

## DRUG QUANTITY MANAGEMENT POLICY – PER RX

**POLICY:** Oncology – Xermelo Drug Quantity Management Policy – Per Rx

- Xermelo® (telotristat ethyl tablets – TerSera)

**REVIEW DATE:** 02/08/2023

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### 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.<sup>1</sup>

### Dosing

The recommended dosage of Xermelo in adults is 250 mg three times daily taken with food.<sup>1</sup>

### Availability

Xermelo is available as 250 mg tablets supplied in a monthly case.<sup>1</sup> 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.<sup>2</sup> 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).

### 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.

**Automation:** None.

### 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

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## CRITERIA

1. 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, then approve 168 tablets per dispensing at retail or 504 tablets per dispensing at home delivery.

## 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.