Medical Drug Clinical Criteria

Subject:	Growth Hormones		
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Overview

This document addresses the use of growth hormone (GH, somatropin). Somatropin is FDA approved in children to treat growth failure due to hormone deficiency (GHD), small for gestational age, idiopathic short stature, Prader-Willi Syndrome, Turner Syndrome, SHOX (Short stature homeobox) gene deficiency, Noonan Syndrome, chronic renal insufficiency, and severe primary insulin-like growth factor-1 (IGFD) deficiency. Somatropin is approved in adults to treat GHD (childhood or adult onset), HIV-associated wasting or cachexia, and short bowel syndrome.

In the absence of known pituitary or hypothalamic pathology, GHD in children is usually first suspected on the basis of height and growth velocity. A period of at least 1 year of data is necessary for reliable calculation of growth velocity of children above the age of 2 years. GHD in children is suggested when there is an abnormal growth velocity in conjunction with a height and bone age that is less than chronological age for gender.

Provocative testing remains a standard in confirmation of a diagnosis of GHD and requires a subnormal response. Since not one GH stimulation test has 100% sensitivity and 100% specificity, most countries have established an arbitrary cut-off for a normal peak serum GH response (usually > 8 to 10 ng/L) to at least two provocative GH stimulation tests. There is growing consensus amongst endocrinologists that a diagnosis of impaired GH secretion can be confirmed if subnormal GH secretion is observed during one test in addition to clinical and auxologic (growth data for height and weight plotted on a growth chart) criteria. The stimulation test parameters used to determine GHD are higher in the pediatric population than the adult population as pediatric individuals show a more robust response to stimulation.

Studies suggest that discontinuation of GH therapy upon reaching final adult height in individuals with severe GHD may contribute to an accelerated accumulation of cardiovascular risk factors. While certain types of pediatric individuals with GHD (organic hypothalamic-pituitary disease, additional pituitary deficiency, or post-irradiation GHD) are more likely than others to have continued GHD into adulthood, retesting a minimum of 3 months after discontinuing previous GH therapy is required to confirm persistent GHD.

Other conditions for which GH therapy is indicated result in lower than average height. These include Turner syndrome, Noonan's syndrome, and small gestational age (SGA).

Growth hormone therapy for certain conditions, including growth hormone deficiency (GHD), multiple pituitary hormone deficiency (MPHD), HIV-related wasting, and short bowel syndrome, may be approved for the treatment of a condition that is expected to result in a significant physical functional impairment AND the treatment can be reasonably expected to improve the physical functional impairment. GHD is associated with a variety of metabolic abnormalities, for example, hypoglycemia, frequently severe, may be seen in neonates with growth hormone deficiency. GHD is also associated with a decrease in bone mass, abnormalities in lipid profiles and increases in other cardiac risk factors. Because these abnormalities are thought to result in an increase in adult morbidity and mortality, based either on an increased incidence of fragility fractures or cardiovascular sequelae, GH therapy for those with documented GHD may be approved.

Growth hormone therapy for certain conditions is considered **reconstructive.** Reconstructive therapies are intended to address a significant variation from normal **related to accidental injury, disease, trauma, treatment of disease or a congenital defect** but do not result in significant functional impairment to the individual. While the use of GH therapy is associated with an increase in height, the use of growth hormone to enhance height is not considered necessary since there is no functional impairment associated with short stature, and no target height that can differentiate the presence or absence of a functional impairment. However, the use of GH to address anticipated height which represents a significant variation from normal can be reconstructive when the cause of the reduced height is related to accidental injury, disease, trauma, treatment of a disease or congenital defect. Not all benefit contracts include benefits for reconstructive services. Benefit language supersedes this document.

Growth hormone therapy for certain conditions are not considered reconstructive and may not be approved when growth hormone use is not expected to correct a significant functional deficit OR when reduced growth is not due to an underlying medical condition. Idiopathic short stature is not considered reconstructive and may not be approved when idiopathic short stature is not associated with a definable physical functional impairment (e.g., limiting ability to drive), is not due to growth hormone deficiency, and is not the result of accidental injury, disease, trauma, or treatment of a disease and is not a congenital defect.

