PRIOR AUTHORIZATION CRITERIA

BRAND NAME*
(generic)

VOQUEZNA
(vonoprazan)

Status: CVS Caremark® Criteria
Type: Initial Prior Authorization with Quantity Limit ***Ref # 6249-C***

**Drugs that are listed in the target drug box include both brand and generic and all dosage forms and strengths unless otherwise stated. OTC products are not included unless otherwise stated.*

FDA-APPROVED INDICATIONS

VOQUEZNA is indicated:

- for healing of all grades of erosive esophagitis and relief of heartburn associated with erosive esophagitis in adults.
- to maintain healing of all grades of erosive esophagitis and relief of heartburn associated with erosive esophagitis in adults.
- for the relief of heartburn associated with non-erosive gastroesophageal reflux disease in adults.
- in combination with amoxicillin and clarithromycin for the treatment of Helicobacter pylori (H. pylori) infection in adults.
- in combination with amoxicillin for the treatment of H. pylori infection in adults.

COVERAGE CRITERIA

Maintenance of Healing of Erosive Esophagitis (EE)
Authorization may be granted when the requested drug is being prescribed for maintenance of healing of all grades of erosive esophagitis and relief of heartburn associated with erosive esophagitis in an adult when ALL of the following criteria are met:

- The patient meets ONE of the following:
  - The patient has experienced an inadequate treatment response to a one-month trial of a proton pump inhibitor (PPI)
  - The patient has experienced an intolerance to a PPI
  - The patient has a contraindication that would prohibit a trial of a PPI
- The request is for Voquezna 10 mg tablets

Relief of Heartburn Associated with Non-erosive Gastroesophageal Reflux (NERD)
Authorization may be granted when the requested drug is being prescribed for the relief of heartburn associated with non-erosive gastroesophageal reflux disease in an adult when ALL of the following criteria are met:

- The patient meets ONE of the following:
  - The patient has experienced an inadequate treatment response to on-demand or intermittent proton pump inhibitor (PPI) therapy
  - The patient has experienced an intolerance to a PPI
  - The patient has a contraindication that would prohibit a trial of a PPI
- The request is for Voquezna 10 mg tablets

Treatment of Healing of Erosive Esophagitis (EE)

Authorization may be granted when the requested drug is being prescribed for the treatment of healing of all grades of erosive esophagitis and relief of heartburn associated with erosive esophagitis in an adult when ALL of the following criteria are met:

- The patient meets ONE of the following:
  - The patient has experienced an inadequate treatment response to a one-month trial of a proton pump inhibitor (PPI)
  - The patient has experienced an intolerance to a PPI
  - The patient has a contraindication that would prohibit a trial of a PPI

Treatment of Helicobacter pylori (H. pylori)
Authorization may be granted when the requested drug is being prescribed for the treatment of Helicobacter pylori (H. pylori) infection in an adult in combination with amoxicillin as dual therapy OR amoxicillin and clarithromycin as triple therapy when the following criteria is met:

- The request is for Voquezna 20 mg tablets

QUANTITY LIMITS APPLY

QUANTITY LIMIT

Drug	1 Month Limit	3 Month Limit
Maintenance of healing of EE	30 tablets / 25 days*	90 tablets / 75 days*
Relief of heartburn associated with NERD	28 tablets / 28 days	Does Not Apply**
Treatment of healing of EE	30 tablets / 25 days*	Does Not Apply**
Treatment of H. Pylori	28 tablets / 14 days	Does Not Apply**

**The duration of 25 days is used for a 30-day fill period and 75 days is used for a 90-day fill period to allow time for refill processing.*
****These drugs are for short-term acute use; therefore, the intent is for prescriptions of the requested drug to be filled one month at a time; there should be no 3-month supplies filled.**

DURATION OF APPROVAL (DOA)

- 6249-C:
  - Treatment of H. pylori: DOA: 14 days
  - Relief of heartburn associated with non-erosive gastroesophageal reflux: DOA: 4 weeks
  - Treatment of healing of erosive esophagitis: DOA: 8 weeks
  - Maintenance of healing of erosive esophagitis: DOA: 6 months

REFERENCES

1. Voquezna [package insert]. Buffalo Grove, IL: Phathom Pharmaceuticals Inc.; July 2024.
2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2024. https://online.lexi.com. Accessed February 27, 2024.
3. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: https://www.micromedexsolutions.com/ (cited: *02/27/2024*).
4. 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.
5. Chey WD, Leontiadis GI, Howden CW, et al. ACG Clinical Guideline: Treatment of Helicobacter pylori Infection. *Am J Gastroenterol*. 2017;112(2):212-239.

