# Drug Coverage Policy

**Effective Date ..... 09/01/2024**
**Coverage Policy Number.....IP0401**
**Policy Title.....Opioid-Induced Constipation**

# Bowel Agents – Opioid-Induced Constipation

- Movantik® (naloxegol tablets – Valinor)
- Relistor® (methylnaltrexone bromide tablets and injection – Salix/Progenics)
- Symproic® (naldemedine tablets – Shionogi/BioDelivery Sciences International)

***INSTRUCTIONS FOR USE***
*The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment and have discretion in making individual coverage determinations. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.*

## Medical Necessity Criteria

**I. Relistor tablets, Movantik, and Symproic are considered medically necessary when ALL of the following criteria are met:**

1. **Opioid-induced constipation (OIC).** Individual meets **ALL** of the following criteria:
   A. Age 18 years or older
   B. Documentation of chronic opioid use

C. According to the prescriber, patient does not require frequent (i.e. weekly) opioid dosage escalation

**II. Relistor injection is considered medically necessary when ONE of the following criteria are met:**

1. **Opioid-induced constipation (OIC).** Individual meets **ALL** of the following criteria:
   A. Age 18 years or older
   B. Documentation of chronic opioid use
   C. According to the prescriber, patient does not require frequent (i.e. weekly) opioid dosage escalation

2. **Opioid-induced constipation (OIC) in individuals with advanced illness or pain caused by active cancer.** Individual meets **ALL** of the following criteria:
   A. Age 18 years or older
   B. Documentation of chronic opioid use
   C. According to the prescriber, patient requires opioid dosage escalation for palliative care

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Receipt of sample product does not satisfy any criteria requirements for coverage.

## Reauthorization Criteria

Continuation of opioid induced constipation products [methylnaltrexone bromide (Relistor), naloxegol (Movantik), and naldemidine (Symproic)] are considered medically necessary for **ALL** covered diagnoses when initial criteria are met AND there is documentation of beneficial response.

## Authorization Duration

Initial approval duration is up to 12 months
Reauthorization approval duration: up to 12 months

## Conditions Not Covered

Any other use is considered experimental, investigational or unproven.

## Background

**OVERVIEW**
Movantik, Relistor (tablets and injection), and Symproic 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.[1-3] Additionally, Relistor injection (not tablets) 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**.[2] Movantik, Relistor, and Symproic are mu-opioid receptor

antagonists that act peripherally in tissues such as the gastrointestinal tract, thereby decreasing the constipating effects of opioids.

**Guidelines**
The American Gastroenterological Association (AGA) published a guideline and technical review on opioid-induced constipation in 2019.[4,5] In patients with laxative-refractory OIC, the AGA recommends Symproic or Movantik and suggests Relistor (tablets or injection).[4] The technical review notes that the quality of evidence was rated down for Relistor due in part to the short duration of the trials (4 weeks, followed by as-needed dosing for 8 weeks).[5]

An additional guideline from the American Academy of Pain Medicine (AAPM) [2017] notes that peripherally-acting mu-opioid receptor antagonists, including Movantik and Relistor, have demonstrated efficacy in reducing OIC.[6] The AAPM guideline was written prior to the approval of Symproic.

## References


1. Movantik® tablets [prescribing information]. Wilmington, DE: Valinor; March 2023.
2. Relistor® tablets and injection [prescribing information]. Bridgewater, NJ: Salix; April 2020.
3. Symproic® tablets [prescribing information]. Raleigh, NC: Shionogi/BioDelivery Sciences International; July 2021.
4. Crockett S, Greer KB, Heidelbaugh JJ, et al., on behalf of the American Gastroenterological Association Institute Clinical Guidelines Committee. American Gastroenterological Association Institute Guideline on the Medical Management of Opioid-Induced Constipation. *Gastroenterology.* 2019;156(1):218-226.
5. Hanson B, Siddique SM, Scarlett Y, Sultan S, on behalf of the American Gastroenterological Association Institute Clinical Guidelines Committee. American Gastroenterological Association Institute Technical Review on the Medical Management of Opioid-Induced Constipation. *Gastroenterology.* 2019;156(1):229-253.e5.
6. Müller-Lissner S, Bassotti G, Coffin B, et al. Opioid-induced constipation and bowel dysfunction: a clinical guideline. *Pain Medicine*. 2017;18:1837-1863.


## Revision Details

| Type of Revision | Summary of Changes | Date |
|---|---|---|
| Selected Revision | *For Relistor tablets, Movantik, and Symproic:*<br>**Opioid-induced constipation (OIC).**<br>Updated the criterion for the patient to not be requiring frequent opioid dosage escalation from documentation to attestation.<br>Removed criterion requiring the failure of laxatives used for a minimum of 4 days within a 2 week period, unless contraindicated or intolerant.<br><br>*For Relistor injection:*<br>**Opioid-induced constipation (OIC).**<br>Updated the criterion for the patient to not be requiring frequent opioid dosage escalation from documentation to attestation. | 9/1/2024 |

| | | |
|---|---|---|
| | Removed criterion requiring the failure of laxatives used for a minimum of 4 days within a 2 week period, unless contraindicated or intolerant.<br>**Opioid-induced constipation (OIC) in individuals with advanced illness or pain caused by active cancer.**<br>Added criterion requiring documentation of chronic opioid use.<br>Updated criterion requiring "Advanced illness or pain caused by active cancer requiring opioid dosage escalation for palliative care" to "According to the prescriber, patient requires opioid dosage escalation for palliative care"<br>Removed criterion requiring the failure of laxatives used for a minimum of 4 days within a 2 week period, unless contraindicated or intolerant. | |
| Annual Revision | No criteria changes | 5/1/2024 |

The policy effective date is in force until updated or retired.