

How to help ensure that more of your patients  
get the treatment you prescribe

# Trulance<sup>®</sup> coverage: Prior authorization considerations for adults with IBS-C and CIC<sup>1</sup>



Once Trulance has been prescribed, a prior authorization (PA) may be needed.  
Submitting a PA is simple—just follow the directions inside.

.....  
**Trulance<sup>®</sup>**  
(plecanatide)

## Indication

Trulance (plecanatide) 3 mg tablets is indicated in adults for the treatment of Chronic Idiopathic Constipation (CIC) and Irritable Bowel Syndrome with Constipation (IBS-C).

## IMPORTANT SAFETY INFORMATION

### WARNING: RISK OF SERIOUS DEHYDRATION IN PEDIATRIC PATIENTS

**Trulance<sup>®</sup> is contraindicated in patients less than 6 years of age; in nonclinical studies in young juvenile mice administration of a single oral dose of plecanatide caused deaths due to dehydration. Use of Trulance should be avoided in patients 6 years to less than 18 years of age. The safety and efficacy of Trulance have not been established in pediatric patients less than 18 years of age.**

Please see additional Important Safety Information throughout and [click here](#) for full Prescribing Information, including BOXED Warning.

For patients with

# Irritable Bowel Syndrome with Constipation (IBS-C)

**Trulance (plecanatide) 3 mg tablets is indicated in adults for the treatment of IBS-C.**

## STEPS

- 1 Provide patient and insurance information
- 2 Include prescriber information (eg, practice name, your name, NPI #, DEA/license #)
- 3 Provide accurate information, including:
  - **Age, diagnosis, dosing** — age of patient, IBS-C, Trulance 3 mg taken orally once daily<sup>1</sup>
  - **Previous therapies tried and failed<sup>3</sup>** — eg, bulking agents, osmotic laxatives, stool softeners, stimulant laxatives, chloride channel activators, and other GC-C agonists
  - **ICD-10 code for IBS-C<sup>4\*</sup>** — K58.1 irritable bowel syndrome with constipation
  - **Rationale for prescribing Trulance**
- 4 Remember to include your signature and the date

## IN 2023...



**84%**

approval rate for commercially insured patients<sup>2†</sup> when submitted through CoverMyMeds



## More savings for your patients

Access that begins with a copay as low as \$25\* for up to a 90-day supply

## If you work with CoverMyMeds

You can start a prior authorization for Trulance to expedite approval:

- 1-866-452-5017
- [CoverMyMeds.com](https://www.covermymeds.com)

## Average out-of-pocket costs<sup>2</sup>

- **\$41.29** for Medicare Part-D patients

Formulary status subject to change. Coverage data is on file with Salix Pharmaceuticals and current as of March 2023.

\* The ICD-10 codes and all other patient-access-related information are provided for informational purposes only. It is the treating physician's responsibility to determine the proper diagnosis, treatment, and applicable ICD-10 code. Salix Pharmaceuticals does not guarantee coverage or reimbursement for the product.

<sup>†</sup> Submission is not a guarantee of coverage or payment. Payer coverage subject to change without notice.

<sup>2</sup> Eligible, commercially insured patients may pay as little as \$25 per prescription fill of Trulance. Patient is not eligible if he/she participates in, seeks reimbursement or submits a claim for reimbursement to any federal or state healthcare program with prescription drug coverage. Maximum benefits and other restrictions apply. Visit [www.trulance.com](http://www.trulance.com) for full eligibility criteria, terms, and conditions.

## IMPORTANT SAFETY INFORMATION (cont'd)

### Contraindications

- Trulance is contraindicated in patients less than 6 years of age due to the risk of serious dehydration.
- Trulance is contraindicated in patients with known or suspected mechanical gastrointestinal obstruction.

**Please see additional Important Safety Information throughout and [click here](#) for full Prescribing Information, including BOXED Warning.**

For patients with

# Chronic Idiopathic Constipation (CIC)

**Trulance (plecanatide) 3 mg tablets is indicated in adults for the treatment of CIC.**

## STEPS

- 1 Provide patient and insurance information
- 2 Include prescriber information (eg, practice name, your name, NPI #, DEA/license #)
- 3 Provide accurate information, including:
  - **Age, diagnosis, dosing** — age of patient, CIC, Trulance 3 mg taken orally once daily<sup>1</sup>
  - **Previous therapies tried and failed**<sup>3</sup> — eg, bulking agents, osmotic laxatives, stool softeners, stimulant laxatives, chloride channel activators, and other GC-C agonists
  - **ICD-10 code for CIC**<sup>4\*</sup> — K59.04 chronic idiopathic constipation
  - **Rationale for prescribing Trulance**
- 4 Remember to include your signature and the date



