

Xermelo[®] (telotristat ethyl) (Oral)

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Date of Origin: 03/21/2017

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I. Length of Authorization

Initial coverage will be provided for 6 months and may be renewed every 12 months thereafter.

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

- Xermelo 250 tablet: 1 monthly case (84 tablets) per 28 days

B. Max Units (per dose and over time) [HCPCS Unit]:

- 250 mg three times daily

III. Initial Approval Criteria

Coverage is provided in the following conditions:

- ONE of the following:
 - The patient has a diagnosis of carcinoid syndrome diarrhea and BOTH of the following:
 - The patient has tried and had an inadequate response with a long-acting somatostatin analog (e.g., Sandostatin LAR [octreotide], Somatuline Depot [lanreotide]) for at least 3 months; **AND**
 - The requested agent will be used in combination with a long-acting somatostatin analog (e.g., Sandostatin LAR [octreotide], Somatuline Depot [lanreotide]); **OR**
 - The patient has another FDA approved indication for the requested agent; **AND**
- If the patient has an FDA approved indication, ONE of the following:
 - The patient's age is within FDA labeling for the requested indication for the requested agent for the requested indication; **OR**
 - The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication; **AND**
- The prescriber is a specialist in the area of the patient's diagnosis (e.g., oncologist, endocrinologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis; **AND**

- The patient does NOT have any FDA labeled contraindications to the requested agent
- † FDA Approved Indication(s), ‡ Compendia Recommended Indication(s); Ⓢ Orphan Drug

IV. Renewal Criteria

Coverage may be renewed based upon the following criteria:

- The patient has been previously approved for the requested agent through the plan's Prior Authorization process; **AND**
- ONE of the following:
 - For a diagnosis of carcinoid syndrome diarrhea, BOTH of the following:
 - The patient has had clinical benefit with the requested agent (e.g., reduction in average number of daily bowel movements); **AND**
 - The requested agent will be used in combination with a long-acting somatostatin analog (e.g., Sandostatin LAR [octreotide], Somatuline Depot [lanreotide]); **OR**
 - For another FDA approved indication, the patient has had clinical benefit with the requested agent; **AND**
- The prescriber is a specialist in the area of the patient's diagnosis (e.g., oncologist, endocrinologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis; **AND**
- The patient does NOT have any FDA labeled contraindications to the requested agent

V. Dosage/Administration

Indication	Dose
Carcinoid Syndrome Diarrhea	Administer 250 mg orally three times daily

VI. Billing Code/Availability Information

HCPCS Code:

J8499 – Prescription drug, oral, non chemotherapeutic, nos

NDC:

- Xermelo 250 mg tablet; monthly case of 84 tablets: 70720-0125-xx

VII. References

1. Xermelo [package insert]. Deerfield, IL; TerSera Therapeutics LLC; September 2022. Accessed March 2023.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for telotristat ethyl. National Comprehensive Cancer Network, 2023. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL

COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed March 2023.

3. Hudgens S, Lapuera P, Floden L, et al. Evaluation of disease-specific and functional symptom items on carcinoid tumor patients treated with telotristat ethyl. Journal of Clinical Oncology 2019 37:4_suppl, 427-427

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C7A.00	Malignant carcinoid tumor of unspecified site
C7A.010	Malignant carcinoid tumor of the duodenum
C7A.011	Malignant carcinoid tumor of the jejunum
C7A.012	Malignant carcinoid tumor of the ileum
C7A.019	Malignant carcinoid tumor of the small intestine, unspecified portion
C7A.020	Malignant carcinoid tumor of the appendix
C7A.021	Malignant carcinoid tumor of the cecum
C7A.022	Malignant carcinoid tumor of the ascending colon
C7A.023	Malignant carcinoid tumor of the transverse colon
C7A.024	Malignant carcinoid tumor of the descending colon
C7A.025	Malignant carcinoid tumor of the sigmoid colon
C7A.026	Malignant carcinoid tumor of the rectum
C7A.029	Malignant carcinoid tumor of the large intestine, unspecified portion
C7A.090	Malignant carcinoid tumor of the bronchus and lung
C7A.091	Malignant carcinoid tumor of the thymus
C7A.092	Malignant carcinoid tumor of the stomach
C7A.093	Malignant carcinoid tumor of the kidney
C7A.094	Malignant carcinoid tumor of the foregut, unspecified
C7A.095	Malignant carcinoid tumor of the midgut, unspecified
C7A.096	Malignant carcinoid tumor of the hindgut, unspecified
C7A.098	Malignant carcinoid tumors of other sites
C7A.8	Other malignant neuroendocrine tumors
C7B.00	Secondary carcinoid tumors, unspecified site
C7B.01	Secondary carcinoid tumors of distant lymph nodes
C7B.02	Secondary carcinoid tumors of liver
C7B.03	Secondary carcinoid tumors of bone
C7B.04	Secondary carcinoid tumors of peritoneum

XERMELO® (telotristat ethyl) Prior Auth Criteria

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ICD-10	ICD-10 Description
C7B.09	Secondary carcinoid tumors of other sites
C7B.8	Other secondary neuroendocrine tumors
D3A.00	Benign carcinoid tumor of unspecified site
D3A.010	Benign carcinoid tumor of the duodenum
D3A.011	Benign carcinoid tumor of the jejunum
D3A.012	Benign carcinoid tumor of the ileum
D3A.019	Benign carcinoid tumor of the small intestine, unspecified portion
D3A.020	Benign carcinoid tumor of the appendix
D3A.021	Benign carcinoid tumor of the cecum
D3A.022	Benign carcinoid tumor of the ascending colon
D3A.023	Benign carcinoid tumor of the transverse colon
D3A.024	Benign carcinoid tumor of the descending colon
D3A.025	Benign carcinoid tumor of the sigmoid colon
D3A.026	Benign carcinoid tumor of the rectum
D3A.029	Benign carcinoid tumor of the large intestine, unspecified portion
D3A.090	Benign carcinoid tumor of the bronchus and lung
D3A.091	Benign carcinoid tumor of the thymus
D3A.092	Benign carcinoid tumor of the stomach
E34.0	Carcinoid syndrome
Z85.020	Personal history of malignant carcinoid tumor of stomach
Z85.030	Personal history of malignant carcinoid tumor of large intestine
Z85.040	Personal history of malignant carcinoid tumor of rectum
Z85.060	Personal history of malignant carcinoid tumor of small intestine
Z85.110	Personal history of malignant carcinoid tumor of bronchus and lung
Z85.230	Personal history of malignant carcinoid tumor of thymus

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

The preceding information is intended for non-Medicare coverage determinations. Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: <https://www.cms.gov/medicare-coverage-database/search.aspx>. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC