



Somatropin (Somatropin Biopartners[®]) powder and solvent for prolonged-release suspension for injection

Biopartners GmbH

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Statement of Advice

In the absence of a submission from the holder of the marketing authorisation, somatropin (Somatropin Biopartners[®]) cannot be endorsed for use within NHS Wales for the replacement therapy of endogenous growth hormone in adults with childhood- or adult-onset growth hormone deficiency (GHD).

- **Adult-onset:** Patients with GHD in adulthood are defined as patients with known hypothalamic-pituitary pathology and at least one additional known deficiency of a pituitary hormone not being prolactin. These patients should undergo a single dynamic test in order to diagnose or exclude a GHD.
- **Childhood-onset:** In patients with childhood-onset isolated GHD (no evidence of hypothalamic-pituitary disease or cranial irradiation), two dynamic tests should be performed after completion of growth, except for those having low insulin-like-growth-factor-1 (IGF-1) concentrations (< -2 standard deviation score [SDS]), who may be considered for one test. The cut-off point of the dynamic test should be strict.

Advice context:

The All Wales Medicines Strategy Group (AWMSG) takes into account the National Institute for Health and Care Excellence (NICE) future work programme when considering whether a product will be appraised. To avoid duplication of effort, AWMSG would not normally consider undertaking an appraisal if NICE intend to publish final technology appraisal advice for the same product within twelve months of the projected Form B submission date. AWMSG advice is interim to that of NICE, should NICE subsequently publish guidance.

The above medicine cannot be endorsed for use within NHS Wales as a technology appraisal by NICE or AWMSG has not been undertaken. The medicine should NOT be prescribed routinely within NHS Wales for the indication stated above.

In the absence of guidance issued by NICE or AWMSG, clinicians should continue to exercise their clinical judgement when providing care for an individual patient. This should be in consultation with the patient and/or guardian or carer, based on the best available evidence.

This statement will be removed on receipt of a submission (i.e. the full submission [Forms A and B] or limited submission [Forms A and C]) or when final technology appraisal advice from NICE becomes available.