Pharmacy Policy

Fulyzaq®

Policy Number: 9.047
Version Number: 4.0
Version Effective Date: 11/09/2017

Product Applicability □ All Plan+ Products

<table>
<thead>
<tr>
<th>Well Sense Health Plan</th>
<th>Boston Medical Center HealthNet Plan</th>
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<tbody>
<tr>
<td>☒ New Hampshire Medicaid</td>
<td>☒ MassHealth</td>
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<td>☒ NH Health Protection Program</td>
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Note: Disclaimer and audit information is located at the end of this document.

Policy Summary

The Plan will authorize coverage of Fulyzaq® when appropriate criteria are met.

Description of Item or Service

Historically, diarrhea in HIV-positive patients was due to opportunistic infections or HIV itself. However, since the advent of highly active antiretroviral therapy (HAART), HAART is a leading diagnostic consideration when diarrhea is the sole complaint. Among the major classes of antiretrovirals, protease inhibitors (particularly nelfinavir and ritonavir) seem to carry the greatest risk of ART-induced diarrhea. The conventional treatment for ART-induced diarrhea includes loperamide, diphenoxylate/atropine and bismuth subsalicylate.

The management of idiopathic, noninfectious diarrhea, associated with HIV or ART use has been nonspecific. Commonly used therapies include antimotility agents such as loperamide, diphenoxylate/atropine, bismuth subsalicylate, bulk-forming fiber supplements and at times, pancrelipase or octreotide. Data supporting the use of such agents are very limited, and randomized controlled trials are lacking.

*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.
Fulyzaq® (crofelemer) was approved by the US Food and Drug Administration (FDA) in 2012 for the symptomatic relief of non-infectious diarrhea in adult patients with HIV/AIDS on anti-retroviral therapy. Derived from the red sap of the Croton lechleri plant, Fulyzaq is the first anti-diarrheal drug for HIV/AIDS patients approved by FDA. It is available as 125mg delayed-release tablet, and the recommended dose is 1 tablet twice a day with or without food. Crofelemer is a chloride channel antagonist that blocks chloride ion (Cl⁻) secretion and results in normalization of Cl⁻ and water flow in the gastrointestinal (GI) tract. The most common adverse reactions are upper respiratory tract infection, bronchitis, cough, flatulence and increased bilirubin. The safety and effectiveness of crofelemer have not been established in pediatric patients less than 18 years of age.

Policy

The Plan may authorize coverage of Fulyzaq® for members meeting the following clinical criteria:

Prior Authorization

Initial Therapy (Duration of approval – 6 months)

A prior authorization request will be required for all prescriptions for Fulyzaq®. These requests will be approved when the following criteria are met:

Documentation of the following:

1. Use of an antiretroviral therapy (ART) regimen for at least one month; AND
2. Age is 18 years of age or older; AND
3. Diagnosis of noninfectious diarrhea due to HIV/AIDS antiretroviral therapy (ART) that has lasted for at least one month; AND
4. Infectious etiologies of diarrhea have been ruled out; AND
5. An inadequate response, intolerance or contraindication trial of at least 2 of the following antidiarrheal agents:
   • loperamide
   • diphenoxylate/atropine
   • bismuth subsalicylate

Re-authorization (Duration of approval – 1 year)

Documentation of the following:

1. Decrease in the number of watery stools by at least 50% per week from the baseline without treatment-related adverse events (medical records must be included); AND
2. There continues to be a medical need for Fulyzaq®

Quantity Limitations Apply - see Appendix A

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Limitations

The Plan will not approve coverage of Fulyzaq® in the following instances:

1. When the above criteria are not met.
2. When being used for non-FDA approved indication

Clinical Background Information and References


Appendix A - Quantity Limitations for Fulyzaq®

<table>
<thead>
<tr>
<th>Medication Name</th>
<th>Maximum Quantity</th>
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<tbody>
<tr>
<td>Fulyzaq® tablet</td>
<td>60 tablets per 30 days</td>
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<table>
<thead>
<tr>
<th>Original Approval Date</th>
<th>Original Effective Date</th>
<th>Policy Owner</th>
<th>Approved by</th>
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<tr>
<td>07/10/2014</td>
<td>11/03/2014</td>
<td>Pharmacy Services</td>
<td>Pharmacy &amp; Therapeutics (P&amp;T) Committee, NH DHHS</td>
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Policy Revisions History

<table>
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<tr>
<th>Review Date</th>
<th>Summary of Revisions</th>
<th>Revision Effective Date</th>
<th>Approved by</th>
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<tr>
<td>07/09/2015</td>
<td>P&amp;T Annual Review, no changes required</td>
<td>11/04/2015</td>
<td>P&amp;T Committee</td>
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<td>07/14/2016</td>
<td>P&amp;T Annual Review, no changes required</td>
<td>11/14/2016</td>
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Next Review Date

07/12/2018

Other Applicable Policies

9.002 Mandatory Generic Substitution Policy
9.015 Quantity Limitation Policy
OCA 3.14 Medically Necessary Policy

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.

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Fulyzaq®

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