Premier Health Plan

POLICY AND PROCEDURE

POLICY TITLE: **Relistor (Methylnaltrexone)**
DEPARTMENT: **Clinical Pharmacy Services- Utilization Management**
ORIGINAL DATE: ***October 2008 (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 Relistor (Methylnaltrexone)

Relistor (Methylnaltrexone) is indicated for the treatment of opioid-induced constipation in patients with an advanced, life-limiting illness when response to laxative therapy has not been sufficient and for the treatment of adult patients with opioid-indiced constipation from non-cancer pain.

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, as defined in CRM.015-Medical Necessity, and approval by the Pharmacy & Therapeutics Committee of the criteria for prior authorization, as described in RX.003-Prior Authorization Process.

The drug, Relistor (Methylnaltrexone), is subject to the prior authorization process.

PROCEDURE

Initial Authorization Criteria:

Must meet all of the criteria listed under the respective diagnosis:

1. **Treatment of opioid-induced constipation in patients with advanced illness (applies to methylnaltrexone injection only)**

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- Must have a diagnosis of opioid-induced constipation
- Must have an advanced, life-limiting illness
- Must have trial and failure of a course of 2 traditional laxatives for treatment of the constipation
- Must not have a known or suspected mechanical gastrointestinal obstruction or be at risk for recurrent obstruction

2. Treatment of opioid-induced constipation in patients with non-cancer pain (applies to methylnaltrexone injection and tablet)

- Must be age 18 years or older
- Must have a diagnosis of opioid-induced constipation
- Must have chronic non-cancer pain
    - Includes chronic pain related to prior cancer or its treatment in members that do not require frequent (e.g. weekly) opioid dosage escalation
- Must not have a known or suspected mechanical gastrointestinal obstruction or be at risk for recurrent obstruction
- Must have documentation of current, ongoing opioid therapy through
- pharmacy claims or physician chart documentation
- Must have documentation of a consult with a pain management specialist to determine if dosage of opioid can be decreased
- Must have an adequate trial (minimum of 3 months) of lubiprostone (Amitiza®) and naloxegol (Movantik®) with an inadequate response or significant side effects/toxicity or a documented contraindication to these therapies. Chart documentation must be included.
- Must have an adequate trial of ALL of the following with inadequate responses or significant side effects/toxicity or have a contraindication to these therapies :
    - Stool softener (eg: docusate, etc.)
    - Stimulant laxatives (eg: senna, bisacodyl, etc.)
    - Bulk laxative (eg: psyllium, etc)
    - Osmotic laxative (eg: lactulose, etc.)
    - Hyperosmotic laxative (eg: polyethylene glycol, etc.)

<u>Reauthorization Criteria</u>:

1. Treatment of opioid-induced constipation in patients with advanced illness

- Reauthorizations are granted every 4 months to determine the medical necessity for continuation of treatment. Authorizations may be extended at 4 months intervals upon documentation from the prescriber that the member's condition has improved as a result of treatment

2. Treatment of opioid-induced constipation in patients with non-cancer pain

- Reauthorizations are granted on an annual basis based upon the following:
    - Chart documentation from the prescriber that the member's condition has improved as a result of treatment as defined by an increase in the number of weekly stools from baseline
    - Continuation of opioid therapy

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	• Advanced illness: 4 months • Non-cancer pain: 3 months
Reauthorization	• Advanced illness: 4 months • Non-cancer pain: 1 year

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

REFERENCES

1. Relistor [package insert]. Raleigh, NC: Salix Pharmaceuticals. January 2017.
2. Michna E, Blonsky ER, Schulman S, et al. Subcutaneous methylnaltrexone for treatment of opioidinduced constipation in patients with chronic, nonmalignant pain: a randomized controlled study. J Pain. 2011; 12(5): 544-562.

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	*02/16, 02/17, 02/18*
Criteria Update	*10/16, 11/17*