AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name:	Sogroya	Page:	1 of 9
Effective Date:	5/19/2026	Last Review Date:	4/2026
Applies to:	☐Illinois ☒New Jersey ☐Pennsylvania Kids	☐Florida ☒Maryland ☐Virginia	☐Florida Kids ☐Michigan ☐Kentucky PRMD

Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Sogroya under the patient's prescription drug benefit.

Description:

FDA-approved Indications[1]

- Sogroya is indicated for the treatment of pediatric patients aged 2.5 years and older with:
  - Growth failure due to inadequate secretion of endogenous growth hormone (GH).
  - Short stature born small for gestational age (SGA) and with no catch-up growth by 2 years of age.
  - Growth failure associated with Noonan syndrome (NS).
  - Idiopathic Short Stature (ISS) (may not be covered by some plans).
- Sogroya is indicated for the replacement of endogenous growth hormone in adults with growth hormone deficiency (GHD).

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

Applicable Drug List:

Sogroya

Policy/Guideline:

Formulary Preferencing
The patient is unable to take Norditropin, the preferred formulary alternative for the given diagnosis, due to a trial and inadequate treatment response or intolerance, or a contraindication.

Documentation
Submission of the following information is necessary to initiate the prior authorization review (where applicable):

Initial requests

- Growth chart, chart notes, or medical record documentation showing height and growth velocity.

- Laboratory test result or medical record documentation of pretreatment insulin-like growth factor-1 (IGF-1) level with laboratory specific values in order to determine whether the value is within the normal range (where applicable).
- Laboratory test, medical record documentation, or imaging report supporting the diagnosis of neonatal or childhood-onset growth hormone (GH) deficiency (where applicable).
- Laboratory test or medical record documentation of pretreatment provocative growth hormone test result(s) (where applicable).

Continuation requests

- Growth chart, chart notes, or medical record documentation showing height and growth velocity relative to population mean for age and gender.
- Laboratory test result or medical record documentation of current insulin-like growth factor-1 (IGF-1) level with laboratory specific values in order to determine whether the value is within the normal range (where applicable).
- Total duration of treatment (approximate duration is acceptable).
- Date of last dose administered.
- Approving health plan/pharmacy benefit manager.
- Date of prior authorization/approval.
- Prior authorization approval letter.

Coverage Criteria

Pediatric Growth Hormone Deficiency (GHD)[1,3,6-9]

Authorization of 12 months may be granted to members 2.5 years of age or older with pediatric growth hormone deficiency (GHD) when EITHER of the following criteria is met:

- Member has a documented diagnosis of GHD as a neonate (e.g., hypoglycemia with random GH level, evidence of multiple pituitary hormone deficiency, magnetic resonance imaging [MRI] results).
- Member meets ALL of the following criteria:
  - Member has either of the following:
    - Two pretreatment pharmacologic provocative GH tests with both results demonstrating a peak GH level < 10 ng/mL
    - A documented pituitary or central nervous system (CNS) disorder (see Appendix A) and a pretreatment IGF-1 level > 2 standard deviations (SD) below the mean
  - Member meets either of the following:
    - Pretreatment height is > 2 SD below the mean and 1-year height velocity is > 1 SD below the mean
    - Pretreatment 1-year height velocity is > 2 SD below the mean

- Epiphyses are open

Idiopathic Short Stature (ISS) (may not be covered by some plans)[1,7-9,11,14]

Authorization of 12 months may be granted to members 2.5 years of age or older with idiopathic short stature (ISS) when ALL of the following criteria are met:

- Pretreatment height is > 2.25 SD below the mean
- Predicted adult height is < 5'3" for boys and < 4'11" for girls
- Pediatric GH deficiency has been ruled out with a provocative GH test (peak GH level ≥ 10 ng/mL)[8]
- Epiphyses are open

Small for Gestational Age (SGA)[1,3,14,15]

Authorization of 12 months may be granted to members 2.5 years of age or older born small for gestational age (SGA) when ALL of the following criteria are met:

- Member meets one of the following criteria:
  - Birth weight < 2500 g at gestational age > 37 weeks
  - Birth weight or length ≥ 2 SD below the mean for gestational age
- Pretreatment age is ≥ 2 years
- Member failed to manifest catch-up growth by age 2 (i.e., pretreatment height > 2 SD below the mean)
- Epiphyses are open

Noonan Syndrome[14,16]

Authorization of 12 months may be granted to members 2.5 years of age or older with Noonan syndrome when BOTH of the following criteria are met:

- Member has either of the following:
  - Pretreatment height is > 2 SD below the mean and 1-year height velocity is > 1 SD below the mean
  - Pretreatment 1-year height velocity is > 2 SD below the mean
- Epiphyses are open

Adult Growth Hormone Deficiency (GHD)[1,17,18]

Authorization of 12 months may be granted to members with adult growth hormone deficiency (GHD) when ANY of the following criteria is met:

- Member has documented childhood-onset GHD due to a congenital genetic abnormality or structural brain defect of the CNS, hypothalamus, or pituitary (see Appendix A)[18,24,25,D]
- Member meets both of the following criteria:

- Member has had 2 pretreatment pharmacologic provocative GH tests and both results demonstrated deficient GH responses defined as any of the following:
  - Insulin tolerance test (ITT) with a peak GH level ≤ 5 ng/mL
  - Macrilen with a peak GH level < 2.8 ng/mL
  - 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
  - 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
- Member has a pretreatment IGF-1 level 0 to 2 SD below the mean for age and gender

