BOSTON MEDICAL CENTER HEALTHNet PLAN

bmchp.org | 888-566-0008

Pharmacy Policy

Mytesi®

Policy Number: 9.903
Version Number: 2.0
Version Effective Date: 3/1/2022

Product Applicability	☐ **All Plan+ Products**
Well Sense Health Plan ☐ New Hampshire Medicaid	**Boston Medical Center HealthNet Plan** ☐ MassHealth - MCO ☐ MassHealth - ACO ☒ Qualified Health Plans/ConnectorCare/Employer Choice Direct ☐ Senior Care Options

Note: Disclaimer and audit information is located at the end of this document.

Prior Authorization Policy

Products Affected:

- **Mytesi® (crofelemer)**

The Plan may authorize coverage of the above products for members meeting the following criteria:

Covered Use	All FDA approved indications unless otherwise excluded
Exclusion Criteria	None
Required Medical Information	1. Diagnosis of noninfectious diarrhea due to HIV/AIDS antiretroviral therapy (ART); ***AND***

+ *Plan* refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name Well Sense Health Plan.

	2. Use of an antiretroviral therapy (ART) regimen for at least one month; ***AND*** 3. Infectious etiologies of diarrhea have been ruled out; ***AND*** 4. An inadequate response, intolerance, or contraindication to a trial of antidiarrheal agents from at least two of the following categories: a. Anti-motility agents (e.g. loperamide, diphenoxylate/atropine) b. Adsorbents (e.g. bismuth subsalicylate) c. Bulk-forming fiber supplements (e.g. Metamucil) d. Calcium supplements
Age Restrictions	18 years of age or older
Prescriber Restriction	None
Coverage Duration	Initial: 6 months Reauthorization: 12 months
Other criteria	**Reauthorization:** 1. Initial criteria met; ***AND*** 2. Number of watery stools has decreased to less than 3 per week ; ***AND*** 3. There continues to be a medical need for Mytesi®

Applicable Coding:

None

Clinical Background Information and References

1. Mytesi® Prescribing Information. Napo Pharmaceuticals, Inc., San Francisco, CA 94105. June, 2016.
2. Wilcox AM. Evaluation of the HIV-Infected Patient with Diarrhea. UpToDate. Last updated March 15, 2017. Available: www.uptodate.com. Accessed June 19, 2018
3. US Food and Drug Administration. FDA News Release. FDA approves first anti-diarrheal drug for HIV/AIDS patients. Available: http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm333701.htm. Accessed June 19, 2018
4. MacArthur RD. Management of Noninfectious Diarrhea Associated With HIV and Highly Active Antiretroviral Therapy. Am J Manag Care. 2013;19(11 suppl): S238-S245
5. Rodger D. MacArthur, Trevor N. Hawkins, Stephen J. Brown, Anthony LaMarca, Patrick G. Clay, Andrew C. Barrett, Enoch Bortey, Craig Paterson, Pamela L. Golden & William P. Forbes (2013) Efficacy and Safety of Crofelemer for Noninfectious Diarrhea in HIVSeropositive Individuals (ADVENT Trial): A Randomized, Double-Blind, Placebo-Controlled, TwoStage Study, HIV Clinical Trials, 14:6, 261-273, DOI: 10.1310/hct1406-261

6. Dikman AE, Schonfeld E, Srisarajivakul NC, Poles MA. Human Immunodeficiency Virus-Associated Diarrhea: Still an Issue in the Era of Antiretroviral Therapy. *Digestive Diseases and Sciences*. 2015;60(8):2236-2245. doi:10.1007/s10620-015-3615-y.

Original Approval Date	Original Effective Date	Policy Owner	Approved by
12/1/2020	1/1/2021	Pharmacy Services	Pharmacy & Therapeutics (P&T) Committee

Policy Revisions History			
Review Date	**Summary of Revisions**	**Revision Effective Date**	**Approved by**
12/1/2020	Discontinued policy 9.047 and created new policy for QHP. Change criteria from requiring 1 trial agent to requiring 2 and addition of 3 mores classes of treatment trial options (Adsorbents (e.g. bismuth subsalicylate), Bulk-forming fiber supplements and Calcium supplements	1/1/2021	Pharmacy & Therapeutics (P&T) Committee
11/11/2021	P&T Annual Review. Adjust trial/failure criteria to make it clear that agents from at least two categories need to be tried. Require initial criteria to be met for reauthorization.	3/1/2022	P&T Committee

Next Review Date

11/2022

Other Applicable Policies

Reference to Applicable Laws and Regulations, If Any

Disclaimer Information

Medical Policies are the Plan's guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and

other Plan Policies, as well as the Member's benefit document, and when appropriate, coordinates with the Member's health care Providers to consider the individual Member's health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan's service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member's benefit document, take precedence over these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.