EXPRESS SCRIPTS®

# PRIOR AUTHORIZATION POLICY

**POLICY:** Oncology – Xermelo™ (telotristat ethyl tablets – Lexicon Pharmaceuticals)

**TAC APPROVAL DATE:** 04/17/2019

## OVERVIEW

Xermelo is indicated for the treatment of carcinoid syndrome diarrhea in combination with somatostatin analog (SSA) therapy in adults inadequately controlled by SSA therapy.[1] Telotristat, the active metabolite, inhibits tryptophan hydroxylase, which mediates the rate limiting step in serotonin biosynthesis. Serotonin plays a role in mediating secretion, motility, inflammation, and sensation of the gastrointestinal tract and is overproduced in patients with carcinoid syndrome. Xermelo specifically reduces the production of peripheral serotonin and decreases the frequency of carcinoid syndrome diarrhea. The inclusion criteria for the TELESTAR pivotal study required all patients randomized to Xermelo or placebo groups to have at least four bowel movements per day while on SSA therapy.[2] The study also required patients to be receiving a stable-dose of SSA therapy for at least 3 months prior to trial enrollment.

## POLICY STATEMENT

Prior authorization is recommended for prescription benefit coverage of Xermelo. All approvals are provided for the duration noted below.

**Automation:** None.

## RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Xermelo is recommended in those who meet the following criteria:

### FDA-Approved Indications

1. **Carcinoid Syndrome Diarrhea.**
   - **A)** Initial Therapy. Approve for 3 years if the patient meets all of the following criteria (i, ii, and iii):
     - **i.** The patient has been on a long-acting somatostatin analog (SSA) therapy (e.g., Somatuline® Depot [lanreotide for injection], Sandostatin® LAR Depot [octreotide for injection]) for at least 3 consecutive months; AND
     - **ii.** While on a long-acting somatostatin analog therapy (prior to starting Xermelo), the patient continues to have at least four bowel movements per day; AND
     - **iii.** Xermelo will be used concomitantly with a long-acting somatostatin analog therapy.
   - **B)** Patient is Currently Receiving Xermelo. Approve for 3 years if the patient is continuing to take Xermelo concomitantly with a long-acting somatostatin analog therapy for carcinoid syndrome diarrhea.

## CONDITIONS NOT RECOMMENDED FOR APPROVAL

Xermelo has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions.

**1.** Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

## REFERENCES

1. Xermelo™ tablets [prescribing information]. The Woodlands, TX: Merck; February 2017.
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* | TAC Approval Date |
|---|---|---|
| New Policy | New criteria | 03/08/2017 |
| Annual revision | No criteria changes | 04/04/2018 |
| Annual revision | No criteria changes | 04/17/2019 |

TAC – Therapeutic Assessment Committee; * For a further summary of criteria changes, refer to respective TAC minutes available at: http://esidepartments/sites/Dep043/Committees/TAC/Forms/AllItems.aspx.