**Date:** <Insert Date>

**Payer Name:** <Insert Payer Name>

**Payer Address**: <Insert Plan Address> **Payer Fax Number:** <Insert Plan Fax Number>

**Attn:** <Appeals Department>

To Whom It May Concern:

I am writing on behalf of my patient <Insert Patient Name>to provide additional information supporting medical necessity for the treatment with TRULANCE® (plecanatide). Within this letter, I am providing my patient’s medical history, diagnosis, a description of their previous drug treatment, and a summary of their proposed treatment plan. I have also provided my clinically based rationale supporting the medical necessity of TRULANCE® (plecanatide) for my patient.

**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 requires a prior authorization prior to treatment

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Medication:**  ☐ **Trulance Tablets**: 3mg taken orally once 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) | | | |
| **Previous Drug Tried** | **Dates of Drug Trials** | | **Results of previous drug trials** |

|  |
| --- |
| **CLINICAL RATIONALE FOR MEDICAL NECESSITY** |
| ☐ **Alternate drug(s) contraindicated or previously tried, but with adverse reaction, e.g. tolerability, allergy, or therapeutic failure.**  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Based on the information provided, I believe that TRULANCE® (plecanatide) is medically necessary for my patient. Please find attached the additional documents that support my clinical decision. If you need additional information for a timely approval, please contact me at <Insert Phone Number>  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 [http://www.trulance.com](http://www.trulance.com/)  **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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