Clinical Policy: Prucalopride (Motegrity)
Reference Number: CP.PMN.194
Effective Date: 01.29.19
Last Review Date: 05.19
Line of Business: Commercial, TBD HIM*; Medicaid

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

*For Health Insurance Marketplace members, if request is through the pharmacy benefit, this policy applies only when the referenced drug is on the health plan approved formulary. Request for non-formulary drugs must be reviewed using the policy: HIM.PA.103.

Description
Prucalopride (Motegrity™) is a serotonin-4 (5-HT₄) receptor agonist.

FDA Approved Indication(s)
Motegrity is indicated for treatment of chronic idiopathic constipation (CIC) in adults.

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 Motegrity is medically necessary when the following criteria are met:

I. Initial Approval Criteria
A. Chronic Idiopathic Constipation
   1. Diagnosis of chronic idiopathic constipation;
   2. Age ≥ 18 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 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 2 mg (1 tablet) 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, HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid.
II. Continued Therapy
   A. Chronic Idiopathic 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. If request is for a dose increase, new dose does not exceed 2 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, HIM.PHAR.21 for health insurance marketplace, 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, HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid or evidence of coverage documents.

IV. Appendices/General Information
   Appendix A: Abbreviation/Acronym Key
   5-HT4: serotonin-4
   CIC: chronic idiopathic constipation
   FDA: Food and Drug Administration

   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>polyethylene glycol 3350 (MiraLax®)</td>
<td>17 g (approximately 1 heaping tablespoon) of powder in 120 to 240 mL of fluid PO once daily</td>
<td>34 grams per day</td>
</tr>
<tr>
<td>sennosides (Senokot®)</td>
<td>1 to 2 tablets (8.6 to 17.2 mg sennosides) PO twice daily</td>
<td>68.8 mg sennosides per day</td>
</tr>
<tr>
<td>bisacodyl (Dulcolax®)</td>
<td>5 to 15 mg/day (1 to 3 tablets) PO given as a single dose, or 1 suppository or retention enema (10 mg) PR once daily</td>
<td>15 mg per day PO or 10 mg per day PR</td>
</tr>
</tbody>
</table>

Either a suppository or oral tablet(s) may be used up to 3 times per week
<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) per day</td>
</tr>
<tr>
<td>calcium polycarbophil (FiberCon®)</td>
<td>1,000 mg PO 1 to 4 times per day or as needed</td>
<td>6,000 mg per day</td>
</tr>
<tr>
<td>methylcellulose (Citrucel®)</td>
<td>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&lt;br&gt;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</td>
<td>Caplet: 12 caplets per day&lt;br&gt;Powder: 6 grams per day</td>
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*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):** hypersensitivity; intestinal perforation or obstruction due to structural or functional disorder of the gut wall, obstructive ileus, severe inflammatory conditions of the intestinal tract such as Crohn’s disease, ulcerative colitis, and toxic megacolon/megarectum
- **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>Chronic idiopathic constipation</td>
<td>Adults: 2 mg PO once daily&lt;br&gt;For CrCl &lt; 30 mL/min: 1 mg PO once daily</td>
<td>2 mg/day</td>
</tr>
</tbody>
</table>

**VI. Product Availability**
Tablets: 1 mg, 2 mg

**VII. References**

3. Suares NC, Ford AC. Prevalence of, and risk factors for, chronic idiopathic constipation in the community: systematic review and meta-analysis. Am J Gastroenterol. 2011 Sep;106(9):1582-91.

<table>
<thead>
<tr>
<th>Reviews, Revisions, and Approvals</th>
<th>Date</th>
<th>P&amp;T Approval Date</th>
</tr>
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<tr>
<td>Policy created</td>
<td>01.29.19</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.
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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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