

## Therapeutic Use Exemption (TUE) Checklist

CANADIAN CENTRE ETHICS PORT



201-2723 chemin Lancaster Rd Ottawa ON Canada K1B OB1 Tel/Tél + 1 613 521 3340 + 1 800 672 7775 Fax/Téléc + 1 613 521 3134

Growth Hormone Deficiency (GHD) and Other Indications for Growth Hormone Therapy

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.

The documents included in your medical file must confirm your diagnosis and prescription and include: A duly completed TUE application form; A letter from your physician confirming you were seen within the current year (See Annex 1 for sample); Medical report should include details of: ☐ 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: a) Adult<sup>1</sup>: Fatigue, poor exercise capacity, abdominal obesity, impaired psychosocial function. b) Transition<sup>2</sup>: 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. ☐ Physical exam: a) Adult: May be unremarkable b) Transition: Height, weight, body mass index Diagnostic test results should include copies of: 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 adrenocorticotropic hormone (ACTH). MRI of pituitary/hypothalamus to assess structural abnormalities for all new onset GHD (any age) ☐ 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 may include: 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. 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 submit, please visit WADA's <u>Medical Information to Support the Decisions of TUECs – Growth Hormone Deficiency</u>.

<sup>&</sup>lt;sup>2</sup> Transition from childhood, i.e. when linear growth has ceased



<sup>&</sup>lt;sup>1</sup> Adult-onset deficiency