MASSACHUSETTS

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Pharmacy Medical Policy
Growth Hormone and Insulin-like Growth Factor

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Policy Number: 257

BCBSA Reference Number: 5.01.06

Related Policies

- N/A

Prior Authorization Information

Policy	☒ Prior Authorization ☐ Step Therapy ☒ Quantity Limit ☐ Administrative	Reviewing Department	**Pharmacy Operations:** Tel: 1-800-366-7778 Fax: 1-800-583-6289
		Policy Effective Date	**1/2025**
Pharmacy (Rx) or Medical (MED) benefit coverage	☒ Rx ☐ MED	**To request for coverage:** Providers may call, fax, or mail the attached form (Formulary Exception/Prior Authorization form) to the address below. **Blue Cross Blue Shield of Massachusetts** **Pharmacy Operations Department** 25 Technology Place Hingham, MA 02043 Tel: 1-800-366-7778 Fax: 1-800-583-6289 **Individual Consideration for the atypical patient:** Policy for requests that do not meet clinical criteria of this policy, see section labeled Individual Consideration	
Policy applies to Commercial Members: • Managed Care (HMO and POS), • PPO and Indemnity • MEDEX with Rx plan • Managed Major Medical with Custom BCBSMA Formulary • Comprehensive Managed Major Medical with Custom BCBSMA Formulary • Managed Blue for Seniors with Custom BCBSMA Formulary **Policy does NOT apply to**: • Medicare Advantage			

Summary

This is a comprehensive policy covering prior authorization requirements for Growth Hormones and Insulin-like Growth Factors.

Formulary status/requirements of the medications affected by this policy

Drug	Formulary Status (BCBSMA Commercial Plan)	Requirement	Additional Considerations
Formulary, Preferred			
Egrifta™ (tesamorelin)	Covered, PA	PA Required. See below for criteria. Supporting Documentation Required	
Genotropin ® (somatropin)			
Genotropin Miniquick ® (somatropin)			
Humatrope ® (somatropin)			
Increlex ® (mecasermin)			
Serostim ® (somatropin)			
Serostim ® LQ (somatropin)			
Zorbtive ® (somatropin)			
Formulary, Non-Preferred			
Skytrofa ™ (lonapegsomatropin-tcgd)	Covered, PA	Meet PA Criteria AND Trial and failure of ONE drug in step 1	*SPBO - Pharmacy benefit coverage only
Non-Formulary, Non-Preferred			
Ngenla ® (Somatrogon)	NFNC, PA	Meet PA criteria AND trial and failure of two covered formulary alternatives	
Norditropin ® (somatropin)			
Nutropin ® Depot (somatropin)			
Nutropin ® (somatropin)			
Nutropin AQ ® (somatropin)			
Omnitrope ® (somatropin)			
Saizen ® (somatropin)			
Saizenprep ® (somatropin)			
Sogroya ® (somapacitan)			
Zomacton ® (somatropin)			

PA – Prior Authorization; NFNC – Non-formulary, Non-Covered; SPBO – Specialty Pharmacy access

Policy

Length of Approval	12 months, unless otherwise specified
Formulary Status	All requests must meet the Prior Authorizations requirement. For non-covered medications, the member **must** also have had a previous treatment failure with, or contraindication to, **at least two** covered formulary alternatives when available. See section on individual consideration for more information if you require an exception to any of these criteria requirements for an atypical patient.
Member cost share consideration	A higher non-preferred cost share may be applied if an exception request is approved for coverage of a non-preferred or a non-formulary/non-covered drug.

Growth Hormones

Zorbtive

Zorbtive may be considered **MEDICALLY NECESSARY** and covered for 4 weeks of treatment when ALL of the below criteria are met:

1. Documented diagnosis of Short Bowel Syndrome; **AND**
2. Age ≥ 18 years; **AND**

3. Currently receiving specialized nutritional support such as dietary adjustments, enteral feedings, parenteral nutrition, or micronutrient supplementation.

Egrifta ™

Egrifta may be covered and considered **MEDICALLY NECESSARY** and covered when ALL of the below criteria are met:

1. Documented HIV infection; **AND**
2. Used for the reduction of excess abdominal fat due to lipodystrophy due to antiretroviral therapy

Serostim ™

Serostim may be covered and considered **MEDICALLY NECESSARY** and covered when ALL of the below criteria are met:

1. Documented HIV infection; **AND**
2. Wasting or cachexia to increase lean body mass and body weight, and improve physical endurance

Humatrope ®, Genotropin ®, Genotropin Miniquick ®

Initial Criteria

Humatrope and Genotropin may be covered and considered **MEDICALLY NECESSARY** for Any of the following indications:

1. Children with proven growth hormone deficiency (GHD)
2. Children with growth failure due to Prader-Willi syndrome, who do not have the following contraindications: history of upper airway obstruction or sleep apnea or severe respiratory impairment
3. Children with height below the 3rd percentile for chronologic age with chronic renal insufficiency
4. Children with Turner syndrome
5. Children and young adults with short stature due to Noonan syndrome
6. Children with short stature due to SHOX (short stature homeobox-containing gene) deficiency
7. Promotion of wound healing in patients with 3rd-degree burns
8. Prevention of growth delay in children with severe burns
9. Patients with HIV/AIDS wasting syndrome who meet all the following:

a. Weight loss of at least 10% from baseline weight or BMI<20 kg/m^2

b. Wasting syndrome rather than malnutrition, mental illness, endocrine disease, or other causes for weight loss

c. Concomitant anti-viral therapy for the duration of treatment

10. Patients with short bowel syndrome receiving specialized nutritional support in conjunction with optimal management of short bowel syndrome
11. Adults with proven growth hormone deficiency (GHD)*

Proven adult GHD Defined as:

- *An abnormal response to TWO provocative stimulation tests, such as L-dopa, clonidine, glucagon, arginine, growth hormone–releasing hormone (GH-RH), or insulin;* ***OR***
- *An abnormal response to ONE provocative stimulation test in patients with defined central nervous system pathology, history of irradiation, multiple pituitary hormone deficiency, or a genetic defect;* ***OR***
- *Low IGF-I concentration in patients with complete hypopituitarism*

Continuation Criteria For Pediatric Patients (Age < 18 Years)

Humatrope and Genotropin may be covered for continuation when ALL of the below criteria are met:

1. Open epiphyses (as determined within the last year by radiographic evidence), **AND**
2. No evidence of active neoplasm, **AND**
3. Growth velocity > 2cm/year, **AND**
4. Absence of significant side effects, **AND**
5. Compliance with therapy, **AND**
6. NOT used in combination with another somatropin agent (such as Serostim, Zorbtive or any other product covered by this policy).
7. **For Nutropin Depot:** Trial and failure or treatment-limiting adverse effects of formulary endogenous growth hormone (GH) products **Humatrope or Genotropin**

Norditropin ®, Nutropin ® or Nutropin AQ ®, Nutropin Depot ®, Omnitrope ®, Saizen ®, Saizenprep®, and Zomacton ®

Genotropin, Genotropin Miniquick, Norditropin, Omnitrope, Saizen, Saizenprep, and **Zomacton** may be covered and considered **MEDICALLY NECESSARY** only after treatment failure with, limiting side effects of, or contraindication to at least TWO formulary alternatives (see drug chart). Please see criteria for Humatrope and Genotropin above for all covered indications.

Long-Acting Growth Hormones

Skytrofa ™

Skytrofa may be considered **MEDICALLY NECESSARY** and covered when ALL of the following criteria met:

1. Age is greater than or equal to 1 years of age, **AND**
2. The child's weight is at least 11.5 kg (are25.3 Lbs.), **AND**
3. Epiphyses are confirmed to still be open, **AND**
4. Proven growth hormone deficiency, **AND**
5. Trial and failure or treatment-limiting adverse effects of formulary endogenous growth hormone (GH) products **Humatrope or Genotropin**

Ngenla ® and Sogroya ®

Ngenla or **Sogroya** may be considered **MEDICALLY NECESSARY** and covered when ALL of the following criteria met:

1. Age is greater than or equal to 1 years of age, **AND**
2. The child's weight is at least 11.5 kg (are25.3 Lbs.), **AND**
3. Epiphyses are confirmed to still be open, **AND**
4. Proven growth hormone deficiency, **AND**
5. Trial and failure or treatment-limiting adverse effects of formulary endogenous growth hormone (GH) products **two Formulary Growth Hormone products (Humatrope and Genotropin).**

Insulin-Like Growth Factors

Increlex ®

Increlex may be considered **MEDICALLY NECESSARY** and covered when ALL of the following criteria are met:

1. Documented diagnosis of growth failure in children with severe primary insulin-like growth factor-1 (IGF-1) deficiency (primary IGFD) OR with growth hormone (GH) gene deletion who have developed neutralizing antibodies to GH; **AND**
2. Height standard deviation score less than or equal to -3 for age and sex; **AND**
3. Basal IGF-1 standard deviation score less than or equal to -3 for age and sex; **AND**
4. Normal or elevated growth hormone (defined as stimulated serum GH peak level of greater than 10 ng/ml or basal (unstimulated) serum GH level greater than 5ng/ml).

BCBSMA does NOT cover **Insulin-like Growth Factor** for secondary forms of IGF-1 deficiency including (but not limited to):[23]

1. GH Deficiency
2. Malnutrition
3. Hypothyroidism
4. Chronic treatment with pharmacologic doses of anti-inflammatory steroids.

