curative

Constipation Agents Prior Authorization

Drug(s) Applied:	**Trulance** (plecanatide), **Linzess** (linaclotide), **Movantik** (naloxegol), **Symproic** (naldemedine)

Criteria:
Drug(s) Applied will be approved when the requested medication is being used for an FDA approved indication and all of the following criteria are met:

I. Initial Therapy Criteria

A. Irritable Bowel Syndrome with Constipation (IBS-C) and Chronic Idiopathic Constipation (CIC) as indicated by chart notes within past 120 days

1. Patient has had IBS-C or CIC symptoms for greater than or equal to 3 months **and**
2. Requested agent is Trulance or Linzess **and**
3. If for Linzess, patient has tried and had an inadequate response to a standard OTC laxative (e.g. osmotic laxative) **and**
4. If for Trulance, ALL of the following:
    a) Patient has tried and had an inadequate response or intolerance to a standard osmotic laxative (e.g. PEG 3350) **and**
    b) Patient has tried and had an inadequate response to at least one other standard laxative therapy class (e.g., bulk-forming, stimulant, enema, or stool softener) or has a documented intolerance or FDA labeled contraindication to all standard laxatives **and**
    c) Patient has tried and had an inadequate response, intolerance, or FDA labeled contraindication to lubiprostone **and**
    d) Patient has tried and had an inadequate response, intolerance, or FDA labeled contraindication to Linzess **and**
5. Chart notes and/or prescriber do not provide documentation of using the requested agent in combination with another secretagogue constipation agent (e.g. linaclotide, plecanatide, lubiprostone, tenapanor) **and**
6. Chart notes and/or prescriber do not provide documentation of any FDA labeled contraindications (e.g. known or suspected mechanical gastrointestinal obstruction) to the requested drug, or prescriber has documented that the benefits outweigh the risk despite having a contraindication

Approval Duration: 12 months

B. Opioid-Induced Constipation (OIC) as indicated by chart notes within past 90 days

1. ONE of the following:
    a) Requested agent is Movantik or Symproic **or**
    b) Requested agent is Linzess and BOTH of the following:
        (1) Patient has refractory opioid-induced constipation **and**
        (2) Patient must try and fail Symproic first **and**
2. Patient has chronic use of an opioid agent in the past 30 days **and**
3. If for Symproic, patient has tried and had an inadequate response to a standard OTC laxative (e.g. osmotic laxative) **and**
4. If for Movantik, ALL of the following:
    a) Patient has tried and had an inadequate response or intolerance to a standard osmotic laxative (e.g. PEG 3350) **and**
    b) Patient has tried and had an inadequate response or intolerance to at least one other standard laxative therapy class (e.g. stimulant, lubricant, or stool softener) or has a documented FDA labeled contraindication to all standard laxatives **and**
    c) Patient has tried and had an inadequate response, intolerance, or FDA labeled contraindication to Symproic **and**
5. Patient's age is within FDA labeling for the requested indication or there is support for using the requested agent for the patient's age for the requested indication **and**
6. Chart notes and/or prescriber do not provide documentation of using the requested agent in combination with another secretagogue constipation agent (e.g. linaclotide, plecanatide, lubiprostone, tenapanor) or another peripherally acting mu-Opioid receptor antagonist (e.g. naloxegol, naldemedine, methylnatrexone) **and**
7. Chart notes and/or prescriber do not provide documentation of any FDA labeled contraindications (e.g. known or suspected mechanical gastrointestinal obstruction) to the requested drug, or prescriber has documented that the benefits outweigh the risk despite having a contraindication

Approval Duration: 3 months

C. Pediatric Functional Constipation as indicated by chart notes within past 180 days

1. Requested agent is Linzess **and**
2. Patient has tried and had an inadequate response to a standard OTC laxative (e.g. osmotic laxative) **and**
3. Chart notes and/or prescriber do not provide documentation of any FDA labeled contraindications (e.g. known or suspected mechanical gastrointestinal obstruction) to the requested drug, or prescriber has documented that the

benefits outweigh the risk despite having a contraindication

Approval Duration: 12 months

II. Continued Therapy Criteria

A. IBS-C, CIC, and Pediatric Functional Constipation as indicated by chart notes within past 12 months

1. Patient meets the initial therapy criteria above **and**
2. Documented clinical benefit since starting the requested agent (i.e., more frequent bowel movements) **and**
3. Chart notes and/or prescriber do not provide documentation of chronic diarrhea **and**
4. Chart notes and/or prescriber do not provide documentation of using the requested agent in combination with another secretagogue constipation agent (e.g. linaclotide, plecanatide, lubiprostone, tenapanor)

Approval Duration: 12 months

B. Opioid-Induced Constipation as indicated by chart notes within past 12 months

1. Patient meets the initial therapy criteria above **and**
2. Documented clinical benefit since starting the requested agent (i.e., more frequent bowel movements) **and**
3. Patient has chronic use of an opioid agent in the past 30 days **and**
4. Chart notes and/or prescriber do not provide documentation of using the requested agent in combination with another secretagogue constipation agent (e.g. linaclotide, plecanatide, lubiprostone, tenapanor) or another peripherally acting mu-Opioid receptor antagonist (e.g. naloxegol, naldemedine, methylnatrexone)

Approval Duration: 12 months

Policy Owned by: Curative PBM team