Reference number(s)
C26448-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 Indications[1]

A. 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. CRITERIA FOR INITIAL APPROVAL

A. **Pediatric Growth Hormone (GH) Deficiency**[1,3,8-13,15]
Authorization of 12 months may be granted to members with pediatric GH deficiency 2.5 years of age or older when EITHER criteria 1. or 2. below is met:
    1. 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).
    2. 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

1.

IV. 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[1,3] (confirmed by X-ray or X-ray is not available[14])
2. Member's growth rate is > 2 cm/year[3,10] 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)[11,14]

V. APPENDICES

A. Appendix A: Examples of Hypothalamic/Pituitary/CNS Disorders [4,7,12,16]

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

VI. REFERENCES

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14. Deal C, Hasselmann C, Pfaffle RW, et al. Associations between pituitary imaging abnormalities and clinical and biochemical phenotypes in children with congenital growth hormone deficiency: data from an international observational study. *Horm Res Paediatr.* 2013;79:283-292.