# Clinical Standards for GH Treatment in Childhood & Adolescence.

The Clinical Standards for GH treatment have been produced by the Clinical Committee of the BSPED. They are evidence based where possible or developed by consensus from Paediatric Endocrinologists and other professionals with relevant expertise and with input from stakeholders. The standards are reviewed regularly to include any new evidence or following a review of the results of the BSPED GH audit.

The BSPED National Growth Hormone audit was initiated at the start of January 2013 at 79 hospitals across the UK. Each participating site is invited to submit quarterly data on patients aged from 0.1-16.0 years who had started GH at their hospital or in their care. The annual summary reports from this audit will provide national and regional benchmarks for each participating site.

**Aim of Standards for GH Treatment:**

- Improve patient experience
- Improve equity of access to specialist services
- Identify optimal service requirements
- Improve clinical outcomes

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**Introduction**

Somatropin (recombinant human growth hormone) is recommended and approved by NICE (1) as a treatment option for children with growth failure associated with any of the following conditions:

1. Growth hormone deficiency
2. Turner syndrome
3. Prader–Willi syndrome
4. Chronic renal insufficiency
5. Born small for gestational age with subsequent growth failure at 4 years of age or later
6. Short stature homeobox-containing gene (SHOX) deficiency.

**Growth hormone deficiency**

**A. Clinical Standards for GH Treatment in children and adolescents with GH deficiency.**

| No | Standard | Adapted from Source |
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| 1 Specialist/Network centre accreditation | | |
| | All centres managing children/young people on GH treatment should submit data to the national BSPED GH audit. | Peer Review |
| 2 Equity of service | | |
| | a. All children and adolescents with GH deficiency will be offered treatment with recombinant human growth hormone (rhGH)<br><br>b. Off label treatment with somatotropin should only be initiated by a tertiary paediatric endocrinologist and the growth response reviewed after 4-6 months. | 1<br><br>1 |
| 3 Professional Expertise | | |
| | Diagnosis & treatment with somatropin should always be initiated and monitored by a paediatrician with specialist expertise in managing growth hormone disorders. | 1,2,3 |

| 4.Diagnostics | | |
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| | a. UK centres undertaking provocation tests for GH status should only use test protocols approved by the BSPED Clinical Committee. | *DELPHI CONSENSUS 91%* |
| | b. GH stimulation testing should only be undertaken in centres with designated nursing personnel trained and experienced in performing these tests who each perform sufficient tests/year to maintain competency (BSPED recommends at least 10 tests per year), and designated medical personnel experienced in their supervision and interpretation. | *DELPHI CONSENSUS 78%* |
| | c. In view of safety concerns, insulin tolerance tests should only be performed in children over 5 years in tertiary endocrine centres with designated trained staff. | *DELPHI CONSENSUS 95%* |
| | d. All UK centres undertaking provocation tests for GH status should use a priming protocol approved by the BSPED Clinical Committee. The use of oestrogen or testosterone to 'prime' the GH axis prior to pharmacological stimulation tests has been demonstrated to increase peak GH concentrations and reduce false positive rates in healthy peri-pubertal subjects from 39% to 5%. | *DELPHI CONSENSUS 94%* |
| | e. A peak GH concentration after stimulation of <6.7 mcg/L (or equivalent assay specific level identified for each centre) in pharmacological stimulation tests undertaken in a child with clinical features/history of GH deficiency supports the diagnosis of GH deficiency (see f below). | *DELPHI CONSENSUS 90%* |
| | f. Unless there is a confirmed genetic cause of GHD the diagnosis of GHD requires evidence of one of the following in addition to one | *DELPHI CONSENSUS 87%* |

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| | abnormal growth hormone provocation test:<br>• Evidence of multiple pituitary hormone deficiency.<br>• Abnormality on hypothalamic-pituitary MRI explaining GHD<br>• Known predisposing cause of GHD (cranial irradiation, hypothalamic-pituitary damage).<br>• A second abnormal GH provocation test. | |
| | g. In the neonatal period where there are clinical and/or radiological features of hypopituitarism, a random GH measurement of <6.7 mcg/L (or equivalent assay specific cut-off) can be used to support the diagnosis of growth hormone deficiency without the use of a provocation test. | *DELPHI CONSENSUS 70%* |
| | h. Children / young people with a diagnosis of GHD should have a pituitary MRI within 3 months of endocrine testing which is reviewed by a paediatric neuroradiologist. | *DELPHI CONSENSUS 96%* |
| | i. Young people diagnosed with childhood onset isolated GHD should have a repeat GH provocation test to confirm GHD at the end of growth (puberty mature and height velocity < 2cm/yr for 6 months) using an appropriate cut-off agreed with the adult endocrinology team of either 5 mcg/l (transition period in accordance with ESPE guidance) or 3 mcg/l (adult cut-off) to identify GHD in young adulthood. | *DELPHI CONSENSUS 98%* |
| | j. For safety and quality assurance, all centres undertaking GH provocation tests should audit the performance of their GH tests 3-5 yearly either via a national audit or the BSPED Peer | *DELPHI CONSENSUS 92%* |

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| | Review process. | |
| 5 Patient Experience | | |
| | a. The start of GH treatment should be within 18 weeks of the time when specific investigation of a licensed indication for GH treatment began (ie after the period of growth monitoring) | NHSE targets for elective treatment. |
| | a. Choice: The choice of GH should be made on an individual basis after informed discussion between the responsible clinician and the patient and/or their carer about the advantages and disadvantages of the products available, taking into consideration therapeutic need and the likelihood of adherence to treatment. | 1, 13 |
| | b. Education of the parents / carers and patient (if old enough) by a designated appropriately trained health care professional should precede the start of GH treatment. This should encompass information concerning GHD and GH treatment and its administration. | 1,2,3, |
| 6 Clinical Outcomes | | |
| | a. Follow-up by a paediatrician with specialist expertise in managing growth disorders should be a minimum of every 6 months in an OP clinic with accurate growth measurements.<br><br>b. Follow-up should monitor and document the response to GH treatment and look for evidence of evolving endocrinopathies.<br><br>c. If growth response is inadequate , the clinician should review the indication to treat, and concordance with treatment and any possibility of additional pathology. In the absence of an adequate response to GH treatment , the responsible | 1<br><br>1, 2,3<br><br>1 |

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| | paediatrician should consider stopping GH treatment. | |
| 7 Transition | | |
| | End of growth GH assessment should always be initiated and monitored by a paediatrician with specialist expertise in managing growth disorders. | 1. |

References


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