

THERAPEUTIC USE EXEMPTIONS - FAQs

WHAT IS A THERAPEUTIC USE EXEMPTION (TUE)?

Athletes, like all people, may have illnesses or conditions that require them to take particular medications or undergo procedures. If the medication or method an athlete requires to treat an illness or condition happens to fall under the Prohibited List, a Therapeutic Use Exemption (TUE) may give that athlete the authorization to take the needed medicine or method. TUEs are granted according to the International Standard for TUEs (ISTUE), a document outlining the conditions, the stakeholder responsibilities, and the TUE process.

HOW CAN AN ATHLETE APPLY FOR A TUE?

The process for an athlete is fairly simple. Each athlete must:

- Contact the relevant International Federations (IFs) or National Anti-Doping Organisations (NADOs) (whichever applies) and ask for information about the TUE Application process. Applications are usually submitted through the Anti-Doping Administration & Management System (ADAMS) or using a paper form.
- Have the physician fill out and sign the TUE Application form and produce the required supporting documentation and forward it to the IF or NADO (whichever applies) for approval. Athletes should remember that the TUE Application should be submitted at least 30 days before participating in an event.

Tips on applying for a TUE:

- Complete the form through ADAMS, either typed or handwritten in block capital letters. If the form is not legible, it is deemed incomplete and will be returned to the athlete.
- If faxing the form, ensure that you include all the required documentation and keep a copy of the request as well as a record of the transmission or acknowledgement of receipt.
- Ensure that your TUE application is complete with all the medical information, tests, laboratory results, imaging studies, clinical information to enable the TUEC to reach a decision in tune with WADA's documents entitled "Medical Information to Support the Decisions of TUECs/TUE Physician Guidelines" available here. Upload all of your medical information to support the use of the prohibited method or substance in ADAMS, under the Diagnosis information tab.
- Always keep a copy of all your medical information, especially the initial diagnostic together with laboratory results, imaging studies and physicians' notes.



WHAT ARE THE CRITERIA FOR GRANTING A TUE?

The criteria are:

- The athlete would experience significant health problems without taking the prohibited substance or method;
- The therapeutic use of the substance would not produce significant enhancement of performance;
- There is no reasonable therapeutic alternative to the use of the otherwise prohibited substance or method;
- The requirement to use that substance or method is not due to the prior use of the substance or method without a TUE which was prohibited at the time of use.

For the TUE to be granted, **all four** criteria must be met.

WHO GRANTS TUES?

All IFs, NADOs and Major Events Organisations (MEOs) must have a clear process in place whereby athletes with documented medical conditions can request a TUE, and have such request appropriately dealt with by a panel of independent physicians called a Therapeutic Use Exemption Committee (TUEC). They must publish details of that process by posting the information in a conspicuous place on their website. IFs and NADOs, through their TUECs, are then responsible for granting or declining such applications.

WHERE SHOULD AN INTERNATIONAL ATHLETE SUBMIT A TUE APPLICATION?

If you are an international level athlete (you are member of World Athletics Registered Testing Pool or you are entered in an international competition), you must submit your TUE Application to the Athletics Integrity Unit, which is responsible for accepting applications and granting TUEs.

It is possible that MEOs choose to recognize pre-existing TUEs automatically, but they must have a mechanism in place for athletes to obtain a new TUE should the need arise. Athletes competing in such events should have the ability to quickly and efficiently obtain that TUE before they compete.

Athletes must not submit TUE Applications to more than one organisation.

WHERE SHOULD A NATIONAL OR LOWER LEVEL ATHLETE SUBMIT A TUE APPLICATION?

If you are a national or lower level athlete, you must submit your TUE Application to your NADO. However, if the NADO considers that the athlete is below the national-level and therefore refuses to consider the application, the athlete should keep that



correspondence and nevertheless collect all the medical information and be ready to present the documentation should there be a need.

Special protocols for TUE Applications may be in effect during Major Events. If you are entered in a Major Event, you are advised to inquire with your IF or NADO whether there is any variation in the TUE submission protocol for the Event. Major Events include those organized by international multi-sport Organisations that function as the ruling body for any continental, regional, or other international event (e.g. International Olympic Committee, International Paralympic Committee).

If you already have a NADO TUE, it is not valid at the international level <u>unless</u> recognized by your governing IF or by a MEO (see more about recognition below). If you already have a TUE from your NADO and are participating in an IF or international event, check if this IF or MEO automatically recognize your TUE as per ISTUE article 7.1(a).

CAN A MEO GRANT A TUE?

Yes, but these TUEs are valid only for the duration of their event. A TUE granted by a NADO or an IF is not valid for the event unless it is recognized by the MEO, although it still is valid outside of that event.

WHAT IS THE ROLE OF WADA IN THE REVIEW OF TUES?

