Drug Coverage Policy

Effective Date 05/01/2024
Coverage Policy Number.....IP0061
Policy Title.....Proton Pump Inhibitors

Proton Pump Inhibitors

- Dexilant™ (dexlansoprazole delayed-release capsules, generic – Takeda)
- Konvomep™ (omeprazole/sodium bicarbonate oral suspension – Azurity)
- Nexium® (esomeprazole delayed-release capsules, generic – AstraZeneca)
- Nexium® (esomeprazole delayed-release granules for oral suspension, generic - AstraZeneca)
- Omeprazole/sodium bicarbonate capsules, generic
- Omeprazole/sodium bicarbonate powder for oral suspension, generic
- Prevacid® Solutab (lansoprazole delayed release orally disintegrating tablets, generic - Takeda)
- Voquezna® (vonoprazan tablets – Phathom)
- Zegerid® (omeprazole/sodium bicarbonate capsules, generic - Salix)
- Zegerid® (omeprazole/sodium bicarbonate powder for oral suspension, generic - Procter & Gamble)

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment and have discretion in making individual coverage determinations. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

OVERVIEW
Although proton pump inhibitors (PPIs) vary in their specific FDA-approved indications, all PPIs are used for the treatment and/or management of acid-related diseases, including duodenal and gastric ulcerations, gastroesophageal reflux disease, Zollinger-Ellison syndrome, and *Helicobacter pylori* infections.[1-14,19,20] Several PPIs are available over-the-counter (OTC).[1-4] Patients should not take the OTC products for more than a 14 day period or more often than every 4 months unless under the supervision of a physician.

Several treatment guidelines support the overall safety and efficacy of these agents for acid-related diseases.[15-18] PPIs are the treatment of choice for many gastrointestinal disorders in adults and pediatrics. Though the available clinical data are not entirely complete for the comparison of these agents, many clinical trials have shown the PPIs to be similar in efficacy and safety.

Pediatrics
Esomeprazole magnesium capsules, Nexium oral suspension, omeprazole capsules, and Prilosec oral suspension are indicated for use in children ≥ 1 month old.[5-7] Aciphex Sprinkle, lansoprazole capsules, and lansoprazole orally disintegrating tablets (ODT) are indicated for use in children **≥** 1 year of age.[8,9] Pantoprazole products are only indicated for patients ≥ 5 years of age.[10] Rabeprazole tablets are not recommended for use in pediatric patients < 12 years of age because the lowest available tablet strength (20 mg) exceeds the recommended dose for these patients.[11] Dexilant is indicated in patients ≥ 12 years of age.[13] Omeprazole/sodium bicarbonate capsules and oral suspension, Konvomep, Voquezna, and the OTC PPI products lack pediatric indications.[12,13,19,20]

Medical Necessity Criteria

Coverage varies across plans and requires the use of preferred products. Proton pump inhibitor (PPI) therapy is specifically excluded under some Employer Group Plans [Value, Advantage, and Total Savings Prescription Drug List Plans]. Please refer to the applicable benefit plan document to determine benefit availability.

Coverage criteria are listed for products **in below table(s):**

Employer Plans:

Product	Criteria
Dexilant delayed-release capsules (dexlansoprazole)	**Standard/Performance/Legacy Drug List Plans:** **Dexilant delayed-release capsules** is considered medically necessary when there is documentation of **BOTH** of the following: 1. Trial of **dexlansoprazole delayed-release capsules** (the bioequivalent generic product) AND cannot take due to a formulation difference in the inactive ingredient(s) which would result in a significant allergy or serious adverse reaction 2. Failure, contraindication, or intolerance to **FOUR** of the following: A. esomeprazole B. lansoprazole C. omeprazole D. pantoprazole E. rabeprazole

Product	Criteria
Konvomep oral suspension (omeprazole/ sodium bicarbonate)	**Standard/Performance/Legacy Drug List Plans:** **Konvomep oral suspension** is considered medically necessary when there is documentation of **ONE** of the following: 1. Failure, contraindication, or intolerance to **FIVE** of the following: A. dexlansoprazole B. esomeprazole C. lansoprazole D. omeprazole E. pantoprazole F. rabeprazole 2. Inability to swallow tablets/capsules and has had failure, contraindication, or intolerance to **ALL** of the following: A. esomeprazole B. lansoprazole C. omeprazole D. pantoprazole suspension
Nexium delayed-release capsules (esomeprazole)	**Standard/Performance/Legacy Drug List Plans:** **Nexium delayed-release capsules** is considered medically necessary when there is documentation of **BOTH** of the following: 1. Trial of **esomeprazole delayed-release capsules** (the bioequivalent generic product) AND cannot take due to a formulation difference in the inactive ingredient(s) which would result in a significant allergy or serious adverse reaction 2. Failure, contraindication, or intolerance to **FOUR** of the following: A. dexlansoprazole B. lansoprazole C. omeprazole D. pantoprazole E. rabeprazole
Nexium delayed-release granules for oral suspension (esomeprazole - 10mg, 20mg, 40mg packet)	**Nexium delayed-release granules** is considered medically necessary when there is documented trial of **esomeprazole granules for oral suspension** (the bioequivalent generic product) AND cannot take due to a formulation difference in the inactive ingredient(s) which would result in a significant allergy or serious adverse reaction
omeprazole/sodium bicarbonate capsules	**Omeprazole/sodium bicarbonate capsules** is considered medically necessary when there is documentation of failure, contraindication, or intolerance to **FIVE** of the following: 1. dexlansoprazole 2. esomeprazole 3. lansoprazole 4. omeprazole 5. pantoprazole 6. rabeprazole
omeprazole/sodium bicarbonate powder for oral suspension	**Omeprazole/sodium bicarbonate powder** is considered medically necessary when there is documentation of failure, contraindication, or intolerance to **FIVE** of the following: 1. dexlansoprazole

