 years: 20 to 40 mg PO QD Age 1 month to < 1 year: Weight 3 kg to 5 kg: 2.5 mg PO QD Weight > 5 kg to 7.5 kg: 5 mg PO QD	80 mg/day
	Risk reduction of NSAID-associated gastric ulcer	20 mg to 40 mg PO QD	40 mg/day
	H. pylori triple therapy	40 mg PO QD for 10 days, in combination with amoxicillin and clarithromycin	40 mg/day
	Pathological hypersecretory conditions, including Zollinger-Ellison Syndrome	40 mg PO BID	240 mg/day
omeprazole (Prilosec Packets)	Duodenal ulcer	20 mg PO QD	20 mg/day
	Symptomatic GERD; Erosive	**Adult** 20 mg PO QD	20 mg/day

Drug Name	Indication	Dosing Regimen	Maximum Dose
	esophagitis (treatment and maintenance)	**Pediatric** Age 1 to 16 years Weight 5 kg to < 10 kg: 5 mg Weight 10 kg to < 20 kg: 10 mg Weight ≥ 20 kg: 20 mg Age 1 month to < 1 year Weight 5 kg to < 10 kg: 5 mg Weight ≥ 10 kg: 10 mg	
	H. pylori	Triple therapy: 20 mg PO BID for 10 days, in combination with amoxicillin and clarithromycin Dual therapy: 40 mg PO QD for 14 days, in combination with clarithromycin	40 mg/day
	Gastric ulcer	40 mg PO QD	40 mg/day
	Pathological hypersecretory conditions, including Zollinger-Ellison Syndrome	60 mg PO QD to 80 mg/day PO in divided doses	360 mg/day
lansoprazole (Prevacid SoluTab)	Duodenal ulcers	15 mg PO QD	90 mg/day
	H. pylori	Triple therapy: 30 mg PO BID for 10 to 14 days, in combination with amoxicillin and clarithromycin Dual therapy: 30 mg PO TID for 14 days, in combination with amoxicillin	90 mg/day
	Gastric ulcer (including benign	**Adult**	30 mg/day

Drug Name	Indication	Dosing Regimen	Maximum Dose
	and healing of NSAID-associated gastric ulcers); Treatment of erosive esophagitis	30 mg PO QD (treatment duration varies) **Pediatric** Age 1-11 years Weight ≤ 30 kg: 15 mg PO QD Weight > 30 kg : 30 mg PO QD Age 12-17 years 15 to 30 mg PO QD	
	Risk reduction of NSAID-associated gastric ulcers; Symptomatic GERD; Maintenance of healing of erosive esophagitis	15 mg PO QD (treatment duration varies)	15 mg/day
	Pathological hypersecretory conditions, including Zollinger-Ellison Syndrome	60 mg PO QD to 90 mg/day PO BID	180 mg/day
omeprazole/ sodium bicarbonate (Zegerid, Zegerid OTC)	Duodenal ulcer; Symptomatic GERD; Erosive esophagitis (treatment and maintenance)	20 mg PO QD (treatment duration varies)	40 mg/day
	Benign gastric ulcer	40 mg PO QD	40 mg/day
	Reduction of risk of upper GI bleeding in critically ill patients	40 mg oral suspension only: 40 mg PO initially, 6 to 8 hours later, then daily for 14 days	40 mg/day
esomeprazole strontium	Treatment of erosive esophagitis; Risk reduction of NSAID-associated gastric ulcers	24.65 to 49.3 mg PO QD (treatment duration varies)	49.3 mg/day
	Symptomatic GERD; Maintenance	24.65 mg PO QD	24.65 mg/day

Drug Name	Indication	Dosing Regimen	Maximum Dose
	of healing of erosive esophagitis		
	H. pylori triple therapy	49.3 mg PO QD for 10 days	49.3 mg/day
	Pathological hypersecretory conditions, including Zollinger-Ellison Syndrome	49.3 mg PO BID	240 mg/day

VI. Product Availability

Drug Name	Availability
rabeprazole (Aciphex)	Tablets, delayed-release: 20 mg
rabeprazole (Aciphex Sprinkle)	Capsules, delayed-release: 5 mg, 10 mg
dexlansoprazole (Dexilant)	Capsules, delayed-release: 30 mg, 60 mg
esomeprazole (Nexium)	• Capsules, delayed-release: 20 mg, 40 mg • Packets, powder for delayed-release oral suspension: 2.5 mg, 5 mg, 10 mg, 20 mg, 40 mg
lansoprazole (Prevacid Solutabs)	Tablets, delayed-release orally disintegrating: 15 mg, 30 mg
omeprazole (Prilosec Packets)	Packets, powder for delayed-release oral suspension: 2.5 mg, 10 mg
omeprazole/sodium bicarbonate (Zegerid)	• Capsules: 20 mg/1100 mg, 40 mg/1100 mg • Unit-dose packets for oral suspension: 20 mg/1680 mg, 40 mg/1680 mg
esomeprazole strontium	Capsules, delayed-release: 24.65 mg (equivalent to 20 mg esomeprazole), 49.3 mg (equivalent to 40 mg esomeprazole)
Available OTC products	
omeprazole/sodium bicarbonate (Zegerid OTC)	Capsules: 20 mg/1100 mg
esomeprazole (Nexium 24HR)	Tablets, delayed-release: 20 mg
esomeprazole (Nexium 24HR ClearMinis)	Capsules, delayed-release: 20 mg

VII. References

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Reviews, Revisions, and Approvals	Date	P&T Approval Date
Converted to new template. Minor changes to verbiage and grammar. References updated.	06.12.17	11.17
4Q 2018 annual review: added Nexium 24HR, Nexium 24HR ClearMinis, and Zegerid OTC products; expanded age requirement for high risk GI bleed to include 60 years per Nexium package insert; defined pediatric members as less than 12 years old; added Prilosec packets to request list of non-preferred agents for members with presence of G-tube or significant dysphasia; added option to allow QD or BID dosing request for *H. pylori*; references reviewed and updated.	08.14.18	11.18
4Q 2019 annual review: no significant changes; references reviewed and updated.	08.13.19	11.19

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.

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