

Checklist for Therapeutic Use Exemption (TUE) Application:

Growth Hormone Deficiency – Child, Adolescent and Adult

ADO logo

Prohibited Substance: Human 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 <u>International Standard for Therapeutic Exemptions (ISTUE)</u> 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 A | pplication form must include: |
|--------|--|
| | All sections completed legibly |
| | All information submitted in [language(s) as per ADO preferences] |
| | A signature from the applying physician |
| | The Athlete's signature |
| Medica | al report 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 growth hormone deficiency (GHD): Adultⁱ: Fatigue, poor exercise capacity, abdominal obesity, impaired psychosocial function Transitionⁱⁱ: Childhood short stature and growth deceleration; childhood human growth hormone (hGH) therapy |
| | Physical exam: Clinical evidence of adult GHD such as central adiposity, pale complexion, thin dry skin, sparse body hairs and for the patient in transition, evidence of developmental or somatic immaturity. |
| | |
| Diagno | ostic test results should include copies of: |
| Diagno | basic test results should include copies of: Laboratory tests (with reference ranges): Insulin-like growth factor-1 (IGF-1) measured after 2 – 4 weeks off hGH 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). |
| | bestic test results should include copies of: Laboratory tests (with reference ranges): Insulin-like growth factor-1 (IGF-1) measured after 2 – 4 weeks off hGH 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. |

ⁱ Adult-onset deficiency

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