WADA's role in the TUE process is two-fold. First, the Agency, through its TUEC, has the right to monitor and review any TUE granted by a federation or anti-doping organization and, following such review, to reverse any decision. Second, an athlete who submits a TUE Application to a federation or anti-doping organization and is denied a TUE, can ask WADA to review the decision. In certain cases, WADA must review TUE decisions of IFs and it may review other TUE decisions. If WADA determines that the denial of the TUE did not comply with the ISTUE, the Agency can reverse the decision.

WADA does not accept TUE applications from athletes.

WHAT IS A RETROACTIVE TUE?

There are situations for which TUEs may be granted retroactively. The evaluation process is identical to the standard TUE application procedure i.e. the TUEC evaluates the application and issues its decision. The ISTUE stipulates which situations may result in the granting of a retroactive TUE, as follows:

 Emergency treatment or treatment of an acute medical condition was necessary*; or



- Due to other exceptional circumstances, there was insufficient time or opportunity for the athlete to submit, or the TUEC to consider, an application for the TUEprior to Sample collection; or
- Applicable rules required the athlete or permitted the athlete to apply for a retroactive TUE. This is applicable to Persons who are not International-Level or National-Level athletes (Code Article 4.4.5) and (where the relevant NADO so chooses) to National-Level Athletes in sports specified by the relevant NADO (ISTUE Article 5.1 Comment); or [Comment: Such athletes are strongly advised to have a medical file prepared and ready to demonstrate their satisfaction of the TUE conditions set out in ISTUE Article 4.1, should an application for a retroactive TUE be necessary following Sample collection.]
- It is agreed, by WADA and by the ADO to whom the application for a retroactive TUE is or would be made, that fairness requires the grant of a retroactive TUE.

*A medical emergency or acute medical situation occurs when the athlete's medical condition justifies immediate Administration of a Prohibited Substance or Method and failure to treat immediately could significantly put the athlete's health at risk. It is always preferable to address a TUE application prospectively rather than retrospectively. ADOs granting TUEs should have internal procedures to expedite the evaluation and granting of TUE for emergency situations, whenever possible, and without putting the athlete's health at risk.

WHAT HAPPENS IF AN ATHLETE IS GRANTED A TUE?

TUEs are granted for a specific method or a substance with a defined dosage and route of administration. They are also granted for a specific period of time and do expire. You need to comply with all the treatment conditions outlined in the TUE Application. Material changes to your treatment require a new application and TUE Committee review.

Once a TUE has been granted by an IF or NADO, it will inform WADA, who will then have the opportunity to review this decision. If the decision does not conform to the International Standard for TUEs, WADA may reverse it and deny the TUE. WADA's decision is not retroactive. Therefore, the reversal shall not apply retroactively and your results prior to such notification shall not be *Disqualified*. Where the *TUE* reversed was a retroactive *TUE*, however, the reversal shall also be retroactive.

WHAT SHOULD AN ATHLETE DO IF HE ALREADY HAS A TUE GRANTED BY A NATIONAL ANTI-DOPING ORGANISATION BUT BECOMES SUBJECT TO THE TUE REQUIREMENTS OF AN INTERNATIONAL FEDERATION OR MAJOR EVENT ORGANIZATION?

The concept of recognition should apply as per the ISTUE's article 7.0. You should not submit an application for a new TUE to the IF or MEO, but should consult their website to check whose TUE decisions they will automatically recognize. If your TUE falls into a



category of TUEs that are automatically recognized in this way, you do not need to take further action. In the absence of such recognition, you should submit a request for recognition of the TUE to the IF or MEO either via ADAMS or as otherwise specified by that IF or MEO.

WHAT HAPPENS IF THE IF REFUSES TO RECOGNISE THE NADO TUE?

If an IF refuses to recognise a TUE granted by a NADO, the TUE is NOT valid for international-level competition. If you or your NADO appeals this decision to WADA within 21 days, the TUE remains valid for national-level competition pending WADA review. If the TUE is not referred to WADA, the TUE is not valid neither at the national nor international level after 21 days.

WHAT HAPPENS IF A NADO DISAGREES WITH THE GRANTING OF A TUE BY AN IF?

The TUE remains valid for international-level competition and out-of-competition testing, but if the NADO refers the matter to WADA, the TUE is not valid for national-level competition pending WADA review. If the TUE is not appealed to WADA within 21 days, the TUE becomes valid for national-level competition as well.

I AM A NATIONAL OR LOWER LEVEL ATHLETE; IS THE TUE GRANTED BY MY NADO VALID FOR AN EVENT OR PERIOD OF COMPETITION WHERE I FALL UNDER THE JURISDICTION OF ANOTHER NADO?

NADOs have the obligation to respect TUEs granted by other NADOs, as long as the granting NADO was competent to grant the TUE (i.e. the athlete is a National or lower level athlete) and the TUE was granted in accordance with the ISTUE.

WHAT CAN AN ATHLETE DO IF WADA REVERSES THE ORIGINAL DECISION GRANTING HIM/HER A TUE?

You or your granting authority may appeal to the Court of Arbitration for Sport (CAS) for a final decision.

