

PHARMACY POLICY STATEMENT

Arkansas PASSE

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| 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) 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. Member has a neuroendocrine tumor; AND
3. 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; AND
4. Member will continue somatostatin therapy in addition to Xermelo.
5. **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. |
| 12/22/2021 | Removed prescriber specialty requirement. Removed the following requirements: Member is experiencing 4 or more bowel movements per day; Member has an elevated urinary 5-hydroxyindoleacetic acid (u5-HIAA) level. |

References:

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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
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Effective date: 01/01/2022

Revised date: 12/22/2021