



Effectiveness of Recombinant Human Growth Hormone (rhGH) in the Treatment of Patients With Cystic Fibrosis: Comparative Effectiveness Review Number 23

U. S. Department of Health and Human Services, Agency for Healthcare Research and Quality

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Cystic fibrosis (CF) is the second most common life-shortening, childhood-onset genetic disease in the United States, affecting approximately 30,000 people in the Nation. The gene responsible for CF encodes the cystic fibrosis transmembrane regulator (CFTR) protein, which regulates sodium and chloride transport across epithelial membranes. This affects nearly all exocrine glands, with abnormally viscous mucus and excessive secretions. The dominant clinical features are chronic lung disease and pancreatic insufficiency with poor nutrition and growth. Treatment advances in CF over the past 25 years have improved measures of nutrition, pulmonary function, and mortality. Growth and nutritional indexes may be predictive of future pulmonary function in children with CF. It has been suggested that improvement of linear growth in children with CF may allow more lung mass and better pulmonary function, independent of improved weight gain. Both poor weight and shorter height have also been shown to be independently associated with increased morbidity and mortality in CF patients in some studies. Recombinant human growth hormone (rhGH) is an anabolic agent with a wide variety of actions. It has been investigated for the treatment of CF because of the decreased growth measures and increased energy expenditures in CF patients. This Review, prepared by the University of Connecticut/Hartford Hospital Evidence-based Practice Center (EPC), examines the benefits and harms associated with using rhGH in patients with CF. The key questions examined are: KQ 1: In patients with CF, does treatment with rhGH as an adjuvant to usual care improve intermediate outcomes, including pulmonary function; growth (height, weight, lean body mass [LBM], protein turnover), exercise tolerance, and bone mineralization, compared with usual care alone? KQ 2: In patients with CF, does treatment with rhGH as an adjuvant to usual care improve health outcomes, including frequency of required intravenous antibiotic treatments, frequency of hospitalization; quality of life; bone fracture or development of osteoporosis/osteopenia, or mortality, compared with usual care alone? KQ 3: In patients with CF, what is the strength of evidence that intermediate outcomes of pulmonary function, growth, and bone mineralization are associated with improvements in health outcomes of quality of life, bone fracture or development of osteoporosis/osteopenia, or mortality? KQ 4: In patients with CF, what is the frequency of nonmalignant serious adverse effects resulting from treatment with rhGH? Adverse effects of interest include, but are not limited to, glucose intolerance, diabetes, and hypoglycemia. KQ 5: What is the risk of malignancy associated with rhGH use as determined by: (a) markers of cancer risk with rhGH (insulin-like growth factor-I [IGF-I] increases over 100 ng/ml or insulin-like growth factor binding protein-3 [IGFBP-3] decreases over 1,000 ng/ml) from studies of rhGH in people with CF and by (b) assessment of evidence on cancer incidence from non-CF patients receiving modest doses of rhGH (0.2 mg/kg/week to 0.6 mg/kg/week) for disorders such as growth hormone deficiency (GHD) and idiopathic short stature (ISS)? KQ 6: In patients with CF, how are efficacy, effectiveness, safety, or adverse events impacted by rhGH dose, therapy duration, baseline nutritional status, and concurrent medical therapies? KQ 7: In patients with CF, how do the efficacy, effectiveness, safety, or adverse events of treatment with rhGH differ between subgroups of patients? Subgroup characteristics of interest include, but are not limited to, age (prepubertal, pubertal, postpubertal), gender, baseline clinical status (height, weight, LBM, pulmonary function, exercise tolerance, nutritional status), and/or the nature, extent, and effectiveness of prior treatment.

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