

Drugs for Constipation

Goal(s): Promote use that is consistent with medical evidence and product labeling.

Length of Authorization:

- Up to 12 months

Requires PA:

- Non-preferred drugs (pharmacy point of sale)

Covered Alternatives:

- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

Table 1. Gastrointestinal Drugs FDA-Approved for Treatment of Constipation in an Outpatient Setting

| Generic (Brand Name) | Indications |
|---|---|
| Linaclotide (LINZESS) | <ul style="list-style-type: none"> • CIC in adults • IBS-C in adults • FC in pediatric patients aged 6 to 17 yo |
| Lubiprostone (AMITIZA) | <ul style="list-style-type: none"> • CIC in adults • IBS-C in females > 18 yo • OIC in adults: 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 |
| Methylnaltrexone (RELISTOR) | <ul style="list-style-type: none"> • OIC in adults with advanced illness (injection only) • OIC in adults with chronic, non-cancer pain (tablets and injection) |
| Naldemedine (SYMPROIC) | OIC in adults with chronic, non-cancer pain |
| Naloxegol (MOVANTIK) | OIC in adults with chronic, non-cancer pain |
| Plecanatide (TRULANCE) | <ul style="list-style-type: none"> • CIC in adults • IBS-C in adults |
| Prucalopride (MOTEGRITY) | CIC in adults |
| Tenapanor (IBSRELA) | IBS-C in adults |
| Abbreviations: CIC = chronic idiopathic constipation; FC = functional constipation; IBS-C = irritable bowel syndrome with constipation; IBS-D = irritable bowel syndrome with diarrhea; OIC = opioid-induced constipation; yo = years old | |

Table 2. Initial Management Strategies for Constipation

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| Dietary Modification | Increased dietary fiber (25 grams/day) and increased fluid consumption |
| Bulk-forming Laxatives | Psyllium (not recommended for opioid-induced constipation) |
| Osmotic Laxatives | Polyethylene glycol, lactulose, magnesium hydroxide, milk of magnesia |
| Stool Softener | Docusate |
| Stimulant Laxatives | Senna, bisacodyl |

Approval Criteria

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| 1. What diagnosis is being treated? | Record ICD10 code. |
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Approval Criteria

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| <p>2. Is the diagnosis funded by the OHP?</p> | <p>Yes: Go to #3</p> | <p>No: Not eligible for EPSDT review: Pass to RPh. Deny; diagnosis not covered by OHP.</p> <p>Eligible for EPSDT review: Go to #3</p> |
| <p>3. Is the request for an FDA-approved age and indication (Table 1)?</p> | <p>Yes: Go to #4</p> | <p>No: Pass to RPh. Deny; medical appropriateness.</p> |
| <p>4. Is there documentation of failure to have benefit with, or contraindication to, at least 2 of the recommended conventional first-line treatments including dietary modifications for at least 4 weeks (Table 2)?</p> | <p>Yes: Go to #5</p> | <p>No: Pass to RPh. Deny for funding</p> <p>Constipation is not funded under the OHP. Therefore, funding for drugs that treat constipation are dependent whether the constipation adversely affects, or is secondary to, the underlying medical condition covered by the Prioritized List.</p> <p>Chronic constipation caused by a funded condition or adversely affecting a funded condition is approvable if medically appropriate and justification is provided for not meeting criterion #4.</p> |
| <p>5. Is the drug prescribed by one of the following: -gastroenterologist OR -other provider after patient consultation with a dietician OR -if patient has PA approval for long-term opioid therapy OR -pain management specialist?</p> | <p>Yes: Go to #6</p> | <p>No: Pass to RPh. Deny for medical appropriateness</p> |

| Approval Criteria | | |
|---|---|----------------------------------|
| 6. Is the request to treat irritable bowel syndrome with constipation in an adult female assigned at birth with lubiprostone? | Yes: Approve for 12 months | No: Go to #7 |
| 7. Is the request to treat opioid-induced constipation in an adult with lubiprostone? | Yes: Go to #8 | No: Approve for 12 months |
| 8. Is request for lubiprostone in a patient that has been prescribed methadone? | Yes: Pass to RPh. Deny; medical appropriateness. The efficacy of lubiprostone in patients taking methadone has not been established. | No: Approve for 12 months |

P&T Review: 2/25 (DM); 6/20 (DM), 7/17 (DM); 3/15; 3/09
Implementation: 3/10/25;7/1/20; 9/1/17; 5/1/16; 10/15, 4/18/15