# PATIENT ASSISTANCE PROGRAM (PAP) APPLICATION FOR Trulance® (plecanatide)

**Fax:** 1-844-627-3827 **Phone:** 1-844-796-3757

## PROGRAM OVERVIEW

**The Trulance® Patient Assistance Program (PAP)** is designed to provide **Trulance®** at no cost to patients who are uninsured or functionally uninsured and are financially distressed. Patients are required to complete the PAP Application and provide such to Trulance Access Services, along with the necessary proof of income documentation. This program can be modified or terminated at anytime without notice by Synergy.

### Program Eligibility

**Patients are eligible if they:**

- **Are a U.S. citizen or legal resident**
- **Have no insurance or are functionally uninsured**
- **Are willing to work with Trulance Access Services to identify and apply for additional insurance coverage or assistance that may be available to them**
- **Meet the income requirements based on the then-current Federal Poverty Level guidelines**

**Any changes in insurance coverage and/or financial circumstances while enrolled in the program may affect the patient's ability to continue to receive free product via the patient assistance program. Patients must re-apply for program eligibility at the end of each calendar year.**

### Program Enrollment Process

**To initiate the enrollment process, the office simply needs to:**

- **Visit the Savings and Support Page at www.trulancehcp.com**
- **Download and complete the Trulance® Service Request Form (SRF)**
  - o If a completed SRF has already been submitted for Benefits Investigation Support, a new form will not be required; the patient will automatically be assessed for eligibility when appropriate
- **Fax the completed form to Trulance Access Services at 1-844-265-0265**

**What to expect next:**

- **Upon receipt of the SRF, a Trulance Access Services Support Specialist will contact the patient to introduce them to the program and walk them through the enrollment process**
  - o The patient will be asked to complete the Patient PAP application, which can be mailed to them or obtained online, and to submit this to Trulance Access Services along with the required financial income documentation
- **Once an eligibility determination has been made, both the patient and the health care provider's office will be informed of the patient's ability to participate in the program**

CALL
**1-844-796-3757**
to speak with a Trulance Access Services Support Specialist
**Monday through Friday from 8am-8pm ET**

FAX
**1-844-627-3827**

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# PATIENT ASSISTANCE PROGRAM (PAP) APPLICATION FOR Trulance® (plecanatide)

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## PART 1: Application

**Please complete all fields and send completed form along with necessary income documentation in order to prevent any delays.**

### 1. Patient Information

First Name | Last Name

Sex | Date of Birth (MM/DD/YYYY)

Address

City | State | ZIP

Cell Phone | Home Phone | Email Address

Preferred Method of Contact: ☐ **Cell Phone** ☐ **Home Phone** ☐ **Email**

Preferred Time of Contact: ☐ **Morning** ☐ **Afternoon** ☐ **Evening**

OK to leave a message: ☐ **Yes** ☐ **No**

Primary Language: ☐ **English** ☐ **Spanish** ☐ **Other:** ________________

The undersigned patient hereby represents and warrants that:

(i) I hereby authorize Trulance Access Services, contractors, and subcontractors to communicate with me via the email address provided for the purpose of providing me with information pertaining to my coverage for Trulance®, my eligibility status for the support programs offered by Synergy, and/or to communicate the need for additional information needed to accurately assess any coverage or assistance available to me for Trulance® through my insurance coverage or Synergy.

**Handwritten signature of patient** ________________________

**Date** ____________________

### 2. Insurance Information

**Primary Insurance** | Phone #

Policy Holder Name | Relationship to Patient

Insurance ID # | Group #

**Secondary Insurance** | Phone #

Policy Holder Name | Relationship to Patient

Insurance ID # | Group #

**Pharmacy Benefit Carrier** | Phone #

ID # | Group #

Bin # | PCN #

### 3. Additional Insurance Information

Are you a veteran?
☐ **Yes** ☐ **No**
If so, have you applied for VA benefits?
☐ **Yes** ☐ **No**

Are you eligible for Medicare?
☐ **Yes** ☐ **No**
Have you ever been denied Medicaid?
☐ **Yes** ☐ **No**

Have you ever been denied extra help (financial assistance from Social Security) through the Low Income Subsidy (LIS) Program?
☐ **Yes** ☐ **No**

### 4. Treating Physician Information

First Name | Last Name

Practice Name

Address

City | State | ZIP

Phone | Fax

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## PART 1: Application (continued)

### 5. Financial Information

# of people in your household Adults _______ Children (under 18) _______

Total combined adjusted net income for all people in your household, including all household dependents $ ___________________

Proof of income that you are providing

- ☐ **Federal Tax Return**
- ☐ **Social Security Awards Letter**
- ☐ **Pay Stubs (full months' worth within the past three months)**
- ☐ **Proof of job termination/ unemployment**



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## PART 2: Release

**Please complete all fields and send completed form along with necessary income documentation in order to prevent any delays.**

(i) I understand and agree that in order to participate in this program, Trulance Access Services, contractors and subcontractors must obtain private personal information from me and my health care provider, including protected health information as defined in the Health Insurance Portability and Accountability Act of 1996 (HIPAA). This information may include name, date of birth, social security number, diagnosis, insurance information, information about my financial condition or other relevant information which Synergy deems necessary to assess my eligibility to participate in this program. Accordingly, I hereby authorize Trulance Access Services, contractors and sub-contractors to collect and maintain such information, to contact me if additional information should be required and to conduct benefit verifications and insurance research on my behalf, to contact my physician and insurer(s), including Medicare, and to exchange information with them in connection with my participation in this program.

(ii) All information provided by me in connection with my application or participation in this program is and will always be complete and accurate and I agree that Trulance Access Services, contractors and subcontractors may verify it at any time.

(iii) I agree to inform Trulance Access Services, contractors, and subcontractors immediately of any financial or insurance changes while enrolled in this program.

(iv) I understand that any assistance provided under this program is contingent upon my ability to meet the eligibility criteria for the program as determined by Synergy. I acknowledge that this assistance is temporary and that I will be required to re-apply at the end of each calendar year to become eligible.

(v) I also authorize Trulance Access Services to contact me directly in the future about available assistance programs.

(vi) I understand that Synergy reserves the right to modify or terminate this program at any time as it deems fit, that Synergy is under no obligation to continue the program and that any decision by Synergy to modify or terminate this program will not give rise to any liability or obligation for Synergy.

(vii) I understand that any medicines I may receive from this program are only for me and I agree that I will not give them to anyone else.

(viii) I understand that I am receiving Trulance™ Product for free under this program, and if I am a Medicare Prescription Drug Plan or Medicare Advantage Prescription Drug Plan beneficiary, that I may not submit a claim for payment to Medicare or any third party payer, and no part of the payment for the product provided hereunder will be claimed as part of my true out-of-pocket expense (TrOOP).

(ix) I understand that my application and enrollment in this program are not conditioned in any way on my purchase of any goods or services and that I may unsubscribe from this program at any time by contacting Trulance Access Services at 1-844-796-3757.

(x) I understand and agree that this authorization will last for up to one (1) year from the date I sign this authorization, or until December 31st of the current year.

**Patient Signature** ______________________ **Date** ______________________



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# PATIENT ASSISTANCE PROGRAM (PAP)
## APPLICATION FOR Trulance® (plecanatide)

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### 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.**

### 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 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, 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 ≥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 ≥2% and greater than in the placebo group) was diarrhea (4.3% vs 1% placebo).

**Please also see the full Prescribing Information, including Box Warning, for additional risk information at www.Trulance.com.**

**References: 1.** Trulance [package insert]. New York, NY: Synergy Pharmaceuticals Inc.

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