

PHARMACY POLICY STATEMENT

Marketplace

DRUG NAME	Xermelo (telotristat ethyl)
BILLING CODE	Must use valid NDC
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
STATUS	Prior Authorization Required

Xermelo is a small molecule tryptophan hydroxylase (TPH) inhibitor indicated for the treatment of carcinoid syndrome diarrhea in combination with somatostatin analog (SSA) therapy in adults inadequately controlled by SSA therapy. TPH mediates the rate limiting step in serotonin biosynthesis, which is overproduced in carcinoid syndrome. Inhibiting TPH therefore reduces the production of peripheral serotonin and the frequency of related diarrhea.

Carcinoid syndrome (CS) refers to a collection of symptoms that primarily occurs with well-differentiated neuroendocrine tumors (NETs) originating midgut with metastases to the liver. Flushing and diarrhea are the

CareSource considers Xermelo (telotristat ethyl) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off- Label policy.

DATE	ACTION/DESCRIPTION
11/12/2020	New policy for Xermelo created.
04/18/2022	Transferred to new template. Added supporting references. Specified SSA therapy as long acting.

References:

1. Xermelo [package insert]. Deerfield, IL: TerSera Therapeutics LLC; 2020.
2. Pavel M, Öberg K, Falconi M, et al. Gastroenteropancreatic neuroendocrine neoplasms: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. *Ann Oncol.* 2020;31(7):844-860. doi:10.1016/j.annonc.2020.03.304.
3. Strosberg JR, Halfdanarson TR, Bellizzi AM, et al. The North American Neuroendocrine Tumor Society Consensus Guidelines for Surveillance and Medical Management of Midgut Neuroendocrine Tumors. *Pancreas.* 2017;46(6):707-714. doi:10.1097/MPA.0000000000000850.
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 4.2021). https://www.nccn.org/professionals/physician_gls/pdf/neuroendocrine.pdf. Accessed April 1, 2022.
6. Pandit S, Annamaraju P, Bhusal K. Carcinoid Syndrome. [Updated 2022 Feb 17]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2022 Jan;46(6).6 (.)3.5 ()TJ 0 -1.243.5 (e)3.6 ()0.5 (l)3.6 (U)-1.6 (pdat)3.6 (e)