Clinical Policy: Dexlansoprazole (Dexilant)

Reference Number: HIM.PA.05
Effective Date: 01.01.20
Last Review Date: 11.22
Line of Business: HIM

Revision Log

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

Description

Dexlansoprazole (Dexilant®) is a proton pump inhibitor (PPI).

FDA Approved Indication(s)

Dexilant is indicated in patients 12 years of age and older for:

- Healing of all grades of erosive esophagitis (EE).
- Maintenance of healed EE and relief of heartburn.
- Treatment of symptomatic non-erosive gastroesophageal reflux disease (GERD).

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 Dexilant is **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, b, c, d, or 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. Age ≥ 12 years;
3. Failure of lansoprazole, omeprazole, and pantoprazole, at up to maximally indicated doses, unless all are contraindicated or clinically significant adverse effects are experienced;

4. Dose does not exceed both of the following (a and b):
   a. 60 mg per day;
   b. 1 capsule per day.

Approval duration: 12 months

B. Other 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 formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: HIM.PA.33 for health insurance marketplace; 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: HIM.PA.103 for health insurance marketplace; 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: HIM.PA.154 for health insurance marketplace.

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 both of the following (a and b):
   a. 60 mg per day;
   b. 1 capsule per day.

Approval duration: 12 months

B. Other 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 formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: HIM.PA.33 for health insurance marketplace; 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: HIM.PA.103 for health insurance marketplace; 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: HIM.PA.154 for health insurance marketplace.

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 – HIM.PA.154 for health insurance marketplace or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

FDA: Food and Drug Administration

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):	40 mg/day (360 mg/day for pathological hypersecretory conditions)

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	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	
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):
  - Hypersensitivity (e.g., to drug or other PPIs, substituted benzimidazoles, or to any components of the formulation)
  - 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.
- Pediatric patients: The safety and efficacy of Dexilant, Zegerid and Protonix in children have not been established.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
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	60 mg/day

VI. Product Availability

Delayed-release capsule: 30 mg, 60 mg

VII. References

1. Dexilant Prescribing Information. Deerfield, IL: Takeda Pharmaceuticals; March 2022. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/022287s034lbl.pdf. Accessed August 27, 2022.
2. Li MJ, Li Q, Sun M, Liu LQ. Comparative effectiveness and acceptability of the FDA-licensed proton pump inhibitors for erosive esophagitis: A PRISMA-compliant network meta-analysis. Medicine (Baltimore). 2017;96(39):e8120.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created per SDC adapted from HIM.PA.109 Step Therapy policy which previously required failure of two of the following: lansoprazole, omeprazole, pantoprazole, or rabeprazole; revised redirection to three of three (lansoprazole, omeprazole, pantoprazole).	12.04.19	02.20
4Q20 annual review: no significant changes; references reviewed and updated.	08.13.20	11.20
4Q 2021 annual review: no significant changes; added age limit per PI; updated reference for HIM off-label use to HIM.PA.154 (replaces HIM.PHAR.21); references reviewed and updated.	08.11.21	11.21
4Q 2022 annual review: no significant changes; references reviewed and updated. Template changes applied to other diagnoses/indications and continued therapy section.	08.27.22	11.22

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.