Clinical Policy: Naloxegol (Movantik)
Reference Number: ERX.NPA.01
Effective Date: 04.01.17
Last Review Date: 02/17
Line of Business: Commercial (Outsourced Formulary) Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Naloxegol (Movantik®) is an opioid antagonist that contains naloxegol oxalate, a PEGylated derivative of naloxone.

FDA approved indication
Movantik is indicated for the treatment of opioid-induced constipation (OIC) in adult patients with chronic non-cancer pain.

Policy/Criteria
Provider must submit documentation (including office chart notes and lab results) supporting that member has met all approval criteria

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ that Movantik is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Opioid-Induced Constipation (OIC) (must meet all)
1. Diagnosis of opioid-induced constipation;
2. Age ≥ 18 years;
3. Member has used an opioid analgesic for at least 4 weeks;
4. Member is not being treated for cancer pain;
5. Failure of at least 2 non-bulk forming laxatives from different classes (see Appendix B) while on opioid therapy, at up to maximally indicated doses unless contraindicated or clinically significant adverse effects are experienced;
6. Member has used at least one laxative in the last 30 days, unless contraindicated;
7. Dose does not exceed 1 tablet per day.

Approval duration: 6 months

B. Other diagnoses/indications
1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized)

II. Continued Therapy

A. Opioid-Induced Constipation (OIC) (must meet all
1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions or member has previously met initial approval criteria;
2. Documentation of positive response to therapy (e.g., a reduction in frequency of constipation);
3. If request is for a dose increase, new dose does not exceed 1 tablet per day.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy. **Approval duration: Duration of request or 12 months (whichever is less)**; or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized)

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – ERX.PA.01 or evidence of coverage documents

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
OIC: opioid-induced constipation
OTC: over-the-counter

Appendix B: General Information

Table A: Different Classes of Laxatives

Osmotic	Bulk-forming	Surfactant	Stimulants
lactulose	methylcellulose	docusate	bisacodyl
polyethylene glycol	psyllium		senna
sorbitol	malt soup extract		cascara
magnesium hydroxide	calcium polycarbophil		
magnesium sulfate			
sodium phosphate			

Appendix C: Therapeutic Alternatives
Prescription and over-the-counter (OTC) medications for the treatment of constipation include the following (note that coverage of OTC agents may vary with plan formulary and benefit design):

Drug	Dosing Regimen	Dose Limit/ Maximum Dose
lactulose	10-20 gm PO QD	40 gm/day
sorbitol	17 g PO QD	17 gm/day
magnesium hydroxide	400 mg/5 ml: 30-60 mL/day once at bedtime or in divided doses	This field intentionally left blank.
magnesium sulfate	2 to 4 level teaspoons of granules dissolved in 8 ounces of water; may repeat in 6 hours.	8 teaspoons/day
sodium phosphate	15 mL as a single dose	45 mL/day
methylcellulose	1 tbsp in 8 oz of water PO QD-TID prn or 2 caplets with 8 oz of water up to 6 times/day	3 tbsp/day (powder) or 12 caplets/day

Drug	Dosing Regimen	Dose Limit/ Maximum Dose
psyllium	1-2 tsp PO QD-TID	6 tsp/day
malt soup extract	Tablets: 4 tablets PO QID for 3-4 days, then 2-4 tablets PO QHS Powder: 2 full tbsp PO BID for 3-4 days, then 1-2 tbsp PO QHS Oral soln: 30 mL PO BID for 3-4 days, then 15-30 ml PO QHS	This field intentionally left blank.
calcium polycarbophil	1250 mg QD-QID	5000 mg/day
docusate sodium	100 mg PO QD-BID	360 mg/day
bisacodyl	5-15 mg PO QD	30 mg/day
senna	1-2 tablets PO BID 10-15 mL PO BID	8 tablets/day 30 mL/day
cascara	1 g of bark, 2 to 6 mL of fluid extract, or 325 mg of dried extract	This field intentionally left blank.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Opioid-induced constipation	25 mg PO QD	25 mg PO QD

VI. Product Availability

Tablets: 12.5 mg, 25 mg

VII. References

1. Movantik [package insert]. Wilmington, DE; AstraZeneca Pharmaceuticals LP.; August, 2016.
2. Movantik Drug Monograph. Clinical Pharmacology. http://www.clinicalpharmacology-ip.com. Accessed January 2017.
3. Micromedex® Healthcare Series [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed January 2017.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	06/15	06/15
Converted policy to new format in written form; Added background to include description, mechanism of action, and FDA approved indication; Added table to show different laxative types; Updated references to show most recent literature search;	03/16	06/16
Converted to new template	01/17	02/17

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.