

Clinical Policy Title:	Eluxadoline
Policy Number:	RxA.548
Drug(s) Applied:	Viberzi®
Original Policy Date:	03/06/2020
Last Review Date:	01/01/2024
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

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

1. Diagnosis of IBS-D;
2. Trial and failure of the following unless contraindicated or clinically significant adverse effects are experienced;
 - i. Anti-diarrheal agent (e.g., loperamide);
 - ii. antispasmodic (e.g., dicyclomine).

Approval Duration

All Lines of Business (except Medicare): 12 months

II. Continued Therapy Approval

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

1. Member is currently receiving medication, excluding manufacturer samples.

Approval Duration

All Lines of Business (except Medicare): 12 months

References

1. 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. <https://pubmed.ncbi.nlm.nih.gov/25224526/>. Accessed December 5, 2023.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	01/2020	03/06/2020
Policy was reviewed: <ol style="list-style-type: none"> 1. Policy title table was updated. 2. Line of Business Policy Applies to was update to all lines of business. 3. Commercial approval duration was updated for initial and Continued approval criteria from length of benefit to 12 months. 4. Continued therapy criteria II.A.1 was 	08/2020	12/07/2020

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

<p>rephrased to “Currently receiving medication that has been authorized by RxAdvance...”.</p> <p>5. References was reviewed and updated.</p>		
<p>Policy was reviewed:</p> <p>1. Continued Therapy Criteria II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance...”.</p> <p>2. References were reviewed and updated.</p>	09/24/2021	12/07/2021
<p>Policy was reviewed:</p> <p>1. Initial Approval Criteria I.A.3 and I.A.4: Updated to remove phrase maximally indicated dose.</p> <p>2. References were reviewed and updated.</p>	09/19/2022	10/19/2022
<p>Policy was reviewed:</p> <p>1. Removed prior age criteria.</p> <p>2. Removed prior dosing criteria.</p> <p>3. Updated approval duration.</p> <p>4. Removed reauthorization requirement for positive response to therapy.</p> <p>5. References were reviewed and updated.</p>	12/5/2023	01/01/2024