- Member meets both of the following criteria:
  - Member has had 1 pretreatment pharmacologic provocative GH test that demonstrated deficient GH responses defined as any of the following:
    - Insulin tolerance test (ITT) with a peak GH level ≤ 5 ng/mL
    - Macrilen with a peak GH level < 2.8 ng/mL
    - 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
    - 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
  - Member has a pretreatment IGF-1 level > 2 SD below the mean for age and gender
- Member meets both of the following criteria:
  - Member has organic hypothalamic-pituitary disease (e.g., suprasellar mass with previous surgery and cranial irradiation) with ≥ 3 documented pituitary hormone deficiencies (i.e., adrenocorticotropic hormone [ACTH], antidiuretic hormone [ADH], follicle stimulating hormone, [FSH], luteinizing hormone [LH], thyroid stimulating hormone [TSH], prolactin)
  - Member has a pretreatment IGF-1 level > 2 SD below the mean for age and gender

Continuation of Therapy

Pediatric Growth Hormone Deficiency (GHD), Idiopathic Short Stature (ISS), Small for Gestational Age (SGA), Noonan Syndrome (NS)[1,3,6-9,11,14]

Authorization of 12 months may be granted for continuation of therapy for pediatric GHD, ISS, SGA, or NS when ALL of the following criteria are met:

- Member is currently receiving the requested medication or another growth hormone product (e.g., Norditropin) indicated for pediatric GHD, ISS, SGA, or NS
- Epiphyses are open (confirmed by X-ray or X-ray is not available)
- 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)

Adult Growth Hormone Deficiency (GHD)[1-7]

Authorization of 12 months may be granted for continuation of therapy for adult growth hormone deficiency (GHD) when BOTH of the following criteria are met:

- Member is currently receiving the requested medication or another growth hormone product (e.g., Norditropin) indicated for adult GHD
- Member meets ANY of the following criteria:
  - Current IGF-1 level is not elevated for age and gender
  - Member has organic hypothalamic-pituitary disease (e.g., suprasellar mass with previous surgery and cranial irradiation) with ≥ 3 documented pituitary hormone deficiencies (i.e., adrenocorticotropic hormone [ACTH], antidiuretic hormone [ADH], follicle stimulating hormone, [FSH], luteinizing hormone [LH], thyroid stimulating hormone [TSH], prolactin)
  - Member has genetic or congenital structural hypothalamic-pituitary defects (see Appendix A)
  - Member has childhood-onset GH deficiency and a congenital abnormality of the CNS, hypothalamus, or pituitary (see Appendix A)

Appendix

Appendix A: Examples of Hypothalamic/Pituitary/CNS Disorders[19,20]

- Congenital genetic abnormalities
  - Transcription factor defects (PIT-1, PROP-1, LHX3/4, HESX-1, PITX-2)
  - Growth hormone releasing hormone (GHRH) receptor gene defects
  - GH secretagogue receptor gene defects
  - GH gene defects
- Congenital structural abnormalities
  - Optic nerve hypoplasia/septo-optic dysplasia

  - Agenesis of corpus callosum
  - Empty sella syndrome
  - Ectopic posterior pituitary
  - Pituitary aplasia/hypoplasia
  - Pituitary stalk defect
  - Holoprosencephaly
  - Encephalocele
  - Hydrocephalus
  - Anencephaly or prosencephaly
  - Arachnoid cyst
  - Other mid-line facial defects (e.g., single central incisor, cleft lip/palate)
  - Vascular malformations
- Acquired structural abnormalities (or causes of hypothalamic/pituitary damage)
  - CNS tumors/neoplasms (e.g., craniopharyngioma, glioma/astrocytoma, pituitary adenoma, germinoma)
  - Cysts (Rathke cleft cyst or arachnoid cleft cyst)
  - Surgery
  - Radiation
  - Chemotherapy
  - CNS infections
  - CNS infarction
  - Inflammatory processes (e.g., autoimmune hypophysitis)
  - Infiltrative processes (e.g., sarcoidosis, histiocytosis, hemochromatosis)
  - Head trauma/traumatic brain injury
  - Aneurysmal subarachnoid hemorrhage
  - Perinatal or postnatal trauma
  - Surgery of the pituitary or hypothalamus

Appendix B: Requirements for GH-Stimulation Testing in Adults[1,5]

- Testing for adult GHD is not required
  - Three or more pituitary hormone deficiencies and low IGF-1
  - Congenital structural abnormalities
- Transcription factor defects (PIT-1, PROP-1, LHX3/4, HESX-1, PITX-2)
- GHRH receptor-gene defects
- GH-gene defects associated with brain structural defects
- Single central incisor
- Cleft lip/palate
  - Acquired causes such as perinatal insults
- Testing for adult GHD is required
  - Acquired

- Skull-base lesions
- Pituitary adenoma
- Craniopharyngioma
- Rathke's cleft cyst
- Meningioma
- Glioma/astrocytoma
- Neoplastic sellar and parasellar lesions
- Chordoma
- Hamartoma
- Lymphoma
- Metastases
- Other brain injury
- Traumatic brain injury
- Sports-related head trauma
- Blast injury
- Infiltrative/granulomatous disease
- Langerhans cell histiocytosis
- Autoimmune hypophysitis (primary or secondary)
- Sarcoidosis
- Tuberculosis
- Amyloidosis

- Surgery to the sella, suprasellar, and parasellar region
- Cranial irradiation
- Central nervous system infections (bacteria, viruses, fungi, parasites)
- Infarction/hemorrhage (e.g., apoplexy, subarachnoid hemorrhage, ischemic stroke, snake bite)
- Empty sella
- Hydrocephalus
- Idiopathic

Approval Duration and Quantity Restrictions:

Initial and Renewal Approval: 12 months

Quantity Level Limit: 4 pens per 28 days

References:

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