MEDICATION COVERAGE POLICY

PHARMACY AND THERAPEUTICS ADVISORY COMMITTEE

POLICY	Growth Disorders	**P & T DATE**	9/12/2023
THERAPEUTIC CLASS	Endocrine Disorders	**REVIEW HISTORY** (MONTH/YEAR)	11/22, 9/21, 09/20, 09/19, 09/18, 12/16, 11/15, 05/14
LOB AFFECTED	Medi-Cal		

This policy has been developed through review of medical literature, consideration of medical necessity, generally accepted medical practice standards, and approved by the HPSJ/MVHP Pharmacy and Therapeutic Advisory Committee.

Effective 1/1/2022, the Pharmacy Benefit is regulated by Medi-Cal Rx. Please visit https://medicalrx.dhcs.ca.gov/home/ for portal access, formulary details, pharmacy network information, and updates to the pharmacy benefit.
All medical claims require that an NDC is also submitted with the claim. If a physician administered medication has a specific assigned CPT code, that code must be billed with the correlating NDC. If there is not a specific CPT code available for a physician administered medication, the use of unclassified CPT codes is appropriate when billed with the correlating NDC.

OVERVIEW

Growth hormones (GH) are produced by the cells located in the anterior pituitary known as somatotropes. The predominant action of GH is to stimulate hepatic synthesis and secretion of insulin-like growth factor 1 (IGF-1), a potent growth and differentiation factor that responsible for most of the growth-promoting activities of GH. Growth hormones also play an important role in adult metabolism. A deficiency of GH in adults can affect lipid and bone metabolism, decrease strength and reduce work capacity.[1] Possible causes of growth disorders varies as they can be genetic, constitutional, or as a result of hormonal disorders. This review will examine the variety of growth-related disorders and their coverage criteria.

Table 1. Available Somatropin Agents:

CPT code	Generic Name (Brand Name)	Available Strengths	Pharmacy Benefit	Medical Benefit (Restrictions)
J2941	**Somatropin** (Genotropin)	5mg/ml, 12mg/ml	Yes	Yes (PA)
J2941	**Somatropin** (Genotropin Miniquick)	0.2mg/0.25ml, 0.4mg/0.25ml, 0.6mg/0.25ml, 0.8mg/0.25ml 1mg/0.25ml, 1.2mg/0.25ml, 1.4mg/0.25ml, 1.6mg/0.25ml, 1.8mg/0.25ml, 2mg/0.25ml	Yes	Yes (PA)
J2941	**Somatropin** (Humatrope)	5mg, 6mg, 12mg, 24mg	Yes	Yes (PA)
J2941	**Somatropin** (Norditropin Flexpro)	5mg/1.5ml, 10mg/1.5ml, 15mg/1.5ml, 30mg/3ml	Yes	Yes (PA)
J2941	**Somatropin** (Nutropin AQ Nuspin)	5mg/2ml, 10mg/2ml, 20mg/2mL	Yes	Yes (PA)
J2941	**Somatropin** (Omnitrope)	5mg/1.5ml, 10mg/1.5ml, 5.8mg	Yes	Yes (PA)
J2941	**Somatropin** (Saizen)	5mg, 8.8mg	Yes	Yes (PA)

J2941	**Somatropin** (Saizen Click-Easy)	8.8mg/1.5ml	Yes	Yes (PA)
J2941	**Somatropin** (Serostim)	4mg, 5mg, 6mg	Yes	Yes (PA)
J2941	**Somatropin** (Zomacton)	5mg, 10mg	Yes	Yes (PA)
J2941	**Somatropin** (Zorbitive)	8.8mg	Yes	Yes (PA)

PA = Prior Authorization

EVALUATION CRITERIA FOR APPROVAL/EXCEPTION CONSIDERATION

Below are the coverage criteria and required information for each agent. These coverage criteria have been reviewed approved by the HPSJ/MVHP Pharmacy & Therapeutics (P&T) Advisory Committee. For conditions not covered under this Coverage Policy, HPSJ/MVHP will make the determination based on Medical Necessity as described in HPSJ/MVHP Medical Review Guidelines (UM06).

