UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2026 P 2081-14
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, 3/2024, 4/2025, 4/2026
Effective Date	7/1/2026

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[a]:

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 12 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.

[a] 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

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4. References:

1. Viberzi [package insert]. North Chicago, IL: AbbVie, Inc; July 2024.
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
Change Control	
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.
3/2024	Annual review. Increased initial authorization to 12 months.
4/2024	Annual review. Updated references.
4/2025	Annual review. Updated references.
4/2026	Annual review. Updated references.

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