## Important considerations if a Letter of Medical Necessity is needed

- ✓ Keep it concise
- ✓ Submit on practice letterhead
- ✓ Include patient name
- ✓ Include name of medication (eg, Trulance 3 mg)
- ✓ Specify diagnosis (eg, IBS-C or CIC)
- ✓ State your treatment rationale
- ✓ Specify duration of the treatment (eg, as long as clinically necessary)<sup>1</sup>
- ✓ Include your name, your signature, and the date

## IMPORTANT SAFETY INFORMATION (cont'd)

### Warnings and Precautions

#### Risk of Serious Dehydration in Pediatric Patients

- Trulance is contraindicated in patients less than 6 years of age. The safety and effectiveness of Trulance in patients less than 18 years of age have not been established. In young juvenile mice (human age equivalent of approximately 1 month to less than 2 years), plecanatide increased fluid secretion as a consequence of stimulation of guanylate cyclase-C (GC-C), resulting in mortality in some mice within the first 24 hours, apparently due to dehydration. Due to increased intestinal expression of GC-C, patients less than 6 years of age may be more likely than older patients to develop severe diarrhea and its potentially serious consequences.
- Use of Trulance should be avoided in patients 6 years to less than 18 years of age. Although there were no deaths in older juvenile mice, given the deaths in young mice and the lack of clinical safety and efficacy data in pediatric patients, use of Trulance should be avoided in patients 6 years to less than 18 years of age.

**Please see additional Important Safety Information throughout and [click here](#) for full Prescribing Information, including BOXED Warning.**

# Common reasons for PA denials

Reason for Denial	Considerations for Avoiding Denial
<b>Prior authorization not completed</b>	Double-check PA, fill in missing information, and resubmit
<b>Dosing does not match indication</b>	Double-check dosing <ul style="list-style-type: none"><li>• For IBS-C: Trulance 3 mg, orally once daily as recommended</li><li>• For CIC: Trulance 3 mg, orally once daily as recommended</li></ul>
<b>Invalid diagnosis code</b>	Double-check ICD-10 code and resubmit <ul style="list-style-type: none"><li>• IBS-C: K58.1 irritable bowel syndrome with constipation*</li><li>• CIC: K59.04 chronic idiopathic constipation*</li></ul>
<b>Did not try and fail formulary alternative</b>	Include information on why Trulance is necessary and how you expect it to help the patient
<b>Product is a plan exclusion</b>	Double-check coverage; Medicare excludes certain kinds of drugs, but Trulance is not in any of those categories
<b>Medication not covered</b>	You can request a medical exception for plans that don't cover Trulance. Most of the time, Trulance is approved in these plans.

\* The ICD-10 codes and all other patient-access-related information are provided for informational purposes only. It is the treating physician's responsibility to determine the proper diagnosis, treatment, and applicable ICD-10 code. Salix Pharmaceuticals does not guarantee coverage or reimbursement for the product.

† Salix Pharmaceuticals does not guarantee coverage or reimbursement for the product. Formulary status subject to change.

## IMPORTANT SAFETY INFORMATION (cont'd)

### Warnings and Precautions (cont'd)

#### Diarrhea

- Diarrhea was the most common adverse reaction in the four placebo-controlled clinical trials for CIC and IBS-C. Severe diarrhea was reported in 0.6% of Trulance-treated CIC patients, and in 1% of Trulance-treated IBS-C patients.
- If severe diarrhea occurs, the health care provider should suspend dosing and rehydrate the patient.

#### Adverse Reactions

- In the two combined CIC clinical trials, the most common adverse reaction in Trulance-treated patients (incidence  $\geq 2\%$  and greater than in the placebo group) was diarrhea (5% vs 1% placebo).
- In the two combined IBS-C clinical trials, the most common adverse reaction in Trulance-treated patients (incidence  $\geq 2\%$  and greater than in the placebo group) was diarrhea (4.3% vs 1% placebo).

**Please see additional Important Safety Information throughout and [click here](#) for full Prescribing Information, including BOXED Warning.**

**References:** **1.** Trulance [prescribing information]. Bridgewater, NJ: Salix Pharmaceuticals. **2.** Data on file. Bridgewater, NJ: Salix Pharmaceuticals. **3.** Mounsey A, Raleigh M, Wilson A. Management of constipation in older adults. *Am Fam Physician*. 2015;92(6):500-504. **4.** ICD-10 data. <http://www.icd10data.com>. Accessed June 22, 2023.