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 Indications
Xermelo is 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 the treatment of carcinoid syndrome diarrhea when both of the following criteria are met:
A. The member has had an inadequate response to somatostatin analog (SSA) therapy alone
B. Xermelo will be used in combination with SSA therapy

III. CONTINUATION OF THERAPY

Authorization of 6 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Section II when all of the following criteria are met:
A. The member is currently receiving the requested medication through a paid pharmacy or medical benefit
B. The member is receiving the requested medication in combination with SSA therapy
C. The member is experiencing benefit from therapy as evidenced by disease stability or disease improvement (e.g., reduction in the number of daily bowel movements).

IV. REFERENCES

1. Xermelo [package insert]. Deerfield, IL: TerSera Therapeutics LLC; October 2020.