Effective Date: 08/01/2016
Last P&T Approval/Version: 04/27/2022
Next Review Due By: 04/2023
Policy Number: C9529-C

Opioid Induced Constipation Agents

PRODUCTS AFFECTED

Relistor (methylnaltrexone), Symproic (naldemedine), Movantik (naloxegol)

COVERAGE POLICY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.
This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive

DIAGNOSIS:
opioid induced constipation

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review

A. OPIOID INDUCED CONSTIPATION:
   1. Documented diagnosis of opioid-induced constipation in adults with chronic, non-cancer pain defined as less than 3 SBMs (spontaneous bowel movements) per week, on average, with one or more of the following symptoms of constipation: Very hard stools for at least a quarter of all bowel movements OR Sensation of incomplete evacuation following at least a quarter of all bowel movements OR Straining with defecation at least a quarter of the time AND
   2. Documentation that member has chronic use of an opioid agent in the past 30 days as documented within claims history or if new to Molina a documented medical chart note of

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last fill date and/or prescription drug monitoring report
AND

3. The member has tried and failed (2 week trial for each agent) or is intolerant to atleast 2 of the following with or without a stool softener in the past 3 months: At least one stimulant laxative (e.g. bisacodyl); OR at least one osmotic laxative (e.g.PEG 3350); OR At least one saline laxative (e.g. magnesium citrate) OR bulk- forming laxative (e.g. psyllium or methylcellulose)
   AND
4. Prescriber attests to (or the clinical reviewer has found that) the member not having anyFDA labeled contraindications that haven't been addressed by the prescriber within the documentation submitted for review [Contraindications to Movantik (naloxegol) include: Serious or severe hypersensitivity reaction to naloxegol or any component of the formulation; GI obstruction (known or suspected) or at risk of recurrent obstruction; concomitant use with strongCYP3A4 inhibitors (e.g., clarithromycin, ketoconazole), Contraindications to Relistor (methylnaltrexone) include: GI obstruction (known or suspected); patients at increased risk of recurrent GI obstruction. Contraindications to Symproic (naldemedine) include: Hypersensitivity to naldemedine or any component of the formulation; GI obstruction (known or suspected) or at increased risk of recurrent obstruction.]
   AND
5. Prescriber attests that or pharmacy claim history supports that member is not on other opioid antagonists

B. OPIOID INDUCED CONSTIPATION WITH ADVANCED ILLNESS (RELISTOR INJ ONLY):

1. Documentation of diagnosis of an advanced illness and member is receiving palliative care
   AND
2. Prescriber attests the member has chronic use of an opioid agent in the past 4 weeks or more
   AND
3. The member has tried and failed (2 week trial for each agent) or is intolerant to at least 2 of the following with or without a stool softener in the past 3 months: At least one stimulant laxative (e.g. bisacodyl); OR at least one osmotic laxative (e.g. PEG 3350); OR At least one saline laxative (e.g. magnesium citrate)
   AND
4. Prescriber attests to (or the clinical reviewer has found that) the member not having any FDA labeledcontraindications that haven't been addressed by the prescriber within the documentation submitted for review [Contraindications to Relistor (methylnaltrexone) include: GI obstruction (known or suspected); patients at increased risk of recurrent GI obstruction..]
   AND
5. Prescriber attests that or pharmacy claim history supports that member is not on other opioid antagonists
   AND
6. Documented member weight for dosing verification.

CONTINUATION OF THERAPY:

A. FOR ALL INDICATIONS:

1. Documentation that the member has demonstrated a beneficial response to therapy, per the prescribing physician (e.g., increased number of bowel movements from baseline)
   AND
2. Documentation member continues to have chronic use of an opioid agent in the past 30 days as documented within claims history or if new to Molina a documented medical chart note of last fill date and/or prescription drug monitoring report

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DURATION OF APPROVAL:
Initial Authorization: 12 months, Continuation of therapy: 12 months

PRESCRIBER REQUIREMENTS:
None

AGE RESTRICTIONS:
18 years of age and older

QUANTITY:
None

PLACE OF ADMINISTRATION:
The recommendation is that oral medications in this policy will be for pharmacy benefit coverage and patient self-administered.

The recommendation is that injectable medications in this policy will be for pharmacy benefit coverage and patient self-administered.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Oral, Subcutaneous

DRUG CLASS:
Peripheral Opioid Receptor Antagonists

FDA-APPROVED USES:
Relistor (methylnaltrexone) tablets and injection are indicated for the treatment of opioid-induced constipation (OIC) in adults with chronic non-cancer pain, including patients with chronic pain related to prior cancer or its treatment who do not require frequent (e.g., weekly) opioid dosage escalation.

RELISTOR injection is indicated for the treatment of OIC in adults with advanced illness or pain caused by active cancer who require opioid dosage escalation for palliative care.

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

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

COMPENDIAL APPROVED OFF-LABELED USES:
None

APPENDIX

APPENDIX:

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Rome IV Diagnostic Criteria for Constipation

Must include two or more of the following criteria for diagnosis:
*Criteria should be fulfilled for the last 3 months with symptom onset at least 6 months prior to diagnosis

- Straining during at least 25% of defecations
- Sensation of anorectal obstruction/blockage for at least 25% of defecations
- Lumpy or hard stools in at least 25% of defecations
- Manual maneuvers to facilitate at least 25% of defecations (e.g. digital evacuation, support of the pelvic floor)
- Sensation of incomplete evacuation for at least 25% of defecations
- Fewer than three spontaneous bowel movements per week.

BACKGROUND AND OTHER CONSIDERATIONS

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

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 noncancer pain while the injection is indicated for the treatment of OIC in adults withchronic non-cancer pain and OIC in adults with advanced illness who are receiving palliative care, when response to laxative therapy has not been sufficient.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
All other uses of Relistor (methylnaltrexone), Symproic (naldemedine) or Movantik (naloxegol) are considered experimental/investigational and therefore, will follow Molina's Off- Label policy. Use of Relistor (methylnaltrexone), Symproic (naldemedine) or Movantik (naloxegol) are excluded in patientswithknown or suspected gastrointestinal obstruction or at increased risk of recurrent obstruction.

OTHER SPECIAL CONSIDERATIONS:
RELISTOR (methylnaltrexone bromide) Injection dosing- Less than 38 kg: 0.15 mg/kg dose; 38 kg to less than 62 kg: 8 mg dose; 62 kg to 114 kg: 12 mg dose; more than 114 kg: 0.15 mg/kg dose

CODING/BILLING INFORMATION

Note: 1) This list of codes may not be all-inclusive. 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

HCPCS CODE	DESCRIPTION
NA	

AVAILABLE DOSAGE FORMS:
Relistor TABS 150MG, Relistor SOLN 8MG/0.4ML, Relistor SOLN 12MG/0.6ML, Symproic

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SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Required Medical Information Duration of Approval Appendix Other Special Considerations	Q2 2022
Q2 2022 Established tracking in new format	Historical changes on file

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