

Clinical Policy: Plecanatide (Trulance)

Reference Number: AZ.CP.PMN.87

Effective Date: 09.19.19

Last Review Date: 10.20

Line of Business: Arizona Medicaid (AzCH-CCP and Care1st)

[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 Arizona Complete Health-Complete Care Plan and Care1st 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[®]), unless 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. Failure of Amitiza[®] and Linzess[®], unless contraindicated or clinically significant adverse effects are experienced;
**Prior authorization may be required for Amitiza and Linzess*
7. Dose does not exceed 3 mg per day (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]), unless contraindicated or clinically significant adverse effects are experienced;

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4. Failure of Amitiza[®] and Linzess[®], unless contraindicated or clinically significant adverse effects are experienced;

**Prior authorization may be required for Amitiza and Linzess*

5. Dose does not exceed 3 mg per day (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): AZ.CP.PMN.53 for Arizona 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 per day (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): AZ.CP.PMN.53 for Arizona 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 – AZ.CP.PMN.53 for Arizona Medicaid.

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.

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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
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
Amitiza® (lubiprostone)	CIC: 24 mcg PO BID IBS-C: 8 mcg PO BID	CIC: 48 mcg/day IBS-C: 16mcg/day
Linzess® (linaclotide)	CIC: 72 – 145 mcg PO QD IBS-C: 290 mcg PO QD	CIC: 145 mcg/day IBS-C: 290mcg/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

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VII. References

1. Trulance Prescribing Information. New York, NY: Synergy Pharmaceuticals Inc.; February 2018. Available at: www.trulance.com. Accessed: September 16, 2019.
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.; 2018. Available at: <http://www.clinicalpharmacology-ip.com/>.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	09.18.19	09.19
4Q 2020 annual review: no significant changes; references reviewed and updated.	10.21.20	10.20
Added Care1st logo. Added verbiage to specify that criteria also applies to Care1st.	5.10.21	04.21

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

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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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