



TUE Application for Testosterone – Physician Worksheet

Attention Physicians - USADA will not process Therapeutic Use Exemptions (TUE) for the use of testosterone unless all of the requirements for documentation are submitted. Please review the bulleted list below for adequate background before proceeding.

Required Documentation for a TUE Application (INCOMPLETE OR DISORGANIZED APPLICATIONS WILL BE RETURNED)

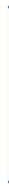
1. A complete TUE application form-pages 1 & 2 filled out by the athlete, pages 3 & 4 filled out by the physician.
2. The Hormone Measurements Summary Data Table must be filled out with details that are validated by the lab and/or clinical notes included in the application.
 - ***If currently on T - therapy, see page 11, WADA TUE Physician Guidelines-ANDROGEN DEFICIENCY/ MALE HYPOGONADISM for washout period guidelines prior to having any samples collected. Anabolic urine screens during washout should be included in the lab data section.***
 - *Results of at least two baseline measurements of Serum total testosterone, Serum LH, Serum FSH, & Serum SHBG. (When indicated, semen analysis including sperm count & motility if fertility is a consideration. A DEXA scan may be included if appropriate.)*
 - *Samples collected in the morning, while fasting between 0700-1000 (within a 4-week period, at least one week apart)*
 - *Results analyzed by an accurate and reliable method. Free-T measured by equilibrium dialysis may be submitted as well as calculated free-T from Total-T. **Direct free-T by immunoassay will not be accepted.***
3. Diagnosis by a physician (***preferably a specialist in endocrinology or andrology***) consisting of but not limited to:
 - *Dates of evaluation (including history & physical exam), copies of laboratory values (with reference ranges) and results. If testosterone deficiency is iatrogenic in origin (orchiectomy, pituitary surgery or irradiation, radiotherapy or chemotherapy), details of the diagnosis and treatment including surgical reports should be submitted. **See Section 2-Diagnosis-Paragraph B. Medical Evaluation-subsections 1-4 of the WADA TUE Physician Guidelines for a detailed list of medical evaluation requirements.***
4. Copies of ***ALL PERTINENT LAB TESTS IN CHRONOLOGICAL ORDER*** (most recent first going backwards).
 - *A cover sheet for this appendix is provided in this packet. Place cover sheet on top of the lab tests before you scan, mail, or fax the packet to USADA so we can clearly identify them.*
5. Copies of ***ALL RELEVANT CLINICAL NOTES IN CHRONOLOGICAL ORDER*** (most recent first going backwards).
 - *A cover sheet for this appendix is provided in this packet. Place cover sheet on top of the clinical notes before you scan, mail, or fax the packet to USADA so we can clearly identify them.*



Physician Considerations for Testosterone TUE Applications

- *Low levels (within or outside normal reference ranges) of any endogenous hormone absent a defined organic etiology will not justify the granting of a TUE, even if within standard of care & prescribed by a physician.*
- *USADA evaluates all complete TUE applications submitted by both males and females under the applicable ISTUE criteria. An unequivocal organic etiology must be demonstrated in all cases.*
- *The use of Testosterone (T) as an anti-aging medication is not justification for a TUE. Similarly, generalized fatigue, slow recovery from exercise and decreased libido are not, in isolation, justification for granting a TUE.*
- *It is extremely unlikely that a TUE will be approved for "functional" hypogonadism (a diagnosis of hypogonadism based on low T levels without a defined, organic etiology).*
- *All TUE applications for T based on secondary hypogonadism should include a detailed history of corticosteroid & opiate use & exclusion of hematochromatosis. Additionally, a pituitary MRI with and without contrast plus pituitary function tests (e.g. morning cortisol, ACTH stimulation, TSH, free T4, Prolactin) may be appropriate.*
- *The Therapeutic Use Exemption Committee (TUEC) will review the entire evaluation and need enough medical information, to make the same diagnosis & arrive at the same treatment plan without ever seeing the patient.*

<i>Diagnosis-Please select one option below and indicate the ICD10 code. If "other," please annotate below:</i>	
<i>Primary Hypogonadism</i>	<i>Secondary Hypogonadism</i>
<input type="checkbox"/> <i>Klinefelter Syndrome</i> <input type="checkbox"/> <i>Bilateral Anorchia</i> <input type="checkbox"/> <i>Cryptorchidism</i> <input type="checkbox"/> <i>Bilateral Orchiectomy</i> <input type="checkbox"/> <i>Other Organic Etiology</i>	<input type="checkbox"/> <i>Panhypopituitarism</i> <input type="checkbox"/> <i>Congenital Hypogonadotropic Hypogonadism</i> <input type="checkbox"/> <i>Constitutional Delay of Puberty</i> <input type="checkbox"/> <i>Hypothalamic or Pituitary Tumor, Destruction or Infiltrative Disease</i>



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*Attachment 2: Clinical and Exam Notes
Organized in Chronological Order*

(Most recent first)

*Please place this coversheet on top of the copies of the
relevant clinical exam notes that you are using
as the basis of your diagnosis.*