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5.50.014

Section:	Prescription Drugs	**Effective Date:**	July 1, 2024
Subsection:	Gastrointestinal Agents	**Original Policy Date:**	March 24, 2017
Subject:	Xermelo	**Page:**	1 of 4

Last Review Date: June 13, 2024

Xermelo

Description

Xermelo (telotristat ethyl)

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).

Related policies

Sandostatin LAR

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Xermelo may be considered **medically necessary** if the conditions indicated below are met.

Xermelo may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

Carcinoid syndrome diarrhea

AND ALL of the following:

a. Inadequate treatment response to at least a 3-month trial of SSA (somatostatin analog) therapy
b. Used in combination with an SSA (somatostatin analog)
c. Four or more bowel movements daily
d. Prescriber agrees to assess the patient for severe constipation and abdominal pain and discontinue the medication if either develops

Prior – Approval *Renewal* Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

Carcinoid syndrome diarrhea

AND ALL of the following:

a. Used in combination with an SSA (somatostatin analog)
b. A decrease from baseline in amount of average daily bowel movements
c. Prescriber agrees to continue to assess the patient for severe constipation and abdominal pain and discontinue the medication if either develops
d. **NO** severe constipation or abdominal pain

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity 252 tablets every 84 days

Duration 6 months

Prior – Approval *Renewal* Limits

Quantity 252 tablets every 84 days

Duration 12 months

Rationale

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.

Policy History

Date	Action
March 2017	Addition to PA
June 2017	Annual review
September 2017	Annual review
March 2018	Annual review
March 2019	Annual review
March 2020	Annual review
December 2021	Annual review and reference update
December 2022	Annual review and reference update. Changed policy number to 5.50.014
June 2023	Annual review
June 2024	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 13, 2024 and is effective on July 1, 2024.