Written by: UM Development (VLS)
Date Written: 11/2023
Revised: (KEJ) 03/2024 (no clinical changes), (MRS) 07/2024 (added coverage and QL for NERD, clarified strength for indication in CC and Qset)

Reviewed: Medical Affairs: (CHART) 11/30/2023, 03/28/2024, 08/08/2024
External Review: (P&T) 02/2024, 06/2024, 10/2024

CRITERIA FOR APPROVAL

1	Is the requested drug being prescribed for the treatment of healing of all grades of erosive esophagitis and relief of heartburn associated with erosive esophagitis in an adult? [If Yes, then go to 2. If No, then go to 6.]	Yes	No
2	Has the patient experienced an inadequate treatment response to a one-month trial of a proton pump inhibitor (PPI)? [If Yes, then go to 5. If No, then go to 3.]	Yes	No
3	Has the patient experienced an intolerance to a proton pump inhibitor (PPI)? [If Yes, then go to 5. If No, then go to 4.]	Yes	No
4	Does the patient have a contraindication that would prohibit a trial of a proton pump inhibitor (PPI)? [If Yes, then go to 5. If No, then no further questions.]	Yes	No
5	Does the patient require MORE than the plan allowance of 30 tablets per month of Voquezna? [No further questions] RPh Note: If yes, then deny and enter a partial approval for 30 tablets / 25 days of Voquezna.	Yes	No
6	Which drug is being requested? [NOTE: Please check which drug.] [] Voquezna 10 mg tablet (If checked, go to 7) [] Voquezna 20 mg tablet (If checked, go to 17)		
7	Is the requested drug being prescribed for maintenance of healing of all grades of erosive esophagitis and relief of heartburn associated with erosive esophagitis in an adult? [If Yes, then go to 8. If No, then go to 12.]	Yes	No
8	Has the patient experienced an inadequate treatment response to a one-month trial of a proton pump inhibitor (PPI)? [If Yes, then go to 11. If No, then go to 9.]	Yes	No
9	Has the patient experienced an intolerance to a proton pump inhibitor (PPI)? [If Yes, then go to 11. If No, then go to 10.]	Yes	No
10	Does the patient have a contraindication that would prohibit a trial of a proton pump inhibitor (PPI)? [If Yes, then go to 11. If No, then no further questions.]	Yes	No

11	Does the patient require MORE than the plan allowance of 30 tablets per month of Voquezna 10 mg? [No further questions] RPh Note: If yes, then deny and enter a partial approval for 30 tablets / 25 days or 90 tablets / 75 days of Voquezna 10 mg.	Yes	No
12	Is the requested drug being prescribed for the relief of heartburn associated with non-erosive gastroesophageal reflux disease in an adult? [If Yes, then go to 13. If No, then no further questions.]	Yes	No
13	Has the patient experienced an inadequate treatment response to on-demand or intermittent proton pump inhibitor (PPI) therapy? [If Yes, then go to 16. If No, then go to 14.]	Yes	No
14	Has the patient experienced an intolerance to a proton pump inhibitor (PPI)? [If Yes, then go to 16. If No, then go to 15.]	Yes	No
15	Does the patient have a contraindication that would prohibit a trial of a proton pump inhibitor (PPI)? [If Yes, then go to 16. If No, then no further questions.]	Yes	No
16	Does the patient require MORE than the plan allowance of 28 tablets per 28 days of Voquezna 10 mg? [No further questions] RPh Note: If yes, then deny and enter a partial approval for 28 tablets / 28 days of Voquezna 10 mg.	Yes	No
17	Is the requested drug being prescribed for the treatment of Helicobacter pylori (H. pylori) infection in an adult in combination with amoxicillin as dual therapy OR amoxicillin and clarithromycin as triple therapy? [If Yes, then go to 18. If No, then no further questions.]	Yes	No
18	Does the patient require MORE than the plan allowance of 28 tablets per 14 days of Voquezna 20 mg? [No further questions] RPh Note: If yes, then deny and enter a partial approval for 28 tablets / 14 days of Voquezna 20 mg.	Yes	No

