Cigna National Formulary Coverage Policy

Effective Date..... 4/18/2023
Next Review Date..... 4/18/2024

Drug Quantity Management – Per Rx
Oncology – Xermelo® (telotristat ethyl tablets)

Table of Contents

Product Identifier(s)

Effective 1/1/23 to 2/6/23: 107960

Effective 2/7/23: 59069

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

National Formulary Medical Necessity

This Drug Quantity Management program has been developed to promote the safe, effective, and economic use of Xermelo, as well as to manage potential dose escalation. If the Drug Quantity Management rule is not met for the requested medication at the point of service, coverage will be determined by the Criteria below. All approvals are provided for 1 year in duration.

Drug Quantity Limits

Product	Strength and Form	Retail Maximum Quantity per Rx	Home Delivery Maximum Quantity per Rx
Xermelo® (telotristat ethyl tablets)	250 mg tablets	84 tablets	252 tablets

Criteria

Cigna covers quantities as medically necessary when the following criteria are met:

1. If the prescriber indicates that a dose of 500 mg three times daily is needed because the individual has been taking Xermelo 250 mg three times daily for at least 12 weeks and has not had an adequate improvement, then approve 168 tablets per dispensing at retail or 504 tablets per dispensing at home delivery.

Conditions Not Covered

Any other exception is considered not medically necessary.

Background

Overview
Xermelo, an inhibitor of tryptophan hydroxylase, is indicated for the treatment of **carcinoid syndrome diarrhea** in combination with somatostatin analog therapy in adults inadequately controlled by somatostatin analog therapy.[1]

Dosing
The recommended dosage of Xermelo in adults is 250 mg three times daily taken with food.[1]

Availability
Xermelo is available as 250 mg tablets supplied in a monthly case.[1] Each monthly case contains 84 tablets (4 weekly boxes, which each contain 7 daily dose-packs). Each daily dose pack contains three 250 mg tablets.

Clinical Efficacy
The efficacy of Xermelo was evaluated in one Phase III, randomized, double-blind, placebo-controlled, multicenter, pivotal study called TELESTAR that enrolled patients with carcinoid syndrome not adequately controlled with somatostatin analog therapy.[2] In TELESTAR (published) [n = 135], the mean reduction in bowel movement (BM) frequency from baseline to Week 12 was -1.43, -1.46, and -0.62 for Xermelo 250 mg, Xermelo 500 mg, and placebo groups, respectively. The estimate of treatment difference in the BM frequency reduction with Xermelo compared with placebo was -0.81 and -0.69 for the Xermelo 250 mg and 500 mg groups, respectively ($P < 0.001$ for both doses). Overall, 44%, 42%, and 20% of patients in the Xermelo 250 mg, 500 mg, and placebo groups, respectively, were considered treatment responders (≥ 30% reduction in BM frequency for ≥ 50% of double-blind period).

References

1. Xermelo® tablets [prescribing information]. The Woodlands, TX: TerSera; September 2022.
2. Kulke MH, Horsch D, Caplin ME, et al. Telotristat ethyl, a tryptophan hydroxylase inhibitor for the treatment of carcinoid syndrome. *J Clin Oncol.* 2017;35:14-23.

Revision History

Type of Revision	Summary of Changes	Approval Date
Early Annual Revision	Policy was updated to reflect the existing quantity limits when a product is obtained via home delivery. Approval duration was changed from 3 years to 1 year. **Xermelo 250 mg tablets**: Quantity limits changed from 90 tablets per dispensing at retail and 270 tablets per dispensing at home delivery to 84 tablets per dispensing at retail and 252 tablets per dispensing at home delivery. Override criteria updated	02/08/2023

	to approve 168 tablets per dispensing at retail or 504 tablets per dispensing at home delivery, if the prescriber indicates that a dose of 500 mg three times daily is needed because the patient has been taking Xermelo 250 mg three times daily for at least 12 weeks and has not had an adequate improvement. Previously, this criteria approved 180 tablets per dispensing at retail or 540 tablets per dispensing at home delivery.	