

# Drug Policy

<b>Policy:</b>	<b>Viberzi (eluxadoline)</b>	<b>Annual Review Date:</b> <b>05/16/2024</b>  <b>Last Revised Date:</b> <b>05/16/2024</b>
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## OVERVIEW

Viberzi (eluxadoline) is an antidiarrheal agent used for the treatment of irritable bowel syndrome with predominant diarrhea symptoms (IBS-D) in men and women. Irritable bowel syndrome (IBS) is one of the most commonly diagnosed gastrointestinal disorder. It affects more than one in ten individuals and twice as many females as males. Symptoms include bloating, lower abdominal pain, and diarrhea or constipation. Individuals with IBS may also have visceral hypersensitivity, abnormal central processing of pain, and higher levels of psychological comorbidity than those without IBS. The exact cause of IBS is unclear. Viberzi modestly improves abdominal pain and loose stools in up to one in eight patients over about six months. It is more effective at improving the symptoms of loose stool and less likely to improve abdominal pain. It may be considered in patients who did not experience relief with the antidiarrheal loperamide or who note excessive constipation while taking loperamide. Viberzi works through a dual mechanism: Peripherally acting mu- and kappa-opioid agonist and delta-opioid antagonist. The 2015 World Gastroenterology Organization Global Guidelines suggest that more studies are needed to define the position of Viberzi in IBS management.

## POLICY STATEMENT

This policy involves the use of Viberzi. Prior authorization is recommended for pharmacy benefit coverage of Viberzi. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

Because of the specialized skills required for evaluation and diagnosis of patients treated with Viberzi as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Viberzi be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

## RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Viberzi is recommended in those who meet the following criteria:

### 1. Irritable Bowel Syndrome with Diarrhea, Initial Therapy

**Criteria.** *Patient must meet the following criteria (A, B, C, D, E, and F):*

**A.** The patient is 18 years of age or older; AND

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- B. Viberzi is prescribed by or in consultation with a gastroenterologist or a physician who specializes in the management of gastrointestinal disease; AND
- C. The patient has attempted lifestyle changes, including maintaining a diet rich in fiber and/or fiber supplementation; AND
- D. The patient has failed or is intolerant to at least 2 of the following in the past three months (a, b, or c):
  - a. At least one antidiarrheal agent (e.g. loperamide); OR
  - b. At least one antispasmodic agent (e.g. dicyclomine); OR
  - c. At least one tricyclic antidepressant (e.g. amitriptyline); AND
- E. The patient has tried Xifaxan OR alosetron tablets (Lotronex, generics); AND
- F. The patient is not taking medications that may lead to severe constipation (e.g. Lotronex [alosecron], anticholinergic medications, and opioids); AND
- G. The patient does not have a known or suspected history of any of the following conditions (a, b, c, d, e, f, g, or h):
  - a. Gallbladder removal; OR
  - b. Alcoholism, alcohol abuse, alcohol addiction, or consumption of more than 3 alcoholic drinks daily; OR
  - c. Biliary duct obstruction; OR
  - d. Sphincter of Oddi disease; OR
  - e. Severe hepatic impairment (Child-Pugh Class C); OR
  - f. Pancreatitis; OR
  - g. Severe constipation; OR
  - h. Gastrointestinal obstruction.

## 2. Irritable Bowel Syndrome with Diarrhea, Continuation of Therapy

**Criteria.** *Patient must meet the following criteria*

- A. The patient is 18 years of age or older; AND
- B. Viberzi is prescribed by or in consultation with a gastroenterologist or a physician who specializes in the management of gastrointestinal disease; AND
- C. The patient has demonstrated a beneficial response to Viberzi, per the prescribing physician (e.g. improved stool consistency from baseline); AND
- D. The patient has no contraindications to Viberzi.

### **Initial Approval/ Extended Approval.**

A) *Initial Approval:* 180 days

B) *Extended Approval:* 365 days

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### **CONDITIONS NOT RECOMMENDED FOR APPROVAL**

Viberzi has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

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1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

## Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

## REFERENCES

1. Peery AF, Dellon ES, Lund J, et al. Burden of gastrointestinal disease in the United States: 2012 update. *Gastroenterology* 2012; 143:1179.
2. Ford AC, Moayyedi P, Lacy BE, et al. American College of Gastroenterology monograph on the management of irritable bowel syndrome and chronic idiopathic constipation. *Am J Gastroenterol* 2014; 109 Suppl 1:S2.
3. Mearin F, Lacy BE, Chang L, et al. Bowel Disorders. *Gastroenterology* 2016.
4. 10. World Gastroenterology Organisation Global Guidelines Irritable Bowel Syndrome: A Global Perspective. Quigley, Eamonn M. M. Fried, Michael. Gwee, Kok-Ann et al. *Journal of clinical gastroenterology* 2015; 50(9):704-713.
5. Viberzi Prescribing Information. Allergan USA, Inc. Irvine, CA. November 2017.
6. Eluxadoline. In: DRUGDEX [online database]. Truven Health Analytics; Greenwood Village, CO. Last updated 29 March 2019. Accessed on 14 May 2019.