MTF Formulary Management for Growth Stimulating Agents (GSAs)

Defense Health Agency Pharmacy Operations Division

Bottom Line

- **Norditropin FlexPro remains on the Extended Core Formulary (ECF). It is now the preferred Growth Stimulating Agent (GSA) for DoD; all other products are non-preferred.**
- **Step therapy requires a trial of Norditropin FlexPro in all new and current users of a GSA.**
- **Prior authorization requirements apply to all the GSA products and must be renewed yearly.**
- **All recombinant human growth hormone (rhGH) agents are bioidentical and therapeutically interchangeable.**

Uniform Formulary Decision: The Director, DHA, approved the recommendations from the May 2018 DoD P&T Committee meeting on August 6, 2018. Implementation will occur on November 7, 2018.

Uniform Formulary (UF) Agents		Nonformulary (NF) Agents
Extended Core Formulary (ECF)* drugs – MTFs must have on formulary	**MTFs may have on formulary**	**MTFs must not have on formulary**
Step preferred:** • Norditropin FlexPro	Non-step-preferred: • Omnitrope • Zomacton	Non-step-preferred: • Genotropin • Genotropin MiniQuick • Humatrope • Nutropin • Saizen • Serostim
*Reminder about Extended Core Formulary (ECF) drugs: The ECF includes medications in therapeutic classes that are used to support more specialized scopes of practice than those on the BCF. MTFs may choose whether or not to include an ECF therapeutic class on the formulary, based on the clinical needs of their patients.		
**Step therapy applies to ALL (new and current) users of the GSAs; no grandfathering applies for any user. See detailed criteria below.		

Clinical Summary

Indications & Efficacy

- The GSA products are considered interchangeable across systematic reviews, meta-analyses, pharmacoeconomic reviews, and guidelines.
- The products differ in FDA-approved indications and dosing regimens but have a high degree of therapeutic interchangeability when used for growth deficiencies.
- All the GSA products now offer 5 and 10 mg dosing options, pen devices, small needle gauges (29, 30, 31 gauge), a needle-guard option, patient support programs, home nurse education, instructional websites, and an emergency hotline.
- Differences remain between the GSAs with regard to storage requirements (refrigeration vs. room temperature), preservative (benzyl alcohol vs. metacresol vs. phenol), available dosage options, delivery devices, smallest dosing delivery increment, and the number of steps required for reconstitution and assembly prior to administration.
- Advantages of Norditropin FlexPro include that it has the greatest number of FDA-approved indications (seven); it does not require refrigeration or mixing prior to administration; it contains phenol as a preservative; and it is administered in a pen device that is convenient and easy to use. Norditropin can also deliver dosage increments down to 0.025 mg with the 5 mg pen. The majority of GSA utilization in the DoD is for Norditropin (72%).
- Although the Genotropin MiniQuick formulation can deliver the lowest dosage options for children, all the products can deliver low dosages, including Norditropin FlexPro.

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- Norditropin FlexPro, Nutropin, Omnitrope, and Saizen are pre-mixed formulations that are convenient for patients.
- Training materials for Norditropin FlexPro are found at: https://www.norditropin.com/how-to-take-it/giving-an-injection

Safety

- The preservative benzyl alcohol is toxic to neonates and infants above a threshold concentration. Omnitrope, Saizen, Serostim, and Zomacton contain benzyl alcohol but are available in alternative devices or dosage options with either a non-toxic preservative or with bacteriostatic water without the benzyl alcohol preservative.
- The package inserts for all the GSAs now caution that patients with Prader-Willi syndrome require a sleep study to rule out obstructive sleep apnea prior to starting GSA therapy.

Manual Prior Authorization (PA) Criteria for GSAs

- All new and current users of a non-step-preferred GSA must try Norditropin FlexPro unless the patient has a contraindication or has experienced an adverse reaction that is unlikely to occur with the non-step-preferred GSA.
- Manual PA criteria allow the FDA-approved uses for patients < 18 years (growth hormone deficiency, small for gestational age, chronic renal insufficiency, Turner's Syndrome, etc.) and > 18 years (GH deficiency due to pituitary disease, hypothalamic disease, trauma or surgery, HIV wasting/cachexia, or short bowel syndrome).
- Manual PA must be renewed yearly. Patients with a current PA approved for a non-step-preferred GSA who switch to Norditropin FlexPro can apply that PA for the remaining time of the original approval.
- GSAs are not allowed for treatment of idiopathic short stature, the normal aging process, obesity, or depression. Additionally, other off-label uses, including non-alcoholic liver disease, cirrhosis, or mild cognitive impairment are not allowed.

References

- DoD P&T Committee minutes: http://www.health.mil/PandT
- Current/future drug classes under review by the DoD P&T Committee: http://www.health.mil/PandT (scroll down to DoD P&T Committee Meeting Schedule)
- TRICARE Formulary Search Tool: http://www.health.mil/formulary
- Prior Authorization/Medical Necessity forms: See Formulary Search Tool above.
- Formulary Management Documents (including this one) available at: http://www.health.mil/DoDPTResources
- Point of contact for additional information: dha.jbsa.pharmacy.list.poduf@mail.mil

GSA Drug Price Comparison at MTF	
Drug	**MTF Cost/Month (May 2018)**
Extended Core Formulary (ECF) Step-preferred	
Norditropin FlexPro	**$ = Most Cost-Effective**
Uniform Formulary (UF) Non-step-preferred	
Zomacton	**$ = Most Cost-Effective**
Omnitrope	**$ = Most Cost-Effective**
Nonformulary (NF) Non-step-preferred	
Serostim	**$$$ = Less Cost-Effective**
Saizen	**$$$ = Less Cost-Effective**
Nutropin	**$$$$ = Least Cost-Effective**
Humatrope	**$$$$ = Least Cost-Effective**
Genotropin, Genotropin MiniQuick	**$$$$ = Least Cost-Effective**

Legend:
$ ="Most Cost-Effective" represents Rxs with the lowest cost and/or best clinical efficacy
$$ ="Less Cost-Effective" represents higher cost Rxs with similar clinical efficacy
$$$ = "Less Cost-Effective" represents next higher cost Rxs with similar clinical efficacy
$$$$ = "Least Cost-Effective" represents Rxs with the highest cost with similar clinical efficacy

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