Therapeutic Use Exemption (TUE) Application

Hypogonadism/Androgen Deficiency

201-2723 chemin Lancaster Rd
Ottawa ON Canada K1B 0B1
Tel/Tél + 1 613 521 3340
+ 1 800 672 7775
Fax/Téléc + 1 613 521 3134
info@cces.ca www.cces.ca

Step 1: Read all about Therapeutic Use Exemptions (TUE)

- Before submitting your application, visit www.cces.ca/medical to review your requirements and the application process.
- To assist physicians in the preparation of complete and thorough TUE applications, WADA maintains a series of TUE application guidelines for a number of medical conditions commonly affecting athletes. These TUE Physician Guidelines can be accessed by entering the search term "Medical Information" on the WADA website: www.wada-ama.org.

Step 2: **Complete the TUE application form**

- The CCES will accept applications submitted on the CCES TUE application form or an IF TUE application form, provided all required information is included.
- All information on the form must be legible (typed or block letters preferred).
- All fields must be properly completed, and the form must be dated and signed by the athlete and the prescribing physician.
- Illegible and/or incomplete forms will be returned to the athlete unprocessed.

Step 3: **Put together a medical file**

- Compile medical evidence confirming the diagnosis and prescription as outlined in Section 2 of the application form.

Step 4: Submit your completed TUE application form and medical file

- Fax: 613-521-3134;
- Email: tue-aut@cces.ca; or
- Mail: Attn: Athlete Services, CCES, 201-2723 Lancaster Road, Ottawa, ON, K1B 0B1.

Please note:

- The CCES will confirm receipt of your TUE application by email within two business days. If you do not receive a confirmation of receipt within that time frame, please contact the CCES.
- The CCES will contact you once a decision has been rendered on the application, or if more information has been deemed necessary.
- A complete TUE application can take up to 21 days to review.
- Incomplete applications will be returned and will need to be resubmitted with further information.
- Keep a copy of your application form and medical file for your records.
- Medical costs incurred for the completion of the TUE application form or additional investigations, examinations, or imaging studies are the responsibility of the athlete.

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Send completed forms to the CCES by: Fax: (613) 521-3134; Email: tue-aut@cces.ca; or
Mail: Attn: Athlete Services, CCES, 201-2723 Lancaster Road, Ottawa, ON, K1B 0B1.
Please complete all sections clearly in block letters or type. Keep a copy for your records.

1. Athlete Information

Surname:		Given Name(s):	
Sex:	☐ Male ☐ Female	Date of Birth (dd/mm/yyyy):	dd / mm / yyyy
Pronouns:		Preferred method of communication:	☐ Email ☐ Canada Post
Email Address:			
Mailing Address:			
City:		Province/State:	
Country:		Postal Code:	
Telephone:			
Sport:		Discipline / Position:	
Are you in your international federation's registered testing pool?		☐ Yes ☐ No ☐ Unsure	
If you know you will be competing at an international event, enter the event name and date:			
If you are an athlete with an impairment, indicate the impairment:			

Have you submitted any previous TUE application(s)?	☐ Yes	☐ No
For which substance(s) or method(s)?		
To which organization?		
When was it submitted?		
Decision:	☐ Approved	☐ Not approved

2. Medical Information **(To be completed by your physician)**

Diagnosis: Check the appropriate box below.			
Primary Hypogonadism		**Secondary Hypogonadism**	
☐	Kleinefelter Syndrome	☐	Hypopituitarism* – spontaneous (e.g., hyperprolactinemia, post-surgery, chemotherapy)
☐	Bilateral Anorchia	☐	Hypogonadotrophic Hypogonadism*
☐	Crystorchidism	☐	Kallmann's Syndrome
☐	Cancer Therapy – Testicular/Other (e.g., surgery, irradiation, chemotherapy)	☐	Constitutional Delay of Puberty
☐	Other:	☐	Other:

Medical History: Summarize the general medical history and that related to Hypogonadism/Androgen Deficiency and the need for androgen therapy.
**please attached document(s) if necessary*

Clinical Examinations: Summarize findings with specific focus on elements relevant to the need for androgen replacement.
**please attached document(s) if necessary*

Clinical Reports and Investigations: The following documentation **<u>must be included</u>** in the TUE application.	
☐	A letter from the treating physician dated within the year prior to submitting this application which clearly states the diagnosis, outlines the general medical history and that related to Hypogonadism/Androgen Defiency and the need for androgen therapy, and any conclusions based on the physical examinations and the laboratory test results.
☐	A report from an endocrinologist.
☐	The results of all pertinent investigations, including any consultation notes, laboratory reports, hospital records and any other clinical investigations.
☐	Relevant correspondence between physicians regarding the diagnosis and prescription.
☐	*In the case of Hypogonadotropic hypogonadism and hypopituitarism, documentation of appropriate evaluation of the etiology, including: • the results of an MRI of the brain with pituitary (sella) cuts with and without contrast; • the 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).

Clinical Reports and Investigations: The following documentation **must be included** in the TUE application.

Baseline Hormone Measurements: Provide below two (2) different baseline hormone measurements within six (6) months of starting treatment. Copies of lab results must be included with the application.

Date of sample collection	Testosterone (total)	Testosterone (free)	LH	FSH
1.				
2.				

3. Medication Details (To be completed by your physician)

Prohibited Substance(s): Generic name	Dose	Route of Administration	Frequency of Administration	Duration of Treatment
Enter all that apply	e.g., 200 mg	e.g., inhalation, local injection	e.g., BID, QID	e.g., one-time use, emergency, one year
1.				
2.				
3.				

