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1518-C

Prior Authorization Criteria

Initial Prior Authorization with Quantity Limit

Konvomep-Zegerid

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Konvomep	omeprazole/sodium bicarbonate
Zegerid	omeprazole/sodium bicarbonate

Indications

FDA-approved Indications

Konvomep

Konvomep is indicated in adults for:

- Short term treatment (4-8 weeks) of active benign gastric ulcer.
- Reduction of risk of upper gastrointestinal (GI) bleeding in critically ill adult patients.

Zegerid

Zegerid for oral suspension and Zegerid capsules are indicated in adults for the:

- Short-term treatment of active duodenal ulcer. Most patients heal within four weeks. Some patients may require an additional four weeks of therapy.

- Short-term treatment (4 to 8 weeks) of active benign gastric ulcer.
- Treatment of heartburn and other symptoms associated with GERD for up to 4 weeks.
- Short-term treatment (4 to 8 weeks) of EE due to acid-mediated GERD which has been diagnosed by endoscopy in adults.
    - The efficacy of Zegerid used for longer than 8 weeks in patients with EE has not been established. If a patient does not respond to 8 weeks of treatment, an additional 4 weeks of treatment may be given. If there is recurrence of EE or GERD symptoms (e.g., heartburn), additional 4 to 8-week courses of Zegerid may be considered.
- Maintenance of healing of EE due to acid-mediated GERD. Controlled studies do not extend beyond 12 months.

Zegerid for oral suspension is indicated in adults for the:

- Reduction of risk of upper GI bleeding in critically ill adult patients.

Coverage Criteria

Duodenal Ulcer, Erosive Esophagitis, Gastric Ulcer, Gastroesophageal Reflux Disease (GERD)

Authorization may be granted for the requested drug when ALL of the following criteria are met:

- The patient has experienced an inadequate treatment response, intolerance, or a contraindication to THREE generic proton pump inhibitors. [ACTION REQUIRED: Documentation is required for approval.]
- The patient meets ONE of the following criteria:
    - The request is for Zegerid (omeprazole/sodium bicarbonate) being prescribed for ANY of the following:
        - Gastroesophageal reflux disease (GERD).
        - Duodenal ulcer.
        - Gastric ulcer.
        - Short-term treatment of erosive esophagitis.
        - Maintenance of healing of erosive esophagitis.
    - The request is for Konvomep (omeprazole/sodium bicarbonate) being prescribed for the short-term treatment of gastric ulcer.

Quantity Limits Apply

Konvomep 600 mL / 25 days or 1800 mL / 75 days.

Zegerid 30 capsules or packets / 25 days or 90 capsules or packets / 75 days.

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.

Duration of Approval (DOA)

- 1518-C:
  - Konvomep: DOA: 3 months
  - Zegerid (Gastroesophageal reflux disease (GERD), Duodenal ulcer, Gastric ulcer, Short-term treatment of erosive esophagitis): DOA: 3 months
  - Zegerid (Maintenance healing of erosive esophagitis): DOA: 12 months

References

1. Konvomep [package insert]. Woburn, MA: Azurity Pharmaceuticals, Inc.; April 2024.
2. Zegerid [package insert]. Bridgewater, NJ: Salix Pharmaceuticals; July 2023.
3. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2025. https://online.lexi.com. Accessed February 07, 2025.
4. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: https://www.micromedexsolutions.com/ (cited: 02/06/2025).
5. Katz P, Dunbar K, Schnoll-Sussman F, et al. ACG Clinical Guideline for the Diagnosis and Management of Gastroesophageal Reflux Disease. Am J Gastroenterol. 2022; 117(1):27-56.
6. Kavitt R, Lipowska A, Anyane-Yeboa A, et al. Diagnosis and Treatment of Peptic Ulcer Disease. The American Journal of Medicine (2019) 132(4):447-456.

