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

Important Safety Information

- **Contraindications:** XERMELO is contraindicated in patients with a history of a hypersensitivity reaction to telotristat. Reactions have included angioedema, rash and pruritis.

- **Warnings and Precautions:** XERMELO may cause constipation, which can be serious. Serious complications of constipation have been reported during clinical trials and post marketing with individual reports of intestinal perforation, obstruction, and fecaloma. 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:** In a clinical trial of patients with carcinoid syndrome diarrhea and 4-12 bowel movements per day, the most common adverse reactions (≥5%) include nausea, headache, increased gamma-glutamyl transferase, depression, flatulence, decreased appetite, peripheral edema, and pyrexia. In a second clinical trial of patients with carcinoid syndrome diarrhea and less than 4 bowel movements per day, additional adverse reactions of abdominal pain and constipation were reported in ≥5% of patients.

- **Drug Interactions:** If necessary, consider increasing the dose of concomitant CYP3A4 and CYP2B6 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.

- **Use in Special Populations:** XERMELO is not recommended in patients with moderate and severe hepatic impairment.

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.

To report suspected adverse reactions, contact the FDA at 1-800-FDA-1088 or www.FDA.gov/medwatch. You may also contact TerSera Therapeutics at 1-844-334-4035 or medicalinformation@tersera.com.

Please see Full Prescribing Information.

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