# PRIOR AUTHORIZATION POLICY

**POLICY:** Oncology – Xermelo Prior Authorization Policy
- Xermelo™ (telotristat ethyl tablets – Lexicon)

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

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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.[1]

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.[1]

## 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.[2]

## 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.

## 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.