

# Initial Prior Authorization

## Viberzi

### Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Viberzi	eluxadoline

### Indications

#### FDA-approved Indications

Viberzi is indicated in adults for the treatment of irritable bowel syndrome with diarrhea (IBS-D).

### Coverage Criteria

#### Irritable Bowel Syndrome with Diarrhea (IBS-D)

Authorization may be granted when the requested drug is being prescribed for the treatment of irritable bowel syndrome with diarrhea (IBS-D) in an adult patient when the following criteria is met:

- The patient does NOT have ANY of the following:
  - A history of cholecystectomy
  - A history of chronic or severe constipation or sequelae from constipation, or known or suspected mechanical gastrointestinal obstruction
  - Known or suspected biliary duct obstruction or sphincter of Oddi disease or dysfunction

- A history of pancreatitis or structural diseases of the pancreas, including known or suspected pancreatic duct obstruction
- Severe hepatic impairment (Child-Pugh Class C)
- Alcoholism, alcohol abuse or alcohol addiction, or a patient who drinks more than 3 alcoholic beverages per day

## Duration of Approval (DOA)

- 1287-A: DOA: 36 months
- 1271-A: DOA: 12 months

## References

1. Viberzi [package insert]. Madison, NJ: Allergan USA, Inc; July 2024.
2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2024. <https://online.lexi.com>. Accessed August 26, 2024.
3. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: <https://www.micromedexsolutions.com/> (cited: 08/26/2024).

## Document History

Written by: UM Development (CT)

Date Written: 06/2015

Revised: 08/2015; (SE) 06/2016 (created separate Med D); (KM) 08/2016 (no clinical changes); (DS) 08/2017, 09/2018 (no clinical changes) (combined comm and MDC-2); (KN) 09/2019 (added 'in an adult' to criteria); (SE/FN) 09/2020 (no clinical changes); (DS) 09/2021 (no clinical changes); (VLS) 09/2022 (no clinical changes); (SS) 09/2023 (no clinical changes); (ANB) 09/2024 (no clinical changes)

Reviewed: Medical Affairs (LCB) 06/2015, 08/2015; (JG) 08/2017; (CHART) 09/26/2019, 09/24/2020, 09/30/2021, 09/22/2022, 09/28/2023, 09/26/2024

External Review: 06/2015, 12/2015, 12/2017, 12/2018, 12/2019, 12/2020, 12/2021, 12/2022, 12/2023, 12/2024

### **CRITERIA FOR APPROVAL**

- |   |   |     |    |
|---|---|-----|----|
| 1 | Is the requested drug being prescribed for the treatment of irritable bowel syndrome with diarrhea (IBS-D) in an adult patient? | Yes | No |
|---|---|-----|----|

[If Yes, then go to 2. If No, then no further questions.]

- 2 Does the patient have ANY of the following: A) A history of cholecystectomy, B) A history of chronic or severe constipation or sequelae from constipation, or known or suspected mechanical gastrointestinal obstruction, C) Known or suspected biliary duct obstruction; or sphincter of Oddi disease or dysfunction, D) A history of pancreatitis; or structural diseases of the pancreas, including known or suspected pancreatic duct obstruction, E) Severe hepatic impairment (Child-Pugh Class C), F) Alcoholism, alcohol abuse or alcohol addiction, or a patient who drinks more than 3 alcoholic beverages per day? Yes No
- [No further questions]

Mapping Instructions			
	Yes	No	DENIAL REASONS
1.	Go to 2	Deny	<p>Your plan only covers this drug when it is used for certain health conditions. Covered use is for irritable bowel syndrome with diarrhea (IBS-D) in an adult patient. Your plan does not cover this drug for your health condition that your doctor told us you have. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review.</p> <p>[Short Description: Diagnosis]</p>
2.	Deny	Approve, 36 Months	<p>Your plan only covers this drug when you do NOT have any of the following: A) A history of gallbladder removal surgery; B) A history of chronic or severe constipation or complications from constipation, or known or possible mechanical gastrointestinal obstruction; C) Known or possible biliary duct obstruction or sphincter of Oddi disease or dysfunction; D) A history of pancreatitis; or structural diseases of the pancreas, including known or possible pancreatic duct blockage; E) Severe liver function issues (Child-Pugh Class C); F) Alcoholism, alcohol abuse or alcohol addiction, or you drink more than 3 alcoholic beverages per day. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet</p>

Reference number(s)
1287-A, 1271-A

			<p>other criteria. You can request the drug policy for more details. You can also request other plan documents for your review.</p> <p>[Short Description: Other: Contraindications]</p>
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