Clinical Policy: Proton Pump Inhibitors

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Line of Business: Arizona Medicaid (AzCH-CCP and Care1st) 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® 24HR, Nexium® 24HR ClearMinis™), omeprazole (Prilosec® Packets), omeprazole/sodium bicarbonate (Zegerid®, Zegerid® OTC).

AHCCCS preferred drugs in this class include: esomepraole magnesium packets (**Nexium ODT- brand preferred**), esomeprazole magnesium capsule DR (Nexium), lansoprazole capsule (Prevacid), lansoprazole orally dispersable tablet (ODT), omeprazole capsule (Prilosec), pantoprazole (Protonix), pantoprazole sodium packets (Protonix Granules).

****NOTE: non-capsule/tablet formulations require a PA for members age >18 years****

FDA approved indications:

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 Triple Therapy	X		X	X	X			X
Helicobacter pylori Dual Therapy				X	X			
Helicobacter pylori Quadruple therapy	*		*	*	*			
Pathological hypersecretory	X		X	X	X			X

CLINICAL POLICY
Proton Pump Inhibitors

Indication	Aciphex	Dexilant	Nexium	Prilosec	Prevacid	Zegerid	Aciphex Sprinkle	ES
conditions, including Zollinger-Ellison Syndrome								
Symptomatic gastroesophageal reflux disease (GERD) (erosive/ulcerative)	X		X^	X	X^	X	X^p^	X
Symptomatic GERD, maintenance (erosive/ulcerative)	X							
Symptomatic GERD (non-erosive)		X	X		X			X
Indigestion	*		*	*				
Drug-induced 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^ Pediatric only

Policy/Criteria
Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria

It is the policy of Arizona Complete Health-Complete Care Plan and Care1st that Aciphex/Aciphex Sprinkle, Dexilant, esomeprazole strontium, Nexium/Nexium 24HR/Nexium 24HR ClearMinis, Prilosec Packets, and Zegerid/Zegrid 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 AcipHex Sprinkle, age ≥ 1 year old;
3. Member meets any of the following (a, b, c, d, or e):
   a. Any age- Request is for AcipHex Sprinkle, Prilosec packets- failure of esomeprazole packets, lansoprazole ODT AND pantoprazole packets, each at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
   b. Age >18- Presence of G-tube or significant dysphagia and request is for esomeprazole packets, lansoprazole disintegrating tablets, pantoprazole packets:
   c. Currently on clopidogrel and request is for Dexilant: Failure of a ≥ 4-week trial of lansoprazole capsules at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
   d. Request is for any non-preferred tablet or capsule {dexlansoprazole (Dexilant®), esomeprazole strontium (ES), esomeprazole (Nexium® 24HR, Nexium® 24HR ClearMinis™), omeprazole/sodium bicarbonate (Zegerid®, Zegerid® OTC)} : failure of a minimum 4 week trial of ALL of the following preferred generic PPI at up to maximally indicated doses unless contraindicated or clinically significant adverse effects are experienced: omeprazole capsules, esomeprazole capsules, and lansoprazole capsules (chart notes and/or claims are required);
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: 12 months

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): AZ.CP.PMN.53 for Arizona Medicaid.

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: 12 months

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): AZ.CP.PMN.53 for Arizona Medicaid.

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 policy – AZ.CP.PMN.53 for Arizona Medicaid.

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)

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
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 ***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	40 mg/day (360 mg/day for pathological hypersecretory conditions)
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	30 mg/day (180 mg/day for pathological hypersecretory conditions)

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	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 **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
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**	80 mg/day

Drug Name	Indication	Dosing Regimen	Maximum Dose
		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	
	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 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 Age 1 month to < 1 year Weight 5 kg to < 10 kg: 5 mg Weight ≥ 10 kg: 10 mg	20 mg/day

Drug Name	Indication	Dosing Regimen	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	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 and healing of NSAID-associated gastric ulcers); Treatment of erosive esophagitis	**Adult** 30 mg PO QD (treatment duration varies) **Pediatric** <u>Age 1-11 years</u> Weight ≤ 30 kg: 15 mg PO QD Weight > 30 kg : 30 mg PO QD <u>Age 12-17 years</u>	30 mg/day

Drug Name	Indication	Dosing Regimen	Maximum Dose
		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 of healing of erosive esophagitis	24.65 mg PO QD	24.65 mg/day
	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 • ODT: 20mg
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
lansoprazole (Prevacid 24 HR)	Capsules, delayed release: 15 mg

