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

ADO logo

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.

☐	**TUE Application form** must include:	
	☐	All sections completed in legible handwriting
	☐	All information submitted in [language]
	☐	A signature from the applying physician
	☐	The Athlete's signature
☐	**Medical report** should include details of:	
	☐	Medical history: Genetic or acquired causes of hypothalamic-pituitary disease (eg pituitary tumor; irradiation, surgery, traumatic brain injury), presence of other pituitary hormone deficiencies and information supporting a diagnosis of GH deficiency : a) Adult[i]: Fatigue, poor exercise capacity, abdominal obesity, impaired psychosocial function b) Transition[ii]: Childhood short stature and growth deceleration; childhood growth hormone therapy
	☐	Physical exam: Clinical evidence of adult GH deficiency such as central adiposity, pale complexion, thin dry skin, sparse body hairs and for the patient in transition, evidence of developmental or somatic immaturity.
☐	**Diagnostic test results** should include copies of:	
	☐	Laboratory tests (with reference ranges): Insulin-like growth factor-1 measured after 2–4 weeks off human growth hormone in those on therapy; no earlier than 12 months after brain injury in those with post-traumatic etiology. Baseline pituitary function: thyroid-stimulating hormone (TSH), follicle-stimulating hormone (FSH), luteinizing hormone (LH), prolactin. Morning cortisol as a reliable indicator of adrenocorticotropic hormone (ACTH) status. MRI of pituitary/hypothalamus to assess structural abnormalities for all new onset GHD (any age) unless of genetic cause (see below).
	☐	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.
	☐	Growth hormone stimulation tests employing in: a) Adults: Insulin tolerance test, glucagon stimulation test, growth hormone–releasing hormone (GHRH)-arginine stimulation test, macimorelin test. b) Transition: Insulin tolerance test, glucagon stimulation test, macimorelin test. **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.**

[i] Adult-onset deficiency
[ii] Transition from childhood, i.e. when linear growth has ceased