

# Xermelo (telotristat ethyl)

Override(s)	Approval Duration
Prior Authorization	Initial approval duration: 3 months
Quantity Limit	Continuing treatment approval duration: 1 year

  

Medications	Quantity Limit
Xermelo (telotristat ethyl)	May be subject to quantity limit

## APPROVAL CRITERIA

Requests for Xermelo (telotristat ethyl) may be approved if the following criteria are met:

- I. Individual is 18 years of age or older; **AND**
- II. Individual is using in combination with somatostatin analog (SSA) therapy (including, but not limited to, lanreotide, octreotide) for the treatment of carcinoid syndrome diarrhea; **AND**
- III. Individual has had an inadequate response on a stable dose of SSA monotherapy for at least 3 months.

Continuing treatment with Xermelo (telotristat ethyl) may be approved when the individual has previously met the initiation criteria above and:

- I. If clinically significant improvements are confirmed after 12 weeks of treatment with Xermelo when added to SSA therapy; **AND**
- II. Individual does not have reports of severe constipation or severe persistent or worsening abdominal pain.

## Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2020. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: August 10, 2020.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2020; Updated periodically.
5. NCCN Clinical Practice Guidelines in Oncology™. © 2020 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on August 10, 2020.
  - a. Neuroendocrine and Adrenal Tumors. V2.2020. Revised July 24, 2020.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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