Effective date: 03/01/2024
Reviewed: 12/2023, 03/2024, 04/2025, 7/2025 Scope: Medicaid

SOGROYA (somapacitan-beco)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

A. Sogroya is indicated for the replacement of endogenous growth hormone (GH) in adults with growth hormone deficiency (GHD).
B. Sogroya is indicated for the treatment of pediatric patients aged 2.5 years and older who have growth failure due to inadequate secretion of endogenous growth hormone (GH).

All other indications are considered experimental/investigational and not medically necessary.

II. PRESCRIBER SPECIALTIES

Therapy must be prescribed by or in consultation with any of the following specialists:
A. Endocrinologist
B. Pediatric endocrinologist

III. CRITERIA FOR INITIAL APPROVAL

Growth charts are required for pediatric or adult patients with growth hormone (GH) deficiency.

A. **Pediatric Growth Hormone (GH) Deficiency**

Authorization of 12 months may be granted to members with documentation of pediatric GH deficiency 2.5 years of age or older when the following criteria is met

1. Documentation that the member meets one of the following:
    a. Member was diagnosed with GH deficiency as a neonate. Medical records must be available to support the diagnosis of neonatal GH deficiency (e.g., hypoglycemia with random GH level, evidence of multiple pituitary hormone deficiency, chart notes, or magnetic resonance imaging [MRI] results) OR
    b. Member meets ALL of the following:
        i. Member has EITHER:
            a. Two pretreatment pharmacologic provocative GH tests with both results demonstrating a peak GH level < 10 ng/mL, OR
            b. A documented pituitary or CNS disorder (refer to Appendix A) and a pretreatment IGF-1 level > 2 standard deviations (SD) below the mean
        ii. Member meets one of the following:

a. Pretreatment height is > 2 SD below the mean and 1-year height velocity is > 1 SD below the mean, OR
b. Pretreatment 1-year height velocity is > 2 SD below the mean

iii. Epiphyses are open

2. Documentation that the member has had a treatment failure with at least 1 daily growth hormone product (e.g., based on claims review of inadequate adherence or documentation of injection site reactions)

B. **Adult Growth Hormone Deficiency**

Authorization of 12 months may be granted to members with documentation of adult GH deficiency when ANY of the following criteria is met:

1. Documentation that the member meets both of the following:
   i. Member has had 2 pretreatment pharmacologic provocative GH tests and both results demonstrated deficient GH responses defined as the following:
      a. Insulin tolerance test (ITT) with a peak GH level ≤ 5 ng/mL
      b. Macrilen with a peak GH level of less than 2.8 ng/mL
      c. Glucagon stimulation test with a peak GH level ≤ 3.0 ng/mL in patients with a body mass index (BMI) ≤ 30 kg/m^2 and a high pretest probability of GHD (e.g., acquired structural abnormalities) OR a BMI < 25 kg/m^2
      d. Glucagon stimulation test with a peak GH level ≤ 1.0 ng/mL in patients with a BMI of ≥ 25 kg/m^2 and a low pretest probability of GHD (e.g., acquired structural abnormalities) OR a BMI > 30 kg/m^2
   ii. Member has a low pretreatment IGF-1 (between 0 to 2 SD below the mean for age and gender)
2. Documentation that the member meets both of the following:
   i. Member has had 1 pretreatment pharmacologic provocative GH test that demonstrated deficient GH responses defined as one of the following:
      a. Insulin tolerance test (ITT) with a peak GH level ≤ 5 ng/mL
      b. Macrilen with a peak GH level of less than 2.8 ng/mL
      c. Glucagon stimulation test with a peak GH level ≤ 3.0 ng/mL in patients with a body mass index (BMI) ≤ 30 kg/m^2 and a high pretest probability of GHD (e.g., acquired structural abnormalities) OR a BMI < 25 kg/m^2
      d. Glucagon stimulation test with a peak GH level ≤ 1.0 ng/mL in patients with a BMI of ≥ 25 kg/m^2 and a low pretest probability of GHD (e.g., acquired structural abnormalities) OR a BMI > 30 kg/m^2
   ii. Member has a pretreatment IGF-1 level that is more than 2 SD below the mean for age and gender
3. Documentation that the member has organic hypothalamic-pituitary disease (e.g., suprasellar mass with previous surgery and cranial irradiation) with ≥ 3 documented pituitary hormone deficiencies (refer to Appendix B) and a low pretreatment IGF-1 more than 2 standard deviations below the mean for age and gender
4. Documentation that the member has genetic or structural hypothalamic-pituitary defects (refer to Appendix C)
5. Documentation that the member has childhood-onset GH deficiency and a congenital abnormality of the CNS, hypothalamus or pituitary (refer to Appendix C)

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IV. CONTINUATION OF THERAPY

For all indications listed below, documentation of the member's diagnosis must be provided.

