



Patient Assistance Program

 **TEV-TROPIN**[®]
[somatropin (rDNA origin) for injection]



Patient Assistance

The TEV-TROPIN[®] Patient Assistance Program was created to provide aid to patients who cannot afford the drug TEV-TROPIN[®] [somatropin (rDNA origin) for injection]. The TEV-TROPIN[®] Patient Assistance Program is an avenue for patients whose resources, including federal, state, or private health insurance, do not cover the cost of TEV-TROPIN[®]. The program is fully sponsored by Teva Biologics and Specialty Products.

People who are prescribed TEV-TROPIN[®] by a physician, but who are unable to pay for the therapy, may submit an application to the TEV-TROPIN[®] Patient Assistance Program in order to be considered for program benefits. An application must include financial information, a medical statement from a physician regarding the patient's condition and recommended therapy regimen, signed waivers of release of liability against the program administrator and Teva, and signed verification and consent forms that the program administrator can submit to third parties for verification purposes. All records submitted will be kept confidential and will not be transmitted to any third party not associated with the TEV-TROPIN[®] Patient Assistance Program without the consent or authorization of the patient or parent/legal guardian.

Upon review of an application, the program administrator may consult with individuals and/or organizations deemed appropriate. It is important to note that while the plan makes efforts to meet the needs of qualified applicants within the program's

limited resources, applicants have no legal right to benefits from the TEV-TROPIN[®] Patient Assistance Program.

- ♥ The program will provide TEV-TROPIN[®] assistance to beneficiaries according to financial need and the amount of TEV-TROPIN[®] available through the program.
- ♥ TEV-TROPIN[®] assistance could include cost-free drug or a cost-sharing program to help families partially offset the financial burden of therapy.
- ♥ A qualified applicant who is granted an award is informed of the starting date and duration for which they will be eligible to receive assistance through the program.
- ♥ Teva sets aside predetermined quantities of product and financial support to be supplied to program beneficiaries. While this means that supplies are limited, Teva strives to provide assistance to as many patients as possible.
- ♥ If an application is denied, in whole or in part, or a beneficiary's award is ended, an applicant or beneficiary may request that the administrator of the TEV-TROPIN[®] Patient Assistance Program reconsider its decision. Any such request must be made in writing and received by the program administrator within 30 days of receipt of their notification letter. The program administrator's decision on any request for reconsideration shall be final.

Who is Eligible?

- ♥ All applicants must be citizens or permanent residents of the United States.
- ♥ Eligibility is determined by medical and financial criteria.
- ♥ An applicant (or parent/legal guardian of a minor receiving the therapy) must prove financial need above and beyond the availability of any federal and state funds, private insurance, or family resources.
- ♥ Patients may apply if they have no private health insurance, have insurance with a pre-existing condition clause, or are not covered by Medicaid.
- ♥ Patients may be eligible for consideration based on reported income figures, assets and liabilities, medical costs, and other out-of-pocket expenditures that are reviewed.

How to Begin the Enrollment Process

Prequalification

To apply to the TEV-TROPIN[®] Patient Assistance Program, the parent/legal guardian can enroll the patient through Growth Solutions[®] (866-TEV-TROP), a patient support program established for children who have growth failure due to an inadequate secretion of normal endogenous growth hormone. The Growth Solutions[®] staff will help find sources of financial support for TEV-TROPIN[®] [somatotropin (rDNA origin) for injection] treatment that may be available.

Application

If it is determined that there are no other sources of financial support to pay for TEV-TROPIN[®], the Growth Solutions[®] staff will direct the parent/legal guardian to the Patient Assistance Program administrator to begin the application process. The program administrator will send all the necessary forms directly to the parent/legal guardian.

Submitted applications must include the following:

- ♥ Financial information with supporting documentation (eg, verification of income and bank statements)
- ♥ Medical statement from the treating physician, including diagnosis and recommended treatment regimen
- ♥ Signed waivers releasing the program administrator and Teva from liability
- ♥ Signed verification and consent forms

All applications are reviewed by the program administrator, and benefits for the applicant are awarded based on the family's financial need. It will be necessary to reapply to the TEV-TROPIN[®] Patient Assistance Program each year so that continued medical and financial need can be confirmed. Acceptance into the program in a given year does not guarantee ongoing eligibility. Although the Patient Assistance Program makes every effort to meet the needs of qualified applicants, the program's resources are limited, and it has no legal obligation to award benefits to any given applicant.

TEV-TROPIN® [somatotropin (rDNA origin) for injection] is indicated only for the treatment of children who have growth failure due to inadequate secretion of normal endogenous growth hormone (GH).

Important Safety Information

TEV-TROPIN® stimulates linear growth in children lacking endogenous GH. Treatment of growth hormone-deficient (GHD) children with TEV-TROPIN® produces growth rate and IGF-1 levels similar to those seen after treatment with hGH of pituitary origin.

Unless patients with Prader-Willi Syndrome (PWS) also have a diagnosis of GHD, TEV-TROPIN® is not indicated for treatment of pediatric patients who have growth failure due to genetically confirmed PWS. Because of reported fatalities, patients with PWS who are severely obese, have severe respiratory impairment, respiratory infections, or sleep apnea should interrupt use of GH.

Patients should be observed for evidence of glucose intolerance, hypopituitarism, malignant transformation of skin lesions, hypothyroidism, slipped capital femoral epiphysis, and intracranial hypertension. Funduscopy examination of patients is recommended at the initiation and periodically during the course of GH treatment. TEV-TROPIN® should not be initiated in patients with acute critical illness as a complication of open heart surgery, abdominal surgery, multiple accidental trauma, or those with acute respiratory failure. TEV-TROPIN®

should not be used in patients with evidence of an active malignancy, progressive or recurrent underlying intracranial tumor, active proliferative or severe nonproliferative diabetic retinopathy, or closed epiphysis.

When somatropin is administered subcutaneously at the same site over a long period of time, tissue atrophy may result. This can be avoided by rotating the injection site.

Because somatropin increases growth rate, patients with a history of scoliosis who are treated with somatropin should be monitored for progression of scoliosis.

Somatropin may alter the clearance of drugs metabolized by the CP450 enzyme system and careful monitoring is advisable.

Benzyl alcohol associated with toxicity in newborns is contained in the diluent supplied with TEV-TROPIN®. Treatment of patients with coexisting ACTH deficiency should have glucocorticoid replacement dose adjusted to avoid inhibition of growth.

In studies of growth hormone-deficient children, headaches occurred infrequently. Injection-site reactions (eg, pain, bruise) occurred in 8 of the 164 treated patients.

Denied Applications

If an application to the TEV-TROPIN® Patient Assistance Program is denied, a request for reconsideration may be made in writing within 30 days of receiving the program's notification letter. The program's decision on any request for reconsideration is final. While the program administrator is considering the request, the applicant (parent/legal guardian) is responsible for obtaining TEV-TROPIN® from other sources.

For more information, please contact:



Patient Assistance Program

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Please see accompanying additional important information.

TEV-TROPIN® is a registered trademark of Teva Pharmaceuticals USA.

Growth Solutions® is a registered service mark of Teva Pharmaceuticals USA.

DISCLAIMER

The TEV-TROPIN® Patient Assistance Program may be modified or discontinued at any time without prior notice. Receipt of benefits does not guarantee the awarding of further benefits in the future. The TEV-TROPIN® Patient Assistance Program has no legal obligation to award benefits to any given applicant.