RXADVANCE
2 Park Central Drive
Southborough, MA 01772

Clinical Policy Title:	plecanatide
Policy Number:	RxA.510
Drug(s) Applied:	Trulance®
Original Policy Date:	03/06/2020
Last Review Date:	12/07/2020
Line of Business Policy Applies to:	All lines of business

Background

Plecanatide (Trulance®) is a guanylate cyclase-C agonist. It is indicated in adults for the treatment of:

- Chronic idiopathic constipation (CIC)
- Irritable bowel syndrome with constipation (IBS-C)

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
Plecanatide (Trulance®)	CIC, IBS-C	3 mg PO OD	3 mg/day

Dosage Forms

- Tablets: 3 mg

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

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 (1 tablet) per day.

Approval duration
Commercial: 12 months
Medicaid: 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 all are contraindicated or clinically significant adverse effects are experienced;
4. Dose does not exceed 3 mg (1 tablet) per day.

Approval duration
Commercial: 12 months
Medicaid: 12 months

II. Continued Therapy Approval

A. All Indications in Section I (must meet all)**:**

1. Member is currently receiving medication that has been authorized by RxAdvance 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
Commercial: 12 months
Medicaid: 12 months

III. Appendices

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
Below are suggested therapeutic alternatives based on clinical guidance. Please check drug formulary for preferred agents and utilization management requirements.

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 Powder: 1 heaping tablespoonful (2 g methylcellulose per 19 g powder) in at least 240 ml	Caplet: 12 caplets/day Powder: 6 grams/day

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	(8 oz) of water PO, given 1 to 3 times per day as needed	
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 OD 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 OD	34 grams/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.

APPENDIX D: General Information

- Trulance® is the first medication for Chronic Idiopathic Constipation (CIC) and Irritable Bowel Syndrome with Constipation (IBS-C) that is designed to work like a natural peptide in our body called uroguanylin. It is very similar to the uroguanylin that our body naturally makes, with the exception of a single small change in the Trulance molecule that improves how it attaches in the small intestine.
- Trulance® can help provide relief from the constipation in as little as 24 hours. It can help people have "Normal" (smooth, soft sausage or snake-shaped) bowel movements. Moreover, it helped patients with IBS-C can have less abdominal pain and more regular, well-formed BMs (bowel movement).

References

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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. Accessed September 9, 2020.

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 September 9, 2020.
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Review/Revision History	Review/Revised Date	P&T Approval Date
Policy was established	01/2020	03/06/2020
Policy was reviewed: 1. Clinical Policy Title was updated. 2. Line of business Policy Applies to was updated to “All lines of business”. 3. Continued therapy approval criteria II.A.1 was rephrased to “Currently receiving medication that has been authorized by RxAdvance…”. 4. Appendix D updated 5. References were reviewed and updated.	09/09/2020	12/07/2020