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PHARMACY POLICY STATEMENT
HAP CareSource™ Marketplace

DRUG NAME	Sogroya (somapacitan-beco)
BENEFIT TYPE	Pharmacy
STATUS	Prior Authorization Required

Sogroya (somapacitan-beco) 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) and the replacement of endogenous growth hormone in adults with growth hormone deficiency. It is administered once weekly by injection under the skin. Growth hormone deficiency (GHD) involves inadequate secretion of growth hormone from the pituitary gland.

Sogroya (somapacitan-beco) will be considered for coverage when the following criteria are met:

Adult Growth Hormone Deficiency

For **initial** authorization:

1. Member is at least 18 years of age or older; AND
2. Medication must be prescribed by or in consultation with an endocrinologist; AND
3. Member has genetic or structural brain hypothalamic-pituitary defect that does not require testing (see appendix B); OR
4. Member must have documentation of **ALL** of the following:
   a) Hypothalamic-pituitary defect (see appendix A);
   b) IGF-1 <-2 standard deviations for age and gender;
   c) Deficiencies in at least **THREE** pituitary axes (see appendix C); OR
5. Member must have documentation of **ALL** of the following:
   a) Hypothalamic-pituitary defect (see appendix A);
   b) IGF-1 <-2 standard deviations for age and gender;
   c) Suboptimal response to **ONE** pre-treatment stimulation test defined as:
      i) Insulin tolerance test (ITT) with a peak serum growth hormone concentration < 5 µg/mL (must include lab results with reference ranges);
      ii) Macrilen (prior authorization required) with a peak serum growth hormone concentration < 2.8 ng/ml;
      iii) Glucagon stimulation test (GST) with a peak serum growth hormone concentration meeting **ONE** of the following:
         (1) <3 µg/L for members with a BMI <25 kg/m^2;
         (2) <1 µg/L for members with a BMI >30 kg/m^2;
         (3) <1 µg/Lfor members with a BMI 25 to 30 kg/m^2 with a low pretest probability; OR
6. Member must have documentation of **ALL** of the following:
   a) Diagnosis of idiopathic isolated GHD;
   b) IGF-1 between 0 to –2 or <-2 standard deviations for age and gender;
   c) Human growth hormone therapy has been discontinued for at least one month;

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d) Suboptimal response to **TWO** pre-treatment stimulation tests defined as:
   i) Insulin tolerance test (ITT) with a peak serum growth hormone concentration < 5 µg/mL (must include lab results with reference ranges);
   ii) Macrilen (prior authorization required) with a peak serum growth hormone concentration < 2.8 ng/ml;
   iii) Glucagon stimulation test (GST) with a peak serum growth hormone concentration meeting **ONE** of the following:
      (1) <3 µg/L in members with a BMI <25 kg/m2;
      (2) <1 µg/L for members with a BMI >30 kg/m2;
      (3) <1 µg/Lfor members with a BMI 25 to 30 kg/m2 with a low pretest probability; AND

7. Member must have a documented 6-month trial and failure of Omnitrope 5.8 mg vial; AND
8. Member does NOT have a history of active malignancy.
9. **Dosage allowed/Quantity limit:** Initial dose of 1.5 mg once weekly given subcutaneously, not to exceed 8 mg once weekly.

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:

1. Member's current IGF-1 level is within -2 and +2 standard deviations for age and gender (must include lab results with reference range).

If all the above requirements are met, the medication will be approved for an additional 12 months.

Pediatric Growth Hormone Deficiency

For **initial** authorization:

1. Member is at least 2.5 years of age or older; AND
2. Medication must be prescribed by or in consultation with an endocrinologist; AND
3. Member was diagnosed with congenital hypopituitarism as a newborn and had **BOTH** of the following:
   a. Hypoglycemia with a serum GH concentration ≤ 5 µg/L;
   b. At least **one** additional pituitary hormone deficiency (see appendix C) or classical imaging triad (ectopic posterior pituitary and pituitary hypoplasia with abnormal stalk); OR
4. Member has documentation of **BOTH** of the following:
   a. Hypothalamic-pituitary defect (see appendix A);
   b. At least **one** additional pituitary hormone deficiency (see appendix C); OR
5. Member must have documentation of **TWO** pre-treatment stimulation tests with a peak serum growth hormone concentration < 10 ng/mL (must include lab results with reference ranges); AND
6. Member must have a documented 6-month trial and failure of Omnitrope 5.8 mg vial; AND
7. Member must have a pretreatment height (must include growth charts) of > 2 SD below the mean for age and gender; AND
8. Member must have a pretreatment height velocity (must include growth charts) below the 25th percentile for age and gender; AND
9. Member does **NOT** have a history of active malignancy; AND
10. Member's weight is provided for dose calculation; AND
11. If member is age 12 or older, radiographic evidence the member's epiphyses are open (x-ray results must be included).
12. **Dosage allowed/Quantity limit:** Administer 0.16 mg/kg subcutaneously once weekly.