Non-Covered Indications for Growth Hormone

The following indications approved by the Food and Drug Administration are considered NOT **MEDICALLY NECESSARY** and therefore not covered:

1. Pediatric patients born small for gestational age who fail to show catch-up growth by age 2 years
2. Children with height standard deviation score of -2.25 or below without documented growth hormone deficiency (Idiopathic short stature).

Other Non-Covered Indications:

1. Children with familial short stature[11] (ie, lower than expected height percentiles based on parents' height)
2. Growth hormone insensitivity (Laron Syndrome)[5]
3. Children with constitutional growth delay[22]
4. Children with growth failure caused by glucocorticoids[22]
5. Children who are not growth hormone deficient but have short stature associated with chronic disease[11]
6. Children with functioning renal transplants
7. Children with chromosomal and genetic disorders[11] including Russell Silver syndrome[21]. (Use in (Turner's, Noonan and Prader Willi Syndromes)[11] and SHOX (short stature homeobox-containing gene) deficiency is covered as above.)
8. Enhancement of body mass or strength for professional, recreational or social reasons[22], with or without anabolic steroids
9. To counteract acute or chronic catabolic illness except for AIDS (e.g., surgery outcomes, trauma, cancer, chronic hemodialysis) in both adult and pediatric patients[22]
10. Altered body habitus or lipodystrophy such as buffalo hump associated with antiviral therapy in HIV-infected patients[22] OTHER THAN abdominal lipodystrophy (see Egrifta, above)
11. Treatment of precocious puberty[22] in conjunction with GnRH (gonadotropin releasing hormone) analogs

12. Treatment of obesity[22]
13. Treatment of cystic fibrosis[22]
14. Treatment of idiopathic dilated cardiomyopathy[22]
15. Treatment of juvenile idiopathic arthritis.[22]
16. Treatment of congestive heart failure (CHF).[10]
17. Adults with age-related GH deficiency (AR-GHD), who have neither organic causes nor childhood origin of growth hormone deficiency.[17]

Investigational Indications

The following indications are considered **INVESTIGATIONAL** and not covered:

1. Treatment of altered body habitus (e.g., buffalo hump) associated with antiviral therapy in HIV-infected patients
2. Constitutional delay (lower than expected height percentiles compared with target height percentiles and delayed skeletal maturation when growth velocities and rates of bone age advancement are normal)
3. Treatment of children with "genetic potential" (ie, lower than expected height percentiles based on parents' height)
4. In conjunction with gonadotropin-releasing hormone analogues as a treatment of precocious puberty
5. Growth hormone therapy in older adults without proven deficiency
6. Treatment of cystic fibrosis
7. Anabolic therapy (except for AIDS) provided to counteract acute or chronic catabolic illness (eg, surgery outcomes, trauma, cancer, chronic hemodialysis, chronic infectious disease) producing catabolic (protein wasting) changes in both adult and pediatric patients
8. Anabolic therapy to enhance body mass or strength for professional, recreational, or social reasons
9. Glucocorticoid-induced growth failure
10. Short stature due to Down syndrome
11. Treatment of obesity
12. Treatment of idiopathic dilated cardiomyopathy
13. Treatment of juvenile idiopathic or juvenile chronic arthritis.

Other Information

Blue Cross Blue Shield of Massachusetts (BCBSMA*) members (other than Medex®; Blue MedicareRx, Medicare Advantage plans that include prescription drug coverage) will be required to fill their prescriptions for the above medications at one of the providers in our retail specialty pharmacy network.

Provider Documentation Requirements

Documentation from the provider to support a reason preventing trial of formulary alternative(s) must include the name and strength of alternatives tried and failed (if alternatives were tried, including dates if available) and specifics regarding the treatment failure. Documentation to support clinical basis preventing switch to formulary alternative should also provide specifics around clinical reason.

Individual Consideration (For Atypical Patients)

Our medical policies are written for most people with a given condition. Each policy is based on peer reviewed clinical evidence. We also take into consideration the needs of atypical patient populations and diagnoses.

If the coverage criteria outlined is unlikely to be clinically effective for the prescribed purpose, the health care provider may request an exception to cover the requested medication based on an individual's unique clinical circumstances. This is also referred to as "individual consideration" or an "exception request."

Some reasons why you may need us to make an exception include: therapeutic contraindications; history of adverse effects; expected to be ineffective or likely to cause harm (physical, mental, or adverse reaction).

