Commercial/Healthcare Exchange PA Criteria
Effective: December 9, 2021

Prior Authorization: Skytrofa™

Products Affected: Skytrofa (lonapegsomatropin subcutaneous injection)

Medication Description: Skytrofa, a weekly human growth hormone product, is indicated for the treatment of pediatric patients ≥ 1 year of age who weigh at least 11.5 kg and have growth failure due to an inadequate secretion of endogenous growth hormone.

Covered Uses: For children who have growth failure due to an inadequate secretion of endogenous growth hormone.

Exclusion Criteria:
1. Central Precocious Puberty
2. Congenital Adrenal Hyperplasia (CAH)
3. Constitutional Delay of Growth and Puberty
4. Acute critical illness after open heart surgery, abdominal surgery or multiple accidental trauma, or those with acute respiratory failure due to the risk of increased mortality with use of pharmacologic doses of somatropin
5. Active Malignancy
6. Pediatric patients with closed epiphyses.
7. Growth failure due to Prader-Willi Syndrome (PW)
8. Investigational/Experimental Indications: Growth hormone therapy for all other indications is considered to be experimental and investigational and therefore not covered by the plan.
9. Geriatric patients

Required Medical Information:
1. Diagnosis
2. Documentation of follow up notes including growth charts
3. Growth velocity in the most recent year
4. Growth hormone stimulation test result if appropriate
5. Genetic testing confirm diagnosis if appropriate
6. All other appropriate lab / testing confirming pituitary deficiencies, renal function, open epiphyses, etc.
7. Current height and weight
8. Bone age for initiation if appropriate

Age Restriction: Pediatric patients ≥ 1year of age (and < 18 years of age) who weigh at least 11.5kg

Prescriber Restriction: The medication is prescribed by or in consultation with an endocrinologist

Coverage Duration:
1. If the above criteria below are met initial authorization is limited to 6 months.
2. Subsequent authorization (up to 1 year) will be granted with documented efficacy.
3. The quantity is limited to a maximum of a 30-day supply per fill.

Other Criteria:

I. Initial Criteria

1. Growth Hormone Deficiency in a Pediatric Patient

Initial Therapy with any Growth Hormone Agent. Approve if the patient meets one of the following (A, B, C, D, **OR** E **AND** F):

A. Patient meets both of the following (i **and** ii):
   i. Patient meets one of the following (a **or** b):
      a. Patient has had two growth hormone stimulation tests performed with any of the following agents: levodopa, insulin-induced hypoglycemia, arginine, clonidine, or glucagon **AND** both tests show an inadequate response as defined by a peak growth hormone response which is below the normal reference range as determined by the testing laboratory; **OR**
      b. Patient meets BOTH of the following criteria (1 **and** 2):
         1. Patient has had at least one growth hormone stimulation test performed with any of the following agents: levodopa, insulin-induced hypoglycemia, arginine, clonidine, or glucagon **AND** the test shows an inadequate response as defined by a peak growth hormone response which is below the normal reference range as determined by the testing laboratory; **AND**
         2. Patient has at least one risk factor for growth hormone deficiency (for example, the height for age curve has deviated downward across two major height percentiles [e.g., from above the 25th percentile to below the 10th percentile]; the child's growth rate is less than the expected normal growth rate based on age and gender; low insulin-like growth factor (IGF)-1 and/or IGFBP-3 levels; the child has a very low peak growth hormone level on provocative testing as defined by the prescribing physician; the child's growth velocity is less than the 10th percentile for age and gender [height velocity percentile is NOT the same as height-for-age percentile]; the patient is status post craniopharyngioma resection; the patient has optic nerve hypoplasia; the patient has a growth hormone gene deletion); **AND**
   ii. Patient has been evaluated by an endocrinologist.

B. Patient has undergone brain radiation or tumor resection **AND** meets both of the following (i **and** ii):
   i. Patient meets at least one of the following (a **or** b):
      a. Patient has had one growth hormone stimulation test with any of the following agents: levodopa, insulin-induced hypoglycemia, arginine, clonidine, or glucagon AND the test shows an inadequate response as defined by a peak growth hormone response which is below the normal reference range as determined by the testing laboratory; **OR**
      b. Patient has a deficiency in at least one other pituitary hormone (i.e., adrenocorticotropic hormone, thyroid-stimulating hormone, gonadotropin [luteinizing hormone and/or follicle stimulating hormone deficiency are counted as one deficiency], or prolactin); **AND**
   ii. Patient has been evaluated by an endocrinologist.

C. Patient has congenital hypopituitarism **AND** meets both of the following (i **and** ii):
   i. Patient meets at least one of the following (a **or** b):
      a. Patient has had one growth hormone stimulation test with any of the following agents: levodopa, insulin-induced hypoglycemia, arginine, clonidine, or glucagon AND the test shows an inadequate response as defined by a peak growth hormone response which is below the normal reference range as determined by the testing laboratory; **OR**
      b. Patient has a deficiency in at least one other pituitary hormone (i.e., adrenocorticotropic hormone, thyroid-stimulating hormone, gonadotropin [luteinizing hormone and/or follicle stimulating hormone

deficiency are counted as one deficiency], or prolactin) and/or the patient has the imaging triad of ectopic posterior pituitary and pituitary hypoplasia with abnormal pituitary stalk; **AND**

ii. Patient has been evaluated by an endocrinologist.

D. Patient has panhypopituitarism and meets both of the following (i **and** ii):

i. Patient meets at least one of the following (a, b, **or** c):

a. Patient has pituitary stalk agenesis, empty sella, sellar or supra-sellar mass lesion, or ectopic posterior pituitary "bright spot" on magnetic resonance imaging or computed tomography; **OR**

b. Patient has three or more of the following pituitary hormone deficiencies: somatropin (growth hormone), adrenocorticotropic hormone, thyroid-stimulating hormone, gonadotropin (luteinizing hormone and/or follicle stimulating hormone deficiency are counted as one deficiency), and prolactin; **OR**

c. Patient has had one growth hormone stimulation test with any of the following agents: levodopa, insulin-induced hypoglycemia, arginine, clonidine, or glucagon AND the test shows an inadequate response as defined by a peak growth hormone response which is below the normal reference range as determined by the testing laboratory; **AND**

ii. Patient has been evaluated by an endocrinologist.

E. Patient has had a hypophysectomy (surgical removal of pituitary gland) **AND**

F. In addition to the above criteria, Skytrofa will be approved if the patient has had an intolerance to, or treatment failure of, Norditropin.

II. Continuation Criteria

Patient is Currently Receiving Skytrofa or is switching to Skytrofa from another Growth Hormone Agent (Patient has been established on either therapy for ≥ 10 months)

Approve if the patient meets one of the following (1 **or** 2 **AND** 3):

1. Patient is < 12 years of age: Height has increased by ≥ 2 cm/year in the most recent year; **OR**
2. Patient is ≥ 12 years of age and < 18 years of age: Patient meets both of the following (i **and** ii):
   i. Height has increased by ≥ 2 cm/year in the most recent year; **AND**
   ii. Patient's epiphyses are open; **AND**
3. In addition to the above criteria, Skytrofa will be approved if the patient has had an intolerance to, or treatment failure of, Norditropin

References:

1. Skytrofa™ subcutaneous injection [prescribing information]. Palo Alto, CA: Ascendis Pharma, Inc.; August 2021.

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	12/9/2021