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Therapeutic Use Exemption (TUE) Checklist

Male Hypogonadism

Prohibited Substances: Testosterone and human Chorionic Gonadotropin (hCG)

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: Summarize the general medical history related to hypogonadism/androgen deficiency and the need for androgen therapy.
	☐ Puberty timing, progression, and relevant family history; libido, erections, ejaculations and frequency of sexual activity including duration and severity of any problems; shaving onset and frequency; hot flushes/sweats; testicular disorders (cryptorchidism, torsion, orchitis, injury); significant head injuries; non-specific symptoms (whether positive or negative)
	☐ Physical examination: acne, gynecomastia, hair pattern (facial, axillary and pubic), testicular volume by orchidometer or ultrasound; height and weight (BMI); muscular development and tone (must be addressed and included)
	☐ Interpretation of history, presentation, and laboratory results by the treating physician, who is preferably a specialist in endocrinology with sub-specialization in andrology
	☐ Diagnosis: primary or secondary hypogonadism; organic/pathologic or functional causes of low testosterone. Please note that TUEs will only be granted for organic causes). **Primary hypogonadism:** - Klinefelter syndrome - Bilateral anorchia - Cryptorchidism - Cancer therapy – testicular or other (e.g., surgery, irradiation, chemotherapy) - If other, please specify. **Secondary hypogonadism:** - Hypopituitarism – spontaneous (e.g., hyperprolactinemia, post-surgery, chemotherapy) - Hypogonadotropic hypogonadism[1] - Kallmann's Syndrome - Constitutional delay of puberty - Other (please specify)
	☐ Substance prescribed (testosterone or human chorionic gonadotropin) including dosage, frequency, and route of administration

[1] In the case of hypogonadotropic hypogonadism and hypopituitarism, the documentation of appropriate evaluation of the etiology should include:

- Results of an MRI of the brain with pituitary (sella) cuts with and without contrast,
- Results of pituitary function tests (if appropriate), and
- Other appropriate diagnostics to identify an organic etiology for secondary hypogonadism (e.g., prolactin, iron studies and genetic testing for hereditary hemochromatosis).

	☐ Treatment and monitoring plan
	☐ Evidence of follow-up/monitoring of athlete by qualified physician for renewals
☐	**Diagnostic test results** should include copies of:
	☐ Laboratory tests: serum testosterone, LH, FSH and SHBG should be measured at least twice (recording the time of day) within a four-week period, and at least one sample taken in the morning.
☐	**Additional information**:
	☐ Semen analysis including sperm count if fertility is an issue
	☐ Inhibin B (if considering congenital hypogonadotropic hypogonadism or constitutional delayed puberty)
	☐ MRI (or CT) of pituitary with and without contrast
	☐ Pituitary function tests to exclude hypopituitarism, if relevant – morning serum cortisol (±ACTH stimulation test), serum TSH, T4, prolactin, IGF-I)
	☐ Other diagnostics to identify an organic etiology for hypogonadism (e.g., karyotype, olfactory function test, genomics for delayed or failed puberty, iron studies (serum ferritin, % saturation) and genetic testing for hereditary hemochromatosis)
	☐ Dexa scan, if appropriate

For more information about WADA's ISTUE criteria and additional information about the documentation to be submitted, please visit WADA's TUE Physician Guidelines - Male Hypogonadism.