Pharmacy Policy Bulletin: J-0739 Viberzi (eluxadoline) - Commercial National Select Formulary	
Number: J-0739	**Category:** Prior Authorization
Line(s) of Business: ☒ Commercial ☐ Healthcare Reform ☐ Medicare	**Benefit(s):** **Commercial:** **Prior Authorization (1.)** **1.** Other Managed Prior Authorization = Yes w/ Prior Authorization
Region(s): ☒ All ☐ Delaware ☐ New York ☐ Pennsylvania ☐ West Virginia	**Additional Restriction(s):** Applies to Commercial National Select formulary only
Version: J-0739-010	**Original Date:** 07/01/2018
Effective Date: 04/25/2025	**Review Date:** 04/09/2025

Drugs Product(s):	• Viberzi (eluxadoline)
FDA-Approved Indication(s):	• Treatment of adults with irritable bowel syndrome with diarrhea (IBS-D).

Background:	• Viberzi (eluxadoline) is a mu-opioid receptor agonist, delta opioid receptor antagonist, and kappa opioid receptor agonist in the gut slowing gastrointestinal tract motility. This receptor activity reduces diarrhea and abdominal pain.
	• Irritable bowel syndrome (IBS) is the most prevalent functional gastrointestinal disorder (FGID). IBS affects approximately 10% to 12% of adults in the United States. IBS is more common among women and is most commonly diagnosed in individuals 50 years of age or younger. IBS is characterized by recurrent abdominal pain and altered bowel habits; bloating and distention frequently coexist.
	• IBS is categorized into three main subtypes based on the predominant bowel habit:
	  ○ IBS with constipation (IBS-C)
	  ○ IBS with diarrhea (IBS-D)
	  ○ IBS with mixed symptomology (IBS-M)
	• IBS-D is defined as more than 25% of bowel movements are fluffy pieces with ragged edges or entirely liquid; less than 25% of bowel movements are hard or lumpy. The Bristol Stool Scale (BSS) may assist in defining the stool consistency. If the patient reports abnormal bowel movements that are usually diarrhea, the patient can be considered to have IBS-D. Experiencing bowel patterns with at least 3 different types of stool in a week also supports a diagnosis of IBS-D.
	• The 2021 American College of Gastroenterology (ACG) guidelines for IBS-D emphasize a positive diagnostic strategy rather than diagnostic strategy of exclusion, as well as diagnostic testing to rule out Celiac disease and inflammatory bowel disease (IBD). A limited trial of a low FODMAP (fermentable oligosaccharides, disaccharides, monosaccharides and polyols) diet is recommended to improve global symptoms of IBS. Soluble fiber (not insoluble

fiber) is suggested to be used in order to treat global ICS symptoms. Gut-directed psychotherapies to treat overall IBS symptoms as part of a comprehensive management strategy can be used in conjunction with dietary therapies and medications. The guidelines:
    - Suggests that mixed opioid agonists/antagonists be used to treat global IBS-D symptoms (conditional recommendation, moderate quality of evidence)
    - Recommend the use of rifaximin to treat global IBS-D symptoms (strong recommendation; moderate quality of evidence)
    - Recommend that tricyclic antidepressants (TCA) be used to treat global symptoms of IBS (strong recommendation; moderate quality of evidence)
    - Recommend alosetron be used to relieve global IBS-D symptoms in women with severe symptoms who have failed conventional therapy (conditional recommendation, low quality of evidence)
    - Do not suggest the use of bile acid sequestrants to treat global IBS-D symptoms (conditional recommendation, very low quality of evidence)
- The 2022 American Gastroenterological Association (AGA) Clinical Practice Guideline on the Pharmacological Management of IBS-D:
    - Suggests using eluxadoline, rifaximin, or alosetron (conditional recommendation, moderate certainty in evidence)
    - Suggests using loperamide (conditional recommendation, very low certainty in evidence)
    - Suggests using TCAs or antispasmodics (conditional recommendation, low certainty in evidence)
    - Suggests against using SSRIs (conditional recommendation, low certainty in evidence)
- Prescribing Considerations:
    - The recommended dosage for Viberzi in adults is 100 mg twice daily taken with food.
    - The recommended dosage is Viberzi 75 mg twice daily taken with food in patients:
        - Unable to tolerate the 100 mg dose
        - Receiving concomitant OATP1B1 inhibitors (e.g., cyclosporine, rifampin, gemfibrozil, antiretrovirals).
        - Mild or moderate hepatic impairment
        - Moderate or severe renal impairment
        - End stage renal disease not yet on dialysis
    - Viberzi contraindications:
        - Patients without a gallbladder
        - Severe (Child-Pugh C) hepatic impairment
        - Known or suspected biliary duct obstruction, or sphincter of Oddi disease or dysfunction
        - Alcohol abuse (more than 3 drinks per day)
        - History of pancreatitis, or known or suspected pancreatic duct obstruction
        - Chronic or severe constipation
        - Known or suspected mechanical gastrointestinal obstruction
    - Viberzi is listed as a Schedule IV controlled substances.
    - Discontinue Viberzi if patients develop severe constipation.
    - Avoid taking Viberzi with other drugs that can cause constipation.