Deficiency in multiple pituitary hormones – multiple pituitary hormone deficiency (MPHD) which is defined as three or more pituitary hormone deficiencies – should be diagnosed with persistent growth hormone deficiency. Pituitary hormones include the following:

- Thyroid Stimulating Hormone (TSH)
- Follicle-Stimulating Hormone (FSH)
- Luteinizing Hormone (LH)
- Prolactin (PRL)
- Growth Hormone (GH)
- Adrenocorticotropic hormone (ACTH)
- Alpha Melanocyte-Stimulating Hormone (α-MSH)
- Vasopressin
- Oxytocin

Sexual Maturity Rating (SMR, Tanner Stage) is a commonly used measurement of sexual maturity in children, based upon the work of Tanner et al. (1962). SMR is based upon clinical findings from physical examination of the individual, as detailed below:

Classification of Sex Maturity States in Girls (Tanner 1962)

SMR STAGE	PUBIC HAIR	BREASTS
1	Preadolescent	Preadolescent
2	Sparse, lightly pigmented, straight, medial border of labia	Breast and papilla elevated as small mound; diameter of areola increased
3	Darker, beginning to curl, increased amount	Breast and areola enlarged, no contour separation
4	Coarse, curly, abundant, but less than in adult	Areola and papilla form secondary mound
5	Adult feminine triangle, spread to medial surface of thighs	Mature, nipple projects, areola part of general breast contour

Classification of Sex Maturity States in Boys (Tanner 1962)

SMR STAGE	PUBIC HAIR	PENIS	TESTES
1	None	Preadolescent	Preadolescent
2	Scanty, long, slightly pigmented	Minimal change/enlargement	Enlarged scrotum, pink, texture altered
3	Darker, starting to curl, small amount	Lengthens	Larger
4	Resembles adult type, but less quantity; coarse, curly	Larger; glans and breadth increase in size	Larger, scrotum dark
5	Adult distribution, spread to medial surface of thighs	Adult size	Adult size

Clinical Criteria

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

Growth Hormone therapy (somatropin, somapacitan-beco, lonapegsomatropin-tcgd, somatrogon-ghla)

Initial requests for growth hormone (GH) therapy (somatropin [Genotropin, Humatrope, Norditropin, Nutropin AQ, Omnitrope, Saizen, Zomacton], lonapegsomatropin-tcgd [Skytrofa], somapacitan-beco [Sogroya], somatrogon-ghla [Ngenla]) **for growth hormone deficiency in children** may be approved if the following criteria are met (GH Research Society 2000, Grimberg 2016):

I. Individual has a diagnosis of idiopathic growth hormone deficiency (GHD) as indicated by the following:
   A. Documentation is provided that individual has signs or symptoms of growth hormone deficiency such as growth velocity 2 Standard Deviations (SD) below age-appropriate mean or height 2.25 SD below the age-appropriate mean; **AND**
   B. Documentation is provided that individual has a subnormal response (less than 10 ng/ml) to any **TWO** of the following standard growth hormone stimulation tests, and documentation is provided for specific stimulation tests:
      1. Arginine; **OR**
      2. Clonidine; **OR**
      3. Glucagon; **OR**
      4. Insulin induced hypoglycemia; **OR**
      5. L-dopa - Propranolol;

OR

II. Documentation is provided that individual has presence of at least two other pituitary hormone deficiencies, in addition to Insulin-like growth factor 1 (IGF-1) measurement below age-appropriate level; **OR**

III. Individual is a neonate with hypoglycemia and clinical and hormone evidence of hypopituitarism (growth hormone level less than 10 ng/ml); **OR**
IV. Documentation is provided that individual has had cranial irradiation and has evidence of IGF-1 measurement below age-appropriate level with normal thyroid function tests results;

AND
V. If individual is requesting Skytrofa (lonapegsomatropin-tcgd), individual is 1 year of age or older, **and** weighs at least 11.5 kg; **OR**
VI. If individual is requesting Sogroya (somapacitan-beco), individual is 2.5 years of age or older; **OR**
VII. If individual is requesting Ngenla (somatrogon-ghla), individual is 3 years of age or older.

