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Prior Authorization Criteria Update: Growth Hormones

Purpose of Update:

The purpose of this prior authorization (PA) update is to align current fee-for-service PA criteria with the Health Evidence Review Commission (HERC) guidance for use of growth hormones (GH). Growth hormones are indicated for a variety of childhood and adult conditions. FDA approved indications for GH vary by brand name product and are presented in **Table 1**. In August 2018, the HERC updated guidelines to remove restrictions on the types of childhood diseases that are covered for treatment with GH. Guidance continues to specify that treatment with GH for children should only continue until adult height, as determined by bone age, is achieved.[1] Treatment for adult human growth hormone deficiency is currently not listed as a funded condition on the prioritized list.[1]

Table 1. Pediatric and Adults FDA Approved Indications for Growth Hormone[2,3]

	Genotropin®	Humatrope®	Norditropin®	Nutropin AQ®	Omnitrope®	Saizen®	Serostim®	Zomacton®	Zorbtive®
Pediatric Indications									
GHD	X	X	X	X	X	X		X	
Prader-Willi Syndrome	X		X		X				
Noonan Syndrome			X						
Turner Syndrome	X	X	X	X	X			X	
Idiopathic Short Stature	X	X	X	X	X			X	
SHOX Deficiency		X						X	
CKD with Growth Failure				X					
Small for Gestational Age	X	X	X		X			X	
HIV Associated Cachexia							X		
Adult Indications									
GHD	X	X	X	X	X	X		X	
HIV Associated Cachexia							X		
Short Bowel Syndrome									X

Abbreviations: CKD = chronic kidney disease; FDA = Food and Drug Administration; GHD = growth hormone deficiency; HIV = human immunodeficiency virus; SHOX = Short stature homeobox-containing gene

Recommendation:

- Update the prior authorization criteria to align with HERC coverage guidance.

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November 2018

References:
1. Health Evidence Review Commission. HERC Draft Meeting Minutes. August 9, 2018. https://www.oregon.gov/oha/HPA/CSI-HERC/MeetingDocuments/HERC-Minutes-8-9-2018.pdf Accessed September 19, 2018.
2. Somatropin, E-Coli Derived. In: IBM Micromedex® DRUGDEX® (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. https://www-micromedexsolutions-com.liboff.ohsu.edu/ Accessed September 18, 2018.
3. Somatropin. In: Lexicomp (electronic database). Wolters Kluwer. Hudson, OH. http://online.lexi.com.liboff.ohsu.edu/action/home. Accessed September 18, 2018.

Appendix 1. Proposed Prior Authorization Criteria

Growth Hormones

Goal(s):
- Restrict use of growth hormone (GH) for funded diagnoses where there is medical evidence of effectiveness and safety.

NOTE: Treatment with GH in children should continue only until adult height as determined by bone age is achieved. Treatment is not included for isolated deficiency of human growth hormone in adults.

Length of Authorization:
- Up to 12 months

Requires PA:
- All GH products require prior authorization for OHP coverage. Treatment of human growth hormone deficiency for adults is not funded by the OHP.

Covered Alternatives:
- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

Initial Approval Criteria		
1. What is the diagnosis being treated?	Record ICD10 code	
2. Is the request for an FDA approved indication?	**Yes:** Go to #3	**No:** Pass to RPh. Deny; medical appropriateness
3. Is this a request for initiation of growth hormone?	**Yes:** Go to #4	**No:** Go to **Renewal Criteria**

Initial Approval Criteria		
4. Is the patient an adult (>18 years of age)?	**Yes:** Go to #9	**No:** Go to #5
5. Is the prescriber a pediatric endocrinologist or pediatric nephrologist?	**Yes:** Go to #6	**No:** Pass to RPh. Deny; medical appropriateness
6. Is the diagnosis promotion of growth delay in a child with 3rd degree burns?	**Yes:** Document and send to DHS Medical Director for review and pending approval	**No:** Go to #7
7. If male, is bone age <16 years? If female, is bone age <14 years?	**Yes:** Go to #8	**No:** Pass to RPh. Deny; medical appropriateness
8. Is there evidence of non-closure of epiphyseal plate?	**Yes:** Go to #10	**No:** Pass to RPh. Deny; medical appropriateness
9. Is the request for isolated human growth hormone deficiency in an adult (E23.0)?	**Yes:** Pass to RPh. Deny; not funded by the OHP.	**No:** Go to #10
10. Is the product requested preferred?	**Yes:** Approve for up to 12 months	**No:** Go to #11
11. Will the prescriber consider a change to a preferred product? Message: • Preferred products are reviewed for comparative effectiveness and safety by the Oregon Pharmacy and Therapeutics (P&T) Committee.	**Yes:** Inform prescriber of covered alternatives in class and approve for up to 12 months.	**No:** Approve for up to 12 months

Renewal Criteria		
1. Document approximate date of initiation of therapy and diagnosis (if not already done).		
2. Is the request for continuation of therapy which was initiated as an adult (>18 years of age)?	**Yes:** Go to #5	**No:** Go to #3
3. Is growth velocity greater than 2.5 cm per year?	**Yes:** Go to #3	**No:** Pass to RPh. Deny; medical appropriateness
4. Is male bone age <16 years or female bone age <14 years?	**Yes:** Go to #6	**No:** Pass to RPh. Deny; medical appropriateness
5. Is the request for isolated human growth hormone deficiency in an adult (E23.0)?	**Yes:** Pass to RPh. Deny; not funded by the OHP.	**No:** Go to #6
6. Is the product requested preferred?	**Yes:** Approve for up to 12 months	**No:** Go to #7
7. Will the prescriber consider a change to a preferred product? Message: • Preferred products are reviewed for comparative effectiveness and safety by the Oregon Pharmacy and Therapeutics (P&T) Committee.	**Yes:** Inform prescriber of covered alternatives in class and approve for up to 12 months	**No:** Approve for up to 12 months

P&T Review: 11/18 (SS); 9/17; 9/16; 9/15; 9/14; 9/10; 5/10; 9/08; 2/06; 11/03; 9/03
Implementation: 1/1/19; 10/13/16; 1/1/11, 7/1/10, 4/15/09, 10/1/03, 9/1/06; 10/1/03