To facilitate a thorough and prompt review of an exception request, we encourage the provider to include additional supporting clinical documentation with their request. This may include:

- Clinical notes or supporting clinical statements;
- The name and strength of formulary alternatives tried and failed (if alternatives were tried) and specifics regarding the treatment failure, if applicable;
- Clinical literature from reputable peer reviewed journals;
- References from nationally recognized and approved drug compendia such as American Hospital Formulary Service® Drug Information (AHFS-DI), Lexi-Drug, Clinical Pharmacology, Micromedex or Drugdex®; and
- References from consensus documents and/or nationally sanctioned guidelines.

Providers may call, fax or mail relevant clinical information, including clinical references for individual patient consideration, to:

Blue Cross Blue Shield of Massachusetts
Pharmacy Operations Department
25 Technology Place
Hingham, MA 02043
Phone: 1-800-366-7778
Fax: 1-800-583-6289

We may also use prescription claims records to establish prior use of formulary alternatives or to show if step therapy criteria has been met. We will require the provider to share additional information when prescription claims data is either not available or the medication fill history fails to establish use of preferred formulary medications or that step therapy criteria has been met.

Policy History

Date	Action
1/2025	Updated to move Nutropin from Preferred Specialty Brand to Non-Formulary, Non-Covered (NFNC) and to move Genotropin from Non-Formulary, Non-Covered (NFNC) to Preferred Specialty Brand.
7/2024	Updated to move Ngenla ® and Sogroya ® to Non-Formulary Non-Covered in the policy.
12/2023	Reformatted Policy.
9/2023	Updated to add Sogroya ® to the policy and updated IC to align with 118E MGL § 51A.
7/2023	Updated to add Saizenprep ® to the policy and remove Tev-Tropin ® and Zorbtive ® due to market withdrawal.
2/2022	Updated policy to include Skytrofa ™ to the policy.
12/2021	BCBSA National medical policy review. No changes to policy statements. New references added.
12/2020	BCBSA National medical policy review. No changes to policy statements. New references added.
10/2020	Clarified coding information
10/2019	Clarified coding information.
1/2019	Clarified coding information.
8/2018	Clarified coding information.
5/2018	Clarify criteria with Association language.
10/2017	Updated to change Walgreens Specialty Name.

7/2017	Updated to add AllCare to Pharmacy Specialty list.
6/2017	Updated address for Pharmacy Operations.
4/2017	Clarified criteria for Omnitrope®.
1/2016	New references added from BCBSA National medical policy.
10/2015	Updated to included revised language for Pharmacy only medications.
7/2015	Added Zomacton® To the policy.
12/2014	New references added from BCBSA National medical policy.
7/2014	Updated to include ICD-10 and to add Coverage for Egrifta™.
2/2014	Removal of Curascript from specialty pharmacy section.
1/2014	Updated ExpressPAth Language and removed Blue Value.
4/2012	Updated 4/2012 to update specialty pharmacy contact information.
11/2011-4/2012	Medical policy ICD 10 remediation: Formatting, editing and coding updates. No changes to policy statements.
1/2012	Updated to include medical necessity criteria requirement to have treatment failure or contraindication to formulary products.
5/2011	Reviewed - Medical Policy Group - Pediatrics and Endocrinology. No changes to policy statements.
5/2011	Updated to include new FDA approved medication Egrifta™.
5/2010	Reviewed - Medical Policy Group - Pediatrics and Endocrinology. No changes to policy statements.
2/2010	Reviewed - Medical Policy Group - Psychiatry and Ophthalmology. No changes to policy statements.
2/2010	Updated to reflect formulary changes and update Specialty Pharmacy information for Walgreens Specialty Pharmacy.
10/2009	Updated to reflect UM requirements and to remove Medicare Part D criteria from policy.
5/2009	Reviewed - Medical Policy Group - Pediatrics and Endocrinology. No changes to policy statements.
2/2009	Reviewed - Medical Policy Group - Psychiatry and Ophthalmology. No changes to policy statements.
5/2008	Reviewed - Medical Policy Group - Pediatrics and Endocrinology. No changes to policy statements.
2/2008	Reviewed - Medical Policy Group - Psychiatry and Ophthalmology. No changes to policy statements.
5/2007	Reviewed - Medical Policy Group - Pediatrics and Endocrinology. No changes to policy statements.
2/2007	Reviewed - Medical Policy Group - Psychiatry and Ophthalmology. No changes to policy statements.
10/1989	New policy, effective 10/1989, describing covered and non-covered indications.

Forms

To request prior authorization using the Massachusetts Standard Form for Medication Prior Authorization Requests (eForm), click the link below:

https://www.bluecrossma.org/medical-policies/sites/g/files/csphws2091/files/acquiadam-assets/023%20E%20Form%20medication%20prior%20auth%20instruction%20prn.pdf

OR

Print and fax, Massachusetts Standard Form for Medication Prior Authorization Requests #434

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