

Effective date: 03/01/2023
Reviewed: 12/2023
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. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review for both initial and continuation or therapy requests (where applicable):

- A. Medical records supporting the diagnosis of neonatal GH deficiency
- B. Pretreatment growth hormone provocative test result(s) (laboratory report or medical record documentation)
- C. Growth chart
- D. Pretreatment and/or current IGF-1 level (laboratory report or medical record documentation)*
- E. The following information must be provided for all continuation of therapy requests:
 1. Total duration of treatment (approximate duration is acceptable)
 2. Date of last dose administered
 3. Approving health plan/pharmacy benefit manager
 4. Date of prior authorization/approval
 5. Prior authorization approval letter

* IGF-1 levels vary based on the laboratory performing the analysis. Laboratory-specific values must be provided to determine whether the value is within the normal range.

III. PRESCRIBER SPECIALTIES

Therapy must be prescribed by or in consultation with any of the following specialists:

- A. Endocrinologist
- B. Pediatric endocrinologist

IV. CRITERIA FOR INITIAL APPROVAL

A. Pediatric Growth Hormone (GH) Deficiency

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

1. 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. Member has had a treatment failure with at least 2 daily growth hormone products (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 adult GH deficiency when ANY of the following criteria is met:

1. 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/m² and a high pretest probability of GHD (e.g., acquired structural abnormalities) OR a BMI < 25 kg/m²
 - d. Glucagon stimulation test with a peak GH level ≤ 1.0 ng/mL in patients with a BMI of ≥ 25 kg/m² and a low pretest probability of GHD (e.g., acquired structural abnormalities) OR a BMI > 30 kg/m²
 - ii. Member has a low pretreatment IGF-1 (between 0 to 2 SD below the mean for age and gender)
2. 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/m² and a high pretest probability of GHD (e.g., acquired structural abnormalities) OR a BMI < 25 kg/m²
- d. Glucagon stimulation test with a peak GH level ≤ 1.0 ng/mL in patients with a BMI of ≥ 25 kg/m² and a low pretest probability of GHD (e.g., acquired structural abnormalities) OR a BMI > 30 kg/m²
- ii. Member has a pretreatment IGF-1 level that is more than 2 SD below the mean for age and gender
- 3. 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. Member has genetic or structural hypothalamic-pituitary defects (refer to Appendix C)
- 5. Member has childhood-onset GH deficiency and a congenital abnormality of the CNS, hypothalamus or pituitary (refer to Appendix C)

V. CONTINUATION OF THERAPY

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. Epiphyses are open (confirmed by X-ray or X-ray is not available)
- 2. 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. 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/m² and a high pretest probability of GHD (e.g., acquired structural abnormalities) OR a BMI < 25 kg/m²
 - d. Glucagon stimulation test with a peak GH level ≤ 1.0 ng/mL in patients with a BMI of ≥ 25 kg/m² and a low pretest probability of GHD (e.g., acquired structural abnormalities) OR a BMI > 30 kg/m²
 - 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. 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/m² and a high pretest probability of GHD (e.g., acquired structural abnormalities) OR a BMI < 25 kg/m²
 - d. Glucagon stimulation test with a peak GH level ≤ 1.0 ng/mL in patients with a BMI of ≥ 25 kg/m² and a low pretest probability of GHD (e.g., acquired structural abnormalities) OR a BMI > 30 kg/m²
- 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. 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. 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. 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

VI. 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. Adrenocorticotrophic 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 (PTT-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

VII. REFERENCES

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