4. Physician's Declaration (To be completed by your physician)

I certify that the information in sections 2 and 3 above is accurate. I acknowledge and agree that my personal information may be used by Anti-Doping Organization(s) (ADO) to contact me regarding this TUE application, to verify the professional assessment in connection with the TUE process, or in connection with Anti-Doping Rule Violation investigations or proceedings. I further acknowledge and agree that my personal information will be uploaded to the Anti-Doping Administration and Management System (ADAMS) for these purposes (see the ADAMS Privacy Policy for more details).

Surname:		Given Name(s):	
Medical Specialty:			
Address:			
City:		Province/state:	
Country:		Postal Code:	
Telephone:		Email Address:	
Signature:		Date (dd/mm/yyyy):	

5. Diagnosing physician (if different from treating physician)

Surname:		Given Name(s):	
Medical Specialty:			
Address:			
City:		Province/state:	
Country:		Postal Code:	
Telephone:		Email Address:	

6. Retroactive applications

Is this a retroactive application?	☐ Yes	☐ No
If yes, on what date was treatment started?	Date (dd/mm/yyyy):	dd / mm / yyyy

Please indicate the reason:

☐ An emergency or urgent treatment of a medical condition was necessary.

☐ There was insufficient time, opportunity or other exceptional circumstances that prevented you from submitting the TUE application, or having it evaluated, before sample collection.

☐ Under the rules of the Canadian Anti-Doping Program (CADP), the CCES did not require you to apply for a TUE in advance of sample collection.

☐ You are using a prohibited substance or method for therapeutic reasons, and you compete in sport at a level that is not considered to be international or national as defined by your international federation or under the CADP (e.g., athletes that are not in the CCES' National Athlete Pool (NAP) who do not compete in international events) and you were tested.

☐ You tested positive after using a substance out of competition that was only prohibited in competition (e.g., glucocorticoids).

Please explain:

☐ Other Retroactive Applications

In rare and exceptional circumstances notwithstanding any other provision in the ISTUE, an Athlete may apply for and be granted retroactive approval for their TUE if, considering the purpose of the Code, it would be manifestly unfair not to grant a retroactive TUE.

In order to apply under this section, please include a full reasoning and attach all necessary supporting documentation.

Please explain:

7. Consent to sharing information

I, _____ authorize the CCES to share my medical information associated with my Therapeutic Use Exemption application with my team's athletic and/or medical personnel or third party, specifically _____name_____. I understand that the CCES can contact this person(s) should more information be required or to provide an update on the status of this application.

Athlete's Signature:		Date (dd/mm/yyyy):	

8. Athlete's Declaration

I, _____, certify that the information set out in this form is accurate and I am requesting approval to use a substance or method from the World Anti-Doping Agency (WADA) Prohibited List. I authorize the release of personal health information to the Canadian Centre for Ethics in Sport (CCES) or other Anti-Doping Agency (ADO) as well as to WADA authorized staff, to the WADA TUEC (Therapeutic Use Exemption Committee) and to other CCES or ADO TUECs and authorized staff that may require access to this information under the World Anti-Doping Code ("*Code*") and/or the International Standard for Therapeutic Use Exemptions. I consent to my physician(s) releasing any personal information or personal health information that they deem necessary in order to consider and determine my application.

I consent to my physician(s) releasing to the above persons any personal information or personal health information that they deem necessary in order for my application to be considered and determined by the CCES or ADOs.

I consent to the use and disclosure of my personal information or personal health information by the CCES or other ADOs for the purposes described in this application or as otherwise required by this application. I consent to the CCES or other ADOs distributing my personal information or personal health information to third parties as required by the *Code*, ISTUE or for any other purpose arising from this application.

I understand and accept that the recipients of my personal health information and of the decision on this application may be located outside the province or country where I reside. In some of these countries data protection and privacy laws may not be equivalent to those in my country of residence. I authorize CCES and/or other ADOs to use or distribute my personal health information to any province or country as required by the *Code*, ISTUE or for any other purpose arising from this application.

I understand that my information will only be used for evaluating my TUE request and in the context of potential anti-doping rule violation investigations and procedures. I understand that if I ever wish to (1) obtain more information about the use of my personal or personal health information; (2) exercise my right of access and correction; or (3) revoke the right of these organizations to obtain my health information, I must notify my medical practitioner and my ADO in writing of that fact. I understand and agree that it may be necessary for TUE-related information submitted prior to revoking my consent to be retained for the sole purpose of establishing a possible anti-doping rule violation, where this is required by the *Code*.

I consent to the decision on this application being made available to all ADOs, or other organizations, with testing authority and/or results management authority over me.

I understand that if I believe that my Personal Information is not used in conformity with this consent and the International Standard for the Protection of Privacy and Personal Information, I can file a complaint with WADA or CAS.

(continued)

8. Athlete's Declaration (con't)

Check the box to authorize the release of personal health information:

☐ I authorize the release of my personal health information to members of the Health Care Team attending Major Games where I may participate, to my Team Physician, and to my national sport organization.

☐ I do not wish to have this information shared with anyone but the CCES, WADA, applicable TUECs and my international federation.

Athlete's Signature:		Date (dd/mm/yyyy):	dd / mm / yyyy
(If the athlete is a minor or has an impairment preventing him/her from signing this form, a parent or guardian is to sign together with, or on behalf of, the athlete.)			
Surname:		Given Name(s):	
Parent/Guardian's signature:		Date (dd/mm/yyyy):	dd / mm / yyyy