Clinical Policy: Tenapanor (Ibsrela)
Reference Number: CP.PMN.224
Effective Date: 03.01.20
Last Review Date: 02.20
Line of Business: Commercial, HIM, Medicaid

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

Description
Tenapanor (Ibsrela®) is a locally acting inhibitor of the sodium/hydrogen exchanger 3 (NHE3), an antiporter expressed on the apical surface of the small intestine and colon primarily responsible for the absorption of dietary sodium.

FDA Approved Indication(s)
Ibsrela is indicated for treatment of irritable bowel syndrome with constipation (IBS-C) 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 Ibsrela 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;
      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. Dose does not exceed 100 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, HIM.PHAR.21 for health insurance marketplace, 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. If request is for a dose increase, new dose does not exceed 100 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, 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
   FDA: Food and Drug Administration
   IBS-C: irritable bowel syndrome with constipation
   NHE3: sodium/hydrogen exchanger 3

   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>calcium polycarbophil (FiberCon®)</td>
<td>1,000 mg 1 to 4 times per day or as needed</td>
<td>6,000 mg/day</td>
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</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
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 < 6 years of age due to the risk of serious dehydration; patients with known or suspected mechanical gastrointestinal obstruction
- Boxed warning(s): contraindicated in patients < 6 years of age; avoid use of Ibsrela in patients 6 years to < 12 years of age; the safety and effectiveness of Ibsrela have not been established in patients < 18 years of age

V. Dosage and Administration

<table>
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<tr>
<th>Indication</th>
<th>Dosing Regimen</th>
<th>Maximum Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>IBS-C</td>
<td>50 mg PO BID</td>
<td>100 mg/day</td>
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VI. Product Availability
- Tablets: 50 mg

VII. References

Reviews, Revisions, and Approvals

<table>
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<th>Reviews, Revisions, and Approvals</th>
<th>Date</th>
<th>P&amp;T Approval Date</th>
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<td>Policy created</td>
<td>11.05.19</td>
<td>02.20</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.

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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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