Approval Criteria

I. Initial Authorization

When a benefit, coverage of Viberzi may be approved when all of the following criteria are met **(A., B., and C.)**:

A. The member is 18 years of age or older.

B. The member has a diagnosis of irritable bowel syndrome with diarrhea (IBS-D) (ICD-10: K58.0).

C. The member has experienced therapeutic failure or intolerance to one (1) agent from any of the following medication classes, or all are contraindicated **(1., 2., or 3.)**:

1. anti-diarrheal (e.g., loperamide)

2. anti-spasmodic (e.g., dicyclomine, hyoscyamine)

3. tricyclic antidepressant (e.g., amitriptyline, nortriptyline)

II. Reauthorization

When a benefit, reauthorization of Viberzi may be approved when all of the following criteria are met **(A. and B.)**:

A. The provider attests that the member's IBS-D symptoms continue to persist.

B. The provider attests that the member has experienced positive clinical response to therapy.

III. An exception to some or all of the criteria above may be granted for select members and/or circumstances based on state and/or federal regulations.

Limitations of Coverage

I. The member does not have any of the following **(A., B., or C.)**:

A. Gallbladder has been removed

B. Severe (Child-Pugh C) hepatic impairment

C. Alcohol abuse (more than 3 drinks per day)

II. Coverage of drug(s) addressed in this policy for disease states outside of the FDA-approved indications should be denied based on the lack of clinical data to support effectiveness and safety in other conditions unless otherwise noted in the approval criteria.

III. For members with a closed formulary, a non-formulary product will only be approved if the member meets the criteria for a formulary exception in addition to the criteria outlined within this policy.

Authorization Duration

- Commercial Plans: If approved, up to a 12 month authorization may be granted.

Automatic Approval Criteria

None

References:

1. Viberzi [package insert]. North Chicago, IL: AbbVie, Inc.; July 2024.
2. Lacy BE, Pimentel M, Brenner DM, et al. ACG Clinical Guideline: Management of Irritable Bowel Syndrome. *The American Journal of Gastroenterology*. 2021 Jan; 116:17-44.
3. Ford AC, Moayyedi P, Lacey BE, et al. American College of Gastroenterology monograph on the management of irritable bowel syndrome. *Am J Gastroenterol.* 2018 Jun;113(Suppl 2):1-18.
4. Evidence-Based Management of Irritable Bowel Syndrome With Diarrhea. AJMC. Available at: https://www.ajmc.com/view/evidencebased-management-of-irritable-bowel-syndrome-with-diarrhea. Accessed March 12, 2025.
5. Lembo A, Sultan S, Chang L, Heidelbaugh JJ, Smalley W, Verne GN. AGA Clinical Practice Guideline on the Pharmacological Management of Irritable Bowel Syndrome With Diarrhea. *Gastroenterology*. 2022;163(1):137-151.