Market Applicability								
Market	GA	KY	MD	NJ	NY			
Applicable	Х	Х	Х	Х	Х			

Mytesi (crofelemer)

Override(s)	Approval Duration		
Prior Authorization	1 year		
Quantity Limit			

Medications	Quantity Limit		
Mytesi (crofelemer)	May be subject to quantity limit		

APPROVAL CRITERIA

Requests for Mytesi (crofelemer) may be approved when the following criteria are met:

- I. Individual has a diagnosis of HIV/AIDS and currently on anti-retroviral therapy (ART); AND
- II. Individual is using for the symptomatic relief of non-infectious diarrhea; AND
- III. Individual has had an inadequate response to one of the following:
 - A. Loperamide; OR
 - B. Diphenoxylate-atropine.

Crofelemer may not be approved for the following:

I. Individual has a confirmed diagnosis of infectious diarrhea or diarrhea has not been assessed for infectious causes.

Key References:

- 1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2021. URL: http://www.clinicalpharmacology.com. Updated periodically.
- 2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website.
- http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: February 25, 2021.
- 3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
- 4. Lexi-Comp ONLINE[™] with AHFS[™], Hudson, Ohio: Lexi-Comp, Inc.; 2021; Updated periodically.

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.

PAGE 1 of 2 06/14/2021 This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

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Market Applicability								
Market	GA	КҮ	MD	NJ	NY			
Applicable	Х	Х	Х	Х	Х			

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