CareSource

PHARMACY POLICY STATEMENT **Indiana Medicaid**	
DRUG NAME	Saizen (somatropin)
BILLING CODE	Must use valid NDC code
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
COVERAGE REQUIREMENTS	Prior Authorization Required (Non-Preferred Product) QUANTITY LIMIT— per diagnosis, see **Dosage allowed**
LIST OF DIAGNOSES CONSIDERED **NOT** MEDICALLY NECESSARY	Click Here

Saizen (somatropin) is a **non-preferred** product and will only be considered for coverage under the **pharmacy** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

Adult GROWTH HORMONE DEFICIENCY (GHD) - Adult or Childhood Onset

For **initial** authorization:

1. Member must have a documented 90-day trial and failure of Omnitrope 5.8 mg vial; AND
2. Member is 18 years of age or older; AND
3. Medication must be prescribed by an endocrinologist; AND
4. Member must have a diagnosis of GHD confirmed by **one** of the following:
   a) Chart notes documentation of acquired structural abnormality (*see Appendix*) of the hypothalamus or pituitary and ≥ 3 documented pituitary hormone deficiencies (*see Appendix*) with included lab results and reference ranges;
   b) Documented childhood-onset of GHD with a documented congenital abnormality (*see Appendix*) of the hypothalamus or pituitary;
   c) Two pre-treatment peak serum growth hormone (GH) concentration < 5 ng/mL by stimulation testing with included lab results and reference ranges, unless Macrilen (prior authorization required) was used, in which case a GH level must be < 2.8 ng/ml.
5. **Dosage allowed:** Weight based dosing: 0.005 mg/kg/day initially; can be increased as tolerated to not more than 0.01 mg/kg/day after 4 weeks. Non-weight based dosing: starting dose 0.2 mg/day (0.15-0.30 mg/day) and increased every 1-2 months in increments of 0.1-0.2 mg/day, doses vary considerably.

If member meets all the requirements listed above, the medication will be approved for 12 months.

For **reauthorization**:

1. Member must be in compliance with all of the initial criteria; AND
2. Member's current IGF-1 level not elevated for age/gender (does not apply to members w/ structural abnormality of hypothalamus/pituitary and at least pituitary hormone deficiencies or childhood onset GHD and congenital abnormality of hypothalamus/pituitary).

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

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Pediatric GROWTH HORMONE DEFICIENCY (GHD)

For **initial** authorization:

1. Member must have a documented 90-day trial and failure of Omnitrope 5.8 mg vial; AND
2. Member is 17 years old or younger; AND
3. Medication must be prescribed by an endocrinologist; AND
4. Member must have a diagnosis of GHD confirmed by **one** of the following:
   a) Neonate or diagnosed with GHD as neonate indicated by ALL of the following:
      i) Chart notes, labs, and documentation must be included to support the diagnosis (e.g, hypoglycemia with random GH level ≤ 5 ng/mL, evidence of multiple pituitary hormone deficiency (*see Appendix*), MRI results);
      ii) Pituitary abnormality (secondary to congenital anomaly (*see Appendix*), pituitary tumor, or irradiation);
      iii) A known deficiency of at least one other pituitary hormone (*see Appendix*);
   b) Two pre-treatment peak serum growth hormone concentration < 10 ng/mL by stimulation testing (*must include lab results with reference ranges*);
   c) A documented pituitary or CNS disorder and a pre-treatment IGF-1 level > 2 Standard Deviations (SD) below the mean (*must include chart notes and documentation to confirm diagnosis and lab results with reference ranges*); AND
5. Member must have a pretreatment height (*must include growth charts*) of > 2 SD below the mean for age and gender; AND
6. If member is age 12 or older, radiographic evidence the member's epiphyses are open (*x-ray results must be included*). Comparison of bone age to chronological age should be documented as abnormal by > 2 SD below the mean for chronological age.
7. **Dosage allowed:** 0.18 mg/kg/week.

If member meets all the requirements listed above, the medication will be approved for 12 months.

For **reauthorization**:

1. Member must be in compliance with all of the initial criteria; AND
2. If member is age 12 or older, radiographic evidence the member's epiphyses are open (*x-ray results must be included*). Comparison of bone age to chronological age should be documented as abnormal by > 2 SD below the mean for chronological age; AND
3. Member has a growth rate > 2.5 cm/year unless there is a documented reason for lack of efficacy (on treatment < 1 year, off treatment for a reason for a period of time, nearing final adult height, late stages of puberty).

