GROWTH HORMONE REPLACEMENT THERAPY FOR ADULT HYPOPITUITARISM

INTRODUCTION

In 2003, NICE approved the use of growth hormone as replacement therapy in adult hypopituitarism. Subsequent approval for the NICE guidelines has been issued in Scotland by the NHS Quality Improvements Scotland organisation and in Lothian by the Formulary Committee.

This protocol is for use in Lothian University Hospitals NHS Trust under the supervision of Consultant Endocrinologists. It is to be used together with the Shared Care Protocol for GPs.

PATIENT SELECTION

Patients are eligible for consideration of Growth Hormone replacement therapy if they are:

- aged >18 years
- are symptomatic despite adequate replacement of all other hormonal deficiencies, eg with lethargy, reduced muscle power, associated with central obesity.
- would consider daily self-injection.
- have no contra-indications, including diabetes mellitus, concurrent malignant disease, cardiac failure, are risk of pregnancy.

FURTHER TESTS IN POTENTIALLY ELIGIBLE PATIENTS

Patients who fulfil selection criteria should have further tests:

- A disease-specific Adult Growth Hormone Deficiency Quality of Life Questionnaire (AGHDA). If the patient scores 10 or less on this questionnaire they are not eligible for growth hormone replacement and no further test should be undertaken.
- If the AGHDA score is >10, the patients should undergo a dynamic test to confirm growth hormone deficiency. They should also have measurement of baseline serum IGF1. The choice of test should be discussed with the Consultant. It will usually be an insulin tolerance test or an arginine stimulation test.

In addition, the patient's General Practitioner should be made aware by letter of the intention to start Growth Hormone therapy. A copy of the shared care protocol should

be sent and the GP given the opportunity to voice any concerns about the initiation or continuation of growth hormone treatment in their patient.

INITIATION OF THERAPY, DOSE TITRATION AND ASSESSMENT

In patients with biochemically confirmed growth hormone deficiency who fulfil ALL of the above criteria, growth hormone therapy should be initiated:

- refer to the Endocrinology Specialist Nurses for education in self administration. The starting dose is 0.2 mg/day (by Miniquick single dose vial) or 0.3 mg/day (by genotropin pen). Be cautious about doses in mg or international units: 1 mg = 3 IU.

- request a 3 month free drug prescription from Pfizer, as appropriate.

- arrange for nurses to take blood at +2 weeks for IGF1 measurement and an out-patient clinic attendance for +4 weeks for review of IGF1, symptomatic review and dose adjustment. Adjust doses to maintain IGF1 in the normal range with increments usually of 0.2 mg/day by Miniquick or 0.1 mg/day by Genotropin pen. Arrange for a further blood to be taken at +6 weeks, further review at +8 weeks, blood to be taken at +10 weeks and review at +12 weeks.

- Once a stable dose is achieved arrange review at 3 and 6 months later for measurement of IGF1 and symptomatic review. At 9 months, re-administer the AGHDA questionnaire.

CONTINUATION OF THERAPY

- *Only patients whose AGHDA score has improved by 7 points or more* AND who wish to continue should continue on growth hormone.

- Review with measurement of IGF1 at least once a year.

Protocol prepared by Brian Walker, November, 2003