



**XERMELO  
(telotristat ethyl)**

**RATIONALE FOR INCLUSION IN PA PROGRAM**

**Background**

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. Telotristat, the active metabolite of telotristat ethyl, is an inhibitor of tryptophan hydroxylase, which mediates the rate limiting step in serotonin biosynthesis. Serotonin plays a role in mediating secretion, motility, inflammation, and sensation of the gastrointestinal tract, and is over-produced in patients with carcinoid syndrome. Through inhibition of tryptophan hydroxylase, telotristat and telotristat ethyl reduce the production of peripheral serotonin, and the frequency of carcinoid syndrome diarrhea (1).

**Regulatory Status**

FDA approved 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 (1).

Xermelo reduces bowel movement frequency, therefore prescribers must monitor patients for constipation and/or severe persistent or worsening abdominal pain and discontinue Xermelo if severe constipation or abdominal pain develops (1).

Safety and effectiveness in pediatric patients have not been established (1).

**Summary**

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. Xermelo reduces bowel movement frequency, therefore prescribers must monitor patients for constipation and/or severe persistent or worsening abdominal pain and discontinue Xermelo if severe constipation or abdominal pain develops (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Xermelo while maintaining optimal therapeutic outcomes.

**References**

1. Xermelo [package insert]. The Woodlands, TX: Lexicon Pharmaceuticals, Inc.; September 2022.