

## POLICY AND PROCEDURE

POLICY NUMBER: *RX.PA.429.E*  
 REVISION DATE: *N/A*  
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**POLICY TITLE:** *Amitiza (lubiprostone)*  
**DEPARTMENT:** *Clinical Pharmacy Services- Utilization Management*  
**ORIGINAL DATE:** *May 2016*

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

**Product Applicability:** *mark all applicable products below:*

<b>COMMERCIAL</b>	<input type="checkbox"/> HMO <input type="checkbox"/> PPO    Products: <input type="checkbox"/> Small    Exchange: <input type="checkbox"/> Shop <input checked="" type="checkbox"/> All <input type="checkbox"/> Indiv. <input type="checkbox"/> Indiv. <input type="checkbox"/> Large
<b>OTHER</b>	<input checked="" type="checkbox"/> Self-funded/ASO

### PURPOSE

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

Amitiza (lubiprostone) is indicated for:

- Treatment of chronic idiopathic constipation in adults
- Treatment of opioid-induced constipation in adults with chronic, non-cancer pain
- Treatment of irritable bowel syndrome with constipation in women  $\geq$  18 years old

### 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.

The drug, Amitiza (lubiprostone), is subject to the prior authorization process.

## PROCEDURE

### Initial Authorization Criteria:

*Must meet all of the criteria listed under the respective header:*

#### 1. Automatic coverage:

- Must have a documented pharmacy claim history for Linzess (linaclotide) or Movantik (naloxegol) in the past 3 months

#### 2. Members without a documented claims history:

- Must have chart documentation which shows the member has failed therapy with Linzess (linaclotide) or Movantik (naloxegol)

### Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	Up to duration of member's membership with plan
Reauthorization	N/A
Quantity Level Limit	
Amitiza	60 capsules per month

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

## REFERENCES

1. Amitiza [package insert]. Deerfield, IL: Takeda Pharmaceuticals America, Inc.; April 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.



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**REVIEW HISTORY**

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
<i>Annual Review</i>	<i>2/17, 02/18</i>