Mapping Instructions			
	Yes	**No**	**DENIAL REASONS**
1.	Go to 2	Go to 6	
2.	Go to 5	Go to 3	

3.	Go to 5	Go to 4	
4.	Go to 5	Deny	Your plan only covers this drug if you have tried a proton pump inhibitor (PPI) for one month, and it did not work well for you. We have denied your request because: A) You have not tried it, and B) You do not have a medical reason not to take it. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Step Therapy]
5.	Deny	[PA Approved for 8 weeks. Approve 30 tablets per 25 days.* No 3 month supplies.]. Approve, 8 Weeks	We have denied your request because it is for more than the amount your plan covers (quantity limit). We reviewed the information we had. We have partially approved your request for this drug up to the amount your plan covers (30 tablets per month). Your request for more drug has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Quantity, Exceeds max limit, Partial denial - EE]
6.	1=7 ;2=17		
7.	Go to 8	Go to 12	
8.	Go to 11	Go to 9	
9.	Go to 11	Go to 10	
10.	Go to 11	Deny	Your plan only covers this drug if you have tried a proton pump inhibitor (PPI) for one month, and it did not work well for you. We have denied your request because: A) You have not tried it, and B) You do not have a medical reason not to take it. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Step Therapy]
11.	Deny	[PA Approved for 6 months. Approve 30 tablets per 25 days* or 90 tablets per 75	We have denied your request because it is for more than the amount your plan covers (quantity limit). We reviewed the information we had. We have partially approved your request for this drug up to the amount your plan covers (30 tablets per month). Your request for more drug has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug

		days* of Voquezna 10 mg.]. Approve, 6 Months	policy for more details. You can also request other plan documents for your review. [Short Description: Quantity, Exceeds max limit, Partial denial - EE]
12.	Go to 13	Deny	Your plan only covers this drug when it is used for certain health conditions. Covered uses are A) Healing erosive esophagitis (EE) in an adult, B) Maintaining healed erosive esophagitis (EE) in an adult, and C) Treating heartburn from non-erosive gastroesophageal reflux disease (NERD) in an adult. Your plan does not cover this drug for your health condition that your doctor told us you have. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Diagnosis, 10 mg]
13.	Go to 16	Go to 14	
14.	Go to 16	Go to 15	
15.	Go to 16	Deny	Your plan only covers this drug if you have tried a proton pump inhibitor (PPI) when needed, and it did not work well for you. We have denied your request because: A) You have not tried it, and B) You do not have a medical reason not to take it. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Step Therapy, On-demand PPI]
16.	Deny	[PA Approved for 4 weeks. Approve 28 tablets per 28 days* of Voquezna 10 mg. No 3 month supplies.]. Approve, 4 Weeks	We have denied your request because it is for more than the amount your plan covers (quantity limit). We reviewed the information we had. We have partially approved your request for this drug up to the amount your plan covers (28 tablets per 28 days). Your request for more drug has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Quantity, Exceeds max limit, Partial denial - NERD]
17.	Go to 18	Deny	Your plan only covers this drug when it is used for certain health conditions. Covered uses are healing erosive esophagitis (EE) in an adult, and treating Helicobacter pylori (H. pylori) infection along with certain antibiotics in an adult. Your plan does not cover this drug for your health condition that your

			doctor told us you have. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Diagnosis, 20 mg]
18.	Deny	[PA Approved for 14 days. Approve 28 tablets per 14 days of Voquezna 20 mg. No 3 month supplies.]. Approve, 14 Days	We have denied your request because it is for more than the amount your plan covers (quantity limit). We reviewed the information we had. We have partially approved your request for this drug up to the amount your plan covers (28 tablets per 14 days). Your request for more drug has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review. [Short Description: Quantity, Exceeds max limit, Partial denial - H. Pylori]