Reference number(s)
4210-A

SPECIALTY GUIDELINE MANAGEMENT

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 Indication
Sogroya is indicated for the replacement of endogenous growth hormone (GH) in adults with growth hormone deficiency (GHD).

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

II. REQUIRED DOCUMENTATION

The following information is necessary to initiate the prior authorization review for both initial and continuation or therapy requests, if applicable:
A. Pretreatment pharmacologic provocative tests
B. Pretreatment and/or current IGF-1 level*

* 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. CRITERIA FOR INITIAL APPROVAL

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:
A. Member meets both of the following:
    1. 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 (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
    2. Member has a low pre-treatment IGF-1 (between 0 to 2 SD below the mean)
B. Member meets both of the following:
    1. 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

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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

2. Member has a pretreatment IGF-1 level that is more than 2 SD below the mean

C. 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 A) and a low pre-treatment IGF-1 more than 2 standard deviations below the mean for age and gender
D. Member has genetic or structural hypothalamic-pituitary defects (refer to Appendix B)
E. Member has childhood-onset GH deficiency and a congenital abnormality of the CNS, hypothalamus or pituitary (refer to Appendix B)

IV. CONTINUATION OF THERAPY

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

A. Member meets all of the following:
1. 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 (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
2. Member has a low pre-treatment IGF-1 (between 0 to 2 SD below the mean)
3. Current IGF-1 level is not elevated for age and gender

B. Member meets all of the following:
1. 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
2. Member has a pretreatment IGF-1 level that is more than 2 SD below the mean
3. Current IGF-1 level is not elevated for age and gender

C. Member meets both of the following:
1. 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 A) and a low pre-treatment IGF-1 more than 2 standard deviations below the mean for age and gender
2. Current IGF-1 level is not elevated for age and gender

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D. Member has genetic or structural hypothalamic-pituitary defects (refer to Appendix B) and current IGF-1 level is not elevated for age and gender
E. Member has childhood-onset GH deficiency and a congenital abnormality of the CNS, hypothalamus or pituitary (refer to Appendix B) and current IGF-1 level is not elevated for age and gender

V. APPENDICES

A. Appendix A: 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

B. Appendix B: 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 hypophsitis (primary or secondary)
      xix. Sarcoidosis
      xx. Tuberculosis
      xxi. Amyloidosis
   b. Surgery to the sella, suprasellar, and parasellar region
   c. Cranial irradiation

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d. Central nervous system infections (bacteria, viruses, fungi, parasites)
e. Infarction/hemorrhage (e.g., apoplexy, Sheehan's syndrome)
f. Empty sella
g. Hydrocephalus
h. Idiopathic

VI. REFERENCES

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