

<b>Policy Name:</b>	<b>Viberzi (eluxadoline)</b>	<b>Policy#:</b>	<b>2458P</b>
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## Purpose of the Policy

The purpose of this policy is to define coverage criteria for Viberzi (eluxadoline).

## Statement of the Policy

Health Alliance Medical Plans will approve the use of Viberzi (eluxadoline) under the specialty pharmacy benefit if the following criteria are met.

## Criteria

### 1. Coverage Criteria

- 1.1 Member is age 18 years or older
- 1.2 Documented diagnosis of moderate to severe Irritable Bowel Syndrome with Diarrhea, defined as the presence of loose or watery stools with 25% of bowel movements and hard or lumpy stools with < 25% of bowel movements
- 1.3 Prescribed by a Gastroenterologist (stomach doctor)
- 1.4 Documented failure to respond or contraindication to loperamide
- 1.5 Documented failure to respond or contraindication to at least one bile acid sequestrant (cholestyramine, colestipol, colesevelam)
- 1.6 Documented failure to respond or contraindication to at least one antispasmodic agent (dicyclomine, hyoscyamine)
- 1.7 Documented failure to respond or contraindication to at least one tricyclic antidepressant (amitriptyline, nortriptyline, and imipramine)
- 1.8 Documented failure to respond or contraindication to alosetron, if female patient
  - If prescribing Gastroenterologist is not a Lotronex prescriber, the member will be exempt from this requirement

### 2. Exclusions

- 2.1 Cholecystectomy: known or suspected biliary duct obstruction or sphincter of Oddi disease or dysfunction.
  - These patients are at increased risk for sphincter of Oddi spasm
- 2.2 Alcoholism, alcohol abuse or alcohol addiction, or in patients who drink more than 3 alcoholic beverages per day.
  - These patients are at increased risk for acute pancreatitis
- 2.3 A history of pancreatitis; or structural disease of the pancreas, including known or suspected pancreatic duct obstruction
  - These patients are at increased risk for acute pancreatitis (inflammation of the pancreas)
- 2.4 Severe hepatic impairment (Child-Pugh Class C).
  - These patients are at risk for significantly increased plasma concentrations of eluxadoline
- 2.5 History of chronic or severe constipation or sequelae from constipation; mechanical gastrointestinal obstruction (known or suspected)

### 3. Approval Period

- 3.1 Initial: 12 months
- 3.2 Reauthorization: 12 months with documented clinical benefit from therapy

CPT Codes	
HCPCS Codes	

References
1. Lembo A, Sultan S, Chang L, et al. AGA Clinical Practice Guideline on the Pharmacological Management of Irritable Bowel Syndrome With Diarrhea. Gastroenterology. 2022 Jul;163(1):137-151.
2. Barshop K, Staller K. Eluxadoline in irritable bowel syndrome with diarrhea: rationale, evidence and place in therapy. Ther Adv Chronic Dis. 2017;8(11):153-160.
3. Viberzi (eluxadoline) [prescribing information]. Madison, NJ: Allergan USA Inc; June 2020.

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