

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

Trulance® coverage: Prior authorization considerations for adults with IBS-C and CIC¹



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

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Trulance®
(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® 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 daily¹
 - **Previous therapies tried and failed**³ — eg, bulking agents, osmotic laxatives, stool softeners, stimulant laxatives, chloride channel activators, and other GC-C agonists
 - **ICD-10 code for IBS-C**^{4*} — K58.1 irritable bowel syndrome with constipation
 - **Rationale for prescribing Trulance**
- 4 Remember to include your signature and the date

IN 2025...



86%

approval rate for commercially insured patients^{2†} 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



86%

approval rate for Medicare Part-D patients^{2†}

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 costs²

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

Formulary status subject to change. Coverage data is on file with Salix Pharmaceuticals and current as of June 2025.

* 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.

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

‡ 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 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 daily¹
 - **Previous therapies tried and failed³** — eg, bulking agents, osmotic laxatives, stool softeners, stimulant laxatives, chloride channel activators, and other GC-C agonists
 - **ICD-10 code for CIC^{4*}** — 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 | ✓ Specify diagnosis (eg, IBS-C or CIC) |
| ✓ Submit on practice letterhead | ✓ State your treatment rationale |
| ✓ Include patient name | ✓ Specify duration of the treatment (eg, as long as clinically necessary) ¹ |
| ✓ Include name of medication (eg, Trulance 3 mg) | ✓ 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
Prior authorization not completed	Double-check PA, fill in missing information, and resubmit
Dosing does not match indication	Double-check dosing • For IBS-C: Trulance 3 mg, orally once daily as recommended • For CIC: Trulance 3 mg, orally once daily as recommended
Invalid diagnosis code	Double-check ICD-10 code and resubmit • IBS-C: K58.1 irritable bowel syndrome with constipation* • CIC: K59.04 chronic idiopathic constipation*
Did not try and fail formulary alternative	Include information on why Trulance is necessary and how you expect it to help the patient
Product is a plan exclusion	Double-check coverage; Medicare excludes certain kinds of drugs, but Trulance is not in any of those categories
Medication not covered	You can request a medical exception for plans that don't cover Trulance. Most of the time, Trulance is approved in these plans.

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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.