# Clinical Policy: Gastrointestinal Agents: Irritable Bowel Syndrome (IBS) - Selected GI

Reference Number: OH.PHAR.PPA.56
Effective Date: 01/01/2020
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Line of Business: Medicaid

Coding Implications
Revision Log

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

**Description**

### IBS WITH CONSTIPATION & CHRONIC IDIOPATHIC CONSTIPATION AGENTS

| NO PA REQUIRED "PREFERRED" | STEP THERAPY REQUIRED "PREFERRED" | PA REQUIRED "NON-PREFERRED" |
|---|---|---|
| BISACODYL(generic of Dulcolax®)<br>CASANTHRANOL/DOCUSATE SODIUM (generic of Peri-Colace®)<br>LACTULOSE (generic of Chronulac®)<br>POLYETHYLENE GLYCOL (generic of Miralax®)<br>PSYLLIUM FIBER (e.g. Konsyl®)<br>SENNA (generic of Senokot®) | AMITIZA® capsule (lubiprostone)<br>LINZESS™ 145mcg & 290mcg capsule (linaclotide) | LINZESS™ 72mcg capsule (linaclotide)<br>MOTEGRITY™ (prucalopride)<br>TRULANCE™ (plecanatide)<br>ZELNORM™ (tegaserod)† |

†Use limited to FDA approved indications.

### IBS WITH DIARRHEA AGENTS

| NO PA REQUIRED "PREFERRED" | PA REQUIRED "NON-PREFERRED" |
|---|---|
| DICYCLOMINE (generic of Bentyl®)<br>DIPHENOXYLATE/ATROPINE (generic of Lomotil®)<br>LOPERAMIDE (Maximum of 16mg per day) | ALOSETRON (generic of Lotronex®)<br>VIBERZI™ (eluxadoline tablet)<br>XIFAXAN® (rifaximin) |

### SHORT BOWEL SYNDROME AGENTS*

| NO PA REQUIRED "PREFERRED" | PA REQUIRED "NON-PREFERRED" |
|---|---|
| | NUTRESTORE ™ (l-glutamine)<br>ZORBTIVE ® (somatropin)<br>GATTEX ® (teduglutide) |

* Note: Clinical criteria must be met

### NON-INFECTIOUS DIARRHEA AGENTS

| NO PA REQUIRED "PREFERRED" | PA REQUIRED "NON-PREFERRED" |
|---|---|
| DIPHENOXYLATE/ATROPINE (generic of Lomotil®)<br>LOPERAMIDE (Maximum of 16mg per day) | MYTESI ™ (crofelemer) |

## CLINICAL POLICY: GASTROINTESTINAL AGENTS: IRRITABLE BOWEL SYNDROME (IBS) - SELECTED GI

**FDA Approved Indication(s):** Varies by drug product, please see package insert; clinical pharmacology or other appropriate clinical reference.

**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 Buckeye Health Plan, an affiliate of Centene Corporation® that Non-preferred Irritable Bowel Syndrome (IBS) -Selected GI agents are medically necessary when the following criteria are met:

**I. Initial Approval Criteria**

**A. Agents for IBS with constipation, IBS with diarrhea, and Chronic Idiopathic Constipation**

1. Prescribed indication is FDA-approved or supported by standard pharmacopeias
2. Member must meet labeled age requirements for the medication;
3. If medication requires **step therapy (see above table)** member must have had an inadequate clinical response to preferred alternatives, including a trial of no less than 14 day trial of at least two medications not requiring prior approval unless one of the following:
   a. Allergy to medications not requiring prior approval
   b. Contraindication to or drug interaction with medications not requiring prior approval
   c. History of unacceptable/toxic side effects to medications not requiring prior approval

4. If medication is a **non-preferred agent** member must have had an inadequate clinical response to preferred alternatives, including a trial of no less than **14 day trial** of at least **two step therapy products** medications unless one of the following:
   a. Allergy to medications not requiring prior approval
   b. Contraindication to or drug interaction with medications not requiring prior approval
   c. History of unacceptable/toxic side effects to medications not requiring prior approval

**Approval duration: 12 months.**

**B. Short Bowel Syndrome Agents (NUTRESTORE, ZORBTIVE, and GATTEX)**

1. Member has a diagnosis of short bowel syndrome (SBS) and evidence of specialize nutritional support
2. Member must meet labeled age requirements for the medication;
3. If prescribed drug is Nutrestore member has evidence of concurrent use of recombinant growth hormone.

4. If prescribed drug is Gattex member has evidence of parenteral nutrition support at least three times per week and appropriate colonoscopy and lab assessment (bilirubin, alkaline phosphatase, lipase, and amylase) 180 days prior to initiation

**Please note: Re-authorization of these therapies requires evidence of improved condition (i.e. as measured by total volume, total calories, or decreased frequency of specialized nutrition support)**

**Approval duration: 12 months.**

**C. Non-infectious Diarrhea agents Mytesi (crofelemer)**

1. Diagnosis of HIV/AIDS;
2. Age ≥ 18 years;
3. Member has non-infectious diarrhea;
4. Member is currently receiving anti-retroviral therapy as evidenced by claims history;
5. Failure of an antidiarrheal medication (e.g., loperamide, diphenoxylate/atropine) unless contraindicated or clinically significant adverse effects are experienced;
6. Dose does not exceed 250 mg (2 tablets) per day.

**II. Diagnoses/Indications for which coverage is NOT authorized:**

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 policy – CP.PMN.53 for Medicaid or evidence of coverage documents.

**III. Appendices/General Information**

*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.*

***See above tables for preferred alternatives*** *Dosing varies by drug product. See FDA approved dosing and administration.*

*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*

- *See package insert; clinical pharmacology or other appropriate clinical reference*

**IV. Dosage and Administration:** varies by drug product. See package insert; clinical pharmacology or other appropriate clinical reference for FDA approved dosing and administration

**V. Product Availability:** See package insert; clinical pharmacology or other appropriate clinical reference for product availability

**VI. References.** Refer to package insert.

| Reviews, Revisions, and Approvals | Date | P&T Approval Date |
|---|---|---|
| New policy created. | 10.19 | N/A |

**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.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

**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.