Product	Criteria
	2. esomeprazole 3. lansoprazole 4. omeprazole 5. pantoprazole 6. rabeprazole
Prevacid SoluTab delayed-release orally disintegrating tablets (lansoprazole)	**Prevacid SoluTab** is considered medically necessary when there is documentation of **BOTH** of the following: 1. Trial of **lansoprazole delayed-release orally disintegrating tablets** (the bioequivalent generic product) AND cannot take due to a formulation difference in the inactive ingredient(s) which would result in a significant allergy or serious adverse reaction 2. Failure, contraindication, or intolerance to **FOUR** of the following: A. dexlansoprazole B. esomeprazole C. omeprazole D. pantoprazole E. rabeprazole
Voquezna (vonoprazan)	**Voquezna** is considered medically necessary when there is failure, contraindication, or intolerance to **ONE** of the following: 1. dexlansoprazole 2. esomeprazole 3. omeprazole 4. pantoprazole 5. rabeprazole
Zegerid capsules (omeprazole/sodium bicarbonate)	**Standard/Performance/Legacy Drug List Plans:** **Zegerid capsules** is considered medically necessary when there is documentation of failure, contraindication, or is intolerant to **FIVE** of the following: 1. dexlansoprazole 2. esomeprazole 3. lansoprazole 4. omeprazole 5. pantoprazole 6. rabeprazole
Zegerid powder for oral suspension (omeprazole/sodium bicarbonate)	**Standard/Performance/Legacy Drug List Plans:** **Zegerid powder** is considered medically necessary when there is documentation of failure, contraindication, or is intolerant to **FIVE** of the following: 1. dexlansoprazole 2. esomeprazole 3. lansoprazole 4. omeprazole 5. pantoprazole 6. rabeprazole

Individual and Family Plans:

Product	Criteria
Voquezna (vonoprazan)	**Voquezna** is considered medically necessary when there is failure, contraindication, or intolerance to **TWO** of the following: 1. dexlansoprazole 2. esomeprazole 3. omeprazole 4. pantoprazole tablet 5. rabeprazole tablet

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Receipt of sample product does not satisfy any criteria requirements for coverage.

References

1. Prilosec OTC® delayed-release tablets [prescribing information]. Cincinnati, OH: Procter and Gamble; October 2022.
2. Prevacid® 24HR delayed-release capsules [prescribing information]. Allegan, MI: Perrigo; June 2022.
3. Zegerid OTC® capsules [prescribing information]. Whippany, NJ: Bayer; March 2022.
4. Nexium® 24HR delayed-release capsules and tablets [prescribing information]. Warren, NJ: GlaxoSmithKline; June 2022.
5. Omeprazole delayed-release capsules [prescribing information]. North Wales, PA: Teva; November 2020.
6. Prilosec® delayed-release suspension [prescribing information]. Zug, Switzerland: Covis; November 2020.
7. Nexium® delayed-release capsules [prescribing information]. Wilmington, DE: AstraZeneca; August 2021.
8. Prevacid® delayed-release capsules and orally disintegrating tablets [prescribing information]. Deerfield, IL: Takeda; March 2022.
9. Aciphex® Sprinkle™ delayed-release capsules [prescribing information]. Woodcliff Lake, NJ: Eisai, December 2020.
10. Protonix® delayed-release tablets and oral suspension [prescribing information]. Philadelphia, PA: Wyeth; March 2022.
11. Aciphex® delayed-release tablets [prescribing information]. Woodcliff Lake, NJ: Eisai, November 2020.
12. Zegerid® capsules [prescribing information]. Bridgewater, NJ: Salix; March 2022.
13. Dexilant™ delayed-release capsules [prescribing information]. Deerfield, IL: Takeda; March 2022.
14. Esomeprazole strontium delayed-release capsules [prescribing information]. Glasgow, KY: Amneal; January 2021.
15. Moayyedi P, Lacy BE, Andrews CN, et al. ACG and CAG Clinical Guideline: Management of Dyspepsia. *Am J Gastroenterol.* 2017; 112(7):988-1013.
16. Katz PO, Dunbar KB, Schnoll-Sussman FH, et al. ACG Clinical Guideline for the Diagnosis and Management of Gastroesophageal Reflux Disease. *Am J Gastroenterol*. 2022; 117(1):27-56.
17. Rosen R, Vandenplas Y, Singendonk M, et al. Pediatric Gastroesophageal Reflux Clinical Practice Guidelines: Joint Recommendations of the North American Society for Pediatric

Gastroenterology, Hepatology, and Nutrition and the European Society for Pediatric Gastroenterology, Hepatology, and Nutrition. *J Pediatr Gastroenterol Nutr.* 2018; 66(3):516-554.
18. Shaheen NJ, Falk GW, Iyer PG, et al. Diagnosis and Management of Barrett's Esophagus: An Updated ACG Guideline. Am J Gastroenterol. 2022; 117(4):559-587.
19. Konvomep oral suspension [prescribing information]. Woburn, MA. Azurity pharmaceuticals; March 2023.
20. Voquezna® tablets [prescribing information]. Buffalo Grove, IL: Phathom Pharmaceuticals Inc.; November 2023.

Revision Details

Type of Revision	Summary of Changes	Date
Annual Revision	No criteria changes	04/15/2024
Selected Revision	Voquezna tablet was added to the policy, for both Employer and IFP.	05/01/2024

The policy effective date is in force until updated or retired.