

PRIOR AUTHORIZATION POLICY

POLICY: Growth Disorders – Sogroya Prior Authorization Policy

- Sogroya® (somapacitan-beco subcutaneous injection – Novo Nordisk)

REVIEW DATE: 06/12/2024

OVERVIEW

Sogroya, a long-acting human growth hormone (hGH) analog, is indicated for the treatment of pediatric patients ≥ 2.5 years of age who have growth failure due to inadequate secretion of growth hormone (GH).¹ Sogroya is also indicated for the replacement of endogenous GH in adults with GH deficiency (GHD).

Disease Overview

GHD in Children and Adolescents

Sogroya is a hGH analog.¹ In children with GHD, somatropin is effective for increasing final adult height.² Somatropin therapy is recommended to normalize adult height and avoid extreme shortness in children and adolescents with GHD.² In addition to congenital causes, hypopituitarism may also be caused by radiation therapy; somatropin may be used to improve final height of children who have undergone radiation.^{3,4}

GHD in Adults or Transition Adolescents

Somatropin is indicated for the replacement of endogenous GH in adults with GH, which may present in adults or children as GHD.¹¹ Patients with other anterior pituitary hormone deficiencies are likely to have GHD. In adults, the diagnosis of GHD usually is made in patients with signs and symptoms of hypothalamic-pituitary disease (endocrine, structural, and/or genetic causes); those who have received cranial irradiation or tumor treatment; or those with traumatic brain injury or subarachnoid hemorrhage.^{11,12} Onset may be in adulthood or childhood. In childhood, the goal of somatropin therapy is primarily for statural growth. When final adult height is attained, somatropin therapy is no longer required for statural growth. Transition is used to describe the period in adolescence after growth is completed and the need for continued replacement into adulthood is assessed. Confirmatory GH stimulation testing may not be required in patients, such as those with congenital/genetic GHD or multiple pituitary hormone deficiencies. When persistent GHD is documented after completion of adult height, somatropin therapy should be continued to attain full skeletal and muscle maturation during the transition period from childhood to adulthood.¹¹ In adults with GHD, somatropin replacement therapy improves abnormalities in substrate metabolism, body composition, and physical and psychosocial function.^{11,12} GH is not approved by the FDA for the treatment of other conditions in adults who may have a low GH response to GH provocative testing (such as obesity, aging, or depression) or to improve athletic performance.^{3,5}

Guidelines

Current guidelines do not specifically address Sogroya. Neither the Pediatric Endocrine Society guidelines for children and adolescents with GH deficiency² (2016) nor the GH Research Society guidelines on children with short stature¹⁵ (2019) recommend a specific GH product for GHD. Both publications note that newer long-acting GH preparations may reduce the frequency of injections. The American Association of Clinical Endocrinologists and the American College of Endocrinology guidelines for management of GHD in adults and patients transitioning from pediatric to adult care¹⁶ (2019) also do not prefer one GH agent over another. These guidelines state that when the clinician is suspicious of adult GHD, establishing a diagnosis is essential before replacement with GH. Adult GHD is associated with numerous adverse metabolic abnormalities (abdominal obesity, reduced lean body mass, increased peripheral insulin resistance, impaired cardiac performance) which may contribute to increased cardiovascular morbidity and mortality.

06/12/2024

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POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Sogroya. All reviews will be directed to a clinician (i.e., pharmacist) for verification of criteria. All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with Sogroya as well as monitoring required for adverse events and long-term efficacy, initial approval requires the patient to be evaluated by a physician who specializes in the condition being treated. Human growth hormone is FDA-approved for treatment of a limited number of conditions. The FDA has not approved the use of human growth hormone as therapy for anti-aging, longevity, cosmetic or performance enhancement. Federal law prohibits the dispensing of human growth hormone for non-approved purposes. A pharmacy's failure to comply with that law could result in significant criminal penalties to the pharmacy and its employees. Accordingly, a pharmacy may decline to dispense prescriptions for human growth hormone when written by a physician or other authorized prescribers who they believe may be involved in or affiliated with the fields of anti-aging, longevity, rejuvenation, cosmetic, performance enhancement, or sports medicine.

