blue of california

NUTROPIN AQ (somatropin)

Diagnoses Considered for Coverage:
In Adults:

- Growth Hormone Deficiency (GHD)

In Pediatrics:

- Growth Hormone Deficiency (GHD)
- Child with growth failure associated with chronic renal insufficiency up until renal transplant
- Prader-Willi Syndrome and Noonan Syndrome
- Small for Gestational Age (SGA)
- Turner Syndrome
- SHOX gene deficiency

Coverage Criteria:

ADULTS: Growth Hormone Deficiency (GHD):

Initial Authorization

- Being prescribed by an Endocrinologist, **and**
- Patient has low IGF-1 (<0 SDS), **and**
- Dose does not exceed FDA label maximum, **and**
- Patient has had any of the following indications:
  - history of brain cancer (e.g. hypothalamic-pituitary tumors, pituitary adenoma, chordoma, hamartoma, lymphoma, metastases, amyloidosis, craniopharyngioma, meningioma, glioma/astrocytoma, neoplastic sellar and parasellar lesions)
  - history of head trauma (e.g. traumatic brain injury, sports-related head trauma, skull base lesions, blast injury)
  - history of pituitary surgery or cranial radiation
  - Sheehan's syndrome,
  - empty sella,
  - pituitary apoplexy,
  - hydrocephalus
  - ischemic stroke,
  - subarachnoid hemorrhage,
  - autoimmune hypophysitis,
  - Rathke's cleft cyst,
  - infiltrative/granulomatous disease,
  - Langerhans cell histiocytosis,
  - Known hypothalamic pituitary congenital or genetic defect,
  - Defects affecting the hypothalamic-pituitary axes or structure,

- ectopic posterior pituitary,
- Transcription factor defects [PIT-1, PROP-1, LHX3/4, HESX-1, PITX-2],
- GHRH receptor gene defects,
- GH-gene defects,
- GH-receptor/post-receptor defects,
- Brain structural defects such as single central incisor, cleft lip/palate, perinatal insults
- autoimmune hypophysitis (primary, secondary),
- sarcoidosis,
- tuberculosis,
- snake bite

AND

- One of the following (**a** or **b**):

  a. For patients with pituitary gland only: Patient has failed growth hormone stimulation test (e.g. ITT Peak GH ≤ 5.0 ug/L, Macimorelin (AEZS-130) Peak GH ≤ 2.8 ug/L, or Glucagon Stimulation Test (GST) level indication treatment is needed)
  OR
  b. Patient has 3 or more documented pituitary hormone deficiencies (ACTH, prolactin, LH, FSH, or TSH).

Coverage duration: 1 year

Reauthorization

- Patient is responding to HGH therapy, **and**
- Dose does not exceed FDA label maximum

Coverage duration: 1 year

ADULTS: Growth hormone deficiency (GHD), continuing from childhood with known prior growth hormone therapy:

Initial Authorization

- Being prescribed by an Endocrinologist, **and**
- Documented diagnosis of childhood GHD continuing into adulthood, **and**
- Dose does not exceed FDA label maximum, **and**
- Patient has been previously treated with growth hormone during childhood, **and**
- Either of the following:
  - Physician attestation that the patient still has potential for growth (e.g. growth not complete) beyond childhood GHD

  OR

- Physician attestation that growth is complete, **and**
- Patient has low IGF-1 (<0 SDS), **and**
- ***For patients with pituitary gland only:*** Patient has failed growth hormone stimulation test (e.g. ITT Peak GH ≤ 5.0 ug/L, Macimorelin Peak GH ≤ 2.8 ug/L, or Glucagon Stimulation Test (GST) level indicating treatment is needed) after the age of 18.

Coverage duration: 1 year

Reauthorization

- Patient is responding to HGH therapy, **and**
- Dose does not exceed FDA label maximum
-

Coverage duration: 1 year

ADULTS: Growth hormone deficiency (GHD), continuing from childhood, no prior growth hormone therapy:

Initial Authorization

- Being prescribed by an Endocrinologist, **and**
- Documented diagnosis of childhood GHD continuing into adulthood, **and**
- Patient has not been previously treated with growth hormone during childhood, **and**
- Patient has low IGF-1 (<0 SDS), **and**
- Dose does not exceed FDA label maximum, **and**
- Patient has any of the following indications:
    - history of brain cancer (e.g. hypothalamic-pituitary tumors, pituitary adenoma, chordoma, hamartoma, lymphoma, metastases, amyloidosis, craniopharyngioma, meningioma, glioma/astrocytoma, neoplastic sellar and parasellar lesions)
    - history of head trauma (e.g. traumatic brain injury, sports-related head trauma, skull base lesions, blast injury)
    - history of pituitary surgery or cranial radiation
    - Sheehan's syndrome,
    - empty sella,
    - pituitary apoplexy,
    - hydrocephalus
    - ischemic stroke,
    - subarachnoid hemorrhage,
    - autoimmune hypophysitis,
    - Rathke's cleft cyst,
    - infiltrative/granulomatous disease,

- Langerhans cell histiocytosis,
- Known hypothalamic pituitary congenital or genetic defect,
- Defects affecting the hypothalamic-pituitary axes or structure,
- ectopic posterior pituitary,
- Transcription factor defects [PIT-1, PROP-1, LHX3/4, HESX-1, PITX-2],
- GHRH receptor gene defects,
- GH-gene defects,
- GH-receptor/post-receptor defects,
- Brain structural defects such as single central incisor, cleft lip/palate, perinatal insults
- autoimmune hypophysitis (primary, secondary),
- sarcoidosis,
- tuberculosis,

snake bite

AND

- One of the following (**a** or **b**):

  a. For patients with pituitary gland only: Patient has failed growth hormone stimulation test (e.g. ITT Peak GH ≤ 5.0 ug/L, Macimorelin (AEZS-130) Peak GH ≤ 2.8 ug/L, or Glucagon Stimulation Test (GST) level indication treatment is needed)
  OR
  b. Patient has 3 or more documented pituitary hormone deficiencies (ACTH, prolactin, LH, FSH, or TSH).

