JOHNS HOPKINS MEDICINE / JOHNS HOPKINS HEALTHCARE	Johns Hopkins HealthCare LLC **Pharmacy Public** **Pharmacy Management Drug Policies**	*Policy Number*	MEDS082
		Effective Date	05/01/2014
		Review Date	06/28/2022
	Subject **Mytesi**	*Revision Date*	05/08/2019
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This document applies to the following Participating Organizations:

Priority Partners

Keywords: Mytesi

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I. POLICY

A. **Mytesi** (crofelemer) will require prior authorization to ensure appropriate use. The process for initiating a prior authorization request can be found in policy PHARM 20.
   1. PPMCO members are subject to the Priority Partners formulary, available at www.ppmco.org.
   2. USFHP members are subject to prior authorization criteria, step-edits and days-supply limits outlined in the Tricare Policy Manual. Tricare Policy supersedes JHHC Medical/Pharmacy Policies. Tricare limits may be accessed at: http://pec.ha.osd.mil/formulary_search.php?submenuheader=1

II. POLICY CRITERIA

A. Mytesi may be approved for patients meeting the following:
   1. Patient has been diagnosed with HIV and is on antiretroviral therapy
   2. Documentation has been submitted showing the following:
      a. A clinical evaluation has occurred to determine that the diarrhea is of non-infectious etiology
      b. Patient has had inadequate response to at least three antidiarrheals (such as loperamide, diphenoxylate/ atropine,bismuth subsalicylate, or opium tinture) after a four-week trial

III. AUTHORIZATION PERIOD/LIMITATIONS

A. Initial approval shall be granted for 6 months.

B. Continuation of therapy may be approved in 12-month intervals with documentation showing clinical benefit with treatment.

IV. EXCLUSIONS

A. Mytesi will not be approved for indications or uses that are not FDA-approved, or guideline-supported.

B. The use of physician samples, or manufacturer product discounts, does not guarantee coverage under the provisions of the medical and/or pharmacy benefit. All pertinent criteria must be met in order to be eligible for benefit coverage.

V. RECOMMENDED DOSE

A. 125mg PO BID

VI. REFERENCES

1. Mytesi [prescribing information]. San Francisco, CA: Napo Pharmaceuticals Inc; November 2020.

VII. APPROVALS

Signature on file at JHHC

DATE OF REVISION	SUMMARY OF CHANGE
03/17/2016	Removed background information
07/27/2017	Updated Exclusion section regarding physician samples
09/14/2018	Updated the policy to reflect Fulyzaq's name change to Mytesi
05/08/2019	Clarified preferred anti-diarrheals in the clinical criteria
06/28/2022	Updated policy layout

Review/Revision Dates: 04/16/2014, 03/17/2016, 07/27/2017, 09/14/2018, 05/08/2019, 06/28/2022