Documentation: Documentation is required for use of Sogroya as noted in the criteria as **[documentation required]**. Documentation may include, but is not limited to, chart notes, prescription claims records, prescription receipts, and/or other information. For patient cases in which documentation is required, if this documentation has been previously received upon a prior coverage review, the documentation requirement is considered to be met.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Sogroya is recommended in those who meet the following criteria:

FDA-Approved Indication

- 1. Growth Hormone Deficiency in a Child or Adolescent (≥ 2.5 years of age).** Approve for 1 year if the patient meets ONE the following (A or B):
 - A) Initial Therapy with any Growth Hormone Agent.** Approve if the patient meets ONE of the following (i, ii, iii, iv, or v):
 - i. Patient meets BOTH of the following (a and b):**
 - a) Patient meets ONE of the following [(1) or (2)]:**
 - (1) Patient has had two growth hormone stimulation tests performed with any of the following agents: levodopa, insulin-induced hypoglycemia, arginine, clonidine, or glucagon AND the peak growth hormone response to both tests are < 10 ng/mL; OR**
 - (2) Patient meets BOTH of the following criteria [(a) and (b)]:**
 - (a) 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 peak growth hormone response to at least one test is < 10 ng/mL; AND**
 - (b) Patient has at least one risk factor for growth hormone deficiency; AND**
 - Note:** Examples of at least one risk factor for growth hormone deficiency includes: 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

- b)** Patient has been evaluated by an endocrinologist.
- ii.** Patient has undergone brain radiation or tumor resection AND meets BOTH of the following (a and b):
 - a)** Patient meets at least ONE of the following [(1) or (2)]:
 - (1)** Patient meets BOTH of the following [(i) and (ii)]:
 - (i)** 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
 - (ii)** The peak growth hormone response to at least one test is < 10 ng/mL; OR
 - (2)** Patient has a deficiency in at least one other pituitary hormone (i.e., adrenocorticotrophic hormone, thyroid-stimulating hormone, gonadotropin [luteinizing hormone and/or follicle stimulating hormone deficiency are counted as one deficiency], or prolactin); AND
 - b)** Patient has been evaluated by an endocrinologist.
- iii.** Patient has congenital hypopituitarism AND meets BOTH of the following (a and b):
 - a)** Patient meets at least ONE of the following [(1), (2), or (3)]:
 - (1)** Patient meets BOTH of the following [(i) and (ii)]:
 - (i)** 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
 - (ii)** The peak growth hormone response to at least one test is < 10 ng/mL; OR
 - (2)** Patient has a deficiency in at least one other pituitary hormone (i.e., adrenocorticotrophic hormone, thyroid-stimulating hormone, gonadotropin [luteinizing hormone and/or follicle stimulating hormone deficiency are counted as one deficiency], or prolactin); OR
 - (3)** Patient has the imaging triad of ectopic posterior pituitary and pituitary hypoplasia with abnormal pituitary stalk; AND
 - b)** Patient has been evaluated by an endocrinologist.
- iv.** Patient has multiple pituitary hormone deficiencies and meets BOTH of the following (a and b):

Note: Growth hormone deficiency may occur in combination with other pituitary hormone deficiencies and is referred to as hypopituitarism, panhypopituitarism, or multiple pituitary hormone deficiency.

 - a)** Patient meets at least ONE of the following [(1) or (2)]:
 - (1)** Patient has three or more of the following pituitary hormone deficiencies: somatropin (growth hormone), adrenocorticotrophic hormone, thyroid-stimulating hormone, gonadotropin (luteinizing hormone and/or follicle stimulating hormone deficiency are counted as one deficiency), and prolactin; OR
 - (2)** Patient meets BOTH of the following [(i) and (ii)]:
 - (i)** Patient had one growth hormone stimulation test with any of the following agents: levodopa, insulin-induced hypoglycemia, arginine, clonidine, or glucagon; AND
 - (ii)** The peak growth hormone response to at least one test is < 10 ng/mL; AND
 - b)** Patient has been evaluated by an endocrinologist.
- v.** Patient has had a hypophysectomy (surgical removal of pituitary gland).

- B) Patient is Currently Receiving Sogroya or is switching to Sogroya from another Growth Hormone Agent (Patient has been established on either therapy for ≥ 10 months). Approve if the patient meets ONE of the following (i, ii, or iii):**
- i. Patient is < 12 years of age: Patient's height has increased by ≥ 2 cm/year in the most recent year; OR**
 - ii. Patient is ≥ 12 years of age and < 18 years of age: Patient meets BOTH of the following (a and b):**
 - a) Patient's height has increased by ≥ 2 cm/year in the most recent year; AND**
 - b) Patient's epiphyses are open; OR**
 - iii. Patient is ≥ 18 years of age. Patient meets ALL of the following (a, b, and c):**
 - a) Patient's height has increased by ≥ 2 cm/year in the most recent year; AND**
 - b) Patient's epiphyses are open; AND**
 - c) Mid-parental height has not been attained.**
 - Note: Mid-parental height is the father's height plus the mother's height divided by 2, plus 2.5 inches if male or minus 2.5 inches if female.
 - Note: Adolescents and young adults with childhood onset growth hormone deficiency who have completed linear growth may continue receiving Sogroya therapy as a transition adolescent or as an adult. See criteria for Growth Hormone Deficiency in an adult or transition adolescent.

