BlueCross BlueShield Arizona

An Independent Licensee of the Blue Cross Blue Shield Association

PHARMACY COVERAGE GUIDELINES
SECTION: DRUGS

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SKYTROFA™ (lonapegsomatropin-tcgd) subcutaneous injection

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Pharmacy Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Pharmacy Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Pharmacy Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Pharmacy Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

This Pharmacy Coverage Guideline does not apply to FEP or other states' Blues Plans.

Information about medications that require precertification is available at www.azblue.com/pharmacy.

Some large (100+) benefit plan groups may customize certain benefits, including adding or deleting precertification requirements.

All applicable benefit plan provisions apply, e.g., waiting periods, limitations, exclusions, waivers and benefit maximums.

Precertification for medication(s) or product(s) indicated in this guideline requires completion of the request form in its entirety with the chart notes as documentation. **All requested data must be provided.** Once completed the form must be signed by the prescribing provider and faxed back to BCBSAZ Pharmacy Management at (602) 864-3126 or emailed to Pharmacyprecert@azblue.com. **Incomplete forms or forms without the chart notes will be returned.**

SKYTROFA™ (lonapegsomatropin-tcgd) subcutaneous injection

Criteria:

- **Criteria for initial therapy:** Skytrofa (lonapegsomatropin) is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

1. Prescriber is a physician specializing in the patient's diagnosis or is in consultation with an Endocrinologist or Pediatric Endocrinologist
2. Individual is 1 to 13 year of age and weighs at least 11.5 kg
3. A confirmed diagnosis of growth failure due to inadequate secretion of endogenous growth hormone (GH)
4. **ALL** of the following **baseline tests** have been completed before initiation of treatment with continued monitoring as clinically appropriate:
    a. GH deficiency is confirmed by 2 different GH stimulation tests with the result showing peak GH level is less than or equal to 10 ng/mL
    b. Height is at least 2 standard deviations (SD) below the mean height for gender and chronological age
    c. Bone age is at least 6 months less than chronological age
    d. Baseline Insulin-like growth factor 1 (IGF-1) is at least 1 SD below the mean peak IGF-1 level standardized for age and gender
    e. Fundoscopic examination for papilledema
5. Documented failure, contraindication per FDA label, intolerance, or not a candidate for Nutropin AQ
6. There are **NO** FDA-label contraindications, such as:
    a. Acute critical illness such as after open heart surgery, abdominal surgery or multiple accidental trauma, or those with acute respiratory failure
    b. Individual with closed epiphyses
    c. Active malignancy
    d. Active proliferative or severe non-proliferative diabetic nephropathy
    e. Individual with Prader-Willi syndrome who are severely obese, have a history of upper airway obstruction or sleep apnea or have severe respiratory impairment due to risk of sudden death
7. Skytrofa (lonapegsomatropin) and Increlex (mecasermin) will not be used in combination
8. Individual has recent (within the last 12 months) radiographic evidence of open epiphyses
9. Individual does not have a diagnosis of idiopathic short stature
10. Individual does not have a diagnosis of small for gestational age
11. There are no significant interacting drugs

Initial approval duration: 12 months

SKYTROFA™ (lonapegsomatropin-tcgd) subcutaneous injection

- **Criteria for continuation of coverage (renewal request):** Skytrofa (lonapegsomatropin) is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

  1. Individual continues to be seen by a physician specializing in the patient's diagnosis or is in consultation with an Endocrinologist or Pediatric Endocrinologist

  2. Individual's condition has responded while on therapy
     a. Response is defined as **THREE** of the following:
        i. Height has increased at least 2-5 cm/year over the previous year (previous height and date obtained and current height and date obtained must be sent)
        ii. Height velocity increased
        iii. Growth hormone levels increased
        iv. Bone age to chronological age increased
        v. IGF-1 levels increased

  3. Individual has been adherent with the medication

  4. Individual has not developed any contraindications or other significant adverse drug effects that may exclude continued use
     a. Contraindications as listed in the criteria for initial therapy section
     b. Significant adverse effect such as:
        i. Intracranial hypertension
        ii. Malignancy
        iii. Pancreatitis

  5. Skytrofa (lonapegsomatropin) and Increlex (mecasermin) will not be used in combination

  6. Individual has recent (within the last 12 months) radiographic evidence of open epiphyses

  7. Individual does not have a diagnosis of idiopathic short stature

  8. Individual does not have a diagnosis of small for gestational age

  9. There are no significant interacting drugs

  Renewal duration: 12 months

- Criteria for a request for non-FDA use or indication, treatment with dosing, frequency, or duration outside the FDA-approved dosing, frequency, and duration, refer to one of the following Pharmacy Coverage Guideline:

  1. **Off-Label Use of a Non-Cancer Medications**

  2. **Off-Label Use of a Cancer Medication for the Treatment of Cancer without a Specific Coverage Guideline**

SKYTROFA™ (lonapegsomatropin-tcgd) subcutaneous injection

Description:

Skytrofa (lonapegsomatropin) is a pegylated pro-drug of human growth hormone (somatropin). Somatropin is conjugated to a methoxypolyethylene glycol carrier and a proprietary linker. Following subcutaneous dose administration, Skytrofa (lonapegsomatropin) releases fully active somatropin via autocleavage of the linkers. Somatropin binds to the growth hormone (GH) receptor in the cell membrane of target cells resulting in intracellular signal transduction and a host of pharmacodynamic effects.

Skytrofa (lonapegsomatropin) prefilled cartridge must be used with SKYTROFA Auto-Injector to provide an automatic mixing step for reconstitution prior to subcutaneous use. The auto-Injector provides a fully automated reconstitution of the lyophilized drug product which is followed by a manual mixing step controlled by the device. When the injection needle is inserted into the skin, the device automatically delivers the drug product. The built-in electronics and software assist the user during the entire preparation and injection sequence and provide confirmation that the full dose has been delivered. The entire process from automatic mixing to administration must occur within 4 hours; if not, the cartridge will release from the device and will be unusable.

Resources:

Skytrofa (lonapegsomatropin-tcgd) product information, revised by Ascendis Pharma, Inc. 08-2021, at DailyMed http://dailymed.nlm.nih.gov. Accessed November 02, 2021.

Thronton PS, Maniatis AK, Aghajanova E, et al. Weekly lonapegsomatropin in treatment-naïve children with growth hormone deficiency: The Phase 3 heiGHt Trial. J Clin Endocrinol Metab 2021 Nov; 106 (11): 3184-3195. Accessed November 02, 2021.

ClinicalTrials.gov Identifier NCT02781727, A Phase 3 Trial of the Safety, Tolerability and Efficacy of TransCon hGH weekly versus Daily hGH in Children with Growth Hormone Deficiency (GHD); Last Updated September 09, 2021. Available from: http://clinicaltrials.gov. Accessed November 02, 2021.