

Clinical Policy Title:	crofelemer
Policy Number:	RxA.232
Drug(s) Applied:	Mytesi®
Original Policy Date:	02/07/2020
Last Review Date:	06/10/2021
Line of Business Policy Applies to:	All lines of business

Background

Crofelemer (Mytesi®) is an anti-diarrheal indicated for the symptomatic relief of non-infectious diarrhea in adult patients with human immunodeficiency virus/acquired immune deficiency syndrome (HIV/AIDS) on anti-retroviral therapy.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
crofelemer (Mytesi®)	Non-infectious diarrhea in HIV/AIDS	One 125 mg tablet orally twice a day	250 mg/day

Dosage Forms

- Delayed-release tablets: 125 mg

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria. The provision of provider samples does not guarantee coverage under the terms of the pharmacy benefit administered by RxAdvance. All criteria for initial approval must be met in order to obtain coverage.

I. Initial Approval Criteria

A. Non-Infectious diarrhea in HIV/AIDS (must meet all):

1. Diagnosis of HIV/AIDS;
2. Age 18 years of age or older;
3. Member has non-infectious diarrhea;
4. Member is currently receiving anti-retroviral therapy as evidenced by claims history;
5. Failure of an antidiarrheal medication (e.g., loperamide, diphenoxylate/atropine, bismuth subsalicylate) unless contraindicated or clinically significant adverse effects are experienced;
6. Dose does not exceed 250 mg (2 tablets) per day.

Approval Duration

Commercial: 6 months

Medicaid: 6 months

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

II. Continued Therapy Approval

A. Non-Infectious diarrhea in HIV/AIDS (must meet all):

1. Currently receiving medication that has been authorized by RxAdvance or member has previously met initial approval criteria listed in this policy.
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 250 mg (2 tablets) per day.

Approval Duration

Commercial: 12 months

Medicaid: 12 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key

AIDS: Acquired Immune Deficiency Syndrome

FDA: Food and Drug Administration

APPENDIX B: Therapeutic Alternatives

Below are suggested therapeutic alternatives based on clinical guidance. Please check drug formulary for preferred agents and utilization management requirements.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
loperamide (Imodium®)	2 mg orally after each loose stool	16 mg/day
diphenoxylate/atropine (Lomotil®)	2 tablets (5-0.05 mg) orally once a day	20 mg/day (diphenoxylate)
bismuth subsalicylate (PeptoBismol®)	Regular strength: 524 mg orally every 0.5-1 hour as needed Extra strength: 1050 mg orally every 1 hour as needed	Regular strength: 4192 mg/day (8 doses/24 hours) Extra strength : 4200 mg/day (4 doses/24 hours)

APPENDIX C: Contraindications/Boxed Warnings

- Contraindication(s)
 - None
- Boxed Warning(s)
 - None

APPENDIX D: General Information

- Crofelemer was known by the trade name Fulyzaq until October 2016.
- In a 12-week, double-blind, placebo-controlled trial evaluating 3 doses (125 mg, 250 mg, 500 mg BID) of crofelemer in 242 patients with diarrhea-predominant irritable bowel syndrome, Mytesi did not produce significant improvement in stool consistency, the primary endpoint.

References

1. Mytesi Prescribing Information. San Francisco, CA: Napo Pharmaceuticals, Inc.; November 2020. Available at: www.mytesi.com. Accessed March 04, 2021.
2. Mangel AW, Chaturvedi P. Evaluation of crofelemer in the treatment of diarrhea- predominant irritable bowel syndrome patients. *Digestion*. 2008; 78(4): 180-186.
3. Micromedex® Healthcare Series [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed July 28, 2020.
4. Mytesi. In: Lexicomp Online Drug Database [database on the Internet]. Hudson, Ohio: Lexicomp, Inc.; 2021 [updated December 13, 2020]. Available at: <http://online.lexi.com>. Subscription required to view. Accessed March 04, 2021.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established.	01/2020	02/07/2020
Policy updated: <ol style="list-style-type: none"> 1. Formatting updated. 2. Policy Title updated. 3. Continued criteria for approval updated. 4. Approval duration updated. 5. Reference updated. 	07/28/2020	09/14/2020
Policy was reviewed: <ol style="list-style-type: none"> 1. Statement about provider sample, “The provision of provider samples does not guarantee coverage...” was added to Clinical Policy. 2. Appendix B: Statement under Therapeutic Alternatives was changed to “Below are suggested therapeutic alternatives based on...”. 3. Appendix B: Therapeutic Alternatives header verbiage has been changed to “Below are suggested therapeutic alternatives based on...”. 4. References were updated. 	03/04/2021	06/10/2021

