BRAND NAME (generic)

ZEGERID

(omeprazole/sodium bicarbonate)

Status: CVS Caremark Criteria Type: Initial Prior Authorization with Quantity Limit

POLICY

FDA-APPROVED INDICATIONS

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

The requested drug will be covered with prior authorization when the following criteria are met:

• The patient has experienced an inadequate treatment response, intolerance, or a contraindication to THREE generic proton pump inhibitors. Documentation is required for approval.

AND

- The requested drug is 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 OR
- The requested drug is being prescribed for the maintenance of healing of erosive esophagitis

Quantity Limits apply.

REFERENCES

- 1. Zegerid [package insert]. Bridgewater, NJ: Salix Pharmaceuticals; November 2020.
- 2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Hudson, OH: Wolters Kluwer Clinical Drug Information, Inc. http://online.lexi.com/. Accessed January 2021.
- 3. Micromedex (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA. http://www.micromedexsolutions.com/. Accessed January 2021.
- 4. Katz P, Gerson L, et al. Guidelines for the Diagnosis and Management of Gastroesophageal Reflux Disease. *Am J Gastroenterol.* 2013; Vol 108:308-328.
- 5. Fashner J, Gitu AC. Diagnosis and Treatment of Peptic Ulcer Disease and *H. pylori* Infection. *American Family Physician.* February 2015; 91(4): 236-242.

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