



INLAND EMPIRE HEALTH PLAN

# PHARMACY TIMES

BY IEHP PHARMACEUTICAL SERVICES DEPARTMENT

September 24, 2009

## Reminder of Formulary Change – Growth Hormones

Dear IEHP Providers,

This letter has been sent as a reminder that effective **August 18<sup>th</sup> 2009** the following change was made to the formulary approved by IEHP’s Pharmacy and Therapeutics Subcommittee.

**The new preferred product for the Growth Hormone Class is now Omnitrope<sup>®</sup> (somatropin).** Providers must use Omnitrope<sup>®</sup> for all approved growth hormone requests.

	FDA Indications*	“Off-Label”
Genotropin <sup>®</sup> (somatropin) <i>“reference drug”</i>	<ul style="list-style-type: none"> <li>• Growth Hormone Deficiency (Adult &amp; Childhood onset)</li> <li>• Prader-Willi Syndrome</li> <li>• Turner Syndrome</li> </ul>	<ul style="list-style-type: none"> <li>• Growth failure due to Chronic Renal Insufficiency</li> <li>• Growth Failure due to Noonan Syndrome</li> <li>• Idiopathic Short Stature</li> </ul>
Omnitrope <sup>®</sup> (somatropin) <i>“bio-similar to Genotropin”</i>	<ul style="list-style-type: none"> <li>• Growth Hormone Deficiency (Adult &amp; Childhood onset)</li> </ul>	<ul style="list-style-type: none"> <li>• Growth failure due to Chronic Renal Insufficiency</li> <li>• Growth Failure due to Noonan Syndrome</li> <li>• Idiopathic Short Stature</li> <li>• Prader-Willi Syndrome</li> <li>• Turner Syndrome</li> </ul>

\* FDA indications based on Package Insert; however, FDA has not taken a position on the interchangeability of somatropin products

Omnitrope<sup>®</sup> is a recombinant human growth hormone and was approved by the FDA on May 30<sup>th</sup> 2006 and is considered a “bio-similar” medicine. This means that Omnitrope is similar to a biological

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medicine that is already authorized by the FDA and contains the same active substance (also known as the 'reference medicine'). The reference medicine for Omnitrope<sup>®</sup> is Genotropin<sup>®</sup>.

In-vitro clinical studies demonstrated that Omnitrope<sup>®</sup> is equivalent to human growth hormone of pituitary origin. In a two-way cross over study, the pharmacokinetics and pharmacodynamics of Omnitrope<sup>®</sup> was compared to Genotropin<sup>®</sup> (reference drug product) in 24 healthy male and female subjects. The results were found to be similar and non-significant with a 90% confidence interval.<sup>1</sup>

National Treatment Guidelines recognize that various somatropin products have the potential to be interchangeable and have shown similar efficacy for various indications, albeit with minute differences in dosing and administration.<sup>2,3</sup>

Since April 2006, Omnitrope<sup>®</sup> has been indicated in Europe by the European Medicines Agency for the indications of Growth Hormone Deficiency, Turner's Syndrome, Short Stature, Small for Gestational Age, and Prader-Willi Syndrome. Clinical trials conducted in Europe have shown that Omnitrope<sup>®</sup> has similar clinical efficacy as Genotropin<sup>®</sup> (reference drug) for those indications.

If you have any questions regarding the change, please feel free to contact me at 909-890-2067.

Sincerely,



Chris Chan, Pharm.D.  
Director, Pharmaceutical Services

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1. Food and Drug Administration. [www.fda.gov](http://www.fda.gov). NDA: 21-426; Clinical Pharmacology and Biopharmaceutics Review for Omnitrope<sup>®</sup>
  2. Guidelines for the use of growth hormone in children with short stature: a report by the Drug and Therapeutics Committee of the Lawson Wilkins Pediatric Endocrine Society. *J Pediatr* 1995;127:857-867.
  3. Consensus guidelines for the Diagnosis and Treatment of adults with Growth Hormone Deficiency in Childhood and Adolescence: Summary Statement of the Growth Hormone Research Society. *J Clin Endocrinol Metab.* 1998;83:379-381.