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

CareSource considers Saizen (somatropin) not medically necessary for the treatment of the following disease states based on a lack of robust clinical controlled trials showing superior efficacy compared to currently available treatments:

- Constitutional growth delay
- Corticosteroid-induced growth failure
- Cystic fibrosis
- Idiopathic, or non-growth hormone dependent, short stature
- Juvenile idiopathic, or chronic, arthritis
- Noonan Syndrome
- Obesity

- Partial growth hormone deficiency
- Pediatric growth failure due to chronic kidney disease
- Prader-Willi Syndrome
- SHOX deficiency
- Small for Gestational Age
- Turner Syndrome
- Wound healing in burns patients

DATE	ACTION/DESCRIPTION
10/25/2018	New policy for Saizen created.

References:

1. Saizen [prescribing information]. Rockland, MD: EMD Serono, Inc.; Revised December 2016.
2. Nemecheck PM, Polsky B, Gottlieb MS. Treatment Guidelines for HIV-associated wasting. May Clinc Proc. 2000; 27: 386-394.
3. Blum WF, Crowe BJ, Quigley CA, et al. Growth hormone in effective in treatment of short stature associated with short stature homeobox-containing gene deficiency: two-year results of a randomized, controlled, multicenter trial. J Clin Endocinol Metab. 2007; 92: 219-228.
4. Blum WF, Ross JL, Zimmermann Ag, et al. Growth hormone treatment to final height produces similar height gains in patients with SHOX deficiency and Tuner syndrome: results of a multicenter trial. J Clin Endocrinol Metab. 2013; 98 (8): 1383-1392.
5. Kirk J, Betts P, Butler G, et al. Short stature in Noonan syndrome: response to growth hormone therapy. Arch Dis Child. 2001; 84(5): 440-443.
6. Raynal P. Growth hormone and noonan syndrome: update in dysfunctional signaling aspects and in therapy for short stature.
7. Mahan JD, Warady BA. Assessment and treatment of short stature in pediatric patients with chronic kidney disease: a consensus statement. Pediatr Nephrol. 2006; 21(7): 917-930.
8. Romano AA, Allanson JE, Dahlgren J, et al. Noonan syndrome: clinical features, diagnosis, and management guidelines. Pediatrics 2010;126(4): 746-759
9. Clayton PE, Cianfarani S, Czernichow P, et al. Management of the Child Born Small for Gestational Age Through to Adulthood: A Consensus Statement of the International Societies of Pediatric Endocrinology and the Growth Hormone Research Society, J Clin Endrocrinol Metab. 2007; 92(3): 804-810.
10. Baxter L, Bryant J, Cave CB, Milne R. Recombinant growth hormone for children and adolescents with Turner syndrome.

Effective date: 05/01/2019
Revised date: 10/25/2018

Appendix:

1) Acquired structural abnormalities:
    - CNS tumor or neoplasm (craniopharyngioma, glioma, pituitary adenoma, etc.)
    - Cysts (Rathke cleft cyst or arachnoid cleft cyst)
    - Surgery
    - Radiation
    - Chemotherapy
    - CNS infection
    - CNS infarction (e.g., Sheehan's syndrome)
    - Inflammatory lesions (e.g., autoimmune hypohysitis)
    - Infiltrative lesions (e.g., sarcoidosis, histiocytosis)
    - Head trauma or traumatic brain injury
    - Aneurysmal subarachnoid hemorrhage
    - Panhypopituitarism

2) Congenital abnormalities:
    - Known genetic mutations in growth-hormone releasing hormone (GHRH) receptor, GH gene, GH receptor or pituitary transcription factors
    - Optic nerve hypoplasia/septo-optic dysplasia
    - Empty sella syndrome
    - Ectopic posterior pituitary
    - Pituitary aplasia/hypoplasia
    - Pituitary stalk defect
    - Anencephaly or prosencephaly
    - Other mid-line defects
    - Vascular malformations

3) Pituitary hormones, other than growth hormone (GH):
    - Adrenocorticotropic hormone (ACTH)
    - Antidiuretic hormone (ADH)
    - Follicle stimulating hormone (FSH)
    - Luteinizing hormone (LH)
    - Oxytocin
    - Prolactin
    - Thyroid stimulating hormone (TSH)