PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 05/25/2022; selected revision 06/22/2022

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 1.2022 – May 23, 2022) recommend Xermelo in combination with Sandostatin® LAR Depot (octreotide subcutaneous injection) or Somatuline® Depot (lanreotide subcutaneous injection) for persistent diarrhea due to poorly controlled carcinoid syndrome.[2] If disease progression occurs, 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 Indication

1. **Carcinoid Syndrome Diarrhea.** Approve for 1 year if the patient meets ONE of the following criteria (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; January 2021.
2. The NCCN Neuroendocrine and Adrenal Tumors Clinical Practice Guidelines in Oncology (version 1.2022 – May 23, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed May 23, 2022.