**Date:** <Insert Date>

**Attn:** <Department>

<Name of health plan><Case ID Number if available>

**Payer Address**: <Insert plan address(es)> **Payer Fax Number:** <Insert plan fax number(s)>

To Whom It May Concern:

I understand that the <Insert plan name>has decided not to provide coverage for Trulance® (plecanatide). However, I believe that <Insert patient name>requires Trulance® (plecanatide) without restriction due to clinical and medical circumstances. Please see below for details about the medical history and treatment rationale that supports the claim for this medical exception request.

**Patient Information:**

|  |  |  |
| --- | --- | --- |
| Patient’s Name | | Date of Birth |
| Patient’s Address | | |
| City | State | Zip Code |
| Member ID # | Policy or Group # | |

☐ I need approval for a drug that is not on the plan’s list of covered drugs

☐ I have been using a drug that was previously included on the plan’s list of covered drugs, but is being removed or was removed from this list during the plan year

☐ I request an exception to the requirement that my patient try another drug before I can prescribe this drug

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Medication:**  ☐ **Trulance**: 3 mg plecanatide (1 x 3 mg tablet) daily. | | | | | |
| Date Started: | | Expected Length of Therapy: | | | |
| **Diagnosis – Please list all diagnoses being treated with the requested drug and corresponding ICD-10 codes.**  □ K58.1 Irritable Bowel Syndrome  □ K59.04 Chronic Idiopathic Constipation | | | | | |
| **Drug History: (**for treatment of the condition(s) requiring the requested drug) | | | |
| **Drug Tried** | **Dates of Drug Trials** | | **Results of previous drug trials** |
| **JUSTIFICATION FOR REQUEST FOR MEDICAL EXCEPTION** | | | | |
| ☐ **Alternate drug(s) contraindicated or previously tried, but with adverse outcome, e.g. toxicity, allergy, or therapeutic failure.**  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Based on the above, I hope that you agree Trulance® (plecanatide) is an appropriate choice for my patient. A timely approval would be greatly appreciated by myself and my patient.  Please contact me at <Insert phone number>if you need more information to approve this medical exception.  Sincerely  <Insert Healthcare Provider Name>  <Insert Signature>  **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)**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | | |
| **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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