Pharmacy Medical Necessity Guidelines: Xermelo (telotristat ethyl)

Effective: April 14, 2020

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:

Commercial Products

☐ Tufts Health Plan Commercial products – large group plans
☐ Tufts Health Plan Commercial products – small group and individual plans
☐ Tufts Health Freedom Plan products – large group plans
☐ Tufts Health Freedom Plan products – small group plans
- CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Tufts Health Public Plans Products

☐ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product)
☐ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans
☒ Tufts Health RITogether – A Rhode Island Medicaid Plan

Fax Numbers:

RXUM: 617.673.0988

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

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

Initial Authorization (6 months)

a) Documented diagnosis of carcinoid syndrome diarrhea;

AND

b) The medication is being prescribed by a gastroenterologist, oncologist, or a hematologist;

AND

c) The member is 18 years of age or older;

AND

d) Documentation the member is inadequately controlled with a somatostatin analog (e.g. octreotide, lanreotide) after at least 3 months of therapy, defined by either:

   a. Experiencing ≥ 4 bowel movements per day

   OR

   b. Experiencing < 4 bowl movements per day and having at least one of the following symptoms:
      i. Diarrhea or soft stools
      ii. Cutaneous flushing
      iii. Abdominal pain
      iv. Nausea
      v. Elevated urinary 5-hydroxyindoleacetic acid (u5-HIAA)

AND

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

Reauthorization (1 year)

a) Documentation the member will continue to use Xermelo (telotristat) along with a somatostatin analog

AND

b) Documentation the member experienced a 30% reduction in bowel movement frequency while on Xermelo (teletristat)

LIMITATIONS

1. Initial authorization will be limited to 6 months.
2. Reauthorization will be limited to 1 year and must meet the reauthorization criteria.

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. (Telestar)
3. Xermelo prescribing information. The Woodland, TX: Lexicon Pharmaceuticals, Inc.; 2017 March.

APPROVAL HISTORY

July 11, 2017: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. April 11, 2017: Administrative update. Effective 6/1/2017, Medical Necessity Guideline applies to Tufts Health RITogether.
2. September 12, 2017: Added oncologists and hematologists to the criteria as authorized prescribers
3. October 16, 2018: Administrative update to template
4. June 11, 2019: Added additional criteria to define a Member not well controlled on a somatostatin analog, per the Telecast trial.
5. April 14, 2020: Effective March 30, 2020, PA no longer required for Commercial and Direct Plans. MNG only applies to MA and RITogether plans.

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.