Initial requests for growth hormone (GH) therapy (somatropin [Genotropin, Humatrope, Norditropin, Nutropin AQ, Omnitrope, Saizen, Zomacton]) **for reconstructive therapy in children** may be approved if the following criteria are met:

I. Individual meets either of the following requirements (Grimberg 2016):
   A. Documentation is provided that the child's height is at least 2.25 but less than 2.5 standard deviations below the mean for his or her age and gender, and growth velocity is less than the 10th percentile over 1 year; **OR**
   B. Documentation is provided that the child's height is at least 2.5 standard deviations below the mean for his or her age and gender, regardless of growth velocity;

AND
II. Individual has a condition known to be responsive to growth hormone therapy, including, but not limited to:
   A. Chronic renal insufficiency; **OR**
   B. Children with Prader-Willi syndrome, who are not severely obese (BMI less than 35), do not have history of upper airway obstruction or sleep apnea, and do not have severe respiratory impairment, and who do not meet the criteria described above; **OR**
   C. Noonan syndrome; **OR**
   D. Turner syndrome; **OR**
   E. Children with Short Stature Homeobox (SHOX) gene; **OR**
   F. Children born small for gestational age defined as **all** of the following:
      1. Child was born small for gestational age (SGA), defined as birth weight or length 2 or more standard deviations below the mean for gestational age (infants with intrauterine growth restriction or Russell-Silver Syndrome resulting in SGA are included in this category); **AND**
      2. Child fails to manifest catch up growth before 4 years of age, defined as height 2 or more standard deviations below the mean for age and sex (Clayton, 2007); **AND**
      3. Other causes for short stature such as growth inhibiting medication, chronic disease, endocrine disorders, and emotional deprivation or syndromes (except for Russell-Silver syndrome) have been ruled out.

Continuation of therapy with growth hormone (GH) therapy (somatropin [Genotropin, Humatrope, Norditropin, Nutropin AQ, Omnitrope, Saizen, Zomacton], lonapegsomatropin-tcgd [Skytrofa], somapacitan-beco [Sogroya], somatrogon-ghla [Ngenla]) **in children (including for reconstructive therapy)** may be approved if the following criteria are met:

I. Individual is evaluated on an annual basis for all conditions; **AND**
II. Growth rate remains above 2.5 cm/year (does not apply to children with prior documented hypopituitarism) (Grimberg 2016); **AND**
III. For children over age 12, either of the following:
   A. Documentation is provided that for an X-ray report with evidence that epiphyses have not yet closed (does not apply to children with prior documented hypopituitarism); **OR**
   B. A Sexual Maturity Rating (SMR, Tanner Stage) less than or equal to 3; **OR**
      1. If SMR, Tanner Stage is greater than or equal to 4, and request is for prior documented hypopituitarism, then follow the criteria titled, "Treatment with growth hormone (GH) (somatropin [Genotropin, Humatrope, Norditropin, Nutropin AQ, Omnitrope, Saizen, Zomacton]) **in transitioning adolescents with childhood onset GH deficiency to adulthood**".

Treatment with growth hormone (GH) **for reconstructive therapy in children** should no longer continue if the following criteria are met:

I. Individual has bone age = 16 years in males or = 14 years in females; **OR**
II. Individual has evidence of epiphyseal fusion; **OR**
III. Documentation is provided that "Mid-parental height" is achieved [NOTE: Mid-parental height = (father's height + mother's height) divided by 2 plus 2.5 inches (male) or minus 2.5 inches (female)].