2. Growth Hormone Deficiency in an Adult or Transition Adolescent. Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):

- A) The endocrinologist must certify that growth hormone therapy is not being prescribed for anti-aging therapy or to enhance athletic ability or for body building; AND**
- B) Patient must have a diagnosis of growth hormone deficiency that is ONE of the following (i or ii):**

[documentation required for all elements]

 - i. Childhood onset; OR**
 - ii. Adult onset that results from one of the following: growth hormone deficiency alone or multiple hormone deficiencies (hypopituitarism) resulting from pituitary disease, hypothalamic disease, pituitary surgery, cranial radiation therapy, tumor treatment, traumatic brain injury, or subarachnoid hemorrhage; AND**
- C) Patient meets at least ONE of the following (i, ii, or iii):**
 - i. Patient (adult or transition adolescent) has known perinatal insults OR congenital or genetic defects; [documentation required] OR**
 - ii. Patient meets ALL of the following (a, b, and c):**
 - a) Patient (adult onset or transition adolescent) has three or more of the following pituitary hormone deficiencies: Adrenocorticotrophic hormone , thyroid-stimulation hormone, gonadotropin deficiency (luteinizing hormone and/or follicle stimulating hormone deficiency are counted as one deficiency), and prolactin [documentation required]; AND**
 - b) The age and gender adjusted serum insulin-like growth factor-1 is below the lower limit of the normal reference range for the reporting laboratory [documentation required]; AND**
 - c) Other causes of low serum insulin-like growth factor-1 have been excluded (e.g., malnutrition, prolonged fasting, poorly controlled diabetes mellitus, hypothyroidism, hepatic insufficiency, oral estrogen therapy); OR**
 - iii. Patient meets at least ONE of the following (a or b):**
 - a) Adult. Patient has had a negative response to at least ONE of the following standard growth hormone stimulation tests (1, 2, 3, 4, 5, or 6) [documentation required for all elements]:**
 - Note: If the patient has had a previous trial of an arginine test with a peak response of ≤ 0.4 mcg/L, this would meet the criteria for a negative response to a growth hormone stimulation test.

- (1) Insulin tolerance test (obtaining at least 3 growth hormone levels in at least a 60 minute timeframe [not including a level at timeframe zero], with adequate hypoglycemia being achieved) with peak response ≤ 5.0 mcg/L; OR
 - (2) Glucagon stimulation test (obtaining at least 3 growth hormone levels in at least 180 minute timeframe [not including a level at timeframe zero]) with peak response ≤ 3.0 mcg/L AND the patient's body mass index (BMI) is < 25 kg/m²; OR
 - (3) Glucagon stimulation test (obtaining at least 3 growth hormone levels in at least 180 minute timeframe [not including a level at timeframe zero]) with a peak response ≤ 3.0 mcg/L AND the patient's BMI is ≥ 25 kg/m² and ≤ 30 kg/m² with, according to the prescriber, a high pretest probability of growth hormone deficiency; OR
 - (4) Glucagon stimulation test (obtaining at least 3 growth hormone levels in at least 180 minute timeframe [not including a level at timeframe zero]) with a peak response ≤ 1.0 mcg/L AND the patient's BMI is ≥ 25 kg/m² and ≤ 30 kg/m² with, according to the prescriber, a low pretest probability of growth hormone deficiency; OR
 - (5) Glucagon stimulation test (obtaining at least 3 growth hormone levels in at least 180 minute timeframe [not including a level at timeframe zero]) with peak response ≤ 1.0 mcg/L AND the patient's BMI is > 30 kg/m²; OR
 - (6) Macrilen (macimorelin oral solution) test (obtaining at least 4 growth hormone levels in at least a 90 minute timeframe [not including a level at timeframe zero]) with peak responses < 2.8 ng/mL (2.8 mcg/L) AND the patient's BMI is ≤ 40 kg/m².
Note: The following formula can be used to calculate BMI: BMI equals body weight in kg divided by height meters squared (m²) [i.e., BMI = kg/m²]; OR
- b) Transition adolescent. Patient meets BOTH of the following (1 and 2): **[documentation required for all elements]**:
- Note: The transition period is the time from late puberty to establishment of adult muscle and bone composition, and encompasses attainment of adult height.
- Note: If the patient has had a trial of a Macrilen test with a peak response of < 2.8 ng/mL (mcg/L), this would meet the criteria for a negative response to a growth hormone stimulation test.
- (1) Patient has been off growth hormone therapy for at least 1 month before retesting with a growth hormone stimulation test; AND
 - (2) Patient meets at least ONE of the following responses to growth hormone stimulation testing (i, ii, iii, iv, v or vi):
 - (i) Insulin tolerance test (obtaining at least 3 growth hormone levels in at least a 60 minute timeframe [not including a level at timeframe zero], with adequate hypoglycemia being achieved) with peak response ≤ 5.0 mcg/L; OR
 - (ii) Glucagon stimulation test (obtaining at least 3 growth hormone levels in at least 180 minute timeframe [not including a level at timeframe zero]) with peak response ≤ 3.0 mcg/L AND the patient's body mass index (BMI) is < 25 kg/m²; OR
 - (iii) Glucagon stimulation test (obtaining at least 3 growth hormone levels in at least 180 minute timeframe [not including a level at timeframe zero]) with a peak response of ≤ 3.0 mcg/L AND the patient's BMI is ≥ 25 kg/m² and ≤ 30 kg/m² with, according to the prescriber, a high pretest probability of growth hormone deficiency; OR
 - (iv) Glucagon stimulation test (obtaining at least 3 growth hormone levels in at least 180 minute timeframe [not including a level at timeframe zero]) with a peak response ≤ 1.0 mcg/L AND the patient's BMI is ≥ 25 kg/m² and ≤ 30 kg/m² with, according to the prescriber, a low pretest probability of growth hormone deficiency; OR

