

Medical Policy: RELISTOR® (methylnatrexone) injection

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.163	May 15, 2023	

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The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as “EmblemHealth”), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

Definitions

Relistor (methylnaltrexone bromide) is an opioid antagonist indicated for the treatment of opioid-induced constipation (OIC) in adult patients 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 also indicated for the treatment of opioid-induced constipation in patients with advanced illness or pain caused by active cancer who require opioid dosage escalation for palliative care.

Length of Authorization

NOT COVERED for our Medicaid Line of Business

Coverage will be provided for 4 months and may be renewed.

Dosing Limits [Medical Benefit]

Max Units (per dose and over time):

Relistor 8mg/0.4mL & 12mg/0.6mL = 30 injections per 30 days

Guideline

I. Initial Approval Criteria

Relistor injection may be considered medically necessary for patients on a stable opioid regimen when the following criteria are met: (NOT COVERED for our Medicaid Line of Business)

1. Relistor is being prescribed for opioid-induced constipation in an adult patient with advanced illness or pain caused by active cancer who require opioid escalation for palliative care; **OR**
2. Relistor is being prescribed for opioid-induced constipation in an adult patient with chronic noncancer pain, including patients with chronic pain related to prior cancer or its treatment who do not require frequent (e.g., weekly) opioid dosage escalation; **AND**
3. The patient is unable to tolerate oral medications; or the patient has an intolerance to, or treatment failure of at least three laxative therapies (i.e. senna, bisacodyl, polyethelene glycol, lactulose, phosphasoda enema)

Limitations/Exclusions

Relistor is not considered medically necessary when any of the following selection criteria is met:

1. Use of Relistor beyond four months has not been studied in the advanced illness population

II. Renewal Criteria

Subsequent authorization will be based on physician documentation of efficacy.

Dosage/Administration

Indication	Dose
OIC in adult patients with chronic non-cancer pain	– The recommended dosage is 12 mg subcutaneously once daily.
OIC in adult patients with advanced illness	– The pre-filled syringe is only for patients who require a RELISTOR injection dose of 8 mg or 12 mg. Use the vial for patients who require other doses of RELISTOR Injection. See full prescribing information for the recommended dosage. Administer one dose every other day, as needed, but no more frequently than one dose in a 24-hour period.

Applicable Procedure Codes

Code	Description
J2212	Injection, methylnaltrexone, 0.1 mg, 1 billable unit = 0.1 mg

Applicable NDCs

Code	Description
65649-0552-xx	Relistor 8 mg/0.4 mL methylnaltrexone bromide in single-dose pre-filled syringe
65649-0551-xx	Relistor 12 mg/0.6 mL methylnaltrexone bromide in a single-dose pre-filled syringe or

	single-dose vial
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ICD-10 Diagnoses

Code	Description
K59.09	Other constipation

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	5/15/2023	Annual Review: no criteria updates
EmblemHealth & ConnectiCare	03/30/2020	Annual Review
EmblemHealth & ConnectiCare	01/01/2022	Annual Review Removed coverage from our Medicaid population.

References

1. Facts & Comparisons Online
2. Relistor manufacturer's insert, Salix Pharmaceuticals, Bridgewater, NJ 08807
3. Clinical Pharmacology Elsevier Gold Standard. 2019.
4. Micromedex® Healthcare Series: Thomson Micromedex, Greenwood Village, Co. 2019.