TELOTRISTAT

Generic	Brand	HICL	GCN	Exception/Other
TELOTRISTAT	XERMELO	44132		

GUIDELINES FOR USE

1. Does the patient have a diagnosis of carcinoid syndrome diarrhea and meet **ALL** of the following criteria?
   - The medication will be used in combination with a somatostatin analog (e.g., octreotide)
   - The patient is 18 years of age or older
   - The medication is being prescribed by or given in consultation with an oncologist or gastroenterologist
   - Documentation that the patient has been receiving or has a contraindication to a stable dose of long-acting somatostatin analog therapy [e.g., Sandostatin LAR (octreotide), Somatuline Depot (lanreotide)] for a minimum of 3 months
   - Physician attestation that the patient's diarrhea is inadequately controlled as defined by the presence of at least four bowel movements per day

   If yes, **approve for 12 months by HICL with a quantity limit of #3 tablets per day.**
   If no, do not approve.
   DENIAL TEXT: The guideline named **TELOTRISTAT (Xermelo)** requires a diagnosis of carcinoid syndrome diarrhea. In addition, the following criteria must be met:
   - The medication will be used in combination with a somatostatin analog (e.g., octreotide)
   - The patient is 18 years of age or older
   - The medication is being prescribed by or given in consultation with an oncologist or gastroenterologist
   - Documentation that the patient has been receiving or has a contraindication to a stable dose of long-acting somatostatin analog therapy [e.g., Sandostatin LAR (octreotide), Somatuline Depot (lanreotide)] for a minimum of 3 months
   - Physician attestation that the patient's diarrhea is inadequately controlled as defined by the presence of at least four bowel movements per day

RATIONALE

Promote appropriate utilization of **TELOTRISTAT** (Xermelo) based on FDA approved indication and dosing.

FDA APPROVED INDICATIONS

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

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TELOTRISTAT

FDA APPROVED INDICATIONS (CONTINUED)

DOSAGE AND ADMINISTRATION
The recommended dosage of Xermelo in adult patients is 250 mg three times daily for patients whose diarrhea is inadequately controlled by SSA therapy. Take Xermelo with food. When short-acting octreotide is used in combination with Xermelo, administer short-acting octreotide at least 30 minutes after administering Xermelo.

AVAILABLE STRENGTHS
Tablets: 250 mg

REFERENCES

- Xermelo [Prescribing Information]. The Woodlands, Texas. Lexicon Pharmaceuticals, Inc; February 2017.
- Kulke MH, Hörsch D, Caplin M,et al. Telotristat Ethyl, a Tryptophan Hydroxylase Inhibitor for the Treatment of Carcinoid Syndrome. *J Clin Oncol*. 2017 Jan; 35(1):14-23.\
- Kulke MH, Shah M, Benson A, et al. Neuroendocrine Tumors. NCCN Clinical Practice Guidelines in Oncology. Updated February 21, 2017.

Library	Commercial	NSA
Yes	Yes	No

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