

PHARMACY POLICY STATEMENT

Marketplace

DRUG NAME

Short-

5. Member must have documentation of **TWO** pre-treatment stimulation tests with a peak serum growth hormone concentration < 10 ng/mL (must include lab results with reference ranges); AND
6. Member must have a pre-treatment height (must include growth charts) of > 2 SD below the mean for age and gender; AND
7. Member must have a pre-treatment height velocity (must include growth charts) below the 25th percentile for age and gender; AND
8. Member must have a documented 6-

2. Chart notes have been provided showing improvement of signs and symptoms of disease (ex. increased height velocity, decreased fat mass, increased lean body mass, etc)

If

in consultation with for prescribe specialty; increased Omnitrope trial from 90 days to 6

24. Goldstone AP, Holland AJ, Hauffa BP, et al. Recommendations for the diagnosis and management of Prader-Willi Syndrome. *J Clin Endocrinol Metab.* 2008; 93: 4183-4197.
25. Grugni G, Sartorio A, Crinò A. Growth hormone therapy for Prader-willi syndrome: challenges and solutions. *Ther Clin Risk Manag.* 2016;12:873-881. Published 2016 Jun 2. doi:10.2147/TCRM.S70068
26. Blum WF, Crowe BJ, Quigley CA, et al. Growth hormone in effective in treatment of short stature associated with short stature homeobox-containing gene deficiency: two-year results of a randomized, controlled, multicenter trial. *J Clin Endocrinol Metab.* 2007; 92: 219-228.
27. Blum WF, Ross JL, Zimmermann Ag, et al. Growth hormone treatment to final height produces similar height gains in patients with SHOX deficiency and Turner syndrome: results of a multicenter trial. *J Clin Endocrinol Metab.* 2013; 98 (8): 1383-1392.
28. Binder G, Rappold GA. SHOX Deficiency Disorders. 2005 Dec 12 [Updated 2018 Jun 28]. In: Adam MP, Feldman J, Mirzaa GM, et al., editors. GeneReviews® [Internet]. Seattle (WA): University of Washington, Seattle; 1993-2024. Available from: <https://www.ncbi.nlm.nih.gov/books/NBK1215/>
29. Pediatric Endocrine Society (PES) Guidelines for growth Hormone and insulin-like growth factor-1 treatment in children and adolescents; *Horm Res Paediatr.* 2016;86(6):361-397.
30. 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; 25:1191-1232
31. Drube J, Wan M, Bonthuis M, et al. Clinical practice recommendations for growth hormone treatment in children with chronic kidney disease. *Nat Rev Nephrol.* 2019;15(9):577-589. doi:10.1038/s41581-019-0161-4
32. Gravholt CH, Andersen NH, Conway GS, et al. Clinical practice guidelines for the care of girls and women with Turner syndrome: proceedings from the 2016 Cincinnati International Turner Syndrome Meeting. *Eur J Endocrinol.* 2017;177(3):G1-G70. doi:10.1530/EJE-17-0430
33. Davenport ML, Crowe BJ, Travers SH, et al. Growth hormone treatment of early growth failure in toddlers with Turner syndrome: a randomized, controlled, multicenter trial. *J Clin Endocrinol Metab.* 2007;92(9):3406-3416. doi:10.1210/jc.2006-2874
34. Saenger P. Turner's syndrome. *N Engl J Med.* 1996 Dec 5;335(23):1749-54. doi: 10.1056/NEJM199612053352307. PMID: 8929268.

Effective date: 07/01/2024

Revised date: 03/27/2024