

### Clinical Pharmacy Program Guidelines for Xermelo

Program	Prior Authorization
Medication	Xermelo™ (telotristat ethyl)
Markets in Scope	Arizona, California, Hawaii, Maryland, Nevada, New Jersey, New York, New York EPP, Pennsylvania-CHIP, Rhode Island, South Carolina
Issue Date	6/2017
Pharmacy and Therapeutics Approval Date	6/2020
Effective Date	8/2020

**1. Background:**

Xermelo™ (telotristat ethyl) is a tryptophan hydroxylase inhibitor indicated for the treatment of carcinoid syndrome diarrhea in combination with somatostatin analog (SSA) therapy in adults inadequately controlled by SSA therapy.<sup>1</sup>

**2. Coverage Criteria:**

<p><b>A. <u>Carcinoid Syndrome Diarrhea</u></b></p> <p><b>1. <u>Initial Authorization</u></b></p> <p>a. <b>Xermelo</b> will be approved based on <b>all</b> of the following criteria:</p> <p>(1) Diagnosis of carcinoid syndrome diarrhea</p> <p style="text-align: center;"><b>-AND-</b></p> <p>(2) Diarrhea is inadequately controlled with somatostatin analog therapy (e.g., octreotide, Sandostatin LAR, Somatuline Depot)</p> <p style="text-align: center;"><b>-AND-</b></p> <p>(3) Used in combination with somatostatin analog therapy (e.g., octreotide, Sandostatin LAR, Somatuline Depot)</p> <p><b>Authorization will be issued for 6 months.</b></p> <p><b>2. <u>Reauthorization</u></b></p>
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a. **Xermelo** will be approved based on the following criterion:

(1) Documentation of positive clinical response to Xermelo

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

**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 be in place.

**4. References:**

1. Xermelo™ [package insert]. The Woodlands, TX: Lexicon Pharmaceuticals, Inc. February 2017.

Program	Prior Authorization – Xermelo (telotristat)
<b>Change Control</b>	
Date	Change
6/2017	New program.
6/2018	Annual review with no change to criteria.
6/2019	Annual review. No changes.
6/2020	Annual review with no changes to criteria or reference. Added Additional Clinical Rules Section.