Clinical Criteria

Subject:	Sogroya (somapacitan-beco)		
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Overview

This document addresses the use of Sogroya (somapacitan-beco) for the treatment of growth hormone deficiency in adults. Sogroya is a growth hormone analog with an albumin binding moiety. It is administered subcutaneously once weekly compared to somatropin which is administered subcutaneously once per day.

Sogroya was approved based on the REAL 1 trial which was designed to show superiority against placebo. While there was a somatropin arm, the study did not make statistical comparisons between Sogroya and somatropin and those receiving daily somatropin were not blinded. The REAL 1 trial showed a reduction in truncal fat percentage Sogroya compared to placebo at week 34.

Dosage of Sogroya for most patients should be initiated at 1.5 mg per week. The dose should be increased every 2-4 weeks by 0.5 mg – 1.5 mg until desired response is achieved. The dose should be based on clinical response and serum insulin-like growth factor 1 (IGF-1) concentrations. The maximum recommended dosage is 8 mg once weekly. The Sogroya prefilled pen dials in 0.05 mg increments and delivers doses from 0.05 mg to 4 mg. The prefilled pens are supplied in one size – 10 mg/1.5 mL.

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.

Sogroya (somapacitan-beco)

Requests for Sogroya (somapacitan-beco) may be approved if the following criteria are met:

I. Individual is 18 years of age or older; AND
II. Individual has documented growth hormone deficiency (GHD), also known as somatropin deficiency syndrome, in childhood; OR
III. Individual has documented 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 reconfirmed at 12 months after the event);

AND

IV. GHD is confirmed or reconfirmed by any of the following:
   A. A documented 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

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B. Subnormal response to one stimulation test for adults with documented hypothalamic or pituitary disease *and* one or more additional pituitary hormone deficits; OR

C. Documented presence of at least three other pituitary hormone deficiencies (that is, growth hormone stimulation tests are not required in this subgroup of individuals).

Quantity Limits

Sogroya (somapacitan-beco) Quantity Limits

Drug	Limit
Sogroya (somapacitan-beco) 10 mg/1.5 mL prefilled pen	4 pens per 28 days

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

J3590	Unclassified biologics (when specified as [Sogroya (somapacitan-beco)]

ICD-10 Diagnosis

All Diagnosis

Document History

New: 11/20/2020

Document History:

- 11/20/2020 – Select Review: Add new clinical criteria document for Sogroya; added step therapy for Sogroya; added quantity limit for Sogroya. Coding Review: Added HCPCS J3590, All diagnosis codes pend.

References

1. Johannsson G, Gordon MB, Højby Rasmussen M, 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;105(4):e1358-e1376. doi:10.1210/clinem/dgaa049 Available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7076631/. Accessed October 8, 2020.
2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2020. URL: http://www.clinicalpharmacology.com. Updated periodically.
3. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: October 8, 2020.
4. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
5. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2020; Updated periodically.

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.