

## **Clinical Policy: Plecanatide (Trulance)**

Reference Number: CP.PMN.87

Effective Date: 02.01.17

Last Review Date: 11.20

Line of Business: Commercial, HIM, Medicaid

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

### **Description**

Plecanatide (Trulance<sup>®</sup>) 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<sup>®</sup> 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  $\geq$  18 years;
3. Failure of one bulk forming laxative (e.g., psyllium (Metamucil<sup>®</sup>), methylcellulose (Citrucel<sup>®</sup>), calcium polycarbophil (FiberCon<sup>®</sup>)), 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<sup>®</sup>) 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  $\geq$  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**

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. All Indications in Section I (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 3 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*

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.*

<b>Drug Name</b>	<b>Dosing Regimen</b>	<b>Dose Limit/ Maximum Dose</b>
psyllium (Metamucil <sup>®</sup> )	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

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
calcium polycarbophil (FiberCon <sup>®</sup> )	1,000 mg 1 to 4 times per day or as needed	6,000 mg/day
methylcellulose (Citrucel <sup>®</sup> )	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
sennosides (Senokot <sup>®</sup> )	1 to 2 tablets (8.6 to 17.2 mg sennosides) PO BID	68.8 mg sennosides/day
bisacodyl (Dulcolax <sup>®</sup> )	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  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 <sup>®</sup> )	17 g (approximately 1 heaping tablespoon) of powder in 120 to 240 mL of fluid PO QD	34 grams/day

*Therapeutic alternatives are listed as Brand name<sup>®</sup> (generic) when the drug is available by brand name only and generic (Brand name<sup>®</sup>) 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.; February 2020. Available at: [www.trulance.com](http://www.trulance.com). Accessed June 29, 2020.
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3. 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.
4. Koliani-pace J, Lacy BE. Update on the Management of Chronic Constipation. *Curr Treat Options Gastroenterol.* 2017.
5. Miner PB, Koltun WD, Wiener GJ, et al. A randomized Phase III clinical trial of plecanatide, an uroguanylin analog, in patients with chronic idiopathic constipation. *Am J Gastroenterol.* February 2017. doi:10.1038/ajg.2016.611.
6. Hayat U, Dugum M, Garg S. Chronic constipation: update on management. *Cleveland Clinic Journal of Medicine.* 2017 May;84(5):397-408.
7. Ottawa (ON): Canadian Agency for Drugs and Technologies in Health. Dioctyl sulfosuccinate or docusate (calcium or sodium) for the prevention or management of constipation: a review of the clinical effectiveness. [www.ncbi.nlm.nih.gov/pubmedhealth/PMH0071207/](http://www.ncbi.nlm.nih.gov/pubmedhealth/PMH0071207/). Accessed November 7, 2017.
8. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2020. Available at: <http://www.clinicalpharmacology-ip.com/>. Accessed June 29, 2020.
9. Paquette IM, Varma M, Ternent C, et al. The American Society of Colon and Rectal Surgeons' Clinical Practice Guideline for the Evaluation and Management of Constipation. *Dis Colon Rectum.* 2016;59:479-492.
10. American Gastroenterological Association, Bharucha AE, Dorn SD et al. American Gastroenterological Association medical position statement on constipation. *Gastroenterol.* 2013;144(1):211-7. doi: 10.1053/j.gastro.2012.10.029.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	02.01.17	05.17.17
1Q18 annual review: Policies combined for Medicaid and commercial lines of business; Modified criterion to require trial of all 3 different laxatives recommended per ACG (bulk-forming, polyethylene glycol, and stimulant) and removed stool softeners as an option since there is little evidence to support the use of such agents in chronic constipation; Updated max dose requirement to include QL of 1 tablet/day; Modified initial approval from 6 to 12 months; References reviewed and updated.	11.06.17	02.18
2Q 2018 annual review: criteria added for new FDA indication: IBS-C; approval duration for CIC and continuation therapy modified to 12 months for commercial; references reviewed and updated.	03.06.18	05.18
4Q 2018 annual review: no significant changes from previously approved corporate policy; references reviewed and updated.	07.20.18	11.18
4Q 2019 annual review: no significant changes; references reviewed and updated.	08.06.19	11.19
4Q 2020 annual review: added HIM line of business; references reviewed and updated.	06.29.20	11.20

**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.

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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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