Clinical Policy: PPI Compunding Kits

Reference Number: IL.PMN.350
Effective Date: 7.1.23
Last Review Date: 3.8.23
Line of Business: YouthCare Health*Choice* Illinois

Coding Implications
Revision Log

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

Description

First-Omeprazole 2mg/mL suspension compounding kit contains omeprazole and diluent. First-Lansoparazole 3mg/mL suspension compounding kits contain lansoprazole and diluent. Omeprazole and Lansoprazole are proton pump inhibitors (PPIs).

FDA Approved Indication(s)

Indication	Omeprazole	Lansoprazole
Duodenal ulcers	X	X
Duodenal ulcers, maintenance	*	X
Duodenal ulcers, giant	*	
Erosive esophagitis	X^	X
Erosive esophagitis, Maintenance	X^	X
Gastric ulcers	X	X
Nonsteroidal anti-inflammatory drug (NSAID)-associated gastric ulcer, risk reduction	*	X
NSAID-associated gastric ulcer, healing of	*	X
Helicobacter pylori (*H.* pylori) Triple Therapy	X	X
H. pylori Dual Therapy	X	X
H. pylori Quadruple therapy	*	*
Pathological hypersecretory conditions, including Zollinger-Ellison Syndrome	X	X
Symptomatic gastroesophageal reflux disease (GERD) (erosive/ulcerative)	X^	X^
Symptomatic GERD, maintenance (erosive/ulcerative)		
Symptomatic GERD (non-erosive)		X
Indigestion	*	
Drug-induced gastrointestinal (GI) disturbance	*	
Esophageal stricture	*	
Heartburn		*
Reduction of risk of upper GI bleed in critically ill patients	*	*

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

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 compounded formulations of lansoprazole and omprezole are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Initial Approval Criteria (must meet all):

1. Must try omeprazole capsules (generic) or lansoprazole ODT unless there is a contraindication or clinically significant adverse effect or meet one of the following (a,b, c or, d);
   a. Age <8 years old;
   b. Documentation why member cannot take solid dosage form (age, g-tube, etc);
   c. Oral-motor difficulties;
   d. Dysphagia;
2. If request is for First-omeprazole Suspension Compunding Kit or Konvomep®, must try First-lansoprazole Suspension Compounding Kit unless there is a contraindication or clinically significant adverse effect;
3. Dose does not exceed the FDA-approved maximum recommended dose (refer to Section V).

Approval duration: 12 months or duration of request, whichever is less

B. Other diagnoses/indications

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.PMN.53 for Medicaid

II. Continued Therapy

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

1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B);*
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 or duration of request, whichever is less

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

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.PMN.53 for 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 policies – CP.PMN.53 for Medicaid, or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

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 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	40 mg/day (240 mg/day for pathological hypersecretory conditions)

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	Pathological hypersecretory conditions, including Zollinger-Ellison Syndrome 40 mg PO BID	
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 Weight ≤ 30 kg: 15 mg PO QD Pediatric (age 12 to 17 years): Non-erosive GERD: 15 mg Erosive esophagitis: 30 mg	30 mg/day (180 mg/day for pathological hypersecretory conditions)

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	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, Konvomep, Nexium, Prevacid, Prilosec, and Zegerid: coadministration with rilpivirine-containing products
- Boxed warning(s): none reported

Appendix D: General Information

- Over 90% of gastric and duodenal ulcers heal within 8 weeks of PPI therapy.
- 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.
- 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** 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

Drug Name	Indication	Dosing Regimen	Maximum Dose
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** <u>Age 1 to 16 years</u> Weight 5 kg to < 10 kg: 5 mg PO QD Weight 10 kg to < 20 kg: 10 mg PO QD Weight ≥ 20 kg: 20 mg QD <u>Age 1 month to < 1 year</u> Weight 3 kg to < 5 kg: 2.5 mg PO QD Weight 5 kg to < 10 kg: 5 mg PO QD Weight ≥ 10 kg: 10 mg PO QD	20 mg/day
	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,	90 mg/day

Drug Name	Indication	Dosing Regimen	Maximum Dose
		in combination with amoxicillin	
	Gastric ulcer (including benign and healing of NSAID-associated gastric ulcers); Treatment of erosive esophagitis	**Adult** 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	30 mg/day
	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 (Konvomep)	Benign gastric ulcer	40 mg PO QD for 4 to 8 weeks	40 mg/day
	Reduction of risk of upper GI bleeding in critically ill patients	40 mg PO initially, followed by 40 mg PO 6 to 8 hours later, then 40 mg PO QD for 14 days	40 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

Drug Name	Indication	Dosing Regimen	Maximum Dose
	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
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 (Konvomep)	Oral suspension: 2 mg/84 mg/mL after reconstitution in 90 mL, 150 mL, or 300 mL bottles
omeprazole/sodium bicarbonate (Zegerid)	• Capsules: 20 mg/1,100 mg, 40 mg/1,100 mg • Unit-dose packets for oral suspension: 20 mg/1,680 mg, 40 mg/1,680 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/1,100 mg
esomeprazole (Nexium 24HR)	Tablets, delayed-release: 20 mg
esomeprazole (Nexium 24HR ClearMinis)	Capsules, delayed-release: 20 mg

VII. References

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Prescribing Information

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Reviews, Revisions, and Approvals	Date	P&T Approval Date
New policy created for HFS PDL	3.9.23	

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.