Growth Hormone Agents (Somatropin)
Genotropin, Genotropin Miniquick, Humatrope, Norditropin Flexpro, Nutropin AQ, Nutropin AQ Nuspin, Omnitrope, Saizen, Saizen Click-Easy, Serostim, Zorbitive

Growth Hormone Deficiency (Children)/ Idiopathic Short-Stature/Turner Syndrome/Prader-Willi Syndrome

- ❒ **Coverage Criteria:** Somatropin is reserved for patients ≤18 years old with documented low IGF-1 AND height that is more than 2 standard deviation below the population mean for age and sex.
- ❒ **Limits:** None
- ❒ **Required Information for Approval:**
  - ○ Growth charts documenting patient's height and weight
  - ○ Labs showing low IGF-1
- ❒ **Other Notes:**
  - ○ Therapy is discontinued when bone age exceeds 14 years OR when growth velocity drops below 2.5 cm/year.
  - ○ Growth hormone supplementation is approved for 6 months at a time.

Growth Hormone Deficiency (Adults)

- ❒ Coverage Criteria; Somatropin is reserved for patients > 18 years old with documented low IGF-1 OR low insulin growth factor binding protein-3 with documented pituitary disease or GH deficiency (GHD) as a result of surgery or radiation therapy.
- ❒ **Limits:** None
- ❒ **Required Information for Approval:**
  - ○ Labs showing low IGF-1 (<5 mcg/L)
  - ○ Clinical documentation of mal-functioning pituitary gland (as a result from surgery, radiation therapy, etc)
- ❒ **Other Notes:** Growth hormone supplementation is approved for 6 months at a time.

CLINICAL JUSTIFICATION

GHD, Turner Syndrome, and idiopathic short stature are treated with growth hormone supplementation, but the treatment approaches vary. In Turner Syndrome or Idiopathic short stature, the 2009 American Academy of Endocrinology Guidelines recommend the discontinuation of growth hormone supplementation when the child reaches their peak height or when their bone age is similar to that of an adult since there is no proven benefit to continuing GH treatment in adulthood.[2] On the other hand, GHD is confirmed via the Insulin Tolerance Test (ITT).

Once growth hormone supplementation is initiated, monitoring of serum IGF-1 levels are recommended every 612 months. GH therapy is often long-term in adult patients with GHD.

All of the currently available growth hormone agents are somatropins. Although direct comparisons between different GH products have not been published and some differences exist in recommended doses, all GH products are generally considered to be equally efficacious. The guidelines do not recommend the use of one commercial product over another.[2]

REFERENCES

1. HPSJ Growth Hormone Class Review—May 2014. Guidelines for use of growth hormone in clinical practice. Endocr. Pract. 2009;15(Suppl 2).
2. Grimberg A., Divall S., 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.
3. 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(11):1191-1232.
4. SOGROYA® Prescribing Information. https://www.novo-pi.com/sogroya.pdf

REVIEW & EDIT HISTORY

Document Changes	Reference	Date	P&T Chairman
Creation of Policy	Growth Hormone Class Review 05-2015.doc	05/2014	Jonathan Szkotak, PharmD, BCACP
Update to Policy	HPSJ Coverage Policy - Endocrine - Growth Hormone 2015-10.docx	11/2015	Johnathan Yeh, PharmD
Update to Policy	HPSJ Coverage Policy - Endocrine - Growth Hormone 2016-12.docx	12/2016	Johnathan Yeh, PharmD
Update to Policy	HPSJ Coverage Policy - Endocrine - Growth Hormone 2018-09.docx	09/2018	Johnathan Yeh, PharmD
Update to Policy	Growth Hormone	09/2019	Matthew Garrett, PharmD
Update to Policy	Growth Hormone	09/2020	Matthew Garrett, PharmD
Review of Policy	Growth Hormone	09/2021	Matthew Garrett, PharmD
Review of Policy	Growth Hormone	11/2022	Matthew Garrett, PharmD
Review of Policy	Growth Hormone	09/2023	Matthew Garrett, PharmD

Note: All changes are approved by the HPSJ/MVHP P&T Committee before incorporation into the utilization policy