Approval duration for children with reconstructive indications: 1 year for individuals 12 and younger; 6 months for individuals 13 and older

Approval duration for children with idiopathic growth hormone deficiency (GHD): 1 year for all ages

Treatment with growth hormone (GH) (somatropin [Genotropin, Humatrope, Norditropin, Nutropin AQ, Omnitrope, Saizen, Zomacton]) **in transitioning adolescents with childhood onset GH deficiency to adulthood** may be approved if the following criteria are met:

I. SMR, Tanner Stage is greater than or equal to 4; **AND**
II. One of the following:
    A. GH treatment has been stopped for at least 1 month; **and** the diagnosis of GHD is as follows:
        1. For individuals with idiopathic isolated GHD: A subnormal response (subnormal response defined as serum GH concentration of less than 10 ng/mL) to **two** standard growth hormone stimulation tests, **or** subnormal response to **one** provocative test (acceptable stimulation tests include: insulin induced hypoglycemia, arginine, glucagon, clonidine, or L-dopa – propranolol) **and** low IGF-1/IGFBP-3, and documentation is provided; **OR**
        2. For individuals with multiple pituitary hormone deficiencies, a subnormal response to **one** provocative GH test **or** low IGF-1/IGFBP-3, and documentation is provided; **OR**
        3. For individuals who have had cranial irradiation, continued and documentation is provided showing IGF-1 measurement below age-appropriate level with normal thyroid function test results; **OR**
    B. Documentation is provided showing presence of any of the following conditions (growth hormone stimulation tests are not required):
        1. A known genetic mutation associated with deficient growth hormone production or secretion; **OR**
        2. Hypothalamic-pituitary tumor or structural defect; **OR**
        3. At least three other pituitary hormone deficiencies.

Approval duration for GH treatment in transitioning adolescents with childhood onset GH deficiency to adulthood: 1 year

Treatment with growth hormone (GH) (somatropin [Genotropin, Humatrope, Norditropin, Nutropin AQ, Omnitrope, Saizen, Zomacton], somapacitan-beco [Sogroya]) **in adults** may be approved if the following criteria are met:

I. Documentation is provided that individual has growth hormone deficiency (GHD), also known as somatropin deficiency syndrome, in childhood; **OR**
II. Documentation is provided that individual has hypopituitarism as a result of pituitary disease, hypothalamic disease, surgery, radiation therapy, trauma, or aneurysmal subarachnoid hemorrhage (NOTE: Individuals being treated for GHD due to trauma or aneurysmal subarachnoid hemorrhage must have GHD reverified at 12 months after the event);

AND

III. GHD is verified or reverified by any of the following:
    A. Documentation is provided showing a subnormal response in adults to **two** standard growth hormone stimulation tests (Possible stimulation tests include, but are not limited to: insulin-induced hypoglycemia and combined arginine-growth hormone releasing hormone); defined as:
        1. Serum GH concentration of less than or equal to 5 ng/ml when using insulin induced hypoglycemia testing; **OR**
        2. Serum GH concentration of less than or equal to 4.1 ng/ml when using arginine; **OR**
    B. Subnormal response to **one** stimulation test for adults with hypothalamic or pituitary disease *and* one or more additional pituitary hormone deficits, and documentation is provided; **OR**
    C. Documentation is provided showing presence of at least three other pituitary hormone deficiencies (that is, growth hormone stimulation tests are not required in this subgroup of individuals).

Approval duration for GH deficiency in adults: 1 year

Initial requests for **Serostim (somatropin)** may be approved if the following criteria are met:

I. Documentation is provided that individual has HIV-associated wasting syndrome or cachexia, defined as one of following (Schambelan 1996):
    A. Unintentional weight loss that is greater than or equal to 10% of baseline weight; **OR**
    B. Weight that is less than 90% of the lower limit of ideal body weight; **AND**
II. Weight loss cannot be explained by a concurrent illness other than HIV infection; **AND**
III. Individual is simultaneously being treated with antiretroviral therapy.

