OVERVIEW

MOVANTIK (naloxegol) is an opioid antagonist indicated for the treatment of opioid-induced constipation (OIC) in adult patients with chronic non-cancer pain.

AMITIZA (lubiprostone) is a chloride channel activator indicated for the treatment of opioid-induced constipation (OIC) in adults with chronic non-cancer pain, chronic idiopathic constipation in adults and treatment of irritable bowel syndrome with constipation in women ≥ 18 years old.

SYMPROIC (naldemedine) is an opioid antagonist indicated for the treatment of opioid-induced constipation (OIC) in adult patients with chronic non-cancer pain. Symproic contains naldemedine, a Schedule II controlled substance.

RELISTOR (methylnaltrexone bromide) is an opioid antagonist that comes as a tablet and an injection. The tablet is indicated for the treatment of opioid-induced constipation (OIC) in adults with chronic non-cancer pain while the injection is indicated for the treatment of OIC in adults with chronic non-cancer pain and OIC in adults with advanced illness who are receiving palliative care, when response to laxative therapy has not been sufficient.

POLICY STATEMENT
Prior authorization is recommended for prescription benefit coverage of Movantik, Amitiza, Symproic, and Relistor.

RECOMMENDED AUTHORIZATION CRITERIA
Coverage of Movantik, Amitiza, Symproic, or Relistor is recommended in those who meet the following criteria:

Movantik (naloxegol)
Initial approval of Movantik for opioid induced constipation if patient meets the following criteria (a, b, c, d, e and f):

a) Patient is 18 years of age or older; AND
b) There is a documented diagnosis of chronic non-cancer pain; AND
c) Patient has been taking opioids for 4 weeks or more; AND
d) Patient has attempted lifestyle changes including maintaining a diet rich in fiber and/or fiber supplementation along with adequate fluid intake; AND
e) Documented trial and failure or intolerance to at least 2 of the following with or without a stool softener (e.g. docusate) in the past 3 months
   i. At least one bowel regimen of an osmotic laxative (e.g. PEG 3350)
   ii. At least one stimulant laxative (e.g. bisacodyl)
iii. At least one saline laxative (eg. milk of magnesia, magnesium citrate or Fleet phospho-soda);
   AND
f) Patient does not have a known or suspected gastrointestinal obstruction or is at increased risk of recurrent obstruction.

Approval Duration
Initial Approval and Re-authorization = 12 months (365 days)

Amitiza (lubiprostone)
Initial approval of Amitiza if patient meets the following criteria for one of the following indications:

1. There is a documented diagnosis of chronic non-cancer pain; AND
   a) There is documented diagnosis of opioid induced constipation; AND
   b) Patient is over the age of 18 years; AND
   c) Patient has attempted lifestyle changes including maintaining a diet rich in fiber and/or fiber supplementation along with adequate fluid intake; AND
   d) Patient has tried and failed or is intolerance to at least 2 of the following with or without a stool softener (e.g. docusate) in the past 3 months
      i. At least one bowel regimen of an osmotic laxative (e.g. PEG 3350)
      ii. At least one stimulant laxative (e.g. bisacodyl)
      iii. At least one saline laxative (eg. milk of magnesia, magnesium citrate or Fleet phospho-soda); AND
   e) Patient is not taking diphenylheptane opioids (eg. Methadone); AND
   f) Patient does not have a known or suspected gastrointestinal obstruction or is at increased risk of recurrent obstruction.

OR

2. There is documented diagnosis of chronic idiopathic constipation established by or in consultation with a specialist in gastroenterology; AND
   a) Patient is over the age of 18 years; AND
   b) Patient has attempted lifestyle changes including maintaining a diet rich in fiber and/or fiber supplementation along with adequate fluid intake; AND
   c) Patient has tried and failed or is intolerance to at least 2 of the following with or without a stool softener (e.g. docusate) in the past 3 months
      i. At least one bowel regimen of an osmotic laxative (e.g. PEG 3350)
      ii. At least one stimulant laxative (e.g. bisacodyl)
      iii. At least one saline laxative (eg. milk of magnesia, magnesium citrate or Fleet phospho-soda); AND
   d) Patient is not taking diphenylheptane opioids (eg. Methadone); AND
   e) Patient does not have a known or suspected gastrointestinal obstruction or is at increased risk of recurrent obstruction.

