Clinical Policy: Plecanatide (Trulance)
Reference Number: ERX.NPA.05
Effective Date: 06.01.17
Last Review Date: 05/17
Line of Business: Commercial [Prescription Drug Plan] Revision Log

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

Description
Plecanatide (Trulance™) is a 16-amino acid peptide analog of uroguanylin, an endogenous agonist that binds and activates guanylate cyclase-C (GC-C) receptors expressed in the epithelial lining of the gastrointestinal mucosa in a pH-sensitive manner.

FDA approved indication
Trulance is indicated for the treatment of chronic idiopathic constipation (CIC) in adult patients.

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

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ 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 at least 1 agent from 2 different classes from the following classes at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced:
   a. Bulk-forming laxatives (e.g., psyllium (Metamucil), calcium polycarbophil (FiberCon), methylcellulose (Citrucel));
   b. Osmotic laxatives (e.g., polyethylene glycol 3350 (MiraLax), lactulose, glycerin, magnesium sulfate, magnesium citrate);
   c. Stimulant laxatives (e.g., senna (Senokot), bisacodyl (Dulcolax));
   d. Emollients (e.g., docusate sodium (Colace));
4. Dose does not exceed 3 mg/day (1 tablet/day).

Approval duration: Length of Benefit

B. Other diagnoses/indications

1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized)

II. Continued Therapy

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

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions or member has previously met initial approval criteria;
2. Member is responding positively to therapy (e.g., increased number of bowel movements from baseline);
3. If request is for a dose increase, new dose does not exceed 3 mg/day (1 tablet/day).

Approval duration: Length of Benefit

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized)

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 – ERX.PA.01 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

Appendix B: Therapeutic Alternatives

Drug	Dosing Regimen	Dose Limit/ Maximum Dose
Linzess® (linaclotide)	72 mcg or 145 mcg PO QD	145 mcg/day
Amitiza® (lubiprostone)	24 mcg PO BID	48 mcg/day
Lactulose	15-30 mL PO QD	60 mL/day
Senokot® (sennosides)	Two 8.6 mg tablets PO QD-BID	68.8 mg/day
Metamucil® (psyllium)	One rounded tsp in 8 oz liquid PO up to TID	3 doses/day
Dulcolax® (bisacodyl)	5 to 15 mg PO or 10 mg PR QD	30 mg/day
FiberCon® (calcium polycarbophil)	Two 625 mg tablets PO QD-QID	5000 mg/day
Citrucel® (methylcellulose)	Caplet: 2 caplets up to 6 times daily Powder: 2 grams in 8 oz of cold water PO up to TID	Caplet: 12 caplets/day Powder: 6 grams/day
MiraLax® (polyethylene glycol 3350)	17 grams in 4-8 oz water PO QD	17 grams/day for 2 weeks
Colace® (docusate sodium)	50-200 mg PO QD-QID	200 mg/day

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Chronic idiopathic constipation	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: www.trulance.com. Accessed February 8, 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.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	02/17	05/17

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.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. 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.