Continuation of therapy for **Serostim (somatropin)** may be approved if the following criteria are met:

I. Individual is simultaneously being treated with antiretroviral therapy; **AND**
II. Documentation is provided that weight is less than 90% of the lower limit of ideal body weight; **AND**
III. Documentation is provided that continued need is demonstrated by clinical effect (for example, patient has had a clinically significant improvement in body weight, lean body mass, or physical endurance from baseline with treatment).

Initial Approval Duration for Serostim: 3 months
Continuation requests for Serostim: 3 months

Requests for **Zorbtive (somatropin)** may be approved if the following criteria are met:

Individual has been diagnosed with short bowel syndrome; **AND**

I. Individual is receiving specialized nutritional support (may consist of a high-carbohydrate, low-fat diet adjusted for individual requirements) in conjunction with optimal management of short bowel syndrome.

Treatment with growth hormone (GH) may not be approved for the following criteria:

I. Individual has a diagnosis of idiopathic short stature (ISS); **OR**
II. Individual is a child who does not have signs or symptoms of idiopathic GHD (for example, reduced height or growth velocity), unless a) criteria for other pituitary hormone deficiencies are met or b) criteria for neonate with hypoglycemia are met or c) criteria for cranial irradiation are met (Note: an individual who does not meet necessity criteria may meet reconstructive criteria); **OR**
III. Individual is an adult being treated for GHD due to trauma or aneurysmal subarachnoid hemorrhage and does not have re-testing confirmatory for growth hormone deficiency; **OR**
IV. Individual is using to treat conditions where applicable criteria above have not been met, including, but not limited to, the following:
    A. After renal transplant.
    B. Anabolic therapy, except for AIDS, provided to counteract acute or chronic catabolic illness (for example, surgery, trauma, cancer, chronic hemodialysis) producing catabolic (protein wasting) changes in both adults and children.
    C. Anabolic therapy to enhance body mass or strength for professional, recreational or social reasons.
    D. Constitutional delay of growth and development.
    E. Cystic fibrosis.
    F. Growth hormone treatment in combination with GnRH agonist (Lupron) as a treatment of precocious puberty.
    G. Hypophosphatemic rickets.
    H. Osteogenesis imperfecta.
    I. Osteoporosis.
    J. Short stature associated with growth hormone insensitivity (Laron Syndrome).
    K. Therapy in older adults with normally occurring decrease in GH, who are not congenitally GH deficient and who have no evidence of organic pituitary disease (this is referred to as age-related GH deficiency).
    L. Treatment of congestive heart failure (CHF).
    M. Treatment of individuals with burns.
    N. Treatment of fibromyalgia.
    O. Treatment of glucocorticoid-induced growth failure.
    P. Treatment of HIV lipodystrophy (fat redistribution syndrome), also referred to as altered body habitus (for example, buffalo hump), associated with antiviral therapy in individuals with HIV-infection.
    Q. Treatment of intrauterine growth restriction (IUGR) or Russell-Silver Syndrome that does not result in SGA.
    R. Treatment of obesity.
    S. Other etiologies of short stature where GH has not been shown to be associated with an increase in final height, including but not limited to achondroplasia and other skeletal dysplasias; **OR**
V. Individual is undergoing diagnostic testing requiring overnight hospitalization for spontaneous growth hormone secretion; **OR**
VI. When the above criteria are not met and for all other indications.

