Pharmacy Policy Bulletin

Title: Crofelemer (Fulyzaq®)
Policy #: Rx.01.137

Application of pharmacy policy is determined by benefits and contracts. Benefits may vary based on product line, group, or contract. Some medications may be subject to precertification, age, gender or quantity restrictions. Individual member benefits must be verified.

This pharmacy policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety, or FDA approval may have changed. This Pharmacy Policy will be regularly updated as scientific and medical literature becomes available. This information may include new FDA-approved indications, withdrawals, or other FDA alerts. This type of information is relevant not only when considering whether this policy should be updated, but also when applying it to current requests for coverage.

Members are advised to use participating pharmacies in order to receive the highest level of benefits.

Intent:
The intent of this policy is to communicate the medical necessity criteria for Crofelemer (Fulyzaq®) as provided under the member's pharmacy benefit.

Description:
Crofelemer (Fulyzaq®) is an antidiarrheal agent that inhibits both the cyclic adenosine monophosphate–stimulated cystic fibrosis transmembrane conductance regulator (CFTR) chloride ion (Cl⁻) channel, and the calcium-activated Cl⁻ channels (CaCC) at the luminal membrane of enterocytes. The CFTR Cl⁻ channel and CaCC regulate Cl⁻ and fluid secretion by intestinal epithelial cells. Crofelemer acts by blocking Cl⁻ secretion and accompanying high volume water loss in diarrhea, normalizing the flow of Cl⁻ and water in the GI tract.

Crofelemer (Fulyzaq®) is indicated for the symptomatic relief of noninfectious diarrhea in patients with HIV/AIDS on antiretroviral therapy (ART).

Policy:
Crofelemer (Fulyzaq®) is approved when ALL of the following inclusion criteria are met:

1. Documentation of use for the symptomatic relief of non-infectious diarrhea in patients with HIV/AIDS on anti-retroviral therapy (ART); and
2. Inadequate response or inability to tolerate ONE of the following:
   a. Loperamide; or
   b. Diphenoxylate-atropine

**Black Box Warning:**
None

**Guidelines:**
Refer to the specific manufacturer's prescribing information for administration and dosage details and any applicable Black Box warnings.

**BENEFIT APPLICATION**

Subject to the terms and conditions of the applicable benefit contract, the applicable drug(s) identified in this policy is (are) covered under the pharmacy benefits of the Company’s products when the medical necessity criteria listed in this pharmacy policy are met. Any services that are experimental/investigational or cosmetic are benefit contract exclusions for all products of the Company.

**References:**


**Applicable Drugs:**

Inclusion of a drug in this table does not imply coverage. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

<table>
<thead>
<tr>
<th>Brand name</th>
<th>Generic name</th>
</tr>
</thead>
</table>
Fulyzaq  Crofelemer

Cross References:

<table>
<thead>
<tr>
<th>Policy Version Number:</th>
<th>4.00</th>
</tr>
</thead>
<tbody>
<tr>
<td>P&amp;T Approval Date:</td>
<td>July 14, 2016</td>
</tr>
<tr>
<td>Policy Effective Date:</td>
<td>September 01, 2016</td>
</tr>
<tr>
<td>Next Required Review Date:</td>
<td>July 14, 2017</td>
</tr>
</tbody>
</table>

The Policy Bulletins on this website were developed to assist AmeriHealth in administering the provisions of the respective benefit programs, and do not constitute a contract. If you are an AmeriHealth member, please refer to your specific benefit program for the terms, conditions, limitations and exclusions of your coverage. AmeriHealth does not provide health care services, medical advice or treatment, or guarantee the outcome or results of any medical services/treatments. The facility and professional providers are responsible for providing medical advice and treatment. Facility and professional providers are independent contractors and are not employees or agents of AmeriHealth. If you have a specific medical condition, please consult with your doctor. AmeriHealth reserves the right at any time to change or update its Policy Bulletins. ©2016 AmeriHealth, Inc. All Rights Reserved.