OR

3. There is documented diagnosis of irritable bowel syndrome with constipation in women
   a) Patient is female 18 years or older; AND
   b) Patient has attempted lifestyle changes including maintaining a diet rich in fiber and/or fiber supplementation along with adequate fluid intake; AND
c) Patient has tried and failed or is intolerance to at least 2 of the following with or without a stool softener (e.g. docusate) in the past 3 months
   i. At least one bowel regimen of an osmotic laxative (e.g. PEG 3350)
   ii. At least one stimulant laxative (e.g. bisacodyl)
   iii. At least one saline laxative (e.g. milk of magnesia, magnesium citrate or Fleet phosphosoda); AND

d) Patient is not taking diphenylheptane opioids (e.g. Methadone); AND

e) Patient does not have a known or suspected gastrointestinal obstruction or is at increased risk of recurrent obstruction.

**Approval Duration**
Initial Approval and Re-authorization = 12 months (365 days)

**Symproic (naldemedine)**
Initial approval of Symproic for opioid induced constipation if patient meets the following criteria (a, b, c, d, e and f):

   a) Patient is 18 years of age or older; AND
   b) There is a documented diagnosis of chronic non-cancer pain; AND
   c) Patient has been taking opioids for 4 weeks or more; AND
   d) Patient has attempted lifestyle changes including maintaining a diet rich in fiber and/or fiber supplementation along with adequate fluid intake; AND
   e) Documented trial and failure or intolerance to at least 2 of the following with or without a stool softener (e.g. docusate) in the past 3 months
      i. At least one bowel regimen of an osmotic laxative (e.g. PEG 3350)
      ii. At least one stimulant laxative (e.g. bisacodyl)
      iii. At least one saline laxative (e.g. milk of magnesia, magnesium citrate or Fleet phosphosoda); AND
   f) Patient does not have a known or suspected gastrointestinal obstruction or is at increased risk of recurrent obstruction.

**Approval Duration**
Initial Approval and Re-authorization = 1 year (365 days)

**Relistor (methylnaltrexone bromide)**
Initial approval of Relistor if patient meets the following criteria:

1. There is a documented diagnosis of chronic non-cancer pain; AND
   a) Documented diagnosis of
      i. Opioid-induced constipation (OIC) in adults with chronic non-cancer pain OR
      ii. OIC in adults with advanced illness who are receiving palliative care
   b) Patient is over the age of 18 years; AND
   c) Patient has been taking opioids for 4 weeks or more; AND
   d) Patient has attempted lifestyle changes including maintaining a diet rich in fiber and/or fiber supplementation along with adequate fluid intake; AND
   e) Patient has tried and failed or is intolerance to at least 2 of the following with or without a stool softener (e.g. docusate) in the past 3 months
      i. At least one bowel regimen of an osmotic laxative (e.g. PEG 3350)
      ii. At least one stimulant laxative (e.g. bisacodyl)
      iii. At least one saline laxative (e.g. milk of magnesia, magnesium citrate or Fleet phosphosoda); AND
f) Patient has tried and failed or is intolerant to Movantik OR Amitiza; AND

g) Patient does not have a known or suspected gastrointestinal obstruction or is at increased risk of recurrent obstruction; AND

h) Patient is not on other opioid antagonists.

**Approval Duration**

**Oral and Injection for OIC**

Initial Approval and Re-authorization = 12 months (365 days)

Injection for OIC in patients with advanced illness receiving palliative care

Approval should be for maximum of 4 months

**Re-approval for Relistor, Symproic, and Movantik:**

Approve if the patient has demonstrated a beneficial response to the requested medication as stated by the prescriber (e.g. increased number of bowel movements from baseline), AND the patient is still on opioid therapy AND the patient has no contraindications to use of requested medication.

**Re-approval for Amitiza for IBS and CIC:**

Approve if the patient has demonstrated a beneficial response to the requested medication as stated by the prescriber (e.g. increased number of bowel movements from baseline) AND the patient has no contraindications to use of requested medication.

**References**

- Amitiza (lubiprostone) [prescribing information]. Deerfield, IL: Takeda Pharmaceuticals America; September 2016.
- Movantik (naloxegol) [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals; August 2016.
- Relistor (methylnaltrexone) [prescribing information]. Raleigh, NC: Salix; July 2016.
- Symproic (naldemedine) [prescribing information]. Stamford, CT: Purdue Pharma L.P.; March 2017
- Pare P, Bridges R, Champion MC, et al. Recommendations on chronic constipation (including constipation associated with irritable bowel syndrome) treatment. Can J Gastroenterol. 2007 Apr;21 Suppl B:3B-22B