Premier Health Plan

POLICY AND PROCEDURE

POLICY NUMBER: *RX.PA.194.E*
REVISION DATE: *N/A*

POLICY TITLE: ***Fulyzaq (crofelemer)***
DEPARTMENT: **Clinical Pharmacy Services- Utilization Management**
ORIGINAL DATE: ***April 2013 (as adopted from UPMC Health Plan)***

Last P & T Committee Approval Date: *February 2018*

Product Applicability: *mark all applicable products below:*

COMMERCIAL	[ ] HMO	[ ] PPO	*Products*: [ ] Small [ ] Indiv. [ ] Large	*Exchange*: [ ] Shop [ ] Indiv.	[x] All
OTHER	[x] Self-funded/ASO				

PURPOSE

The purpose of this policy is to define the prior authorization process for Fulyzaq (crofelemer).

Fulyzaq (crofelemer) is indicated for the symptomatic relief of non-infectious diarrhea in adult patients with HIV/AIDS on anti-retroviral therapy

DEFINITIONS

N/A

POLICY

It is the policy of the Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity, and approval by the Pharmacy & Therapeutics Committee of the criteria for prior authorization, as described in RX.002 Pharmacy and Therapeutics Committee and RX.003-Prior Authorization Process.

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The drug, Fulyzaq (crofelemer), is subject to the prior authorization process.

PROCEDURE

Initial Authorization Criteria:

Must meet all of the criteria listed below:

- Must be prescribed by an infectious disease specialist or HIV specialist
- Must be 18 years of age or older
- Must have a diagnosis of non-infectious diarrhea
- Must be actively utilizing antiretroviral agents to treat HIV/AIDS
- Must have documentation of persistent loose stools despite regular use of an anti-diarrheal medication (e.g., loperamide, diphenoxylate, and bismuth subsalicylate)

Reauthorization Criteria:

All prior authorization renewals are reviewed on a six-month basis to determine the Medical Necessity for continuation of therapy. Authorization may be extended at 6-month intervals based upon the following:

- Documentation of a decrease in number of watery bowel movements and improvement in the condition based upon the prescriber's assessment while on treatment
- Must be continuously utilizing antiretroviral agents to treat HIV/AIDS

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	Up to 1 month
Reauthorization	Up to 6 months
Quantity Level Limit	
Fulyzaq	60 tablets per 30 days

If the established criteria are not met, the request is referred to a Medical Director for review.

REFERENCES

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1. Fulyzaq [package insert]. Salix Pharmaceuticals, Inc. Raleigh, NC. January 2013.

RECORD RETENTION

Records Retention for Evolent Health documents, regardless of medium, are provided within the Evolent Health records retention policy and as indicated in CORP.028.E Records Retention Policy and Procedure.

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
Annual review	*02/17,02/18*

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