



Checklist for Therapeutic Use Exemption (TUE) Application:
Growth Hormone Deficiency (GHD) and Other Indications for Growth Hormone Therapy – Adult and Transition from Childhood



Prohibited Substance: Growth Hormone

This Checklist is to guide the athlete and their physician on the requirements for a TUE application that will allow the TUE Committee to assess whether the relevant ISTUE Criteria are met.

Please note that the completed TUE application form alone is not sufficient; supporting documents **MUST** be provided. A *completed application and checklist DO NOT guarantee the granting of a TUE*. Conversely, in some situations a legitimate application may not include every element on the checklist.

<input type="checkbox"/>	TUE Application form must include:
<input type="checkbox"/>	All sections completed in legible handwriting
<input type="checkbox"/>	All information submitted in [language]
<input type="checkbox"/>	A signature from the applying physician
<input type="checkbox"/>	The Athlete's signature
<input type="checkbox"/>	Medical report should include details of:
<input type="checkbox"/>	<p>Medical history: Aetiology: Genetic growth hormone deficiency, intracranial disease, pituitary tumor; irradiation, surgery, or bleeding in the hypothalamic-pituitary area; traumatic brain injury or whole body irradiation. Treatment of other pituitary hormone deficiencies. Furthermore, in case of:</p> <p>a) Adultⁱ: Fatigue, poor exercise capacity, abdominal obesity, impaired psychosocial function. b) Transitionⁱⁱ: Evidence of short stature and growth deceleration based on standard deviation; any specific treatment as a child. Physician's interpretation of diagnostic tests performed during transition.</p>
<input type="checkbox"/>	<p>Physical exam:</p> <p>a) Adults: May be unremarkable b) Transition: Height, weight, body mass index</p>
<input type="checkbox"/>	Diagnostic test results should include copies of:
<input type="checkbox"/>	<p>Laboratory tests: Insulin-like growth factor-1 (in ng/mL) measured after 2–4 weeks off recombinant human growth hormone in those on therapy; no earlier than 12 months after brain injury in those with post-traumatic etiology. Other hormone levels: thyroid-stimulating hormone (TSH), follicle-stimulating hormone (FSH), luteinizing hormone (LH), prolactin. Morning cortisol as a reliable indicator of adrenocorticotrophic hormone (ACTH). MRI of pituitary/hypothalamus to assess structural abnormalities for all new onset GHD (any age)</p>
<input type="checkbox"/>	If diagnosed during childhood, gene (GH-1 or GHRH-R) or transcription factor mutations (e.g., PROP-1, POU1F1 (Pit-1)) known to result in hypopituitarism
<input type="checkbox"/>	<p>Growth hormone stimulation tests may include:</p> <p>a) Adults: Insulin tolerance test, glucagon stimulation test, growth hormone–releasing hormone (GHRH)-arginine stimulation test, macimorelin test. Results of stimulation testing during transition (if performed). b) Transition: Insulin tolerance test, glucagon stimulation test, macimorelin test.</p> <p>Note: Stimulation tests are not required when hypopituitarism is diagnosed (≥3 other pituitary hormone deficits or gene or transcription factor mutations present (see above). Additional tests are also not required if IGF-1 levels 2–4 weeks after stopping treatment remain below -2 SD.</p>

ⁱ Adult-onset deficiency

ⁱⁱ Transition from childhood, i.e. when linear growth has ceased