

Clinical Policy: Plecanatide (Trulance)

Reference Number: CP.PMN.87

Effective Date: 02.01.17

Last Review Date: 05.18

Line of Business: Commercial, 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 for the treatment of:

- Adults with chronic idiopathic constipation (CIC)
- Adults with 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 \geq 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. 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 3 mg/day (1 tablet/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 all are contraindicated or clinically significant adverse effects are experienced;
4. Dose does not exceed 3 mg/day (1 tablet/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 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/day (1 tablet/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 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 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

GC-C: guanylate cyclase-C

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) per day
calcium polycarbophil (FiberCon®)	1,000 mg 1 to 4 times per day or as needed	6,000 mg per day

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
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 per day Powder: 6 grams per day
sennosides (Senokot [®])	1 to 2 tablets (8.6 to 17.2 mg sennosides) PO twice daily	68.8 mg sennosides per 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 once daily Either a suppository or oral tablet(s) may be used up to 3 times per week	15 mg per day PO or 10 mg per day PR
polyethylene glycol 3350 (MiraLax [®])	17 g (approximately 1 heaping tablespoon) of powder in 120 to 240 mL of fluid PO once daily	34 grams per 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.

V. Dosage and Administration

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

VI. Product Availability

Tablets: 3 mg

VII. References

1. Trulance Prescribing Information. New York, NY: Synergy Pharmaceuticals Inc.; January 2018. Available at: www.trulance.com. Accessed January 29, 2018.
2. Bharucha AE, Pemberton JH, Locke GR. American Gastroenterological Association technical review on constipation. *Gastroenterology*. 2013;144(1):218-38.
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. *The American Journal of Gastroenterology*. February 2017. doi:10.1038/ajg.2016.611. Accessed February 7, 2017.
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/. Accessed November 7, 2017.
8. *Clinical Pharmacology* [database online]. Tampa, FL: Gold Standard, Inc.; 2017. Available at: <http://www.clinicalpharmacology-ip.com/>.

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

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.

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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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