

Market Applicability							
Market	DC	GA	KY	MD	NJ	NY	WA
Applicable	X	X	X	X	X	X	NA

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 has been on Viberzi (eluxadoline) in the past 180 days (medication samples/ coupons/ discount cards are excluded from consideration as a trial) **(DOES NOT APPLY FOR EXCHANGE BUSINESS)**;

OR

- II. Individual is 18 years of age or older; **AND**
- III. Individual is using for the treatment of irritable bowel syndrome with diarrhea (IBS-D); **AND**
- IV. Individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) and inadequate response or intolerance to two of the following medications or has a contraindication to all of the following medications:
 - A. Loperamide; **OR**
 - B. Antispasmodics (hyoscyamine, dicyclomine); **OR**
 - C. Tricyclic antidepressants (ACG 2018).

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

- I. History of 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.

Market Applicability							
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Applicable	X	X	X	X	X	X	NA

State Specific Mandates		
State name	Date effective	Mandate details (including specific bill if applicable)
N/A	N/A	N/A

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). Accessed on: June 6, 2019.
2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2019. 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>. Accessed: June 6, 2019.
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. Available at: https://journals.lww.com/ajg/Fulltext/2018/06002/American_College_of_Gastroenterology_Monograph_on.1.aspx Accessed on June 9, 2019.
6. Lauritano EC, Gabrielli M, Scarpellini E, et. al. Antibiotic therapy in small intestinal bacterial overgrowth: rifaximin versus metronidazole. *Eur Rev Med Pharmacol Sci*. 2009; 13(2): 111-6.
7. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2019; Updated periodically.
8. Vilstrup H, Amodio P, Bajaj J, et al. Hepatic Encephalopathy in Chronic Liver Disease: 2014 Practice Guideline by American Association for the Study of Liver Diseases and the European Association for the Study of the Liver. *Hepatology*. 2014;60(2):715-35.
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.

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.