



AETNA BETTER HEALTH®
Coverage Policy/Guideline

Name: Skytrofa Page: 1 of 7

Effective Date: 11/12/2025 Last Review Date: 10/2025

Applies to:	<input checked="" type="checkbox"/> Illinois	<input type="checkbox"/> Florida	<input type="checkbox"/> Florida Kids
	<input type="checkbox"/> New Jersey	<input type="checkbox"/> Maryland	<input type="checkbox"/> Michigan
	<input type="checkbox"/> Pennsylvania Kids	<input type="checkbox"/> Virginia	<input type="checkbox"/> Kentucky PRMD

Intent:

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

Description:

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 Indications¹

- Skytrofa is indicated for the treatment of pediatric patients 1 year and older who weigh at least 11.5 kg and have growth failure due to inadequate secretion of endogenous growth hormone (GH).
- Skytrofa 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.

Applicable Drug List:

Skytrofa

Policy/Guideline:

Documentation

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

Both initial and continuation of therapy requests:

- Growth chart
- Pretreatment or current insulin-like growth factor-1 (IGF-1) level (laboratory report or medical record documentation)

Initial requests:

- Support for the diagnosis of neonatal growth hormone (GH) deficiency (medical documentation, laboratory report, or imaging report)
- Pretreatment growth hormone provocative test result(s) (laboratory report or medical record documentation)



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Continuation of therapy requests:

- 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

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.

Coverage Criteria

Pediatric Growth Hormone (GH) Deficiency¹⁻⁶

Authorization of 12 months may be granted to members 1 year of age and older with pediatric growth hormone (GH) deficiency when EITHER of the following criteria is met:

- Member has a documented diagnosis of GH deficiency 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
 - For members < 2.5 years of age at initiation of treatment, the pretreatment height is > 2 SD below the mean and growth velocity is slow
 - For members ≥ 2.5 years of age at initiation of treatment, 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 (GH) Deficiency^{1,2,7,8}

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

- Member meets both of the following criteria:



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- 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/m² and a high pretest probability of GHD (e.g., acquired structural abnormalities) OR a BMI < 25 kg/m²
 - 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
- 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/m² and a high pretest probability of GHD (e.g., acquired structural abnormalities) OR a BMI < 25 kg/m²
 - 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
 - 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 (see Appendix B)
 - Member has a pretreatment IGF-1 level > 2 SD below the mean for age and gender
- Member has genetic or congenital structural hypothalamic-pituitary defects (see Appendix C)
- Member has childhood-onset GH deficiency and a congenital abnormality of the CNS, hypothalamus, or pituitary (see Appendix C)



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Continuation of Therapy

Pediatric Growth Hormone (GH) Deficiency

Authorization of 12 months may be granted for continuation of therapy for pediatric growth hormone (GH) deficiency 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 GH deficiency
- Epiphyses are open^{1,2} (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 (GH) Deficiency

Authorization of 12 months may be granted for continuation of therapy for adult growth hormone (GH) deficiency 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 GH deficiency
- 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 (see Appendix B)
 - Member has genetic or congenital structural hypothalamic-pituitary defects (see Appendix C)
 - Member has childhood-onset GH deficiency and a congenital abnormality of the CNS, hypothalamus, or pituitary (see Appendix C)

Appendix

Appendix A: Examples of Hypothalamic/Pituitary/CNS Disorders⁹

- 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



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- 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: Pituitary Hormones (Other than Growth Hormone)

- Adrenocorticotrophic hormone (ACTH)
- Antidiuretic hormone (ADH)
- Follicle stimulating hormone (FSH)
- Luteinizing hormone (LH)
- Thyroid stimulating hormone (TSH)
- Prolactin

Appendix C: Requirements for GH-Stimulation Testing in Adults⁸

- 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



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- 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:



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- Skytrofa (lonapegsomatropin-tcgd): 4 cartridges per 28 days

References:

1. Skytrofa [package insert]. Princeton, NJ: Ascendis Pharma Endocrinology, Inc.; July 2025.
2. Gharib H, Cook DM, Saenger PH, et al. American Association of Clinical Endocrinologists Growth Hormone Task Force. Medical guidelines for clinical practice for growth hormone use in adults and children 2003 Update. *Endocr Pract.* 2003;9(1):64-76.
3. National Institute for Clinical Excellence: Guidance on the use of human growth hormone (somatropin) for the treatment of growth failure in children. May 2010. <http://www.nice.org.uk/guidance/ta188>. Accessed January 14, 2025.
4. Wilson TA, Rose SR, Cohen P, et al. Update of Guidelines for the Use of Growth Hormone in Children: The Lawson Wilkins Pediatric Endocrinology Society Drug and Therapeutics Committee. *J Pediatr.* 2003;143:415-421.
5. Franklin SL, Geffner ME. Growth hormone: the expansion of available products and indications. *Pediatr Clin North Am.* 2011;58:1141-1165.
6. Grimberg A, DiVall SA, Polychronakos C, et al. Guidelines for growth hormone and insulin-like growth factor-I treatment in children and adolescents: growth hormone deficiency, idiopathic short stature, and primary insulin-like growth factor-I deficiency. *Horm Res Paediatr.* 2016;86:361-397.
7. Molitch ME, Clemmons DR, Malozowski S, et al. Evaluation and treatment of adult growth hormone deficiency: an Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab.* 2011;96:1587-1609.
8. Yuen KCJ, Biller BMK, Radovick S, et al. American Association of Clinical Endocrinologists and American College of Endocrinology Guidelines for management of growth hormone deficiency in adults and patients transitioning from pediatric to adult care. *Endocr Pract.* 2019; 25: 1191-1232.
9. 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.