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| [Date] [Formulary director] [Name of health plan] [Mailing address]  | Re: [Patient’s name] [Plan identification number] [Date of birth][Case identification]  |

To Whom it May Concern:

My name is [HCP’s name], and I am a [board-certified medical specialty] [NPI]. I am writing to request a tiering exception for my patient, [patient’s name], who is currently a member of [name of health plan].\*

The prescription is for Trulance, which is medically appropriate and necessary for this patient who has been diagnosed with [Chronic Idiopathic Constipation, K59.04] [Irritable Bowel Syndrome, K58.1].

I am requesting that Trulance be made available to my patient as a preferred medication.

In the past, [patient’s name] has attempted other treatments for [Chronic Idiopathic Constipation] [Irritable Bowel Syndrome], but those trials have failed due to either inadequate efficacy or lack of tolerability.

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| **Past Treatment(s)†** | **Start/Stop Dates** | **Reason(s) for Discontinuing** |
| [Drug name] | [MM/YY] - [MM/YY] | [Please list side effects, lack of efficacy, etc] |
| [Drug name] | [MM/YY] - [MM/YY] | [Please list side effects, lack of efficacy, etc] |

The patient’s present treatment(s) are as follows:

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| --- | --- | --- |
| **Current Treatment(s)†** | **Start Date** | **Dosage** |
| [Drug name] | [MM/YY] | [XX] |
| [Drug name] | [MM/YY] | [XX] |

Currently, [patient’s name] has the following unresolved symptoms:

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| • [Symptom 1] | • [Symptom 2] |

Along with this letter, I have enclosed a copy of my patient’s medical records and a Letter of Medical Necessity.
The letter describes why Trulance is medically necessary for my patient’s care over the preferred drugs listed in
the plan’s formulary.

[Explain why lower-tiered formulary drugs would not be as effective as product].

The reason I am requesting a tiering exception is because the cost associated with the Trulance assigned tier would present a financial burden to [patient’s name]. Furthermore, it prevents my patient from utilizing a medication that will help treat the [Chronic Idiopathic Constipation] [Irritable Bowel Syndrome].

To summarize, I consider Trulance to be the most appropriate option in helping to successfully treat my patient.

Please contact me, [name], at [telephone number] to answer any pending questions.

Sincerely,

[Physician’s name and signature]

[Physician’s medical specialty] [Physician’s NPI]

[Physician’s practice name]

[Phone #] [Fax #]

Encl: [Medical records, photo(s), Letter of Medical Necessity, statement of financial hardship, case number, written response to denial]

NPI, National Provider Identifier

 \*Include patient’s medical records and supporting documentation, including clinical evaluation.

 †Identify drug name, strength, dosage form, and therapeutic outcom

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| For the prescribers background information:Indications* Trulance (plecanatide) 3 mg tablets are indicated in adults for the treatment of Chronic Idiopathic

Constipation (CIC) and Irritable Bowel Syndrome with Constipation (IBS-C).IMPORTANT SAFETY INFORMATIONWARNING: RISK OF SERIOUS DEHYDRATION IN PEDIATRIC PATIENTSTrulance® 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 effectiveness of TRULANCE have not been established in patients less than 18 years of age.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.

Warnings and PrecautionsRisk 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 into the intestines 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.

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, suspend dosing and rehydrate the patient.

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

Please see the accompanying full [Prescribing Information](https://pi.bauschhealth.com/globalassets/BHC/PI/trulance-pi.pdf).Trulance is a trademark of Salix Pharmaceuticals or its affiliates. All other trademarks are the property of their respective owners. © 2025 Salix Pharmaceuticals or its affiliates. TRU.0033.USA.25 |