Viberzi (eluxadoline)

**Background**
Viberzi is an oral medication that activates receptors in the nervous system that can lessen bowel contractions in adult patients with irritable bowel syndrome with diarrhea (IBS-D) (1).

**Regulatory Status**
FDA-approved indication: Viberzi is a mu-opioid receptor agonist, indicated in adults for the treatment of irritable bowel syndrome with diarrhea (IBS-D) (1).

Viberzi is contraindicated in people with known or suspected biliary duct obstruction or sphincter of Oddi disease or dysfunction, alcoholism, alcohol abuse or drink more than 3 alcoholic beverages per day, a history of pancreatitis including known or suspected pancreatic duct obstruction, severe hepatic impairment (Child-Pugh Class C), severe constipation or sequelae from constipation or mechanical gastrointestinal obstruction (1).

In patients with mild (Child-Pugh Class A) or moderate (Child-Pugh Class B) hepatic impairment, plasma concentrations of Viberzi increase. Viberzi should be given at a reduced dose of 75 mg twice daily to these patients. Monitor patients with any degree of hepatic impairment for impaired mental or physical abilities needed to perform potentially hazardous activities such as driving a car or operating machinery and for other drug-related adverse reactions (1).
Also, Viberzi should be given at a reduced dose of 75 mg twice daily in patients who do not have a gallbladder, are unable to tolerate the 100 mg dose, or are receiving concomitant OATP1B1 inhibitors (1).

Safety and effectiveness in pediatric patients have not been established (1).

**Related policies**

Xifaxan

**Policy**

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Viberzi may be considered medically necessary for patients 18 years of age or older with irritable bowel syndrome with diarrhea and if the conditions indicated below are met.

Viberzi is considered investigational in patients less than 18 years of age and for all other indications.

**Prior-Approval Requirements**

**Age** 18 years of age or older

**Diagnosis**

Patient must have the following:

Irritable bowel syndrome with diarrhea

AND ALL of the following:

1. Inadequate treatment response, intolerance, or contraindication to TWO anti-diarrheal medications
2. Average daily stool consistency score (Bristol Stool Scale or BSS) of Type 5 or higher ([available at https://www.bladderandbowel.org/help-information/resources/bristol-stool-form-scale/](https://www.bladderandbowel.org/help-information/resources/bristol-stool-form-scale/))

AND NONE of the following:

1. Biliary duct obstruction or sphincter of Oddi disease
2. Alcoholism or drink more than 3 alcoholic beverages per day
3. History of pancreatitis, structural diseases of the pancreas, including known or suspected pancreatic duct obstruction
4. Severe hepatic impairment (Child-Pugh Class C)
5. Gastrointestinal obstruction
6. Severe constipation

Prior – Approval Renewal Requirements

Age
18 years of age or older

Diagnosis

Patient must have the following:

Irritable bowel syndrome with diarrhea

AND ALL of the following:
1. Reduction in stool consistency score BSS

AND NONE of the following:
1. Biliary duct obstruction or sphincter of Oddi disease
2. Alcoholism or drink more than 3 alcoholic beverages per day
3. Pancreatic duct obstruction
4. Severe hepatic impairment (Child-Pugh Class C)
5. Gastrointestinal obstruction
6. Severe constipation

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity

75mg  180 capsules per 90 days OR
100mg  180 capsules per 90 days
Duration 3 months

Prior – Approval *Renewal Limits*

**Quantity**

- 75mg 180 capsules per 90 days OR
- 100mg 180 capsules per 90 days

Duration 3 months

**Rationale**

**Summary**

Viberzi is an oral medication that activates receptors in the nervous system that can lessen bowel contractions in adult patients with irritable bowel syndrome with diarrhea (IBS-D) in patients 18 years of age or older. Safety and effectiveness in pediatric patients have not been established (1).

Prior approval is required to ensure the safe, clinically appropriate and cost effective use of Viberzi while maintaining optimal therapeutic outcomes.

**References**


**Policy History**

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<tr>
<td>July 2015</td>
<td>New addition to PA</td>
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<td>September 2015</td>
<td>Annual review</td>
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<td>December 2015</td>
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<tr>
<td>March 2016</td>
<td>Change of the BSS score from 5.5 to 5</td>
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### 5.50.07

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<th>Prescription Drugs</th>
<th>Effective Date:</th>
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<tr>
<td>Subsection:</td>
<td>Anti-diarrheal Agents</td>
<td>Original Policy Date:</td>
<td>July 24, 2015</td>
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September 2016  
Annual review and reference update  
Added the age to renewal and 3 month duration  

March 2017  
Annual review  

November 2017  
Addition of the Bristol Stool chart link (available at https://www.bladderandbowel.org/help-information/resources/bristol-stool-form-scale/) and reference  

March 2018  
Annual review and reference update  

March 2019  
Annual review and reference update  

### Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 15, 2019 and is effective on April 1, 2019.