- (v) Glucagon stimulation test (obtaining at least 3 growth hormone levels in at least 180 minute timeframe [not including a level at timeframe zero]) with peak response ≤ 1.0 mcg/L AND the patient's BMI is > 30 kg/m²; OR
- (vi) If both the insulin tolerance test AND glucagon stimulation test are contraindicated, the arginine test can be used (obtaining at least 3 growth hormone levels in at least 120 minute timeframe [not including a level at timeframe zero]) with a peak response ≤ 0.4 mcg/L; AND

D) Patient has been evaluated by an endocrinologist.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Sogroya is not recommended in the following situations:

Note: For some of the following indications, authorization for coverage is not recommended because this indication is excluded from coverage in a typical pharmacy benefit.

1. **Acute Critical Illness Due to Complications Following Surgery, Multiple Accidental Trauma, or with Acute Respiratory Failure.**¹ Sogroya is contraindicated in acute critical illness after open-heart surgery, abdominal surgery, multiple accidental trauma, or those with acute respiratory failure because of the risk of increased mortality.
2. **Aging (i.e., Anti-Aging), to Improve Functional Status in an Elderly Patient, and Somatopause.**^{13,14,17,18} Somatropin is not FDA-approved for anti-aging therapy, to improve functional status in elderly patients, or to treat somatopause. Federal law prohibits the distribution or dispensing of somatropin for non-FDA approved uses. There are no long-term studies assessing somatropin efficacy and safety for anti-aging therapy. Short-term therapy with somatropin may improve some measures of body composition, including increased muscle mass, reduced total body fat, improved skin elasticity, and reduced rate of bone demineralization, but somatotropin does not have positive effects on strength, functional capacity, or metabolism. Somatropin is associated with considerable adverse effects in non-growth hormone deficient adults (e.g., carpal tunnel syndrome, soft tissue edema, arthralgias, glucose intolerance, increased serum lipids). Another concern is the possible increased risk of cancer with long-term use of somatropin and the potentiating effects of insulin growth factor (IGFs) on cancer. Somatropin is not indicated for the age-related decrease in growth hormone/IGF-1 status.¹²
3. **Athletic Ability Enhancement.**⁵ Somatropin is not FDA-approved for athletic performance enhancement or for body building in nonathletes. Federal law prohibits the distribution or dispensing of somatropin for non-FDA approved uses. Short-term administration of somatropin to increase strength and endurance in athletes is no more effective than training alone and somatropin should not be administered to athletes or other persons for the purpose of enhancing athletic ability or improving personal appearance (i.e., to appear leaner and more muscular). Somatropin has been used in supraphysiologic doses alone or in combination with other performance enhancing drugs (PEDs) in users who are not athletes.³⁴ Use of PEDs has been linked to an increased risk of death and many adverse effects including cardiovascular, psychiatric, metabolic, endocrine, neurologic, infectious, hepatic, renal, and musculoskeletal disorders.
4. **Central Precocious Puberty (CPP).** Children with precocious puberty are often treated with gonadotropin releasing hormone (GnRH) agonists (Lupron® [leuprolide acetate injection]) to suppress pituitary gonadal activity, to slow the advancement of bone age (prevent premature fusion of the epiphyseal growth plates), and to improve adult height. There are some limited studies which have shown somatropin given in combination with a GnRH analog for patients with CPP and low predicted

adult height has been associated with height increases.^{6,7} There are no large well-controlled trials on the efficacy and safety of adding somatropin to GnRH agonist therapy in a patient with CPP.

