

## Xermelo (telotristat ethyl)

Document Number: IC-0293

Last Review Date: 03/21/2017

Date of Origin: 03/21/2017

Dates Reviewed: 03/2017

### I. Length of Authorization

Coverage will be provided for 6 months and may be renewed.

### II. Dosing Limits

#### A. Quantity Limit (max daily dose) [Pharmacy Benefit]:

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

#### B. Max Units (per dose and over time) [Medical Benefit]:

- 250 mg three times daily

### III. Initial Approval Criteria

Coverage is provided in the following conditions:

#### Carcinoid Syndrome Diarrhea †

- Patient is at least 18 years old; **AND**
- Patient has a carcinoid/neuroendocrine tumor and has been diagnosed with carcinoid syndrome; **AND**
- Patient has been receiving therapy with the FDA-approved maximum (or highest tolerated) dose of a somatostatin analog therapy (SSA) (i.e., octreotide solution/depot or lanreotide depot) for at least 3 months; **AND**
- Patient will continue to receive this SAA therapy in combination with Xermelo; **AND**
- Patient has received an inadequate response to antidiarrheals (e.g., loperamide); **AND**
- Patient's baseline bowel movements per day are  $\geq 4$

† FDA Approved Indication(s), ‡ Compendia Recommended Indication(s)

### IV. Renewal Criteria

Authorizations may be renewed based upon the following:

- Patient continues to meet the criteria identified in section III; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: severe constipation, abdominal pain, etc.); **AND**
- Patient has responded to therapy as indicated by a reduction in the number of bowel movements per day from pre-treatment baseline

## V. Dosage/Administration

Indication	Dose
Diarrhea inadequately controlled by SSA therapy	250 mg orally three times daily

## VI. Billing Code/Availability Information

Jcode:

J8499 – Prescription drug, oral, non chemotherapeutic, nos

NDC:

- Xermelo 250 mg tablet; monthly case of 84 tablets: 70183-0125-xx

## VII. References

1. Xermelo [package insert]. Woodlands, TX; Lexicon Pharmaceuticals, Inc.; February 2017. Accessed March 2017.

## 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

ICD-10	ICD-10 Description
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.1	Malignant poorly differentiated neuroendocrine tumors
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
C7B.09	Secondary carcinoid tumors of other sites
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
D3A.093	Benign carcinoid tumor of the kidney
D3A.094	Benign carcinoid tumor of the foregut, unspecified
D3A.095	Benign carcinoid tumor of the midgut, unspecified

ICD-10	ICD-10 Description
D3A.096	Benign carcinoid tumor of the hindgut, unspecified
D3A.098	Benign carcinoid tumors of other sites
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
Z85.520	Personal history of malignant carcinoid tumor of kidney

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

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 Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: <http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx>. Additional indications may be covered at the discretion of the health plan.

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

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 Corporation (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 Corporation (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Cahaba Government Benefit Administrators, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.

### Medicare Part B Administrative Contractor (MAC) Jurisdictions

Jurisdiction	Applicable State/US Territory	Contractor
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC