CareSource

PHARMACY POLICY STATEMENT
North Carolina Marketplace

DRUG NAME	Sogroya (somapacitan-beco)
BILLING CODE	Must use valid NDC code
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
STATUS	Prior Authorization Required

Sogroya (somapacitan-beco) was approved by the FDA on August 28, 2020 for adults with growth hormone deficiency. It is administered once weekly by injection under the skin. Growth hormone deficiency involves inadequate secretion of growth hormone from the pituitary gland.

Efficacy of Sogroya was established in a 34-week randomized, double-blind, placebo-controlled trial. At the end of the treatment period, patients in the weekly Sogroya group experienced a decrease in truncal fat by 1.06%, patients taking placebo experienced truncal fat increase by 0.47%, and patients in the daily somatropin group experienced truncal fat decrease by 2.23%.

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 eighteen years of age or older;
2. Medication must be prescribed by an endocrinologist; AND
3. Member must have a diagnosis of GHD confirmed by **one** of the following:
   a) Two pre-treatment stimulation tests with a peak serum growth hormone concentration < 5 µg/mL (must include lab results with reference ranges), unless Macrilen (prior authorization required) was used, in which case a GH level must be < 2.8 ng/ml; OR
   b) One pre-treatment stimulation test with a peak serum growth hormone concentration < 5 µg/mL (must include lab results with reference ranges) AND one of the following:
      i) Documentation of structural abnormalities of the growth hormone axis (see appendix)
      ii) Documentation of childhood-onset GHD due to congenital abnormalities of the growth hormone axis (see appendix)
      iii) Documentation of at least two other pituitary growth hormone deficiencies (see appendix)
4. Member must have a 90-day trial of Omnitrope 5.8 mg vial which was documented as ineffective, or contraindicated.
5. **Dosage allowed/Quantity limit:** Initial dose of 1.5mg once weekly given subcutaneously, not to exceed 8 mg once weekly

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

For **reauthorization**:
Sogroya will be reauthorized when chart notes show all of the following:
1. Member must be in compliance with all of the initial criteria; AND
2. Member's current IGF-1 level not elevated for age/gender (does not apply to members w/ structural abnormality of hypothalamus/pituitary and at least pituitary hormone deficiencies or childhood onset GHD and congenital abnormality of hypothalamus/pituitary).

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

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

References:

1. Sogroya [package insert]. Plainsboro, NJ: Novo Nordisk, Inc; August 2020
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. 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

Effective date: 04/01/2023
Creation date: 10/13/2021

Appendix:

1) 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

2) 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

3) Pituitary hormones, other than growth hormone (GH)
    - Adrenocorticotropic hormone (ACTH)
    - Antidiuretic hormone (ADH)
    - Follicle stimulating hormone (FSH)
    - Luteinizing hormone (LH)
    - Oxytocin
    - Prolactin
    - Thyroid stimulating hormone (TSH)