Once-weekly
Skytrofa®
lonapegsomatropin-tcgd

Authorization Requirements: **Growth Hormone Therapy**

This resource provides an overview of common information that a patient's insurance company may request when reviewing a prescription for once-weekly SKYTROFA®. It is important to provide all criteria and appropriate documentation when submitting an authorization for your patient. Use the submission checklists provided for your **treatment-naïve patients** and **patients switching from their current growth hormone therapy.**

Please note that Ascendis Pharma makes no representation, warranty, or guarantee that the information included will satisfy the requirements of the patient's insurance company or payor, or result in payment. All information included in this resource is for educational purposes only. It is the sole responsibility of the healthcare provider to determine if SKYTROFA is an appropriate treatment for a patient and ensure the accuracy of all claims submitted for reimbursement.

INDICATION

SKYTROFA® is a human growth hormone (GH) indicated for the treatment of pediatric patients aged ≥ 1 years weighing ≥ 11.5 kg with growth failure due to inadequate secretion of endogenous GH.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

SKYTROFA is contraindicated in patients with:

- **Acute critical illness** after open heart surgery, abdominal surgery or multiple accidental trauma, or those with acute respiratory failure due to risk of increased mortality with use of pharmacologic doses of somatropin
- **Hypersensitivity** to somatropin or any of the excipients in SKYTROFA. Systemic hypersensitivity reactions have been reported with post-marketing use of somatropin products
- **Closed epiphyses**
- **Active malignancy**
- Active proliferative/severe non-proliferative **diabetic retinopathy**
- **Prader-Willi syndrome** who are severely obese, have a history of upper airway obstruction or sleep apnea or have severe respiratory impairment due to the risk of sudden death

Please see Important Safety Information throughout and click here for full Prescribing Information for SKYTROFA.

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Completed PA request form

You may use an ePA platform, obtain the correct form from the insurance company, or complete a verbal PA request. Include the following in your submission:

- ✓ Patient name, date of birth, body weight, insurance policy number
- ✓ Physician name, practice name, and NPI number
- ✓ Patient diagnosis and corresponding ICD-10 code
- ✓ Product NDC

Most commonly used ICD-10 codes for pediatric GHD:

- E23.0 Isolated GH deficiency
- E23.0 Idiopathic GH deficiency
- E23.0 Hypopituitarism*
- E23.0 Panhypopituitarism*
- E23.1 Drug-induced hypopituitarism*
- E89.3 Postprocedural hypopituitarism*

*Confirmation of clinical diagnosis may require separate documentation beyond evidence of pediatric GHD. Please consult the insurance company or utilization management criteria for the most comprehensive clinical practice guidelines.

Medical history

Submit documentation to support the treatment decision.

- ✓ **Patient-specific clinical assessment** confirming the pediatric GHD diagnosis, such as evidence of slowed growth. Some plans may require documentation that shows at least one of the following for your patient:
  - 2 standard deviations below mid-parental height
  - 2.25 standard deviations below the population mean height
  - 2 standard deviations below mean growth velocity for age and sex
- ✓ **Relevant laboratory results and dates of assessments**, such as:
  - GH stimulation test, agents (eg, insulin-tolerance test, glucagon, clonidine, L-dopa, and arginine), and peak levels
  - MRI of pituitary gland
  - IGF-1 test results and SDS
  - Bone-age X-ray versus chronological age
  - Growth charts

IMPORTANT REMINDERS

PA requirements can vary by plan. It is critical to submit all requested clinical documentation to obtain positive outcomes.

Contact the patient's insurance company for specific requirements to ensure efficient and timely review.

ePA platforms will generally suggest a preferred daily somatropin therapy, even when SKYTROFA® is readily available. Therefore, it is important to provide justification for why you are prescribing SKYTROFA.

ePA = electronic prior authorization; GH = growth hormone; GHD = growth hormone deficiency; IGF-1 = insulin-like growth factor-1; MRI = magnetic resonance imaging; NDC = National Drug Code; PA = prior authorization; SDS = standard deviation score.

