PHARMACY PRE-AUTHORIZATION CRITERIA

DRUG (S)	**Xermelo (telotristat ethyl)**
POLICY #	**21106**
INDICATIONS	**Xermelo** is indicated for the treatment of carcinoid syndrome diarrhea in combination with somatostatin analog (SSA) therapy in adults inadequately controlled by SSA therapy.
CRITERIA	**Xermelo** is covered only if the following prior authorization criteria are met: • The patient is 18 years or older AND • The patient has been on a long-acting somatostatin analog (SSA) therapy (e.g. Somatuline Depot [lanreotide for injection], Sandostatin LAR Depot [octreotide for injection], for at least 3 consecutive months AND • While on long-acting somatostatin analog therapy (prior to starting Xermelo), the patient continues to have at least four bowel movements per day AND • Xermelo will be used in combination with a long-acting somatostatin analog therapy AND • Prescribed by, or in consultation with, an oncologist or gastroenterologist for patients with a diagnosis of refractory carcinoid syndrome diarrhea
LIMITATIONS	Xermelo will not be approved in treatment naïve patients. Xermelo will not be approved as monotherapy. If approved, an authorization will be granted for 12 weeks. For reauthorization, documentation showing a decrease in the number of bowel movements per day is required.
REFERENCES	1. Facts & Comparisons Online 2. Xermelo™ tablets [prescribing information]. The Woodlands, TX: Merck; February 2017.
P&T REVIEW HISTORY	5/17, 1/18
REVISION RECORD	1/18