Pharmacy Medical Necessity Guidelines:
Xermelo (telotristat ethyl)

Effective: April 14, 2026

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	RX	Department to Review	RxUM
These pharmacy medical necessity guidelines apply to the following: ☒ Tufts Health RITogether – A Rhode Island Medicaid Plan		**Fax Numbers:** RXUM: 617.673.0939	

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

OVERVIEW

Xermelo (telotristat ethyl) tablets are indicated in combination with somatostatin analog (SSA) therapy for the treatment of carcinoid syndrome diarrhea in adult patients inadequately controlled by SSA therapy.

COVERAGE GUIDELINES

The plan may authorize coverage of Xermelo (telotristat) tablets for Members, when **ALL** the following criteria are met:

1. Documented diagnosis of carcinoid syndrome diarrhea

AND

2. The medication is being prescribed by a gastroenterologist, oncologist, or a hematologist

AND

3. The member is 18 years of age or older

AND

4. Documentation the member has had an inadequate response to a somatostatin analog (e.g. octreotide, lanreotide)

AND

5. Documentation the member will use Xermelo (telotristat) along with a somatostatin analog

LIMITATIONS

None

CODES

None

REFERENCES

1. Endocr Relat Cancer. 2018 Mar;25(3):309-322. doi: 10.1530/ERC-17-0455. Epub 2018 Jan 12. (TELECAST)
2. Kulke MH, Horsch D, caplin ME et al. Telotristat ethyl, a tryptophan hydroxylase inhibitor for the treatment of carcinoid syndrome. *J Clin Oncol.* 2016; 35:14-23.
3. Pavel M, Gross DJ, Perros P, et al. Telotristat ethyl in carcinoid syndrome: safety and efficacy in the TELECAST phase 3 trial. *Endocrine-Related Cancer.* 2018;25:309-322.
4. Xermelo (telotristat ethyl) [prescribing information]. Deerfield, IL: TerSera Therapeutics, LLC; October 2022.

APPROVAL HISTORY

October 11, 2022: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. June 13, 2023: Effective August 1, 2023, updated reauthorization criteria to require documentation of a reduction from baseline in bowel movement frequency instead of a 30% reduction.
2. April 9, 2024: Effective May 1, 2024, updated criteria to remove definition of inadequate response to the somatostatin analog from the criteria. Remove reauthorization criteria, as requests will now be approved for life of plan. Updated RxUM fax number.
3. April 8, 2025: No changes
4. April 14, 2026: No changes.

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage

decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.

Provider Services