



Therapeutic Use Exemptions (TUEs) Regulations and Procedures

Information regarding the [Prohibited List](#) and
[Therapeutic Use Exemptions](#) (TUEs)

SUMMARY OF MAJOR MODIFICATIONS AND EXPLANATORY NOTES

2021 Prohibited List

SPECIFIED METHODS

- M2.2 is now a Specified Method in accordance with Article 4.2.2 of the 2021 World Anti-Doping Code (the Code).

SUBSTANCES OF ABUSE

- Article 4.2.3 of the *Code* defines *Substances of Abuse* as those “*Prohibited Substances* which are specifically identified as *Substances of Abuse* on the *Prohibited List* because they are frequently abused in society outside of the context of sport.”
- Cocaine, diamorphine (heroin), methylenedioxymethamphetamine (MDMA/“ecstasy”) and tetrahydrocannabinol (THC) are designated as *Substances of Abuse*.
- Other substances are currently under review and may be designated as *Substances of Abuse* in the future.

SUBSTANCES AND METHODS PROHIBITED AT ALL TIMES (IN- AND OUT-OF-COMPETITION)

PROHIBITED SUBSTANCES

S2. Peptide Hormones, