



UnitedHealthcare Pharmacy  
Clinical Pharmacy Programs

Program Number	2023 P 2081-11
Program	Prior Authorization/Medical Necessity
Medication	Viberzi (eluxadoline)
P&T Approval Date	4/2016, 3/2017, 3/2018, 3/2019, 3/2020, 3/2021, 3/2022, 3/2023
Effective Date	6/1/2023; Oxford Only: 6/1/2023

**1. Background:**

Viberzi (eluxadoline) is a mu-opioid receptor agonist, indicated for the treatment of irritable bowel syndrome with diarrhea (IBS-D) in adults.

**2. Coverage Criteria<sup>a</sup>:**

**A. Initial Authorization**

1. **Viberzi** will be approved based on **all** of the following criteria:

a. Diagnosis of irritable bowel syndrome with diarrhea (IBS-D)

**-AND-**

b. History of failure, contraindication or intolerance to a tricyclic antidepressant (e.g. amitriptyline)

**Authorization will be issued for 6 months.**

**B. Reauthorization**

1. **Viberzi** will be approved based on the following criterion:

a. Documentation of positive clinical response to Viberzi therapy

**Authorization will be issued for 12 months.**

<sup>a</sup> State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

### 3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may apply

### 4. References:

1. Viberzi Prescribing Information. Madison, NJ: Allergan USA, Inc.; June 2020.
2. Lacey, BE, Pimentel, M, Brenner, DM, et. al. ACG Clinical Guideline: Management of Irritable Bowel Syndrome. *Am J Gastroenterol.* 2021; 116 (1): 17-44.
3. Lembo, A., Sultan, S, et. al. AGA Clinical Practice Guideline on the Pharmacological Management of Irritable Bowel Syndrome with Diarrhea. *Gastroenterology.* 2022;163:137-151

Program	Prior Authorization/Medical Necessity – Viberzi
<b>Change Control</b>	
Date	Change
4/2016	New program.
7/2016	Added Indiana and West Virginia coverage information.
11/2016	Administrative change. Added California coverage information.
3/2017	Annual review. References updated. State mandate reference language updated.
3/2018	Annual review. References updated.
12/2018	Administrative change to add statement regarding use of automated processes.
3/2019	Annual review. References updated.
3/2020	Annual review. References updated.
3/2021	Annual review. Removed antispasmodic and antidiarrheal agent as a step 1 option based on updated ACG guidelines.
3/2022	Annual review. Updated references.
3/2023	Annual review. Updated references.