Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	November 20, 2020

Mytesi ® (crofelemer)

INITIAL THERAPY LENGTH OF AUTHORIZATION: UP TO 6 MONTHS

CONTINUATION OF THERAPY LENGTH OF AUTHORIZATION: UP TO 1 YEAR

INITIAL REVIEW CRITERIA (ALL OF THE FOLLOWING MUST BE TRUE):

- Patient must be ≥18 years old
- Patient must have a diagnosis of HIV/AIDS
- Patient is experiencing diarrhea (e.g.: one or more watery stools daily for 5 out of 7 days per week)
- Antiretroviral therapy claims history evident within the past 30 days.
- Active infection has been ruled out via fecal collection and microbiologic culture
- Secondary causes of diarrhea (e.g.: irritable bowel syndrome, gluten and lactose intolerance, traveler's diarrhea, functional diarrhea, and antiretroviral therapy associated diarrhea) have been ruled out by complete and appropriate physical and historical examination
- Patient has tried and failed the preferred antidiarrheals: loperamide, atropine-diphenoxylate

CONTINUATION OF THERAPY CRITERIA (ALL OF THE FOLLOWING MUST BE TRUE):

- Documented reduction in the frequency and quantity of liquid stool volume (e.g.: less than 2 watery bowel movements per week) since the initiation of Mytesi therapy
- Consistent antiretroviral therapy claims history during Mytesi therapy
- Documented follow-up with patient that includes re-culture for microbiologic agents if breakthrough diarrhea occurs while on Mytesi therapy.

DOSING & ADMINISTRATION:

- Recommended dosage: 125 mg orally twice a day
- Maximum dosage of 250 mg per day
- Dosage Form: 125 mg delayed release enteric coated tablet