

IROs Help Determine Medical Necessity of Growth Hormone Therapy

Lansdale, Penn. — April 14, 2009 —Today the human growth hormone (HGH) industry approaches \$2 billion a year. It claims benefits for enhancing athletic performance, anti-aging and stimulating growth. Unfortunately, many of these remain unproven says NAIRO, trade association of independent review organizations (IROs) whose members see daily requests from health plans asking about the medical necessity of growth hormone therapies (www.nairo.org).

Because of its dangers, the Food and Drug Administration (FDA) tightly controls HGH and prohibits doctors from prescribing it for any use the agency has not specifically approved. For example, if doctors prescribe the drug to enhance athletic performance or reverse aging they are breaking the law.

“There’s much confusion about growth hormone therapy, even among healthcare professionals,” said Joyce Muller, NAIRO president. “Health plans wanting to determine the approved uses and standard of care for the drug should consult an IRO.”

Limited Approval for Children

The FDA has approved HGH for children to treat rare genetic conditions, such as Prader-Willi Syndrome (PWS) or Pituitary Dwarfism where it has shown therapeutic benefits. In all cases, HGH treatment requires the assistance of a pediatric endocrinologist. Although it has some rare side effects, treatment with synthetic (recombinant) HGH is generally safe. FDA approved uses include idiopathic short stature, growth-hormone deficiency, and chronic kidney disease.

Anti-aging and Performance Enhancement Unproven

In 2002, the National Institute on Aging sponsored the most comprehensive single study on the anti-aging effects of HGH. It discovered marginal benefits and significant side effects. It warned that HGH should be limited “to controlled research studies” and not widely prescribed.

Despite professional sports outlawing HGH, the belief persists that it makes athletes stronger and faster. Nevertheless, there is insufficient scientific evidence to support this.

The FDA approves HGH in adults only for relatively rare diseases—adult growth hormone deficiency and the wasting syndrome of late stage AIDS. In these treatments, after diagnosing patients with extensive blood tests doctors must monitor them closely.

Unapproved use of HGH can lead to increased health problems including diabetes, heart problems, liver problems, kidney problems, cancer, or death. Moreover, purchasing HGH online is risky because of the possible lack of quality control by manufacturers not approved by the FDA that can result in contamination by other drugs or steroids. Additionally, HGH misuse and its related side effects can increase health plan administrative and litigation costs that cause consumer premiums to rise.

“Health plans should be cautious about approving HGH therapies,” Muller said. “Because HGH carries sanctions for indications not approved by the FDA, health plans must consider the medical necessity of each case carefully to protect themselves, their providers, and their members. IROs can help them determine whether there’s a real medical need.”

For help finding an IRO to review the medical necessity of HGH therapy, health plans and payers can contact NAIRO (www.nairo.org).

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