

Relistor® (methylnaltrexone) Prior Authorization Program Summary

OBJECTIVE

The intent of the prior authorization (PA) program for methylnaltrexone is to ensure appropriate selection of patients for treatment according to product labeling and/or clinical studies and/or guidelines. The PA defines appropriate use as therapy of opioid-induced constipation (OIC) in patients with advanced illness who are receiving palliative care and who have tried at least two traditional laxative agents (stimulant laxatives, enemas, osmotic agents, or stool softeners) or have a documented intolerance, FDA labeled contraindication, or hypersensitivity to traditional laxative agents. Criteria do not allow coverage for methylnaltrexone in patients who have FDA labeled contraindications. Requests for methylnaltrexone will be reviewed when patient-specific documentation has been provided.

TARGET DRUG

Relistor[®] (methylnaltrexone)

PRIOR AUTHORIZATION CRITERIA FOR APPROVAL

Relistor will be approved when ALL of the following are met:

- The patient has advanced illness and is receiving palliative care AND
- 2. The patient has chronic use of an opioid agent
- 3. The patient has a diagnosis of opioid-induced constipation **AND**
- 4. ONE of the following:
 - a. The patient has tried a minimum of two standard laxative agents OR
 - b. The patient has a documented intolerance, contraindication, or hypersensitivity to standard laxative therapy

AND

5. The patient does NOT have any FDA labeled contraindication(s) to therapy

Length of Approval: 12 months

FDA Labeled Contraindications

Agent	Contraindications
Relistor (methylnaltrexone)	Known or suspected mechanical gastrointestinal obstruction