Coverage duration: 1 year

Reauthorization

- Patient is responding to HGH therapy, **and**
- Dose does not exceed FDA label maximum

Coverage duration: 1 year

PEDIATRICS: For diagnosis of growth hormone deficiency (GHD) with known pituitary disease:

Initial Authorization

- Being prescribed by a Pediatric Endocrinologist, **and**
- Dose does not exceed FDA label maximum, **and**
- One of the following (**1, 2, 3, or 4**) must be met:
  1. Provider attestation of slowing in growth velocity,
     AND
     Child has pituitary abnormality (e.g., CNS lesion, absence or damage to pituitary stalk, genetic defect affecting the GH axis, history of

irradiation, tumor),
AND
One of the following:
a. Patient has at least one other pituitary hormonal deficiency (ACTH, prolactin, LH, FSH, or TSH), or
b. ***For patients with pituitary gland only:*** Failure of one standard growth hormone provocative test (e.g., clonidine, arginine, glucagon) done within 1 year prior to starting growth hormone therapy.

2. Patient is a newborn, **and**
AND
One of the following:
a. Patient has congenital pituitary abnormality (ectopic posterior pituitary and pituitary hypoplasia with abnormal stalk), or
b. Patient has at least 1 pituitary hormone deficiency and hypoglycemia with a serum GH concentration <5 ug/L

3. Patient has a document causal genetic mutation or specific or specific pituitary/hypothalamic structural defect (not ectopic posterior pituitary)

4. Patient has more than 3 pituitary hormone deficiencies (ACTH, prolactin, LH, FSH, or TSH).

Coverage duration: 1 year

Reauthorization

- Patient is responding to HGH therapy, **and**
- Dose does not exceed FDA label maximum
-

Coverage duration: 1 year

PEDIATRICS: For diagnosis of growth hormone deficiency (GHD) WITHOUT known pituitary disease:

Initial Authorization

- Being prescribed by a Pediatric Endocrinologist, **and**
- Patient's height must be 2 or more standard deviations below the mean (less than the 3rd percentile) for age and sex prior to growth hormone therapy, **and**
- Height Velocity is less than 10th percentile of normal for age and sex, tracked over at least one year prior to growth hormone therapy (see chart below), **and**
- Dose does not exceed FDA label maximum, **and**

- Failure of at least 2 standard growth hormone provocative tests (e.g., clonidine, arginine, glucagon) (defined as a peak growth hormone level < 10 ng/ml) done within 1 year prior to initiating GH therapy, with peak value assessed using more than one point in time (e.g. 0, 30, 60, 90, 120 minutes)[1]

Coverage duration: 1 year

Reauthorization

- Patient has a growth velocity of at least 3 cm/year while on growth hormone, **and**
- Dose does not exceed FDA label maximum
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Coverage duration: 1 year

PEDIATRICS: For diagnosis of Turner's, CRF, Prader-Willi/Noonan's Syndrome, SHOX gene abnormality:

Initial Authorization

- *For chronic renal insufficiency only*. Renal GFR is less than 50 ml/min, **and**
- Prescribed by a Pediatric Endocrinologist (except if diagnosis is CRF), **and**
- Dose does not exceed FDA label maximum

Coverage duration: 1 year

Reauthorization

- Dose does not exceed FDA label maximum, **and**
- One of the following:
  - Patient has Turner's or Prader-Willi Syndrome, has no side effects to HGH and is compliant with the HGH, **OR**
  - Patient has CRF and did not receive a kidney transplant within the past year.

Coverage duration: 1 year

PEDIATRICS: For a diagnosis of Small for Gestational Age (SGA):

Initial Authorization

- Being prescribed by a Pediatric Endocrinologist, **and**
- Patient's length at birth or birth weight must be 2 or more standard deviations below the mean (less than the 3rd percentile) for gestational age (adjusted for prematurity), **and**
- Patient's height is 2 or more standard deviations below the mean (less

than the 3rd percentile) at 2 years of age (boys 80-81cm; girls 79-80 cm), **and**

- Dose does not exceed FDA label maximum

Coverage duration: 1 year

Reauthorization

- Patient has a growth velocity of at least 3 cm/year while on growth hormone, **and**
- Dose does not exceed FDA label maximum

Coverage duration: 1 year

Coverage Duration: see above

References:

1. Yuen, K. C., Biller, B. M., Radovick, S., Carmichael, J. D., Jasim, S., Pantalone, K. M., & Hoffman, A. R. (2019). American Association of Clinical Endocrinologists and American College of Endocrinology guidelines for management of growth hormone deficiency in adults and patients transitioning from pediatric to adult care. Endocrine Practice, 25(11), 1191-1232.

Effective Date: 11/02/2023