Quantity Limits

Growth Hormone Agents Quantity Limits

Drug	Limit
Genotropin [somatropin (rDNA origin)] Cartridge 5 mg/mL, 12 mg/mL	1 cartridge per day
Genotropin MiniQuick® delivery device [somatropin (rDNA origin)] 0.2 mg/0.25 mL, 0.4 mg/0.25 mL, 0.6 mg/0.25 mL, 0.8 mg/0.25 mL, 1 mg/0.25 mL, 1.2 mg/0.25 mL, 1.4 mg/0.25 mL, 1.6 mg/0.25 mL, 1.8 mg/0.25 mL, 2 mg/0.25 mL	1 syringe per day
Humatrope [somatropin (rDNA origin)] Cartridge 6 mg, 12 mg, 24 mg	1 cartridge per day
Ngenla (somatrogon-ghla) 24 mg/1.2 mL, 60 mg/1.2 mL prefilled pen	4 pens per 28 days
Norditropin FlexPro® [somatropin (rDNA origin)] Pen 5 mg/1.5 mL, 10 mg/1.5 mL, 15 mg/1.5 mL, 30 mg/3 mL	1 pen per day
Nutropin AQ NuSpin® [somatropin (rDNA origin)] Pen Cartridge 5 mg/2 mL, 10 mg/2 mL, 20 mg/2 mL	1 cartridge per day
Omnitrope [somatropin (rDNA origin)] Vial 5.8 mg	1 vial per day
Omnitrope [somatropin (rDNA origin)] Cartridge 5 mg/1.5 mL, 10 mg/1.5 mL	1 cartridge per day
Saizen [somatropin (rDNA origin)] Vial 5 mg, 8.8 mg	1 vial per day
Saizenprep [somatropin (rDNA origin)] 8.8 mg/1.5 mL	1 cartridge per day
Serostim [somatropin (rDNA origin)] Vial 4 mg, 5 mg, 6 mg	1 vial per day
Skytrofa (lonapegsomatropin-tcgd) cartridge 3 mg, 3.6 mg, 4.3 mg, 5.2 mg, 6.3 mg, 13.3 mg	4 cartridges per 28 days

Skytrofa (lonapegsomatropin-tcgd) cartridge 7.6 mg, 9.1 mg, 11 mg	8 cartridges per 28 days
Sogroya (somapacitan-beco) 5 mg/1.5 mL, 10 mg/1.5 mL, 15 mg/1.5 mL prefilled pen	4 pens per 28 days
Zomacton [somatropin (rDNA origin)] Vial 5 mg, 10 mg	1 vial per day
Zorbtive [somatropin (rDNA origin)] Vial 8.8 mg	1 vial per day

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

HCPCS

J2940	Injection, somatrem, 1 mg
J2941	Injection, somatropin, 1 mg [Genotropin, Humatrope, Norditropin, Nutropin, Omnitrope, Saizen, Serostim, Zomacton, Zorbtive]
J3490	Unlisted Drugs (when specified as [Skytrofa] lonapegsomatropin-tcgd) or [Sogroya] (Somapacitan-beco) [Sogroya] (Somapacitan-beco))
J3590	Unclassified biologics (when specified as [Skytrofa] lonapegsomatropin-tcgd or [Sogroya] (Somapacitan-beco), NGENLA (somatrogon-ghla))
C9399	Unlisted drugs or Biologicals (when specified as [Sogroya] (Somapacitan-beco) [Skytrofa] lonapegsomatropin-tcgd), NGENLA (somatrogon-ghla))
S9558	Home injectable therapy; growth hormone, including administrative services, professional pharmacy services, coordination of care, and all necessary supplies and equipment, per diem

ICD-10 Diagnosis

B20	Human immunodeficiency virus [HIV] disease
C71.0	Malignant neoplasm of cerebrum, except lobes and ventricles [specified as hypothalamus]
C75.1	Malignant neoplasm of pituitary gland
D33.0	Benign neoplasm of brain, supratentorial [specified as hypothalamus]
D35.2	Benign neoplasm of pituitary gland
D43.0	Neoplasm of uncertain behavior of brain, supratentorial [specified as hypothalamus]
D44.3	Neoplasm of uncertain behavior of pituitary gland
E23.0-E23.7	Hypofunction and other disorders of the pituitary gland
E88.89	Other specified metabolic disorders [e.g., when related to hypothalamic dysfunction]
I60.00-I60.9	Nontraumatic subarachnoid hemorrhage
K91.2	Postsurgical malabsorption, not elsewhere classified [short bowel syndrome]
N18.1-N18.9	Chronic kidney disease (CKD)
N25.0	Renal osteodystrophy
P05.00-P05.09	Newborn light for gestational age
P05.10-P05.19	Newborn small for gestational age
P05.9	Newborn affected by slow intrauterine growth, unspecified
Q77.8	Other osteochondrodysplasia with defects of growth of tubular bones and spine [Leri-Weill syndrome, SHOX gene deficiency]
Q87.1	Congenital malformation syndromes predominantly associated with short stature [when specified as Prader-Willi syndrome, Noonan syndrome, Russell-Silver syndrome]
Q96.0-Q96.9	Turner’s syndrome
R62.0	Delayed milestone in childhood
R62.52	Short stature (child) [only when specified as related to SHOX gene deficiency] Note: Considered Note Medically Necessary when specified as idiopathic short stature
R64	Cachexia
S06.6X0S-S06.6X9S	Traumatic subarachnoid hemorrhage, sequela [includes codes S06.6X0S, S06.6X1S, S06.6X2S, S06.6X3S, S06.6X4S, S06.6X5S, S06.6X9S]

