MEDICAL MUTUAL®

# Drug Policy

| Policy: | Trulance (plecanatide) | Annual Review Date:<br>07/21/2022<br>Last Revised Date:<br>07/21/2022 |
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## OVERVIEW

Trulance is a guanylate cyclase-C agonist which increases cyclic guanosine monophosphate (cGMP) levels, thereby increasing intestinal fluid and transit. Trulance is indicated for the treatment of chronic idiopathic constipation and IBS-C in adult patients. The safety and efficacy of Trulance in the pediatric population has not been evaluated. The use of Trulance is contraindicated in patients less than 6 years of age due to the risk of serious dehydration.

## POLICY STATEMENT

This policy involves the use of Trulance. Prior authorization is recommended for pharmacy benefit coverage of Trulance. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

Because of the specialized skills required for evaluation and diagnosis of patients treated with Trulance as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Trulance be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

## RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Trulance is recommended in those who meet the following criteria:

1. **Chronic Idiopathic Constipation (CIC), Initial Therapy**
   **Criteria.** *Patient must meet the following criteria*
   - **A.** The patient is 18 years of age or older; AND
   - **B.** Trulance is prescribed by or in consultation with a gastroenterologist or a physician who specializes in the management of gastrointestinal disease; AND
   - **C.** The patient has attempted lifestyle changes, including maintaining a diet rich in fiber and/or fiber supplementation along with adequate fluid intake; AND

**D.** The patient has failed on or is intolerant to at least 2 of the following with or without a stool softener in the past 3 months:
  - **i.** At least one stimulant laxative (e.g. bisacodyl); OR
  - **ii.** At least one osmotic laxative (e.g. PEG 3350); OR
  - **iii.** At least one saline laxative (e.g. magnesium citrate); AND

**E.** The patient does not have a known or suspected gastrointestinal obstruction and is not at increased risk of recurrent obstruction; AND

**F.** For members with the Basic/Basic Plus formulary the patient has failed on or is intolerant to a trial of Amitiza or Linzess for a minimum of 90 days.

**G.** For members with National Preferred/National Preferred Plus formularies the patient has failed on or is intolerant to a trial of Linzess for a minimum of 90 days.

**H.** For members with the High Performance formulary the patient has failed on or is intolerant to a trial of lubiprostone for a minimum of 90 days.

**2. Irritable Bowel Syndrome with Constipation (IBS-C), Initial Therapy**

**Criteria.** *Patient must meet the following criteria*

**A.** The patient is 18 years of age or older; AND

**B.** Trulance is prescribed by or in consultation with a gastroenterologist or a physician who specializes in the management of gastrointestinal disease; AND

**C.** The patient has attempted lifestyle changes, including maintaining a diet rich in fiber and/or fiber supplementation along with adequate fluid intake; AND

**D.** The patient has failed on or is intolerant to at least 2 of the following, with or without a stool softener, in the past 3 months:
  - **i.** At least one stimulant laxative (e.g. bisacodyl); OR
  - **ii.** At least one osmotic laxative (e.g. PEG 3350); OR
  - **iii.** At least one saline laxative (e.g. magnesium citrate); AND

**E.** The patient does not have a known or suspected gastrointestinal obstruction and is not at increased risk of recurrent obstruction; AND

**F.** For members with the Basic/Basic Plus formulary the patient has failed on or is intolerant to a trial of Amitiza or Linzess for a minimum of 90 days.

**G.** For members with National Preferred/National Preferred Plus formularies the patient has failed on or is intolerant to a trial of Linzess for a minimum of 90 days.

**H.** For members with the High Performance formulary the patient has failed on or is intolerant to a trial of lubiprostone for a minimum of 90 days.

**3. Continuation of Therapy**

**Criteria.** *Patient must meet the following criteria.*

**A.** The patient has demonstrated a beneficial response to Trulance, per the prescribing physician (e.g. increased number of bowel movements from baseline); AND
**B.** The patient has no contraindications to Trulance; AND
**C.** The patient continues to meet all above criteria per indication.

**Initial Approval/ Extended Approval.**
**A)** *Initial Approval:* 1 year
**B)** *Extended Approval:* 1 year

## CONDITIONS NOT RECOMMENDED FOR APPROVAL

Trulance has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

**1.** Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

**Documentation Requirements:**

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

## REFERENCES

1. Trulance (plecanatide) [prescribing information]. New York, NY: Synergy Pharmaceuticals Inc.; May. 2019.
2. Plecanatide. In: DRUGDEX [online database]. Truven Health Analytics; Greenwood Village, CO. Last updated 01 May 2019. Accessed on 15 August 2019.