

## PRIOR AUTHORIZATION POLICY

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

- Xermelo™ (telotristat ethyl tablets – Lexicon)

**REVIEW DATE:** 05/15/2024

---

### 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 1.2023 – August 2, 2023) state that Xermelo can be considered in combination with long-acting somatostatin analog (e.g. Sandostatin® LAR Depot [octreotide subcutaneous injection] or Somatuline® Depot [lanreotide subcutaneous injection]) for persistent diarrhea due to poorly controlled carcinoid syndrome.<sup>2</sup>

### 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 Indication

- 1. Carcinoid Syndrome Diarrhea.** Approve for 1 year if the patient meets ONE of the following (A or B):
  - A) Initial Therapy.** Approve 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 subcutaneous injection) and Sandostatin LAR Depot (octreotide subcutaneous 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 if the patient is continuing to take Xermelo concomitantly with a long-acting somatostatin analog therapy for carcinoid syndrome diarrhea.

05/15/2024

© 2024. All Rights Reserved.

This document is confidential and proprietary. Unauthorized use and distribution are prohibited.

### **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; September 2022.
2. The NCCN Neuroendocrine and Adrenal Tumors Clinical Practice Guidelines in Oncology (version 1.2023 – August 2, 2023). © 2023 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on May 13, 2024.