Pharmacy Policy

Xermelo®

Policy Number: 9.701
Version Number: 2
Version Effective Date: 9/1/2021

Product Applicability	☐ **All Plan⁺ Products**
Well Sense Health Plan	**Boston Medical Center HealthNet Plan**
☐ New Hampshire Medicaid	☒ MassHealth - MCO ☒ MassHealth - ACO ☐ Qualified Health Plans/ConnectorCare/Employer Choice Direct ☐ Senior Care Options

Note: Disclaimer and audit information is located at the end of this document.

Prior Authorization Policy

Products Affected:

- **Xermelo (telotristat ethyl)**

The Plan may authorize coverage of the above products for members meeting the following criteria:

Covered Use	All FDA approved indications not otherwise excluded
Exclusion Criteria	None
Required Medical Information	1. A diagnosis of carcinoid syndrome diarrhea; AND 2. Medication is prescribed by or in consultation with an oncologist or gastroenterologist; AND

⁺ *Plan* refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name Well Sense Health Plan.

	3. Inadequate response to at least a 3 month trial of somatostatin analog therapy (as evidenced by four or more bowel movements daily); AND 4. Attestation that the medication will be used in combination with somatostatin analog therapy or that there is a contraindication to somatostatin analog therapy
Age Restriction	18 years or older
Prescriber Restriction	Medication is prescribed by or in consultation with an oncologist or gastroenterologist
Coverage Duration	12 months
Quantity Limit	3 tablets per day
Other criteria	Reauthorization: 1. Reduction in the frequency of bowel movements associated with Carcinoid syndrome 2. Provider attestation that member will continue to use the medication in combination with somatostatin analog therapy or has a contraindication to somatostatin analog therapy

Clinical Background Information and References

1. Xermelo (telotristat ethyl) [prescribing information]. The Woodlands, TX: Lexicon Pharmaceuticals Inc; October 2020, (Accessed April 2021).
2. "Xermelo" Lexicomp®. Walters Kluwer; Accessed March 8, 2017. http://www.lexi.com
3. "Xermelo" Micromedex®. Truven Health Analytics; Accessed April 2021. http://www.micromedexsolutions.com
4. "Xermelo" UpToDate®. Walters Kluwer; Accessed August 16, 2017. Clinical Background Information and References

Original Approval Date	Original Effective Date	Policy Owner	Approved by
9/10/2020	1/1/2021	Pharmacy Services	Pharmacy & Therapeutics (P&T) Committee

Policy Revisions History			
Review Date	**Summary of Revisions**	**Revision Effective Date**	**Approved by**

Policy Revisions History			
9/10/2020	9.078 Xermelo Policy retired, new policy created. Added attestation requirement	1/1/2021	P&T Committee
05/13/2021	No changes or updates recommended.	9/1/2021	Pharmacy & Therapeutics (P&T) Committee

Next Review Date

5/2022

Other Applicable Policies

Reference to Applicable Laws and Regulations, If Any

Disclaimer Information

Medical Policies are the Plan's guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other Plan Policies, as well as the Member's benefit document, and when appropriate, coordinates with the Member's health care Providers to consider the individual Member's health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan's service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member's benefit document, take precedence over these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.