VII. References

1. Bhatt DL, Scheiman J, Abraham NS, et al. ACCF/ACG/AHA 2008 expert consensus document on reducing the gastrointestinal risks of antiplatelet therapy and NSAID use: a report of the American College of Cardiology Foundation Task Force on Clinical Expert Consensus Documents. J Am Coll Cardiol 2008;52(18):1502-1517.
2. Laine L and Jensen DM. Management of patients with ulcer bleeding. Am J Gastroenterol 2012; 107:345-360.
3. Devault K, Castell D. Updated Guidelines for the Diagnosis and Treatment of Gastroesophageal Reflux Disease. Am J Gastroenterol 2005;100:190-200.
4. Wang K, Sampliner R. Updated Guidelines for the Diagnosis, Surveillance, and Therapy of Barrett's Esophagus. Am J Gastroenterol 2008;103:788-797.

5. Laryngopharyngeal reflux: Position statement of the Committee on Speech, Voice, and Swallowing Disorders of the American Academy of Otolaryngology-Head and Neck Surgery. Otolaryngology-Head and Neck Surgery. 2002;127:30-35
6. Laryngopharyngeal Reflux: Prospective Cohort Study Evaluating Optimal Dose of Proton-Pump Inhibitor Therapy and Pretherapy Predictors of Response. Laryngoscope. 2005; 115.
7. Lanas A. Potent gastric acid inhibition in the management of Barrett's oesophagus. Drugs. 2005;65 Suppl 1:75-82.
8. Spechler, S. Barrett's Esophagus. N Engl J Med. 2002;346:836-842.
9. Katz PO, Gerson L, Vela M. Guidelines for the diagnosis and management of gastroesophageal reflux disease. American Journal of Gastroenterology. 2013;108(3):308-328.
10. Aciphex Prescribing Information. Woodcliff Lake, NJ: Eisai, Inc; June 2018. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/020973s039lbl.pdf. Accessed May 29, 2020.
11. Aciphex Sprinkle Prescribing Information. Research Triangle Park, NC: Eisai, Inc; June 2018. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/204736s010lbl.pdf. Accessed May 29, 2020.
12. Dexilant Prescribing Information. Deerfield, IL: Takeda Pharmaceuticals; June 2018. Available at: https://general.takedapharm.com/DEXILANTPI. Accessed May 29, 2020.
13. Nexium Prescribing Information. Wilmington, DE: AstraZeneca; June 2018. Available at: https://www.azpicentral.com/nexium/nexium.pdf#page=1. Accessed May 29, 2020.
14. Prevacid Prescribing Information. Deerfield, IL: Takeda Pharmaceuticals; June 2018. Available at: http://general.takedapharm.com/content/file/pi.pdf?filetypecode=PREVACIDPI. Accessed May 29, 2020.
15. Prilosec Prescribing Information. Wilmington, DE: AstraZeneca; May 2018. Available at: https://www.prilosecpackets.com/_resources/Prilosec-PI-2018.pdf. Accessed May 29, 2020.
16. Zegerid Prescribing Information. Bridgewater, NJ: Valeant Pharmaceuticals; June 2018. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/021849s014,021636s019lbl.pdf. Accessed May 29, 2020.
17. Esomeprazole strontium Prescribing Information. Carmel, IN: ParaPRO LLC; June 2018. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/202342s005lbl.pdf. Accessed May 29, 2020.
18. Protonix Prescribing Information. Philadelphia, PA: Pfizer Inc.; June 2018. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/020987s054,022020s016,020988s060lbl.pdf. Accessed May 29, 2020.

CLINICAL POLICY
Proton Pump Inhibitors

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
Changed document to reflect coverage of compounded Omeprazole and Lansoprazole by state Medicaid.	3.29.19	04.19
Added criteria for members age 1 month to less than 1 year old; Therapeutic Alternatives moved from Appendix C to Appendix B; added Appendix C: Contraindications/Boxed Warnings; updated Section V. Dosage and Administration; references reviewed and updated; AHCCCS preferred drugs section added; Changed name from AZ.CP.PHAR.209 to AZ.CP.PMN.1002 to align with Corporate naming convention.	6.8.20	07.20
Updated to reflect AHCCCS preferred drug changes.	01.13.21	02.21
Added Care1st logo. Added verbiage to specify that criteria also applies to Care1st.	5.10.21	04.21

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.