Clinical Policy Title:	telotristat ethyl
Policy Number:	RxA.305
Drug(s) Applied:	Xermelo®
Original Policy Date:	02/07/2020
Last Review Date:	10/19/2023
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 an SSA (e.g., octreotide, lanreotide), unless contraindicated or clinically significant adverse effects are experienced;
3. Xermelo® is prescribed in combination with an SSA, unless contraindicated or clinically significant adverse effects are experienced;
4. Dose does not exceed 750 mg per day.

Approval duration
Commercial: 6 months
Medicaid: 6 months

II. Continued Therapy Approval

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

1. Member is currently receiving medication that has been authorized by RxAdvance or the member has met initial approval criteria listed in this policy;
2. Member is responding positively to therapy;
3. Member continues to have diarrhea;
4. Xermelo® is prescribed in combination with an SSA, unless contraindicated or clinically significant adverse effects are experienced;
5. If request is for a dose increase, new dose does not exceed 750 mg per day.

Approval duration
Commercial: 12 months
Medicaid: 12 months

References

1. National Comprehensive Cancer Network. Neuroendocrine Tumors Version 2.2022. Available at: https://www.nccn.org/professionals/physician_gls/pdf/neuroendocrine.pdf. Accessed January 16, 2023.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	01/2020	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..." 5. Commercial approval duration and Medicaid approval duration updated. 6. References were updated	06/30/2020	09/14/2020
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.	7/12/2021	9/14/2021
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