RXADVANCE
2 Park Central Drive
Southborough, MA 01772

Clinical Policy Title: **Eluxadoline (Viberzi)**
Policy Number: **RxA.548**
Drug(s) Applied: **Eluxadoline (Viberzi™)**
Last Review Date: **01/2020**
Line of Business: **Commercial, Medicaid**

Background

Eluxadoline (Viberzi™) is a mu-opioid receptor agonist.
It is indicated in adults for the treatment of irritable bowel syndrome with diarrhea (IBSD).

Indication	Dosing Regimen	Maximum Dose
IBS-D	100 mg PO BID or 75 mg PO BID in patients who: • Are unable to tolerate the 100 mg dose of Viberzi • Are receiving concomitant OATP1B1 inhibitors • Have mild (Child-Pugh Class A) or moderate (Child-Pugh Class B) hepatic impairment	200 mg/day

Tablets: 75 mg, 100 mg

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

I. Initial Approval Criteria

A. Irritable Bowel Syndrome with Diarrhea (must meet all)**:**

1. Diagnosis of IBS-D;
2. Age ≥ 18 years;
3. Failure of an anti-diarrheal agent (e.g., loperamide) at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
4. Failure of an antispasmodic (e.g., dicyclomine) at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
5. Dose does not exceed 200 mg (2 tablets) per day.

Approval duration:
Medicaid – 12 months
Commercial – Length of Benefit

II. Continued Therapy

A. Irritable Bowel Syndrome with Diarrhea (must meet all)**:**

1. Currently receiving medication via RxAdvance benefit or member has previously met initial approval criteria;
2. Member is responding positively to therapy;

3. If request is for a dose increase, new dose does not exceed 200 mg (2 tablets) per day.

Approval duration:
Medicaid – 12 months
Commercial – Length of Benefit

III. Appendices

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
IBS-D: irritable bowel syndrome with diarrhea

Appendix B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
loperamide (Imodium A-D®)	Adults: 4 mg PO followed by 2 mg after each unformed stool until diarrhea is resolved; then individualize dose. Administer optimal daily dose (4-8 mg) as single or divided doses.	If no clinical improvement after treatment with 16 mg/day for at least 10 days, symptoms are unlikely to be controlled by further use.
diphenoxylate/atropine (Lomotil®)	Initially, 5 mg (2 tablets) PO QID; Discontinue after 10 days if clinical improvement is not observed	20 mg/day (of diphenoxylate)
dicyclomine (Bentyl®)	Adults: 20 mg PO QID up to 1 week, then increase to 40 mg PO QID	160 mg/day (40 mg PO QID)
hyoscyamine (Levsin®, Levbid®)	Adults: Levsin: 0.125 – 0.25 mg PO Q 4h Levbid: 0.375 – 0.75 mg PO Q 12h	1.5 mg/day

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings
- Contraindication(s):
  - Patients without a gallbladder
  - Known or suspected biliary duct obstruction; or sphincter of Oddi disease or dysfunction
  - Alcoholism, alcohol abuse or alcohol addiction, or in patients who drink more than 3 alcoholic beverages per day
  - A history of pancreatitis; or structural diseases of the pancreas, including known or suspected pancreatic duct obstruction
  - Known hypersensitivity reaction to Viberzi
  - Severe hepatic impairment (Child-Pugh Class C)
  - History of chronic or severe constipation or sequelae from constipation, or known or suspected mechanical gastrointestinal obstruction
- Boxed warning(s): none reported

References

1. Viberzi Prescribing Information. Madison, NJ: Allergan; June 2018. Available at: https://www.viberzi.com/. Accessed August 8, 2019.
2. Weinberg DS, Smalley W, Heidelbaugh JJ, Shahnaz S. American Gastroenterological Association Institute guideline on the pharmacological management of irritable bowel syndrome. Gastroenterology. 2014; 147: 1146-1149.
3. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2019. Available at: http://www.clinicalpharmacology-ip.com/.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy was established	01/2020	03/06/2020