5. **Chronic Fatigue Syndrome.** There is no evidence of GHD in chronic fatigue syndrome.¹⁹
6. **Congenital Adrenal Hyperplasia (CAH).**^{8,9} The Endocrine Society clinical practice guidelines on CAH due to steroid 21-hydroxylase deficiency recommend against the use of experimental treatment approaches outside of formally approved clinical trials.⁹ Children with predicted adult height standard deviation ≤ -2.25 may be considered for growth-promoting treatments in appropriately controlled trials.
7. **Constitutional Delay of Growth and Puberty.** These children have delayed skeletal maturation and pubertal development. Administering somatropin does not increase adult height (which is usually normal).¹⁰ Short-term androgen therapy accelerates growth and the rate of pubertal advancement in boys.
8. **Fibromyalgia.** In one placebo-controlled study, 120 non-GHD adult women with severe fibromyalgia and low levels of IGF-1 were randomized to somatropin 0.006 mg/kg/day for 12 months (dose was adjusted) or placebo for 6 months.²⁰ Patients receiving placebo initially were switched to somatropin from Months 6 to 12 (open label). Standard therapy for fibromyalgia was continued. After 6 months, there were no differences between somatropin and placebo in the percentage of patients with fewer than 11 positive tender points, mean number of tender points, intensity of pain in every point evaluated, and other measures. After 12 months of somatropin therapy, 53% of patients had less than 11 positive tender points compared with 33% of patients who received placebo and then somatropin for 6 months ($P < 0.05$). At 18 months follow-up evaluation when somatropin was discontinued, impairment in pain perception worsened in both groups but to a lesser extent in the patients on somatropin for 12 months. Further controlled trials are needed with a longer duration,²¹ with different doses, and using the 2010 American College of Rheumatology criteria for fibromyalgia. Some patients with fibromyalgia may have adult GHD.
9. **Infertility.**^{22,23} Clinical trials indicate that somatropin is not useful as an adjunct during *in vitro* fertilization, for induction of ovulation in polycystic ovary syndrome, or for assisted reproductive technology. The authors of a recent meta-analysis concluded there is no evidence of an increased chance of a live birth with use of somatropin.
10. **Obesity.**^{24,25} Somatropin is not indicated for the treatment of obesity. Low growth hormone levels are a consequence of central obesity and not a cause. Obesity is associated with decreased basal and pulsatile release of growth hormone and decreased stimulated growth hormone release. Somatropin therapy does not have significant beneficial effects on obesity in persons without GHD and does not produce significant overall weight loss. Supraphysiologic doses of somatropin have been used to treat obesity. Effects of long-term therapy with somatropin are unknown.
11. **Osteoporosis.**^{13,14} Guidelines for treatment or prevention of osteoporosis do not include recommendations for use of somatropin. In one double-blind trial, 80 postmenopausal women with osteoporosis (56% of patients [$n = 45/80$] had a of fractures) were randomized to somatropin 0.33 mg/day or 0.83 mg/day or to placebo for 3 years.¹³ The double-blind phase was 18 months and patients on somatropin continued drug for another 18 months and patients on placebo stopped at 18 months. Patients were compared with an age-matched random population sample of women ($n = 120$). All patients received calcium 750 mg, vitamin D 400 units, and hormone replacement therapy. All women were followed for 10 years total. Bone mineral density increased in the patients receiving somatropin at Years 4 and 5, and after 10 years, had decreased to similar levels as before treatment. At 10 years, 28% of women ($n = 22/80$) had fractures. In the control group, fractures increased from 8% of patients

at baseline to 32% of patients after 10 years. At 10 years, 41% of patients (n = 33/80) had stopped hormone replacement therapy; 23% had started bisphosphonates due to fractures, and 3% had received Forteo® (teriparatide injection). Larger studies are needed to determine the effects of somatropin therapy on bone mineral density and fractures in non-growth hormone deficient persons.

12. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

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