



Uniform Formulary Medical Necessity Criteria for Growth Stimulating Agents

Drug Class - Growth Stimulating Agents. This class includes growth hormone (somatropin) products which are marketed under a number of different brand names, and the insulin-like growth factor-1 (IGF-1) agent mecasermin (Increlex). Most somatropin products are used for the treatment of growth hormone deficiency (GHD) and other conditions associated with short stature; all contain the same active ingredient (somatropin). Differences among products include availability of various delivery devices, formulation differences (e.g., preservatives), issues affecting administration and storage, and availability of educational materials.

Mecasermin is an orphan drug used to treat severe primary insulin-like growth factor deficiency (IGFD), which affects a very small number of patients. It is not interchangeable with somatropin.

Background - After evaluating the relative clinical and cost effectiveness of the growth stimulating agents, the DoD P&T Committee recommended that the following brands of somatropin products be designated as non-formulary: Genotropin, Humatrope, Omnitrope, and Saizen. This recommendation was approved by the Director, TMA.

Effective Date: 19 Dec 2007

Patients or parents of patients currently using a nonformulary growth hormone product may wish to ask their doctor to consider a formulary alternative.

Uniform Formulary Status, Cost Shares, and Therapeutic Alternatives for Growth Stimulating Agents

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Uniform Formulary Status	Medication	Military Treatment Facilities (MTFs) cost share for up to a 90 day supply	Mail Order cost share for up to a 90 day supply	Retail Network cost share for up to a 30 day supply
Non-Formulary (Tier 3)	<i>Growth hormone products</i> Genotropin Humatrope Omnitrope Saizen	Not available ²	Non-Formulary cost share applies	Non-Formulary cost share applies
Formulary: Brand Name (Tier 2)	<i>Growth hormone products</i> Norditropin, Norditropin Nordiflex Nutropin, Nutropin AQ Serostim ³ Tev-Tropin Zorbtive ³ <i>Insulin-like</i>	\$0	Formulary (Brand) cost share applies	Formulary (Brand) cost share applies

	<i>growth factor-1 agent</i> Mecasermin (Increlex)			
Formulary: Generic (Tier 1)	-	\$0	Generic cost share applies	Generic cost share applies
<ol style="list-style-type: none"> 1. Active duty cost share always \$0 in all points of service for all three tiers; active duty service members may not fill prescriptions for a non-formulary medication unless it is determined to be medically necessary. 2. MTFs will be able to fill non-formulary requests for non-formulary medications only if both of the following conditions are met: 1) a MTF provider writes the prescription, and 2) medical necessity is established for the non-formulary medication. MTFs may (but are not required to) fill a prescription for a non-formulary medication written by a non-MTF provider to whom the patient was referred, as long as medical necessity has been established. 3. Although all growth hormone (somatotropin) products contain the same active ingredient in the same concentration, Serostim and Zorbtive are not considered to be formulary alternatives to Genotropin, Humatrope, Omnitrope, and Saizen. These products are approved and packaged for non-growth related indications and not for growth hormone deficiency (GHD), which may result in wastage if used for GHD. 				

Special Notes

Coverage of both somatotropin (growth hormone) products and mecaseermin (Increlex) requires [prior authorization](#).

Medical Necessity Criteria for Growth Hormone Products

The non-formulary cost share may be reduced to the formulary cost share IF one or more of the following criteria are met:

1. Use of ALL of the following formulary growth hormone products is contraindicated (e.g., due to hypersensitivity to a preservative or other inactive ingredient) : Norditropin, Norditropin Nordiflex, Nutropin, Nutropin AQ, and Tev-Tropin.
2. The patient has experienced or is likely to experience significant adverse effects (e.g., due to a preservative or other inactive ingredient) from ALL of the following growth hormone products: Norditropin, Norditropin Nordiflex, Nutropin, Nutropin AQ, and Tev-Tropin.

Criteria recommended by the DoD Pharmacy & Therapeutics Committee at the August 2007 meeting & approved by the Director, TMA on 17 Oct 2007. For more information, please see the August 2007 [DoD P&T Committee minutes](#).

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TRICARE Management Activity,
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Skyline 5, Suite 810, 5111 Leesburg Pike,
Falls Church, VA 22041-3206

