# Clinical Policy: Plecanatide (Trulance)

Reference Number: NH.PMN.87
Effective Date: 09.24
Last Review Date: 04.25
Line of Business: Medicaid

Revision Log

**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 clinically significant adverse effects are experienced or all are contraindicated;
4. Failure of one stimulant laxative (e.g., bisacodyl, senna), unless clinically significant adverse effects are experienced or all are contraindicated;
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 (Citrucel), calcium polycarbophil (FiberCon)), unless clinically significant adverse effects are experienced or all are contraindicated;
4. Dose does not exceed 3 mg (1 tablet) per day.

**Approval duration: 12 months**

**C. Other diagnoses/indications** (must meet 1 or 2)**:**
1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the PDL, the no coverage criteria policy: CP.PMN.255; or
   b. For drugs NOT on the PDL, the non-formulary policy: CP.PMN.16; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy: CP.PMN.53.

## II. Continued Therapy

**A. All Indications in Section I** (must meet all)**:**
1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B);*
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. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the PDL, the no coverage criteria policy: CP.PMN.255; or
   b. For drugs NOT on the PDL, the non-formulary policy: CP.PMN.16; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy: CP.PMN.53.

## 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.PMN.53 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.*

| Drug Name | Dosing Regimen | Dose Limit/ Maximum Dose |
|---|---|---|
| psyllium (Metamucil®) | 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) | 7.2 g (as soluble dietary fiber)/day |
| calcium polycarbophil (FiberCon®) | 1,000 mg 1 to 4 times per day or as needed | 6,000 mg/day |
| 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<br><br>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<br>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<br><br>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 |
| lubiprostone (Amitiza®) | IBS-C: 8 mcg PO BID<br>CIC: 24 mcg PO BID | IBS-C: 16 mcg/day<br>CIC: 48 mcg/day |
| Linzess® (linaclotide) | IBS-C: 290 mcg PO QD<br>CIC: 72 mcg or 145 mcg PO QD | IBS-C: 290 mcg/day<br>CIC: 145 mcg/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

| Indication | Dosing Regimen | Maximum Dose |
|---|---|---|
| CIC, IBS-C | 3 mg PO QD | 3 mg/day |

## VI. Product Availability

Tablet: 3 mg

## VII. References

1. Trulance Prescribing Information. New York, NY: Synergy Pharmaceuticals Inc.; April 2021. Available at: www.trulance.com. Accessed July 5, 2023.
2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2020. Available at: http://www.clinicalpharmacology-ip.com/. Accessed July 11, 2023.

***Chronic Idiopathic Constipation***

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4. Ford AC, Moayyedi P, Lacy BE, et al. American College of Gastroenterology monograph on the management of irritable bowel syndrome and chronic idiopathic constipation. *Am J Gastroenterol*. 2014;109 Suppl 1:S2-26.
5. Koliani-pace J, Lacy BE. Update on the Management of Chronic Constipation. Curr Treat Options *Gastroenterol*. 2017.
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***Irritable Bowel Syndrome with Constipation***

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13. Lacy BE, Pimentel M, Brenner DM. ACG clinical guideline: Management of irritable bowel syndrome. American Journal of Gastroenterology. 2021; 116(1): 17-44.

14. Chang L, Sultan S, Lembo A, et al. AGA clinical practice guideline on the pharmacological management of irritable bowel syndrome with constipation. Gastroenterology. 2022;163:118-136.

| Reviews, Revisions, and Approvals | Date | P&T Approval Date |
|---|---|---|
| Policy Created | 08.24 | 08.24 |
| Annual review, no significant changes | 04.25 | 04.25 |

**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.