UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 1221-8
Program	Prior Authorization/Notification
Medication	Xermelo® (telotristat ethyl)
P&T Approval Date	6/2017, 6/2018, 6/2019, 6/2020, 6/2021, 6/2022, 6/2023, 6/2024
Effective Date	9/1/2024

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.

2. Coverage Criteria[a]:

A. Carcinoid Syndrome Diarrhea

1. **Initial Authorization**

a. **Xermelo** will be approved based on **all** of the following criteria:

(1) Diagnosis of carcinoid syndrome diarrhea

-AND-

(2) Diarrhea is inadequately controlled with somatostatin analog therapy (e.g., octreotide, Sandostatin LAR, Somatuline Depot, Lanreotide)

-AND-

(3) Used in combination with somatostatin analog therapy (e.g., octreotide, Sandostatin LAR, Somatuline Depot, Lanreotide)

Authorization will be issued for 12 months.

2. **Reauthorization**

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.

[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 be in place.

4. References:

1. Xermelo® [package insert]. Deerfield, IL: TerSera Therpeutics LLC; September 2022.

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Change Control	
6/2017	New program.
6/2018	Annual review with no change to criteria.
6/2019	Annual review with no changes to criteria.
6/2020	Annual review with no changes to criteria or reference.
6/2021	Annual review with no changes to criteria.
6/2022	Annual review with no changes to criteria. Updated references.
6/2023	Annual review. Added Lanreotide to SSA examples. Updated reference and added state mandate footnote.
6/2023	Annual review. Updated initial authorization duration to 12 months.