RXADVANCE
2 Park Central Drive
Southborough, MA 01772

Clinical Policy Title:	Eluxadoline
Policy Number:	RxA.548
Drug(s) Applied:	Viberzi®
Original Policy Date:	03/06/2020
Last Review Date:	12/07/2020
Line of Business Policy Applies to:	All lines of business

Background

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

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
eluxadoline (Viberzi®)	IBS-D	100 mg orally BID or 75 mg orally 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 • With moderate or severe renal impairment (eGFR less than 60 mL/min/1.73 m²); and in patients with end stage renal disease (ESRD) not yet on dialysis (eGFR less than 15 mL/min/1.73 m²)	200 mg/day

Dosage Forms

- 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
Commercial: 12 months
Medicaid: 12 months

II. Continued Therapy Approval

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

1. Currently receiving medication that has been authorized by RxAdvance or member has previously met initial approval criteria listed in this policy;
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
Commercial: 12 months
Medicaid: 12 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key

FDA: Food and Drug Administration
IBS-D: Irritable bowel syndrome with diarrhea
ESRD: End stage renal disease

APPENDIX B: Therapeutic Alternatives

Below are suggested therapeutic alternatives based on clinical guidance. Please check drug formulary for preferred agents and utilization management requirements.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
loperamide (Imodium® A-D)	Adults: 4 mg orally 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) orally QID; Discontinue after 10 days if clinical improvement is not observed	20 mg/day (of diphenoxylate)
dicyclomine (Bentyl®)	Adults: 20 mg orally QID up to 1 week, then increase to 40 mg orally QID	160 mg/day (40 mg orally QID)

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
hyoscyamine (Levsin®, Levbi®)	Adults: Levsin®: 0.125 – 0.25 mg orally Q 4h Levbid®: 0.375 – 0.75 mg orally 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

APPENDIX D: General Information

- Not applicable

References

1. Viberzi® Prescribing Information. Madison, NJ: Allergan; June 2020. Available at: https://www.viberzi.com/. Accessed August 16, 2020.
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/Revision Date	P&T Approval Date
Policy established.	01/2020	03/06/2020
Policy was reviewed: 1. Policy title table was updated. 2. Line of Business Policy Applies to was update to all lines of business. 3. Dosing Information updated to include dosing regimen for moderate or severe renal impairment and in patients with	08/2020	12/07/2020

end stage renal disease (ESRD) not yet on dialysis. 4. Commercial approval duration was updated for initial and Continued approval criteria from length of benefit to 12 months. 5. Continued therapy criteria II.A.1 was rephrased to “Currently receiving medication that has been authorized by RxAdvance…”. 6. APPENDIX A: Updated to include ESRD: End stage renal disease. 7. APPENDIX B: Therapeutic Alternatives statement was rephrased to “Below are suggested therapeutic alternatives based on clinical guidance. Please check drug formulary for preferred agents and utilization management requirements”. 8. References was reviewed and updated.		