



# Therapeutic Use Exemption (TUE) Checklist

## Male Hypogonadism

Prohibited Substances: Testosterone and human Chorionic Gonadotropin (hCG)



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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.

<input type="checkbox"/> <b>TUE application form must include:</b>												
<input type="checkbox"/> All sections completed in legible handwriting												
<input type="checkbox"/> All information submitted in English or French												
<input type="checkbox"/> A signature from the prescribing physician												
<input type="checkbox"/> Athlete’s signature in all appropriate sections												
<input type="checkbox"/> <b>A letter from the athlete’s prescribing physician</b> confirming they were seen within the current year (see Annex 1 for example):												
<input type="checkbox"/> <b>Medical reports</b> should include details of:												
<input type="checkbox"/> Medical history: Summarize the general medical history related to hypogonadism/androgen deficiency and the need for androgen therapy.												
<input type="checkbox"/> 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)												
<input type="checkbox"/> 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)												
<input type="checkbox"/> Interpretation of history, presentation, and laboratory results by the treating physician, who is preferably a specialist in endocrinology with sub-specialization in andrology												
<input type="checkbox"/> Diagnosis: primary or secondary hypogonadism; organic/pathologic or functional causes of low testosterone. Please note that TUEs will only be granted for organic causes).												
<table border="0"> <tr> <td><b>Primary hypogonadism:</b></td> <td><b>Secondary hypogonadism:</b></td> </tr> <tr> <td>- Klinefelter syndrome</td> <td>- Hypopituitarism – spontaneous (e.g., hyperprolactinemia, post-surgery, chemotherapy)</td> </tr> <tr> <td>- Bilateral anorchia</td> <td>- Hypogonadotropic hypogonadism<sup>1</sup></td> </tr> <tr> <td>- Cryptorchidism</td> <td>- Kallmann’s Syndrome</td> </tr> <tr> <td>- Cancer therapy – testicular or other (e.g., surgery, irradiation, chemotherapy)</td> <td>- Constitutional delay of puberty</td> </tr> <tr> <td>- If <b>other</b>, please specify.</td> <td>- Other (please specify)</td> </tr> </table>	<b>Primary hypogonadism:</b>	<b>Secondary hypogonadism:</b>	- Klinefelter syndrome	- Hypopituitarism – spontaneous (e.g., hyperprolactinemia, post-surgery, chemotherapy)	- Bilateral anorchia	- Hypogonadotropic hypogonadism <sup>1</sup>	- Cryptorchidism	- Kallmann’s Syndrome	- Cancer therapy – testicular or other (e.g., surgery, irradiation, chemotherapy)	- Constitutional delay of puberty	- If <b>other</b> , please specify.	- Other (please specify)
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- If <b>other</b> , please specify.	- Other (please specify)											

<sup>1</sup> 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).

<input type="checkbox"/> Substance prescribed (testosterone or human chorionic gonadotropin) including dosage, frequency, and route of administration
<input type="checkbox"/> Treatment and monitoring plan
<input type="checkbox"/> Evidence of follow-up/monitoring of athlete by qualified physician for renewals
<input type="checkbox"/> <b>Diagnostic test results</b> should include copies of:
<input type="checkbox"/> 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.
<input type="checkbox"/> <b>Additional information:</b>
<input type="checkbox"/> Semen analysis including sperm count if fertility is an issue
<input type="checkbox"/> Inhibin B (if considering congenital hypogonadotropic hypogonadism or constitutional delayed puberty)
<input type="checkbox"/> MRI (or CT) of pituitary with and without contrast
<input type="checkbox"/> Pituitary function tests to exclude hypopituitarism, if relevant – morning serum cortisol ( $\pm$ ACTH stimulation test), serum TSH, T4, prolactin, IGF-I)
<input type="checkbox"/> 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)
<input type="checkbox"/> 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](#).