Reference number(s)
1670-A

SPECIALTY GUIDELINE MANAGEMENT

XERMELO (telotristat ethyl)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indication
Indicated for the treatment of carcinoid syndrome diarrhea in combination with somatostatin analog (SSA) therapy in adults inadequately controlled by SSA therapy.

All other indications are considered experimental/investigational and not medically necessary.

II. CRITERIA FOR INITIAL APPROVAL

Carcinoid syndrome diarrhea
Authorization of 3 months may be granted for adult members for treatment of carcinoid syndrome diarrhea when both of the following criteria are met:
1. The member has had an inadequate response to somatostatin analog (SSA) therapy alone
2. The requested medication will be used in combination with SSA therapy

III. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for all adult members (including new members) who are using the requested medication for carcinoid syndrome diarrhea in combination with SSA therapy and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition (e.g., reduction in the number of daily bowel movements).

IV. REFERENCES

1. Xermelo [package insert]. Deerfield, IL: TerSera Therapeutics LLC; September 2022.
2. Kulke MH, Hörsch D, Caplin ME, et al. Telotristat Ethyl, a Tryptophan Hydroxylase Inhibitor for the Treatment of Carcinoid Syndrome. *J Clin Oncol*. 2017;35(1):14-23.