IMPORTANT SAFETY INFORMATION (continued)
WARNINGS AND PRECAUTIONS

- Increased mortality in patients with acute critical illness due to complications following open heart surgery, abdominal surgery or multiple accidental trauma, or those with acute respiratory failure has been reported after treatment with pharmacologic doses of somatropin. The safety of continuing SKYTROFA treatment in patients receiving replacement doses for approved indications who concurrently develop these illnesses has not been established
- Serious systemic hypersensitivity reactions including anaphylaxis and angioedema have been reported with post-marketing use of somatropin products. Inform patients and caregivers that such reactions are possible and that prompt medical attention should be sought if an allergic reaction occurs. Do not use SKYTROFA in patients with known hypersensitivity to SKYTROFA or any of its excipients

Patients Switching From Current Treatment

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When submitting an insurance authorization for pediatric patients currently on a different GH therapy, you may need to provide original documentation used to confirm the GHD diagnosis as well as justification for a switch to SKYTROFA.

Completed PA request form

You may use an ePA platform, obtain the correct form from the insurance company, or complete a verbal PA request. Include their pediatric GHD treatment history, including:

- ✓ Current GH treatment
- ✓ List of previous daily or weekly GH treatments
- ✓ Starting date, duration, and outcome

Original and updated diagnostic criteria

Include the following confirming documentation and dates of assessment:

- ✓ GH stimulation test, agents (eg, insulin-tolerance test, glucagon, clonidine, L-dopa, and arginine), and peak levels
- ✓ MRI of pituitary gland
- ✓ Baseline height SDS
- ✓ Current height SDS
- ✓ Bone-age X-ray versus chronological age
- ✓ Growth charts

It is critical to submit the appropriate documentation above to meet the criteria for SKYTROFA coverage.

Considerations for switch

You should also provide clinical rationale for switching your patient to SKYTROFA. Be sure to document if they experience any of the following with their current treatment:

- ✓ Pain or discomfort at the injection site
- ✓ Sensitivities or allergies to preservatives
- ✓ Poor adherence or noncompliance (consistently missing injections)
- ✓ Nonadherence due to active lifestyle
- ✓ Comorbidities that may impact treatment outcomes or adherence
- ✓ Increased dosage due to lack of growth or nonadherence
- ✓ Issues with managing medication supply
- ✓ Anxiety or stress related to frequency of injections
- ✓ Split household impacting daily injection routine

A·S·A·P ASCENDIS SIGNATURE ACCESS PROGRAM®

For assistance with benefits verification or a PA denial, contact the Ascendis Signature Access Program® (A·S·A·P) at 1-844-442-7236 (available from 8 AM to 8 PM ET, Monday through Friday) to see what reimbursement support is available or to submit a SKYTROFA Statement of Medical Necessity form.

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IMPORTANT SAFETY INFORMATION (continued)
WARNINGS AND PRECAUTIONS (continued)

- Patients with active malignancy have an increased risk of progression with somatropin treatment. Any preexisting malignancy should be inactive and treatment complete before instituting therapy with SKYTROFA. In childhood cancer survivors treated with radiation to the brain/head for their first neoplasm who developed subsequent GHD treated with somatropin, an increased risk for a second neoplasm has been reported. Monitor patients with a history of GHD secondary to an intracranial neoplasm routinely for progression/recurrence of the tumor. Monitor patients carefully for development of neoplasms and/or increased growth/potential malignant changes of preexisting nevi
- Treatment with somatropin may decrease insulin sensitivity, and new onset type 2 diabetes mellitus has been reported. Previously undiagnosed impaired glucose tolerance and overt diabetes mellitus may be unmasked. Patients with type 1 and 2 diabetes mellitus or impaired glucose tolerance should be monitored closely, and antihyperglycemic drugs may require adjustment

