

Title: methylnaltrexone bromide (Relistor®)

Origination: 05/27/09	Revised: 11/16/11	Annual Review: 12/15/11
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Purpose:

To provide guidelines and criteria for the review and decision determination of requests for medications that requires prior authorization.

Background Information:

Medication Summary

- Methylnaltrexone (Relistor®) is a peripherally-acting mu-opioid receptor antagonist indicated for the treatment of opioid-induced constipation in patients with advanced illness who are receiving palliative care when response to laxative therapy has been insufficient. Since it is a quaternary derivative of naltrexone and crosses the blood-brain barrier less readily, it does not reverse centrally-mediated analgesia or opioid-induced respiratory depression nor does it cause opioid withdrawal.
- Methylnaltrexone bromide is administered subcutaneously and is available as a 12mg/0.6mL single-dose vial. It is normally dosed by weight, as needed, every other day, but no more frequently than one dose per 24-hour period.
- A dose reduction by 50% is recommended in members with severe renal impairment (creatinine clearance less than 30 mL/min).

Background Information, continued:

Reference Statement

- Guidelines will be compiled from available US Food and Drug Administration (FDA) approved indications, general practice guidelines, and/or evidence-based uses established through phase III clinical studies without published conflicting data. Only clinical studies published in their entirety in reputable peer-reviewed journals will be evaluated.

Eligibility Criteria

- Member must be eligible and have applicable benefits.
- Prior authorization requests that do not meet clinical criteria in this Procedure will be forwarded to a Clinical Pharmacist for review.

Exclusions

- Member with known or suspected mechanical GI obstruction.
- Members under the age of 18, as safety and efficacy data have not been established.

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Procedure:

- 1.0 Request for *therapy* requires documentation from the Member’s medical records maintained by the requesting independent practitioner verifying **ALL** of the following:
 - 1.1 A diagnosis of opioid-induced constipation; **AND**
 - 1.2 Is receiving palliative care with a life expectancy of six (6) months or less; **AND**
 - 1.3 Has not had laxation for at least 48 hours; **AND**
 - 1.4 Has trialed and failed at least three (3) other laxatives;
- 2.0 If Member meets all of the above criteria, may approve **up to 15 doses per month for four (4) months** based on the Member’s weight (in kilograms) as outlined below:
 - 2.1 Recommended dosing per the manufacturer (based on member’s weight):

Member’s Weight (in Kilograms)	Dose
Less than 38	0.15 mg/kg
38 to 61	8 mg
62 to 114	12 mg
More than 114	0.15 mg/kg

The dose should be decreased by 50% if CrCl < 30 mL/min.

- 2.2 Available as a 12mg/0.6mL single-dose vials, calculate dose according to weight to determine number of vials required for **up to 15 doses per month**.

References:

1. *Relistor*[™] [package insert]. Philadelphia, PA: Wyeth Pharmaceuticals, Inc.; April 2008.
2. Portenoy RK, Thomas J, Moehl Boatwright ML, et al. Subcutaneous methylnaltrexone for the treatment of opioid-induced constipation in patients with advanced illness: a double-blind, randomized, parallel group, dose-ranging study. *Journal of Pain and Symptom Management*. 2008;35(5):458-68.
3. Yuan C, Foss JF, O’Connor M, et al. Methylnaltrexone for Reversal of Constipation Due to Chronic Methadone Use. *JAMA*. 2000; 283(3):367-372.
4. Yuan C, Wei G, Foss J et al. Effects of Subcutaneous Methylnaltrexone on Morphine-Induced Peripherally Mediated Side Effects: A Double-Blind Randomized Placebo-Controlled Study. *JPET* 2001; 300(1):118-123.

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Disclaimer Information:

Prior Authorization criteria are developed to determine coverage for AvMed Health Plans' benefits, and are published to provide a better understanding of the basis upon which coverage decisions are made. AvMed Health Plans makes coverage decisions based on the Member's benefit plan contract and these criteria. This guideline sets forth concise clinical coverage criteria which have been developed from a review of current literature, policies of the FDA and other government agencies, and other appropriate references, in consultation and with approval from practicing physicians who are members of AvMed's Pharmacy and Therapeutic committee. Treating providers are solely responsible for the medical advice and treatment of Members. This guideline may be updated and therefore is subject to change. The use of these criteria is neither a guarantee of payment nor a final prediction of how specific claim(s) will be adjudicated.