If all the above requirements are met, the medication will be approved for 12 months.

For **reauthorization**:

1. Member has a growth rate of at least 2 cm/year; AND
2. If member is age 12 or older, radiographic evidence the member's epiphyses are open (x-ray results must be included).

If all the above requirements are met, the medication will be approved for an additional 12 months.

HAP CareSource considers Sogroya (somapacitan-beco) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
10/13/2021	Sogroya policy creation
07/26/2023	Pediatric growth hormone deficiency indication added; added/updated references; Adults: Updated requirements for diagnosis of GHD including when testing is not required and the addition of IGF-1 levels; updated and added to appendix; removed diagnoses that were excluded from reauthorization criteria; added/updated references; added glucagon stimulation test option, added exclusion of active malignancy; added in consultation with for prescribe specialty; increased Omnitrope trial from 90 days to 6 months; reduced initial authorization length from 12 months to 6 months.

References:

1. Sogroya [package insert]. Plainsboro, NJ: Novo Nordisk, Inc; April 2023.
2. 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
3. Johannsson G, Gordon MB, et al. Once-weekly Somapacitan is Effective and Well Tolerated in Adults with GH Deficiency: A Randomized Phase 3 Trial. *J Clin Endocrinol Metab*. 2020 Apr 1;105 (4): 1358-1376
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. Boguszewski MC. Growth hormone deficiency and replacement in children. *Rev Endocr Metab Disord.* 2021 Mar; 22: 101–108.
6. Pediatric Endocrine Society (PES) Guidelines for growth Hormone and insulin-like growth factor-1 treatment in children and adolescents; *Horm Res Paediatr.* 2016;86(6):361-397
7. Rogol AD, Hayden GF. Etiologies and early diagnosis of short stature and growth failure in children and adolescents. *J Pediatr.* 2014 May;164(5 Suppl):S1-14.e6
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
9. Wilson TA, Rose SR, Cohen P, et al. Update of guidelines for the use of growth hormone in children: The Lawson Wilkins Endocrinology Society Drug and Therapeutics Committee. *J Pediatr.* 2003; 143: 415-421

Effective date: 01/01/2025
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Appendix A:

A) Acquired structural abnormalities
- CNS tumor or neoplasm (craniopharyngioma, glioma, pituitary adenoma, etc.)
- Cysts (Rathke cleft cyst or arachnoid cleft cyst)
- Surgery
- Radiation
- Chemotherapy
- CNS infection
- CNS infarction (e.g., Sheehan's syndrome)
- Inflammatory lesions (e.g., autoimmune hypohysitis)
- Infiltrative lesions (e.g., sarcoidosis, histiocytosis)
- Head trauma or traumatic brain injury
- Aneurysmal subarachnoid hemorrhage
- Panhypopituitarism

B) Congenital abnormalities
- Known genetic mutations in growth-hormone releasing hormone (GHRH) receptor, GH gene, GH receptor or pituitary transcription factors
- Optic nerve hypoplasia/septo-optic dysplasia
- Empty sella syndrome
- Ectopic posterior pituitary
- Pituitary aplasia/hypoplasia
- Pituitary stalk defect
- Anencephaly or prosencephaly
- Other mid-line defects
- Vascular malformations

Appendix B:

A) Congenital and acquired abnormalities that do not require adult testing
- Genetic
- 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
- Associated with brain structural defects
- Single central incisor
- Cleft lip/palate
- Perinatal insults

Appendix C:

A) Pituitary hormones (other than growth hormone)
- Adrenocorticotropic hormone (ACTH)
- Antidiuretic hormone (ADH)
- Follicle stimulating hormone (FSH)

- Luteinizing hormone (LH)
- Oxytocin
- Prolactin
- Thyroid stimulating hormone (TSH)