Medical Necessity Checklist

Justification of medical necessity is predicated upon demonstrating that the level of care is a part of generally accepted medical practice and that it is appropriate for the patient's specific medical condition.

There are several areas to consider in determining whether your patient will meet the medical necessity criteria for XERMELO® (telotristat ethyl).

□ **Diagnosis**

- Patients must have a confirmed diagnosis consistent with the indication in the XERMELO Prescribing Information

□ **Treatment history**

- To justify adding XERMELO to an existing somatostatin analog (SSA) therapy will require documenting the effectiveness of the SSA over time. Any history of dose escalation and/or switching, and the response to those strategies, should also be included
- Also note the impact of other treatment strategies beyond SSAs

□ **Patient characteristics**

- XERMELO is not for patients in the following categories:
  - Pregnant women
  - Breastfeeding women
  - Pediatric patients

INDICATION

XERMELO is a tryptophan hydroxylase inhibitor indicated for the treatment of carcinoid syndrome diarrhea in combination with somatostatin analog (SSA) therapy in adults inadequately controlled by SSA therapy.

IMPORTANT SAFETY INFORMATION

Warnings and Precautions: XERMELO may cause constipation, which can be serious. Monitor for signs and symptoms of constipation and/or severe, persistent, or worsening abdominal pain in patients taking XERMELO. Discontinue XERMELO if severe constipation or severe, persistent, or worsening abdominal pain develops.

Adverse Reactions: The most common adverse reactions (≥5%) include nausea, headache, increased gamma-glutamyl-transferase, depression, flatulence, decreased appetite, peripheral edema, and pyrexia.

Drug Interactions: If necessary, consider increasing the dose of concomitant CYP3A4 substrates, as XERMELO may decrease their systemic exposure. If combination treatment with XERMELO and short-acting octreotide is needed, administer short-acting octreotide at least 30 minutes after administering XERMELO.

For more information about XERMELO, see full Prescribing Information.

Lexicon® pharmaceuticals