Clinical Policy: Plecanatide (Trulance)
Reference Number: CP.PMN.87
Effective Date: 02.01.17
Last Review Date: 11.19
Line of Business: Commercial, Medicaid

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

Description
Plecanatide (Trulance®) is a guanylate cyclase-C agonist.

FDA Approved Indication(s)
Trulance is indicated in adults for the treatment of:
• Chronic idiopathic constipation (CIC)
• Irritable bowel syndrome with constipation (IBS-C)

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Trulance is medically necessary when the following criteria are met:

I. Initial Approval Criteria
   A. Chronic Idiopathic Constipation (must meet all):
      1. Diagnosis of CIC;
      2. Age ≥ 18 years;
      3. Failure of one bulk forming laxative (e.g., psyllium (Metamucil®), methylcellulose (Citrucel®), calcium polycarbophil (FiberCon®)), unless all are contraindicated or clinically significant adverse effects are experienced;
      4. Failure of one stimulant laxative (e.g., bisacodyl, senna), unless all are contraindicated or clinically significant adverse effects are experienced;
      5. Failure of polyethylene glycol (MiraLax®) at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
      6. Dose does not exceed 3 mg (1 tablet) per day.
   Approval duration: 12 months

   B. Irritable Bowel Syndrome with Constipation (must meet all):
      1. Diagnosis of IBS-C;
      2. Age ≥ 18 years;
      3. Failure of one bulk-forming laxative (e.g. psyllium (Metamucil), methylcellulose (Citruce)), calcium polycarbophil (FiberCon)), unless all are contraindicated or clinically significant adverse effects are experienced;
      4. Dose does not exceed 3 mg (1 tablet) per day.
   Approval duration: 12 months
C. Other diagnoses/indications
   1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial and CP.PMN.53 for Medicaid.

II. Continued Therapy
   A. All Indications in Section I (must meet all):
      1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
      2. Member is responding positively to therapy;
      3. If request is for a dose increase, new dose does not exceed 3 mg (1 tablet) per day.

   Approval duration: 12 months

   B. Other diagnoses/indications (must meet 1 or 2):
      1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.

      Approval duration: Duration of request or 12 months (whichever is less); or

      2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial and CP.PMN.53 for Medicaid.

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 policies – CP.CPA.09 for commercial and CP.PMN.53 for Medicaid or evidence of coverage documents.

IV. Appendices/General Information
   Appendix A: Abbreviation/Acronym Key
   CIC: chronic idiopathic constipation
   FDA: Food and Drug Administration
   IBS-C: irritable bowel syndrome with constipation

   Appendix B: Therapeutic Alternatives
   This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Dosing Regimen</th>
<th>Dose Limit/Maximum Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>psyllium (Metamucil®)</td>
<td>1 rounded teaspoonful, tablespoonful, or premeasured packet in 240 mL of fluid PO, 1 to 3 times per day (2.4 g of soluble dietary fiber per dose)</td>
<td>7.2 g (as soluble dietary fiber)/day</td>
</tr>
<tr>
<td>Drug Name</td>
<td>Dosing Regimen</td>
<td>Dose Limit/Maximum Dose</td>
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<tr>
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</tr>
<tr>
<td>calcium polycarbophil (FiberCon®)</td>
<td>1,000 mg 1 to 4 times per day or as needed</td>
<td>6,000 mg/day</td>
</tr>
</tbody>
</table>
| methylcellulose (Citrucel®) | Caplet: 2 caplets (total 1 g methylcellulose) PO with at least 240 ml (8 oz) of liquid, up to 6 times per day as needed  
Powder: 1 heaping tablespoonful (2 g methylcellulose per 19 g powder) in at least 240 ml (8 oz) of water PO, given 1 to 3 times per day as needed | Caplet: 12 caplets/day  
Powder: 6 grams/day |
| sennosides (Senokot®)     | 1 to 2 tablets (8.6 to 17.2 mg sennosides) PO BID                           | 68.8 mg sennosides/day  |
| bisacodyl (Dulcolax®)     | 5 to 15 mg/day (1 to 3 tablets) PO given as a single dose, or 1 suppository or retention enema (10 mg) PR QD  
Either a suppository or oral tablet(s) may be used up to 3 times per week | 15 mg/day PO or 10 mg/day PR |
| polyethylene glycol 3350 (MiraLax®) | 17 g (approximately 1 heaping tablespoon) of powder in 120 to 240 mL of fluid PO QD | 34 grams/day            |

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): patients less than 6 years of age due to the risk of serious dehydration, patients with known or suspected mechanical gastrointestinal obstruction
- Boxed warning(s): risk of serious dehydration in pediatric patients

V. Dosage and Administration

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dosing Regimen</th>
<th>Maximum Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>CIC, IBS-C</td>
<td>3 mg PO QD</td>
<td>3 mg/day</td>
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</tbody>
</table>

VI. Product Availability

Tablet: 3 mg

VII. References


<table>
<thead>
<tr>
<th>Reviews, Revisions, and Approvals</th>
<th>Date</th>
<th>P&amp;T Approval Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Policy created</td>
<td>02.01.17</td>
<td>05.17.17</td>
</tr>
<tr>
<td>1Q18 annual review: Policies combined for Medicaid and commercial lines of business; Modified criterion to require trial of all 3 different laxatives recommended per ACG (bulk-forming, polyethylene glycol, and stimulant) and removed stool softeners as an option since there is little evidence to support the use of such agents in chronic constipation; Updated max dose requirement to include QL of 1 tablet/day; Modified initial approval from 6 to 12 months; References reviewed and updated.</td>
<td>11.06.17</td>
<td>02.18</td>
</tr>
<tr>
<td>2Q 2018 annual review: criteria added for new FDA indication: IBS-C; approval duration for CIC and continuation therapy modified to 12 months for commercial; references reviewed and updated.</td>
<td>03.06.18</td>
<td>05.18</td>
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<td>4Q 2018 annual review: no significant changes from previously approved corporate policy; references reviewed and updated.</td>
<td>07.20.18</td>
<td>11.18</td>
</tr>
<tr>
<td>4Q 2019 annual review: no significant changes; references reviewed and updated.</td>
<td>08.06.19</td>
<td>11.19</td>
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**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. The Health Plan makes no representations and
accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. 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. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

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Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.