A. Pediatric Growth Hormone Deficiency

Authorization of 12 months may be granted for continuation of therapy when ALL of the following criteria are met:

1. Documentation that the epiphyses are open (confirmed by X-ray or X-ray is not available)
2. Documentation that the member's growth rate is > 2 cm/year unless there is a documented clinical reason for lack of efficacy (e.g., on treatment less than 1 year, nearing final adult height/late stages of puberty)

B. Adult Growth Hormone Deficiency

Authorization of 12 months may be granted for continuation of therapy when ANY of the following criteria is met:

1. Documentation that the member meets all of the following:
    i. Member has had 2 pretreatment pharmacologic provocative GH tests and both results demonstrated deficient GH responses defined as the following:
        a. Insulin tolerance test (ITT) or another provocative GH test with a peak GH level ≤ 5 ng/mL
        b. Macrilen with a peak GH level of less than 2.8 ng/ml
        c. Glucagon stimulation test with a peak GH level ≤ 3.0 ng/mL in patients with a body mass index (BMI) ≤ 30 kg/m^2 and a high pretest probability of GHD (e.g., acquired structural abnormalities) OR a BMI < 25 kg/m^2
        d. Glucagon stimulation test with a peak GH level ≤ 1.0 ng/mL in patients with a BMI of ≥ 25 kg/m^2 and a low pretest probability of GHD (e.g., acquired structural abnormalities) OR a BMI > 30 kg/m^2
    ii. Member has a low pretreatment IGF-1 (between 0 to 2 SD below the mean for age and gender)
    iii. Current IGF-1 level is not elevated for age and gender
2. Documentation that the member meets all of the following:
    i. Member has had 1 pretreatment pharmacologic provocative GH test that demonstrated deficient GH responses defined as one of the following:
        a. Insulin tolerance test (ITT) or another provocative GH test with a peak GH level ≤ 5 ng/mL
        b. Macrilen with a peak GH level of less than 2.8 ng/mL
        c. Glucagon stimulation test with a peak GH level ≤ 3.0 ng/mL in patients with a body mass index (BMI) ≤ 30 kg/m^2 and a high pretest probability of GHD (e.g., acquired structural abnormalities) OR a BMI < 25 kg/m^2
        d. Glucagon stimulation test with a peak GH level ≤ 1.0 ng/mL in patients with a BMI of ≥ 25 kg/m^2 and a low pretest probability of GHD (e.g., acquired structural abnormalities) OR a BMI > 30 kg/m^2
    ii. Member has a pretreatment IGF-1 level that is more than 2 SD below the mean for age and gender
    iii. Current IGF-1 level is not elevated for age and gender

3. Documentation that the member meets both of the following:
   i. Member has organic hypothalamic-pituitary disease (e.g., suprasellar mass with previous surgery and cranial irradiation) with ≥ 3 documented pituitary hormone deficiencies (refer to Appendix B) and a low pretreatment IGF-1 more than 2 standard deviations below the mean for age and gender
   ii. Current IGF-1 level is not elevated for age and gender
4. Documentation that the member has genetic or structural hypothalamic-pituitary defects (refer to Appendix C) and current IGF-1 level is not elevated for age and gender
5. Documentation that the member has childhood-onset GH deficiency and a congenital abnormality of the CNS, hypothalamus or pituitary (refer to Appendix C) and current IGF-1 level is not elevated for age and gender

V. APPENDICES

A. Appendix A: Examples of Hypothalamic/Pituitary/CNS Disorders

1. Congenital genetic abnormalities
   a. Transcription factor defects (PIT-1, PROP-1, LHX3/4, HESX-1, PITX-2)
   b. Growth hormone releasing hormone (GHRH) receptor gene defects
   c. GH secretagogue receptor gene defects
   d. GH gene defects
   e. GH receptor/post receptor defects
2. Congenital structural abnormalities
   a. Optic nerve hypoplasia/septo-optic dysplasia
   b. Agenesis of corpus callosum
   c. Empty sella syndrome
   d. Ectopic posterior pituitary
   e. Pituitary aplasia/hypoplasia
   f. Pituitary stalk defect
   g. Holoprosencephaly
   h. Encephalocele
   i. Hydrocephalus
   j. Anencephaly or prosencephaly
   k. Arachnoid cyst
   l. Other mid-line facial defects (e.g., single central incisor, cleft lip/palate)
   m. Vascular malformations
3. Acquired structural abnormalities (or causes of hypothalamic/pituitary damage)
   a. CNS tumors/neoplasms (e.g., craniopharyngioma, glioma/astrocytoma, pituitary adenoma, germinoma)
   b. Cysts (Rathke cleft cyst or arachnoid cleft cyst)
   c. Surgery
   d. Radiation
   e. Chemotherapy
   f. CNS infections
   g. CNS infarction (e.g., Sheehan's syndrome)

h. Inflammatory processes (e.g., autoimmune hypophysitis)
i. Infiltrative processes (e.g., sarcoidosis, histiocytosis, hemochromatosis)
j. Head trauma/traumatic brain injury
k. Aneurysmal subarachnoid hemorrhage
l. Perinatal or postnatal trauma
m. Surgery of the pituitary or hypothalamus

