Clinical Policy Title:	telotristat ethyl
Policy Number:	RxA.305
Drug(s) Applied:	Xermelo®
Original Policy Date:	02/07/2020
Last Review Date:	08/28/2024
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Carcinoid Syndrome Diarrhea (must meet all)**:**

1. Diagnosis of carcinoid syndrome diarrhea;
2. Trial and failure of a one-month trial of a somatostatin analog (e.g., octreotide, lanreotide), unless contrainicated or clinically significant adverse effects are experienced;
3. Xermelo is prescribed in combination with a somatostatin analog, unless contraindicated or clinically significant adverse effects are experienced.

Approval duration

All Lines of Business (except Medicare): 6 months

II. Continued Therapy Approval

A. Carcinoid Syndrome Diarrhea (must meet all)**:**

1. Auto-approval based on lookback functionality within the past 120 days as a proxy for member responding positively to therapy.

Approval duration

All Lines of Business (except Medicare): 12 months

References

1. National Comprehensive Cancer Network. Neuroendocrine Tumors Version 2.2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/neuroendocrine.pdf. Accessed August 28, 2024.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	01/31/2020	02/07/2020
Policy was reviewed: 1. Clinical Policy Title was updated. 2. Drug(s) Applied was updated 3. Line of Business Policy Applies to was updated. 4. Continued Therapy criteria II.A.1 was rephrased to "Currently receiving medication that has been authorized by RxAdvance..."	06/30/2020	09/14/2020

5. Commercial approval duration and Medicaid approval duration updated. 6. References were updated		
Policy was reviewed: 1. Continued Therapy Approval Criteria II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance...". 2. References were reviewed and updated.	07/12/2021	09/14/2021
Policy was reviewed: 1. References were reviewed and updated.	02/03/2022	04/18/2022
Policy was reviewed: 1. Initial Approval Criteria I.A.2: Updated to remove maximally indicated doses. 2. References were reviewed and updated.	01/16/2023	04/13/2023
Policy was reviewed.	10/19/2023	10/19/2023
Policy was reviewed: 1. Removed dose restrictions. 2. Updated Continued therapy approval with auto-approval based on lookback functionality within the past 120 days. 3. Removed other reauthorization requirements including positive response to therapy 4. Updated approval duration verbiage. 5. References were reviewed and updated.	08/28/2024	09/13/2024