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Therapeutic Use Exemption (TUE) Checklist

Growth Hormone Deficiency (GHD) and Other Indications for Growth Hormone Therapy – Adult and Transition from Childhood

Prohibited Substances: Growth Hormone

This checklist provides the athlete and their physician with a list of requirements for a TUE application. A TUE application must include a completed form and a medical file that confirms the diagnosis and prescription. If it is not possible to submit all mandatory items on the checklist, please have the treating physician explain why.

A complete application with a medical file will be reviewed by the CCES TUE Committee to assess whether it meets the criteria of the International Standard for Therapeutic Use Exemption (ISTUE). There are no guarantees that a TUE will be granted.

When an application is submitted without a complete medical file the CCES will advise the applicant which documents are missing and ask them to submit them.

☐	**TUE application form** must include:
	☐ All sections completed in legible handwriting
	☐ All information submitted in English or French
	☐ A signature from the prescribing physician
	☐ Athlete's signature in all appropriate sections
☐	**A letter from the athlete's prescribing physician** confirming they were seen within the current year (see Annex 1 for example)
☐	**Medical reports** should include details of:
	☐ Medical history: Genetic or acquired causes of hypothalamic-pituitary disease (e.g., pituitary tumor, irradiation, surgery, traumatic brain injury), presence of other pituitary hormone deficiencies and information supporting a diagnosis of GH deficiency: a) Adult[1]: Fatigue, poor exercise capacity, abdominal obesity, impaired psychosocial function b) Transition[2]: 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 for 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., PROP1, 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.

[1] Adult-onset deficiency.

[2] Transition from childhood, i.e., when linear growth has ceased.

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.

For more information about WADA's ISTUE criteria and additional information about the documentation to be submitted, please visit WADA's TUE Physician Guidelines - Growth Hormone Deficiency (children and adolescents).