S06.890S-S06.899S	Other specified intracranial injury, sequela [includes codes S06.890S, S06.891S, S06.892S, S06.893S, S06.894S, S06.895S, S06.899S]
T66.XXXS	Radiation sickness, unspecified, sequela
Z85.841	Personal history of malignant neoplasm of brain
Z87.441	Personal history of nephrotic syndrome
Z87.448	Personal history of other diseases of urinary system
Z99.2	Dependence on renal dialysis

Document History

Revised: 05/17/2024
Document History:

- 05/17/2024 – Annual Review: Remove obsolete product Humatrope 5mg vial from quantity limits. Coding Reviewed: Removed HCPCS Code Q0515 sermorelin acetate 1 mg (obsolete product).
- 03/15/2024 – Add quantity limits.
- 11/17/2023 – Select Review: Update criteria for pediatric use to add minimum age for Sogroya and Ngenla per label. Wording and formatting updates. Coding Reviewed: Removed NGENLA from J3490. Added NGENLA to J3590, and C9399.
- 09/11/2023 – Select Review: Update document to add new agent Ngenla to clinical criteria. Coding Reviewed: Added NGENLA to HCPCS J3490.
- 05/19/2023 – Annual Review: Add new indication for Sogroya for pediatric population. Add non-approvable statement for all other indications. Wording and formatting updates. Coding Reviewed: Removed Sogroya from HCPCS J2941. Added Sogroya to HCPCS J3490.
- 08/01/2022 – Administrative update to add documentation.
- 05/20/2022 – Annual Review: Updated Serostim criteria to further define HIV-wasting syndrome/cachexia, add continuation criteria, and add approval durations. Wording and formatting updates. Coding Reviewed: No changes. Effective 8/1/2022 Added HCPCS J3590.
- 11/19/2021 – Select Review: Added Skytrofa to clinical criteria for GHD in pediatric patients. Updated criteria to incorporate Sogroya from ING-CC-0183, added Sogroya into clinical criteria for GHD in adults; Coding Reviewed: Added J3490 for Skytrofa. Added HCPCS C9399 for Sogroya.
- 08/01/2021 – Administrative update to add documentation.
- 05/21/2021 – Annual Review: Removed SaizenPrep as no longer available in the drug file. Coding Reviewed: Removed the word Saizen from J2941.
- 5/15/2020 – Annual Review: Updated approval duration for GH use in reconstructive therapy to 1 year for individuals 12 and younger and 6 months for individuals 13 years and older; clarified approval duration for other indications; remove Nutropin AQ Pen Cartridge as it has been removed from the drug file. Coding Review: Removed Nutropin AQ wording from J2941
- 5/17/2019 – Annual Review: No Changes. Coding reviewed: no changes
- 11/16/2018 – Select Review: First review of growth hormone. Updated FDA approval chart with new indications for Zomacton; removed references to Tev-Tropin (no longer in the drug file); updated continuation of therapy criteria for children to remove first year requirement for either doubling of growth rate or 3 cm growth. HCPCS Coding Review: no change. ICD-10 Coding Review: no change.

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Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.