

PATIENT ASSISTANCE PROGRAM MEDICARE PART-D (MED-D PAP) APPLICATION FOR Trulance® (plecanatide)

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



PROGRAM OVERVIEW

The Trulance® Medicare Part-D Patient Assistance Program (MED-D PAP) is designed to provide Trulance® at no cost to patients who have been denied coverage. This program can be modified or terminated at anytime without notice by Synergy. Patients are required to complete the PAP application and provide such to Trulance Access Services, along with the necessary proof of income documentation **and denial letters from insurance.**

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
- Have been denied coverage through Medicare Part D



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)
 - 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
 - The patient will be asked to complete the 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

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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: _____

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 # _____

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 _____

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 _____ Phone _____ Fax _____

Practice Name _____

Address _____

City _____ State _____ ZIP _____

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Trulance Access Services

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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
 - Letter of Coverage Denial (Required)
 - Proof of job termination/unemployment
 - Social Security Awards Letter
 - Pay Stubs (full months' worth within the past three months)
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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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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 $\geq 2\%$ 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 $\geq 2\%$ 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.