B. Appendix B: Pituitary Hormones (Other than Growth Hormone)

1. Adrenocorticotropic hormone (ACTH)
2. Antidiuretic hormone (ADH)
3. Follicle stimulating hormone (FSH)
4. Luteinizing hormone (LH)
5. Thyroid stimulating hormone (TSH)
6. Prolactin

C. Appendix C: Requirements for GH-Stimulation Testing in Adults

1. Testing for adult GHD is not required
   a. Three or more pituitary hormone deficiencies and low IGF-1
   b. Congenital structural abnormalities
      i. Transcription factor defects (PIT-1, PROP-1, LHX3/4, HESX-1, PITX-2)
      ii. GHRH receptor-gene defects
      iii. GH-receptor/post-receptor defects
      iv. GH-gene defects associated with brain structural defects
      v. Single central incisor
      vi. Cleft lip/palate
   c. Acquired causes such as perinatal insults
2. Testing for adult GHD is required
   a. Acquired
      i. Skull-base lesions
      ii. Pituitary adenoma
      iii. Craniopharyngioma
      iv. Rathke's cleft cyst
      v. Meningioma
      vi. Glioma/astrocytoma
      vii. Neoplastic sellar and parasellar lesions
      viii. Chordoma
      ix. Hamartoma
      x. Lymphoma
      xi. Metastases
      xii. Other brain injury
      xiii. Traumatic brain injury
      xiv. Sports-related head trauma
      xv. Blast injury
      xvi. Infiltrative/granulomatous disease
      xvii. Langerhans cell histiocytosis

xviii. Autoimmune hypophysitis (primary or secondary)
xix. Sarcoidosis
xx. Tuberculosis
xxi. Amyloidosis

b. Surgery to the sella, suprasellar, and parasellar region
c. Cranial irradiation
d. Central nervous system infections (bacteria, viruses, fungi, parasites)
e. Infarction/hemorrhage (e.g., apoplexy, Sheehan's syndrome, subarachnoid hemorrhage, ischemic stroke, snake bite)
f. Empty sella
g. Hydrocephalus
h. Idiopathic

VI. REFERENCES

1. Sogroya [package insert]. Plainsboro, NJ: Novo Nordisk, Inc; February 2025. Accessed June 2025.
2. U.S. National Library of Medicine. ClinicalTrials.gov. Trial to Compare the Efficacy and Safety of NNC0195-0092 (Somapacitan) With Placebo and Norditropin FlexPro (Somatropin) in Adults With Growth Hormone Deficiency (REAL 1). https://clinicaltrials.gov/ct2/show/study/NCT02229851. Accessed January 2, 2023.
3. Gharib H, Cook DM, Saenger PH, et al. American Association of Clinical Endocrinologists Growth Hormone Task Force. Medical guidelines for clinical practice for growth hormone use in adults and children 2003 Update. *Endocr Pract*. 2003;9(1):64-76.
4. Molitch ME, Clemmons DR, Malozowski S, et al. Evaluation and treatment of adult growth hormone deficiency: an Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab*. 2011;96:1587-1609.
5. Cook DM, Yuen KCJ, Biller BMK, Kemp SF, Lee Vance M. American Association of Clinical Endocrinologists. Medical guidelines for clinical practice for growth hormone use in growth hormone-deficient adults and transition patients 2009 update. *Endocr Pract*. 2009;15(2):1-28.
6. National Institute for Clinical Excellence: Human growth hormone (somatropin) in adults with growth hormone deficiency. August 2003.
7. Yuen KCJ, Biller BMK, Radovick S, et al. 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. *Endocr Pract*. 2019; 25: 1191-1232.
8. National Institute for Clinical Excellence: Guidance on the use of human growth hormone (somatropin) for the treatment of growth failure in children. May 2010. http://www.nice.org.uk/nicemedia/live/12992/48715/48715.pdf. Accessed January 9, 2023.
9. Wilson TA, Rose SR, Cohen P, et al. Update of Guidelines for the Use of Growth Hormone in Children: The Lawson Wilkins Pediatric Endocrinology Society Drug and Therapeutics Committee. *J Pediatr*. 2003;143:415-421.
10. Franklin SL, Geffner ME. Growth hormone: the expansion of available products and indications. *Pediatr Clin North Am*. 2011;58:1141-1165.
11. Grimberg A, DiVall SA, Polychronakos C, et al. Guidelines for growth hormone and insulin-like growth factor-I treatment in children and adolescents: growth hormone deficiency, idiopathic short stature, and primary insulin-like growth factor-I deficiency. *Horm Res Paediatr*. 2016;86:361-397.
12. Deal C, Hasselmann C, Pfaffle RW, et al. Associations between pituitary imaging abnormalities and clinical and biochemical phenotypes in children with congenital growth hormone deficiency: data from an international observational study. *Horm Res Paediatr*. 2013;79:283-292.