

Clinical Policy: Plecanatide (Trulance)

Reference Number: HIM.PA.158

Effective Date: 06.01.21

Last Review Date: 11.21

Line of Business: HIM

[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 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[®] 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 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[®]) at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
6. Failure of generic lubiprostone and Linzess[®], unless clinically significant adverse effects are experienced or both are contraindicated;
7. 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. Failure of generic lubiprostone and Linzess, unless clinically significant adverse effects are experienced or both are contraindicated;
5. 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): HIM.PA.154 for health insurance marketplace.

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): HIM.PA.154 for health insurance marketplace.

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 – HIM.PA.154 for health insurance marketplace.

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.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
psyllium (Metamucil [®])	1 rounded teaspoonful, tablespoonful, or premeasured packet in 240 mL of fluid	7.2 g (as soluble dietary fiber)/day

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	PO, 1 to 3 times per day (2.4 g of soluble dietary fiber per dose)	
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 (8 oz) of water PO, given 1 to 3 times per day as needed	Caplet: 12 caplets/day Powder: 6 grams/day
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 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 [®])	17 g (approximately 1 heaping tablespoon) of powder in 120 to 240 mL of fluid PO QD	34 grams/day
lubiprostone (Amitiza [®])	IBS-C: 8 mcg PO BID CIC: 24 mcg PO BID	IBS-C: 16 mcg/day CIC: 48 mcg/day
Linzess [®] (linaclotide)	IBS-C: 290 mcg PO QD CIC: 72 mcg or 145 mcg PO QD	IBS-C: 290 mcg/day CIC: 145 mcg/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

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.; April 2021. Available at: www.trulance.com. Accessed August 12, 2021.
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Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created (HIM line of business removed from CP.PMN.87) per March SDC addition of redirection to generic lubiprostone and Linzess.	03.26.21	05.21
4Q 2021 annual review: no significant changes; updated reference for HIM off-label use to HIM.PA.154 (replaces HIM.PHAR.21); references reviewed and updated.	08.12.21	11.21

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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