Indiana Medicaid Therapeutics Committee
Therapeutic Class Review Summary

Therapeutic Class:
Growth Hormones

Overview:
Somatropin is a synthetic form of the naturally occurring human growth hormone produced in the pituitary gland. Growth hormone secretion contributes to several direct and indirect effects on the body by stimulating the liver's production of insulin-like growth factor. These effects include stimulation of cell growth in all organs, induction of protein synthesis, an increase in calcium retention and mineralization of bones, and an increase in metabolism.

Available growth hormones have varying indications and provide several treatment options. The following are agents approved for growth hormone deficiency in pediatric and adult patients: Genotropin®, Humatrope®, Norditropin®, Nutropin®, Nutropin® AQ, Omnitrope®, and Saizen®. Tev-Tropin™ is approved for growth hormone deficiency in pediatric patients only. In addition, Genotropin®, Humatrope®, Norditropin®, Nutropin®, Nutropin® AQ are indicated for the treatment of growth failure associated with Turner Syndrome in patients who have open epiphyses. Genotropin®, Humatrope®, Nutropin®, Nutropin® AQ, and Omnitrope® are also approved for the treatment of idiopathic short stature. Humatrope® is additionally indicated for the treatment of short stature or growth failure in children with SHOX (short stature homebox-containing gene) deficiency whose epiphyses are open. Nutropin® and Nutropin® AQ are also indicated for the treatment of growth failure associated with chronic renal insufficiency up to the time of renal transplantation. Norditropin® is also approved for the treatment of children with short stature associated with Noonan syndrome. Genotropin®, Humatrope®, Norditropin®, and Omnitrope®, comprise an additional indication for the treatment of growth failure in children born small for gestational age who fail to manifest catch-up growth by age 2 to 4 years. Genotropin® and Omnitrope® are additionally approved for the treatment of growth failure due to Prader-Willi syndrome. Serostim® is indicated for the treatment of HIV patients with wasting or cachexia to increase lean body mass and body weight, and improve physical endurance. Finally, Zorbtive™ is approved for the treatment of Short Bowel

Syndrome in patients receiving specialized nutritional support. None of these agents have generic equivalents.

The growth hormones are given by intramuscular or subcutaneous injection. Several delivery devices are available for convenient administration of the growth hormones. However, Saizen®, Humatrope®, and Tev-tropin™ are the only agents that may be administered with the needle hidden from view. Though adverse reactions resulting from growth hormone therapy are rare, treatment has been known to occasionally cause fluid retention, hypoglycemia, hyperglycemia, abnormal bone growth, carpal tunnel syndrome, and joint pain.

Generic Name	Brand Name	Manufacturer	Generic Available
Somatropin	Genotropin® Humatrope® Norditropin® Nutropin® Nutropin®AQ Omnitrope® Saizen® Serostim® Tev-Tropin™ Zorbtive™	Pfizer Eli Lilly Novo Nordisk Genentech Genentech Sandoz Serono Serono Gate Serono	N

Summary:

Somatropin is a synthetic version of human growth hormone. Although several somatropin products are available for growth hormone therapy, none of these agents have generic equivalents. Several delivery devices are available for convenient administration of the growth hormones. However, Saizen®, Humatrope®, and Tev-tropin™ are the only agents that may be administered with the needle hidden from view. Selection for the preferred drug list should be based upon FDA-approved indications, efficacy, safety, and cost.