



Medication Policy Manual

Policy No: dru377

Topic: Movantik™, naloxegol

Date of Origin: December 12, 2014

Committee Approval Date: August 12, 2016

Next Review Date: August 2017

Effective Date: September 1, 2016

IMPORTANT REMINDER

This Medication Policy has been developed through consideration of medical necessity, generally accepted standards of medical practice, and review of medical literature and government approval status.

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control.

The purpose of Medication Policy is to provide a guide to coverage. Medication Policy is not intended to dictate to providers how to practice medicine. Providers are expected to exercise their medical judgment in providing the most appropriate care.

Description

Naloxegol (Movantik) is an oral opioid receptor antagonist used to relieve opioid-induced constipation in adult patients with chronic non-cancer pain.

Policy/Criteria

- I. Most contracts require prior authorization approval of naloxegol (Movantik) prior to coverage. Naloxegol (Movantik) may be considered medically necessary when criteria A, B, and C below are met.
 - A. Diagnosis of opioid-induced constipation in a patient with chronic non-cancer pain.
AND
 - B. The member is receiving chronic opioid therapy.
AND
 - C. Documentation that at least FOUR therapies, as specified in criteria 1, 2, 3, and 4 below were ineffective, not tolerated, or are contraindicated.
 - 1. A bulk-forming laxative (including, but not limited to, psyllium or methylcellulose)
AND
 - 2. An osmotic agent (including, but not limited to, polyethylene glycol or magnesium citrate)
AND
 - 3. A stimulant laxative (including, but not limited to, bisacodyl or senna)
AND
 - 4. A stool softener (including, but not limited to, docusate)

- II. Administration, Quantity Limitations, and Authorization Period
 - A. OmedaRx considers naloxegol (Movantik) to be a self-administered medication.
 - B. When prior authorization is approved, naloxegol (Movantik) may be authorized in quantities of 30 tablets per month.
 - C. Authorization shall be reviewed in the timeframes defined below:
 - 1. **Initial Authorization:** Authorization shall be reviewed at 4 months to confirm that current medical necessity criteria are met, the patient is currently on opioid therapy, and that the medication is effective.
 - 2. **Continued Authorization:** After initial reauthorization, authorization shall be reviewed at least every 6 months to confirm that current medical necessity criteria are met, the patient is currently on opioid therapy, and that the medication is effective.

- III. Naloxegol (Movantik) is considered investigational when used for all other conditions including, but not limited to:
 - A. Constipation not caused by opioid use
 - B. Use in patients less than 18 years of age
 - C. Opioid-induced constipation in patients with cancer pain

Position Statement

Summary

- Standard bowel regimens are recognized as standard of care to treat opioid-induced constipation. Standard bowel regimens are: [1,2]
 - * effective for most people on chronic opioid therapy and provide the best value.
 - * a prescribed combination of laxatives, stool softeners, osmotic agents and/or bulk forming agents.
- In addition, there is no evidence stating that naloxegol (Movantik) is more effective than optimal doses of standard bowel regimens.
- There are additional alternatives for the treatment of opioid-induced constipation that provide a better value.

Clinical Efficacy

- Naloxegol has not been proven in reliable clinical studies to be more effective than generic or over-the-counter options for managing opioid-induced constipation.
- There are two identical, randomized, double-blind 12 week studies comparing 12.5 mg and 25 mg daily doses of naloxegol to placebo for the treatment of opioid-induced constipation in adult patients with chronic non-cancer pain. The efficacy of the 12.5 mg daily dosing regimen of naloxegol was found to inconsistent between treatment groups. The efficacy of the 25 mg daily dosing regimen of naloxegol was found to be statistically significant and consistent between treatment groups with a number needed to treat (NNT) of 7-10. [3]
- The primary end point was the 12-week response rate (≥ 3 spontaneous bowel movements per week and an increase from baseline of ≥ 1 spontaneous bowel movements for at least 9 out of 12 weeks and for at least 3 of the final 4 weeks). [3]
- During the trials, patients were prohibited from using laxatives other than bisacodyl, the rescue laxative, when they did not have a bowel movement for 72 hours. If three doses of bisacodyl were ineffective, patients were allowed a one-time use of an enema.
- The evidence does not address the efficacy of naloxegol (Movantik) with repeated use beyond 12 weeks.
- Naloxegol (Movantik) has not been compared to any active comparators, only to placebo.

Safety

- Naloxegol carries warnings for gastrointestinal perforation and opioid withdrawal. [4]
- The safety and effectiveness of naloxegol has not been established in pediatric patients.
- There is a 52-week, open-label, randomized trial comparing 25 mg daily dose naloxegol to usual-care laxative regimen chosen by study investigators. During the trial, the naloxegol treatment group was assessed to have more adverse events, such as abdominal pain, diarrhea, headache, nausea, and flatulence. [5]

- There is an unpublished 12 week extension study looking at the long term safety and tolerability effects of naloxegol 12.5 mg or 25 mg daily compared with placebo. Adverse events (e.g. arthralgia, diarrhea) were more prevalent in the active comparator groups.
[6]

Cross References
Amitiza®, lubiprostone, dru436
Relistor®, methylnaltrexone, dru161

Codes	Number	Description
N/A		

References

1. Bharucha, AE, Dorn, SD, Lembo, A, Pressman, A. American Gastroenterological Association medical position statement on constipation. *Gastroenterology*. 2013 Jan;144(1):211-7. PMID: 23261064.
2. Goodheart CR, Leavitt SB. Managing opioid-induced constipation in ambulatory-care patients. *Pain Treatment Topics*. Aug 2008.
3. Chey, WD, Webster, L, Sostek, M, Lappalainen, J, Barker, PN, Tack, J. Naloxegol for opioid-induced constipation in patients with noncancer pain. *The New England journal of medicine*. 2014 Jun 19;370(25):2387-96. PMID: 24896818.
4. Movantik (naloxegol) [prescribing information]. Wilmington DE: AstraZeneca; September 2014.
5. Webster, L, Chey, WD, Tack, J, Lappalainen, J, Diva, U, Sostek, M. Randomised clinical trial: the long-term safety and tolerability of naloxegol in patients with pain and opioid-induced constipation. *Alimentary pharmacology & therapeutics*. 2014 Oct;40(7):771-9. PMID: 25112584.
6. Dossier Movantik™ (naloxegol). Wilmington, DE; October 2014. AstraZeneca. 2014.

Revision History

Revision Date	Revision Summary
08/12/16	Added coverage criteria for opioid-induced constipation in patients with chronic non-cancer pain. Added quantity limit.
11/23/15	No criteria changes.