

## PRIOR AUTHORIZATION POLICY

**POLICY:** Oncology – Xermelo Prior Authorization Policy

- Xermelo™ (telotristat ethyl tablets – Lexicon Pharmaceuticals)

**REVIEW DATE:** 05/26/2021

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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>

The efficacy of Xermelo was evaluated in patients with metastatic neuroendocrine tumor and carcinoid syndrome diarrhea who were having between 4 to 12 daily bowel movements despite the use of somatostatin analog therapy at a stable dose for at least 3 months.<sup>1</sup>

### Guidelines

The National Comprehensive Cancer Network (NCCN) guidelines for treatment of neuroendocrine and adrenal tumors (version 01.2021 – April 14, 2021) recommend Xermelo in combination with Sandostatin® LAR Depot (octreotide injection) or Somatuline® Depot (lanreotide injection) for persistent diarrhea due to poorly controlled carcinoid syndrome.<sup>2</sup> If disease progression, Xermelo may be continued for persistent diarrhea in combination with Sandostatin LAR Depot or Somatuline Depot.

### 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.** Approve for the duration noted below if the patient meets ONE of the following criteria (A or B):
  - A) Initial Therapy.** Approve for 3 years if the patient meets all of the following (i, ii, and iii):
    - i.** Patient has been on a long-acting somatostatin analog therapy for at least 3 consecutive months; AND  
Note: Examples of long-acting somatostatin analog therapy are Somatuline® Depot (lanreotide injection) and Sandostatin® LAR Depot (octreotide injection).
    - 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**

Coverage of Xermelo is not recommended in the following situations:

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.