Clinical Policy: Plecanatide (Trulance)

Reference Number: PA.CP.PMN.87
Effective Date: 02.01.17
Last Review Date: 07.18

Revision Log

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).

Policy/Criteria
Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria

It is the policy of health plans affiliated with PA Health & Wellness 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 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. Other diagnoses/indications

1. Refer to PA.CP.PMN.53.

II. Continued Therapy

A. Chronic Idiopathic Constipation (must meet all)**:**

1. Currently receiving medication via PA Health &Wellness benefit or member has met all initial approval criteria or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies;
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 PA Health &Wellness benefit or member has met all initial approval criteria or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies;
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to PA.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 policy – PA.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

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
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

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
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 once daily	3 mg/day

VI. Product Availability

Tablet: 3 mg

VII. References

1. Trulance Prescribing Information. New York, NY: Synergy Pharmaceuticals Inc.; January 2017. Available at: https://www.trulance.com/. Accessed November 6, 2017.
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