WHAT SHOULD AN ATHLETE DO IF HE/SHE IS NOTIFIED FOR DOPING CONTROL WHILE USING A PROHIBITED SUBSTANCE UNDER A GRANTED TUE?

When filling out the doping control form, make sure that you declare the substance or method being used and that you specify that a TUE has been granted. Although not mandatory, you are strongly encouraged to show your TUE Approval certificate to the doping control official.

WHAT WILL HAPPEN IF THE PROHIBITED SUBSTANCE IS DETECTED DURING THE ANALYSIS?

When the doping control authority receives the report from the laboratory, an initial evaluation will take place to verify that the TUE is still in effect and that the results of the analysis are consistent with the TUE granted (nature of substance, route of administration, dose, time frame of administration, etc.). If the review is satisfactory, the result of your test will be recorded as negative.

WHAT CAN AN ATHLETE DO IF HIS/HER TUE IS DENIED BY THE GRANTING AUTHORITY?

If your TUE is denied by your IF, WADA must review the TUE decisions as per article 8.1 of the ISTUE. It may review any other decisions.

The review process is as follows:

- 1. The request for review must be sent via registered letter to WADA's Medical Director within 21 days of the decision by the TUE granting authority. Include your full contact details as well as your e-mail address. WADA will inform you whether or not your case can be reviewed by WADA's Therapeutic Use Exemption Committee (TUEC), as per article 8.0 of the ISTUE;
- 2. If your case is accepted, you will be asked to pay WADA an administrative fee of US\$500 and further information will be provided regarding the payment of this fee;
- 3. WADA's TUEC will review the same documentation as the TUE granting authority. WADA may ask you to provide additional information or documents;
- 4. WADA's TUEC will render its decision in a reasonable time, given the circumstances of the case;
- 5. The original denial of the TUE will remain in effect until WADA's TUEC reaches a decision. You are therefore not permitted to use the substance while waiting for the decision from WADA's TUEC. If the TUE is granted by WADA's TUEC, the TUE immediately goes into effect in accordance with the conditions outlined by WADA's TUEC.
- 6. WADA's TUEC's decision may be appealed to the Court of Arbitration for Sport (CAS).

WHAT IF WADA DECIDES NOT TO REVIEW MY CASE AFTER MY NATIONAL ANTI-DOPING ORGANISATION (NADO) DECLINES TO GRANT MY TUE?

WADA reserves the right not to review your case for various reasons. In that event, you may always reapply to your NADO to have a new TUE application considered, especially if there is new compelling medical information presented.

WHAT CAN AN ATHLETE DO IF WADA UPHOLDS THE GRANTING AUTHORITY'S DECISION NOT TO GRANT THE TUE?

For athletes applying to an International Federation:

You may appeal the IF decision to CAS for a final decision.



For athletes applying to a National Anti-Doping Organization:

You may appeal the NADO decision to an independent appeal body in your country. If this body grants the TUE, WADA could appeal this decision to CAS for a final decision.

WHAT IS THE ROLE OF THE COURT OF ARBITRATION FOR SPORT (CAS) IN THE APPEAL OF TUE REVIEW DECISIONS?

WADA TUE review decisions can be appealed to CAS. If WADA upholds the IF decision, the athlete and/or the NADO can appeal to CAS. If the IF decision is reversed by WADA, the IF may appeal to CAS. If an international-level athlete does not have a TUE, he should apply to his IF. If the IF denies the TUE, WADA may agree to review the decision not to grant the TUE. If WADA refuses to review the decision, the athlete may appeal to CAS.

WILL THE INFORMATION ON THE ATHLETE'S TUE APPLICATION REMAIN CONFIDENTIAL?

All the information contained in a TUE Application will be kept strictly confidential, the same as any medical information normally kept by your doctor. All members of the Therapeutic Use Exemption Committee (TUECs) are required to sign confidentiality agreements and if they require advice from other scientific experts on a particular case, your name is not used when circulating the application outside the TUEC.

MY DOCTOR RECOMMENDS THAT I USE A NEBULIZER TO HELP WITH DELIVERY OF MY ASTHMA MEDICATION. DOES WADA PROHIBIT THE USE OF NEBULIZERS?

Nebulizers are not prohibited as a device; however the amount of beta-2-agonist administered by nebulisation may surpass the allowed maximum doses of salbutamol, salmeterol or formoterol by inhalation; therefore the dose may be prohibited.

WHERE CAN AN ATHLETE FIND OUT MORE ABOUT TUES?

The procedures for applying for and granting a TUE are outlined in the International Standard for TUEs, published by WADA. You may also contact your IF or NADO for more information. You may also consult the below-described TUE Guidelines, also published by WADA.

WADA produces a series of useful guidelines entitled *Medical Information to Support the Decisions of TUECs/TUE Physician Guidelines* that address common health conditions confronted by athletes (e.g. asthma, joint and muscle disease and injury etc.) in the context of TUEs. These documents are intended to inform NADO and IF TUEC Physicians, but also provide useful information to help athletes and their doctors to know what diagnostic criteria and tests must be included in their TUE application.