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Clinical Policy Title:	crofelemer
Policy Number:	RxA.232
Drug(s) Applied:	Mytesi®
Original Policy Date:	02/07/2020
Last Review Date:	08/28/2024
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

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

1. Diagnosis of HIV/AIDS;
2. Member has non-infectious diarrhea;
3. Member is currently receiving anti-retroviral therapy;
4. Trial and failure of an antidiarrheal medication (e.g., loperamide, diphenoxylate/atropine, bismuth subsalicylate) unless contraindicated or clinically significant adverse effects are experienced.

Approval Duration

All Lines of Business (except Medicare): 6 months

II. Continued Therapy Approval

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

1. Auto-approval based on lookback functionality within the past 120 days as a proxy for member responding positively to therapy.

Approval Duration

All Lines of Business (except Medicare): 12 months

References

1. Mangel AW, Chaturvedi P. Evaluation of crofelemer in the treatment of diarrhea- predominant irritable bowel syndrome patients. Digestion. 2008; 78(4): 180-186. Available at: https://www.karger.com/Article/Abstract/185719. Accessed August 28, 2024.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established.	01/2020	02/07/2020
Policy updated: 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:	03/04/2021	06/10/2021

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.

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1. References were updated.		
Policy was reviewed: 1. Continued Therapy Approval Criteria II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance...". 2. References were reviewed and updated.	01/20/2022	04/18/2022
Policy was reviewed: 1. References were reviewed and updated.	12/27/2022	4/13/2023
Policy was reviewed.	10/19/2023	10/19/2023
Policy was reviewed: 1. Removed age restrictions. 2. Removed dose restrictions. 3. Updated Continued therapy approval with auto-approval based on lookback functionality within the past 120 days. 4. Removed reauthorization requirement for positive response to therapy. 5. Updated approval duration verbiage. 6. Reference was reviewed and updated.	08/28/2024	09/13/2024

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