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IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS (continued)

- Intracranial hypertension (IH) with papilledema, visual changes, headache, nausea, and/or vomiting has been reported in a small number of patients treated with somatropin. Symptoms resolved rapidly after cessation of therapy/reduction of the dose. Perform fundoscopic examination routinely before initiating treatment with SKYTROFA to exclude preexisting papilledema, and periodically thereafter. If papilledema is observed, stop the treatment. If somatropin-induced IH is diagnosed, restart treatment at a lower dose after IH-associated signs and symptoms have resolved
- Fluid retention during somatropin therapy may occur. Clinical manifestations of fluid retention (eg, edema, arthralgia, myalgia, nerve compression syndromes including carpal tunnel syndrome/paresthesia) are usually transient and dose dependent
- Patients receiving somatropin therapy may be at risk for reduced serum cortisol levels and/or unmasking of central hypoadrenalism. Patients treated with glucocorticoid replacement for previously diagnosed hypoadrenalism may require an increase in their maintenance/stress doses following initiation of SKYTROFA therapy. Monitor patients with known hypoadrenalism for reduced serum cortisol levels and/or need for glucocorticoid dose increases
- Undiagnosed or untreated hypothyroidism may prevent response to SKYTROFA. Central hypothyroidism may first become evident or worsen with treatment. Perform periodic thyroid function tests and initiate/properly adjust thyroid hormone replacement therapy when indicated
- Slipped capital femoral epiphysis may occur more frequently in patients undergoing rapid growth. Evaluate pediatric patients with the onset of a limp or complaints of persistent hip or knee pain, as slipped capital femoral epiphysis has been reported during lonapegsomatropin treatment. Patients and caregivers should be made aware that osteonecrosis is considered a potential risk for human growth hormone products
- Monitor patients for progression of preexisting scoliosis
- Cases of pancreatitis have been reported in pediatric patients receiving somatropin. Consider pancreatitis in patients with persistent severe abdominal pain
- Lipoatrophy may result when somatropin is administered at the same site over a long period of time. Rotate injection sites to reduce this risk
- There have been reports of fatalities after initiating therapy with somatropin in pediatric patients with Prader-Willi syndrome who had one or more of the following risk factors: severe obesity, history of upper airway obstruction or sleep apnea, or unidentified respiratory infection. Male patients with one or more of these factors may be at greater risk than females. SKYTROFA is not indicated for the treatment of pediatric patients who have growth failure due to genetically confirmed Prader-Willi syndrome
- Serum levels of inorganic phosphorus, alkaline phosphatase, and parathyroid hormone may increase after somatropin treatment. Monitor abnormal laboratory tests as appropriate

ADVERSE REACTIONS

The most common adverse reactions (≥ 5%) in patients treated with SKYTROFA were: viral infection (15%), pyrexia (15%), cough (11%), nausea and vomiting (11%), hemorrhage (7%), diarrhea (6%), abdominal pain (6%), and arthralgia and arthritis (6%).

DRUG INTERACTIONS

- **Glucocorticoids:** SKYTROFA may reduce serum cortisol concentrations, which may require an increase in the dose of glucocorticoids
- **Cytochrome P450-metabolized drugs:** Somatropin may increase cytochrome P450 (CYP450)-mediated antipyrine clearance. Carefully monitor patients using drugs metabolized by CYP450 liver enzymes in combination with SKYTROFA
- **Oral estrogen:** May reduce the response to SKYTROFA. Higher doses of SKYTROFA may be required
- **Insulin and/or other hypoglycemic agents:** SKYTROFA may decrease insulin sensitivity. Patients with diabetes mellitus may require adjustment of insulin or hypoglycemic agents

You are encouraged to report side effects to FDA at (800) FDA-1088 or www.fda.gov/medwatch.
You may also report side effects to Ascendis Pharma at 1-844-442-7236.

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