

PHARMACY POLICY STATEMENT

Georgia Medicaid

DRUG NAME	Xermelo (telotristat ethyl)
BILLING CODE	Must use valid NDC code
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
COVERAGE REQUIREMENTS	Prior Authorization Required (Non-Preferred Product) QUANTITY LIMIT— 84 tablets per 28 days
LIST OF DIAGNOSES CONSIDERED NOT MEDICALLY NECESSARY	Click Here

Xermelo (telotristat ethyl) is a **non-preferred** product and will only be considered for coverage under the **pharmacy** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

CARCINOID SYNDROME DIARRHEA

For **initial** authorization:

1. Member is 18 years old or older; AND
2. Medication must be prescribed by or in consultation with an oncologist or gastroenterologist; AND
3. Member has a neuroendocrine tumor; AND
4. Member has a diagnosis of refractory diarrhea secondary to carcinoid syndrome, despite a stable dose of somatostatin analog (i.e. octreotide, lanreotide) for at least 3 months, as evidenced by at least one of the following:
 - a) Member is experiencing 4 or more bowel movements per day;
 - b) Member has an elevated urinary 5-hydroxyindoleacetic acid (u5-HIAA) level; AND
5. Member will continue somatostatin therapy in addition to Xermelo.
6. **Dosage allowed:** 250mg three times daily.

If member meets all the requirements listed above, the medication will be approved for 3 months.

For **reauthorization**:

1. Chart notes have been provided that show a decrease in frequency of bowel movements; AND
2. Member is continuing somatostatin analog unless contraindicated or not tolerated.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

CareSource considers Xermelo (telotristat ethyl) not medically necessary for the treatment of the diseases that are not listed in this document.

DATE	ACTION/DESCRIPTION
11/12/2020	New policy for Xermelo created.

References:

1. Xermelo [package insert]. Deerfield, IL: TerSera Therapeutics LLC; 2020.
2. Pavel M, Öberg K, Falconi M, Krenning EP, Sundin A, Perren A, Berruti A; ESMO Guidelines Committee. Electronic address: clinicalguidelines@esmo.org. Gastroenteropancreatic neuroendocrine neoplasms: ESMO

Clinical Practice Guidelines for diagnosis, treatment and follow-up. *Ann Oncol*. 2020 Jul;31(7):844-860. doi: 10.1016/j.annonc.2020.03.304. Epub 2020 Apr 6. PMID: 32272208.

3. Strosberg JR, Halfdanarson TR, Bellizzi AM, Chan JA, Dillon JS, Heaney AP, Kunz PL, O'Dorisio TM, Salem R, Segelov E, Howe JR, Pommier RF, Brendtro K, Bashir MA, Singh S, Soulen MC, Tang L, Zacks JS, Yao JC, Bergsland EK. The North American Neuroendocrine Tumor Society Consensus Guidelines for Surveillance and Medical Management of Midgut Neuroendocrine Tumors. *Pancreas*. 2017 Jul;46(6):707-714. doi: 10.1097/MPA.0000000000000850. PMID: 28609356; PMCID: PMC5642985.
4. Cook R, Hendifar AE. Evidence-Based Policy in Practice: Management of Carcinoid Syndrome Diarrhea. *P T*. 2019;44(7):424-427.
5. National Comprehensive Cancer Network. Neuroendocrine and Adrenal Tumors. (Version 2.2020). https://www.nccn.org/professionals/physician_gls/pdf/neuroendocrine.pdf. Accessed November 3, 2020.
6. Pandit S, Annamaraju P, Bhusal K. Carcinoid Syndrome. [Updated 2020 Jun 25]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2020 Jan-. Available from: <https://www.ncbi.nlm.nih.gov/books/NBK448096/>
7. Pavel M, Gross DJ, Benavent M, et al. Telotristat ethyl in carcinoid syndrome: safety and efficacy in the TELECAST phase 3 trial. *Endocr Relat Cancer*. 2018;25(3):309-322. doi:10.1530/ERC-17-0455
8. Lyseng-Williamson KA. Telotristat Ethyl: A Review in Carcinoid Syndrome Diarrhoea. *Drugs*. 2018;78(9):941-950. doi:10.1007/s40265-018-0935-1

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