Clinical Policy: Tegaserod (Zelnorm)
Reference Number: CP.PMN.206
Effective Date: 05.14.19
Last Review Date: 08.20
Line of Business: Commercial, Medicaid

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

Description
Tegaserod (Zelnorm®) is a serotonin-4 (5-HT₄) receptor agonist.

FDA Approved Indication(s)
Zelnorm is indicated for the treatment of adult women less than 65 years of age with irritable bowel syndrome with constipation (IBS-C).

Limitation(s) of use: The safety and effectiveness of Zelnorm in men with IBS-C have not been established.

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 Zelnorm is medically necessary when the following criteria are met:

I. Initial Approval Criteria
   A. Irritable Bowel Syndrome with Constipation (must meet all):
      1. Diagnosis of IBS-C;
      2. Age ≥ 18 years and < 65 years;
      3. Failure of one bulk forming laxative (e.g., psyllium [Metamucil®], methylcellulose [Citrucei®], calcium polycarbophil [FiberCon®]), unless all are contraindicated or clinically significant adverse effects are experienced;
      4. Failure of Linzess®, Amitiza®, or Trulance® (whichever is preferred), unless all are contraindicated or clinically significant adverse effects are experienced;
         *Prior authorization may be required for Linzess, Amitiza, and Trulance
      5. At the time of request, member does not have any of the following contraindications: a history of myocardial infarction, stroke, transient ischemic attack, or angina;
      6. Dose does not exceed 12 mg (2 tablets) per day.

   Approval duration: 12 months

   B. 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. Irritable Bowel Syndrome with Constipation (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. At the time of request, member does not have any of the following contraindications:
         history of myocardial infarction, stroke, transient ischemic attack, or angina;
      4. If request is for a dose increase, new dose does not exceed 12 mg (2 tablets) 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 document.

IV. Appendices/General Information
   Appendix A: Abbreviation/Acronym Key
   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</td>
<td>1 rounded teaspoonful, tablespoonful, or premeasured packet in 240 mL of fluid PO, QD to TID (2.4 g of soluble dietary fiber per dose)</td>
<td>7.2 g (as soluble dietary fiber) per day</td>
</tr>
<tr>
<td>(Metamucil®) [OTC]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>calcium polycarbophil</td>
<td>2 tablets (1,250 mg calcium polycarbophil) PO 1 to 4 times daily</td>
<td>8 tablets/day (5,000 mg/day)</td>
</tr>
<tr>
<td>(FiberCon®) [OTC]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>methylcellulose</td>
<td>Caplet: 2 caplets PO up to 6 times daily Powder: 1 heaping tablespoonful in at least 240 ml of water PO, given 1 to 3 times per day as needed</td>
<td>Caplet: 12 caplets/day Powder: 3 tablespoons/day</td>
</tr>
<tr>
<td>(Citrucel®) [OTC]</td>
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<td></td>
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</tbody>
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### Appendix C: Contraindications/Boxed Warnings

- **Contraindication(s):**
  - Major adverse cardiovascular events (MACE): history of myocardial infarction, stroke, transient ischemic attack, or angina
  - History of ischemic colitis or other forms of intestinal ischemia
  - Severe renal impairment (eGFR < 15 mL/min/1.73 m²) or end-stage renal disease
  - History of bowel obstruction, symptomatic gallbladder disease, suspected sphincter of Oddi dysfunction, or abdominal adhesions
  - Moderate or severe hepatic impairment (Child-Pugh B or C)
  - Hypersensitivity to tegaserod

- **Boxed warning(s):** none reported

### V. Dosage and Administration

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dosing Regimen</th>
<th>Maximum Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>IBS-C</td>
<td>6 mg PO BID at least 30 minutes before meals. Discontinue in patients who have not had adequate control of symptoms after 4 to 6 weeks of treatment.</td>
<td>12 mg/day</td>
</tr>
</tbody>
</table>

### VI. Product Availability

Tablet: 6 mg

### VII. References


3. FDA Briefing Document for Zelnorm (tegaserod maleate) for treatment of Irritable Bowel Syndrome with Constipation (IBS-C). Louisville, KY: US WorldMeds, LLC: October 2018. Available at:
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<table>
<thead>
<tr>
<th>Reviews, Revisions, and Approvals</th>
<th>Date</th>
<th>P&amp;T Approval Date</th>
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</thead>
<tbody>
<tr>
<td>Policy created</td>
<td>05.14.19</td>
<td>08.19</td>
</tr>
<tr>
<td>Removed HIM line of business per SDC.</td>
<td>12.03.19</td>
<td></td>
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<tr>
<td>3Q 2020 annual review: no significant changes; references reviewed and updated</td>
<td>05.08.20</td>
<td>08.20</td>
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</table>

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...
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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.

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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.

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