

Viberzi (eluxadoline)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Viberzi (eluxadoline)	May be subject to quantity limit

APPROVAL CRITERIA

Requests for Viberzi (eluxadoline) may be approved for individuals who meet the following criteria:

- I. Individual is 18 years of age or older; **AND**
- II. Individual is using for the treatment of irritable bowel syndrome with diarrhea (IBS-D); **AND**
- III. Individual has had a trial and inadequate response or intolerance to two of the following medications or has a contraindication to all of the following medications. Medication samples/coupons/discount cards are excluded from consideration as a trial.:
 - A. Loperamide; **OR**
 - B. Antispasmodics (hyoscyamine, dicyclomine) (AGA 2022); **OR**
 - C. Tricyclic antidepressants (ACG 2021).

Viberzi (eluxadoline) may not be approved for an individual with any of the following:

- I. History of chronic or severe constipation or complications resulting from constipation; **OR**
- II. Biliary duct obstruction or sphincter of Oddi dysfunction; **OR**
- III. History of pancreatitis or structural disease of the pancreas; **OR**
- IV. Excessive alcohol intake (more than 3 alcoholic beverages per day); **OR**
- V. Severe hepatic impairment (Child-Pugh Class C); **OR**
- VI. Concomitant use with Lotronex (alosetron); **OR**
- VII. History of cholecystectomy or absence of a gallbladder.

Key References:

1. Chang L, Lembo A, Sultan S. American Gastroenterological Association Institute Technical Review on the Pharmacological Management of Irritable Bowel Syndrome. *Gastroenterology*. 2014; 147(5):1149–1172. Available from: [http://www.gastrojournal.org/article/S0016-5085\(14\)01090-7/pdf](http://www.gastrojournal.org/article/S0016-5085(14)01090-7/pdf).
2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2023. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
3. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>.
4. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
5. Ford AC, Moayyedi P, Chey WD; ACG Task Force on Management of Irritable Bowel Syndrome. American College of Gastroenterology Monograph on Management of Irritable Bowel Syndrome. *Am J Gastroenterol*. 2018. Jun;113(Suppl 2):1-18.
6. Lacy BE, Pimentel M, Brenner DM, et al; ACG Clinical Guideline: Management of Irritable Bowel Syndrome. *Am J Gastroenterol*. 2021 Jan 1;116:17-44.
7. Lembo, A., Sultan, S., Chang, L., Heidelbaugh, J. J., Smalley, W., & Verne, G. N. (2022). AGA Clinical Practice Guideline on the Pharmacological Management of Irritable Bowel Syndrome With Diarrhea. *Gastroenterology*, 163(1), 137–151. <https://doi.org/10.1053/j.gastro.2022.04.017>
8. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2023; Updated periodically.
9. Weinberg DS, Smalley W, Heidelbaugh JJ, et. al. American Gastroenterological Association Institute Guideline on the Pharmacological Management of Irritable Bowel Syndrome. *Gastroenterology*. 2014; 147(5):1146-48.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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