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Section:	Prescription Drugs	**Effective Date:**	July 1, 2024
Subsection:	Gastrointestinal Agents	**Original Policy Date:**	July 24, 2015
Subject:	Viberzi	**Page:**	1 of 5

Last Review Date: June 13, 2024

Viberzi

Description

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).

Following a single oral 100 mg dose in subjects with varying degrees of liver impairment and healthy subjects, mean Viberzi plasma exposure was 6-fold, 4-fold, and 16-fold higher in mild, moderate, and severe hepatically impaired subjects (Child Pugh Class A, B, C), respectively, compared to subjects with normal liver function (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** if the conditions indicated below are met.

Viberzi may be considered **investigational** 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/)*

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	180 capsules per 90 days
Duration	12 months

Prior – Approval *Renewal* Limits

Same as above

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

1. Viberzi [package insert]. Madison, NJ: Allergan USA, Inc.; June 2020.
2. Blake MR, Raker JM, Whelan K. Validity and reliability of the Bristol Stool Form Scale in healthy adults and patients with diarrhoea-predominant irritable bowel syndrome. Aliment Pharmacol Ther. 2016 Oct;44(7):693-703. doi: 10.1111/apt.13746. Epub 2016 Aug 5.

Policy History

Date	Action
July 2015	New addition to PA
September 2015	Annual review
December 2015	Annual review
March 2016	Change of the BSS score from 5.5 to 5 Policy change from 5.09.07 to 5.50.07
June 2016	Annual Review
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
March 2020	Annual review. Changed quantity to 180 capsules per 90 days so the strengths are set together. Changed approval durations to 12 months
June 2020	Annual review
December 2021	Annual review and reference update
September 2022	Annual review. Per SME, added a warning regarding higher plasma exposure in hepatic impairment to regulatory status section
December 2023	Annual review
June 2024	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 13, 2024 and is effective on July 1, 2024.