Document History

Written by: UM Development (RP)

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External Review: 12/2016, 12/2017, 12/2018, 12/2019, 12/2020, 06/2021, 06/2022, (FYI) 10/2022, 06/2023, 06/2024, 06/2025

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CRITERIA FOR APPROVAL

1	Has the patient experienced an inadequate treatment response, intolerance, or does the patient have a contraindication to THREE generic proton pump inhibitors? ACTION REQUIRED: If yes, then documentation is required for approval. Document the drug names: _____ [If Yes, then go to 2. If No, then no further questions.]	Yes	No
2	Has documentation of the patient's previous drug trials or contraindication, including the drug names (THREE generic proton pump inhibitors) been submitted to CVS Health? [If Yes, then go to 3. If No, then no further questions.]	Yes	No
3	Is this request for Zegerid (omeprazole/sodium bicarbonate)? [If Yes, then go to 4. If No, then go to 8.]	Yes	No
4	Is the requested drug being prescribed for ANY of the following: A) Gastroesophageal reflux disease (GERD), B) Duodenal ulcer, C) Gastric ulcer, D) Short-term treatment of erosive esophagitis? [If Yes, then go to 5. If No, then go to 6.]	Yes	No
5	Does the patient require MORE than the plan allowance of 30 capsules or 30 packets for oral suspension per month of Zegerid (omeprazole/sodium bicarbonate)? [No further questions] RPh Note: If yes, then deny and enter a partial approval for 30 capsules or packets per 25 days or 90 capsules or packets per 75 days of Zegerid (omeprazole/sodium bicarbonate).	Yes	No
6	Is the requested drug being prescribed for the maintenance of healing of erosive esophagitis? [If Yes, then go to 7. If No, then no further questions.]	Yes	No
7	Does the patient require MORE than the plan allowance of 30 capsules or 30 packets for oral suspension per month of Zegerid (omeprazole/sodium bicarbonate)? [No further questions] RPh Note: If yes, then deny and enter a partial approval for 30 capsules or packets per 25 days or 90 capsules or packets per 75 days of Zegerid	Yes	No

(omeprazole/sodium bicarbonate).

8	Is the requested drug being prescribed for the short-term treatment of gastric ulcer? [If Yes, then go to 9. If No, then no further questions.]	Yes	No
9	Does the patient require MORE than the plan allowance of 600 mL per month of Konvomep (omeprazole/sodium bicarbonate)? [No further questions] RPh Note: If yes, then deny and enter a partial approval for 600 mL per 25 days or 1800 mL per 75 days of Konvomep (omeprazole/sodium bicarbonate).	Yes	No

Mapping Instructions			
	Yes	**No**	**DENIAL REASONS**
1.	Go to 2	Deny	Your plan only covers this drug if you have tried other drugs and they did not work well for you. We have denied your request because: A) You have not tried THREE generic proton pump inhibitors (PPIs), and B) You do not have a medical reason not to take them. 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 - three generic PPIs]
2.	Go to 3	Deny	Your plan only covers this drug when records with your previous drug trials or contraindication are sent to us. Your records must be provided and must show what your doctor tells us. We denied your request because we did not receive your records. 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: Documentation]

3.	Go to 4	Go to 8	
4.	Go to 5	Go to 6	
5.	Deny	[PA approved for 3 months. Approve 30 capsules or packets per 25 days or 90 capsules or packets per 75 days]. Approve, 3 Months	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 capsules or 30 packets 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 - Zegerid]
6.	Go to 7	Deny	Your plan only covers this drug when it is used for certain health conditions. Covered uses are A) Gastroesophageal reflux disease (GERD), B) Duodenal ulcer, C) Gastric Ulcer, D) Erosive esophagitis that needs short-term treatment, and E) Erosive esophagitis that needs maintenance of healing. 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 - Zegerid]
7.	Deny	[PA approved for 12 months. Approve 30 capsules or packets per 25 days or	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 capsules or 30 packets 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

		90 capsules or packets per 75 days]. Approve, 12 Months	other plan documents for your review. [Short Description: Quantity, Exceeds max limit, Partial denial - Zegerid]
8.	Go to 9	Deny	Your plan only covers this drug when it is used for certain health conditions. Covered use is for the short-term treatment of gastric ulcer. Your plan does not cover the 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 - Konvomep]
9.	Deny	[PA approved for 3 months. Approve 600 mL per 25 days or 1800 mL per 75 days]. Approve, 3 Months	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 (600 mL 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 - Konvomep]