DRUG QUANTITY MANAGEMENT POLICY – PER RX

POLICY: Oncology – Xermelo Drug Quantity Management Policy – Per Rx
- Xermelo® (telotristat ethyl tablets – TerSera)

REVIEW DATE: 02/10/2025

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. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. 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.

CIGNA NATIONAL FORMULARY COVERAGE:

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 (TID) 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.

Off-Label Dosing
Xermelo 500 mg TID dosing was evaluated in one Phase III pivotal study and was found to significantly reduce bowel movement frequency at 12 weeks compared with placebo.[2] Therapy with Xermelo 500 mg TID also resulted in significantly more

patients achieving a treatment response (≥ 30% reduction in BM frequency for ≥ 50% of double-blind period) vs. placebo.

POLICY STATEMENT

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

Oncology – Xermelo Drug Quantity Management Policy – Per Rx product(s) is(are) covered as medically necessary when the following criteria is(are) met. Any other exception is considered not medically necessary.

CRITERIA

1. If Approve 168 tablets per dispensing at retail or 504 tablets per dispensing at home delivery, if the patient meets ALL of the following (A, B, and C):
   A) Patient has been receiving Xermelo 250 mg three times daily for at least 12 weeks; AND
   B) Patient has not had adequate improvement with Xermelo 250 mg three times daily; AND
   C) Patient requires a dose of 500 mg three times daily, according to the prescriber.

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.

HISTORY

Type of Revision	Summary of Changes	Review 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.	02/08/2023

	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 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.	
Annual Revision	No criteria changes.	02/09/2024
Annual Revision	No criteria changes.	02/10/2025