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Pharmacy Policy

Mytesi®

Policy Number: 9.903

Revision Number: R0

Version Effective Date: 1/1/2021

Product Applicability <input type="checkbox"/> All Plan+ Products	
Well Sense Health Plan <input checked="" type="checkbox"/> New Hampshire Medicaid <input type="checkbox"/> _____	Boston Medical Center HealthNet Plan <input type="checkbox"/> MassHealth - MCO <input type="checkbox"/> MassHealth - ACO <input type="checkbox"/> Qualified Health Plans/ConnectorCare/Employer Choice Direct <input type="checkbox"/> Senior Care Options <input type="checkbox"/> _____

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	N/A
Required Medical Information	<ol style="list-style-type: none"> 1. Diagnosis of noninfectious diarrhea due to HIV/AIDS antiretroviral therapy (ART) that has lasted for at least one month; AND 2. Use of an antiretroviral therapy (ART) regimen for at least one month; AND 3. Infectious etiologies of diarrhea have been ruled out; AND

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	<p>4. An inadequate response, intolerance or contraindication trial of at least two (2) of the following antidiarrheal agents:</p> <ul style="list-style-type: none"> 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	Member is 18 years of age or older
Prescriber Restriction	None
Coverage Duration	Initial: 6 months Reauthorization: 12 months
Other criteria	<p>Reauthorization</p> <p>Documentation of the following:</p> <ul style="list-style-type: none"> 1. Number of watery stools has decreased to less than 3 per week without treatment-related adverse events (medical records must be included); AND 2. There continues to be a medical need for Mytesi[®]

Applicable Coding:

Clinical Background Information and References

1. Mytesi[®] Prescribing Information. Napo Pharmaceuticals, Inc., San Francisco, CA 94105. June, 2016 (updated 2/2018)
2. Wilcox AM. Evaluation of the HIV-Infected Patient with Diarrhea. UpToDate. Last updated March 15, 2017. Available: www.uptodate.com. Accessed July 2020
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.

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

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 NH. Change criteria from requiring 1 trial agent to requiring 2 and adding 3 more classes of treatment trial options (Adsorbents (e.g. bismuth subsalicylate), Bulk-forming fiber supplements and Calcium supplements	1/1/2021	P&T Committee, NH DHHS

Next Review Date

2021

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

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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.

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