<Date> **PATIENT NAME:** <Patient Name>

<Prior Authorization/Appeals Department> **DATE OF BIRTH:** <Patient Date of Birth>

<Payer/Health Plan Name> **POLICY ID NUMBER:** <Patient Policy ID Number>

<Payer Address>

**PROVIDER ID NUMBER:** <Provider ID Number> <Optional: Claim rejection number>

**REGARDING:** Denied Claim for Trulance® (plecanatide)

Dear <Health Plan Contact Name>:

I am writing to appeal the denied claim for Trulance® (plecanatide) for my patient, <Patient Name>, for which the reason for denial was <quote the specific reason for denial in denial letter>. I have prescribed Trulance because this patient has been diagnosed with <chronic idiopathic constipation><irritable bowel syndrome>. Attached to this request are clinical notes regarding this patient’s disease state and the Trulance package insert.

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).

The following is the medical history of <Patient Name> and the rationale for treatment with Trulance.

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| **Date of Diagnosis** | <MM/DD/YY> |
| **Diagnosis (ICD-10 Code)** | □ K58.1 Irritable Bowel Syndrome □ K59.04 Chronic Idiopathic Constipation  |
| **Summary of clinical symptoms** | <Patient’s current condition, including an overview of symptoms and quality of life or functional impairment as applicable><Prognosis without treatment> |
| **Previous and current treatment regimens** | <If applicable, include previous and current pharmacologic treatments for IBS or CIC, including drug name, dates of use, and reasons for stopping> |
|  **Other Information** | ☐ **Alternate drug(s) contraindicated or previously tried, but with adverse outcome, e.g. toxicity, allergy, or therapeutic failure** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

<Restate the denial reason and your clinical rationale for why the denial should be overturned and why Trulance is medically necessary for this patient.>

Based on the evidence provided, I hope you agree with my clinical opinion that treatment with Trulance® (plecanatide) is appropriate. We appreciate your prompt review and reconsideration of this case. If you need additional information for a timely approval, please contact my office at <Office Number>

Sincerely,

 <Physician Signature>

<Physician Name>

<Physician Contact Information>

**Enclosures:** Consider including patient medical history, relevant state therapy legislation, notes and product prescribing information which can be found at [www.trulance.com/hcp](http://www.trulance.com/hcp)

**State Therapy Law Information (www.steptherapy.com)**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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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 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 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 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 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). |

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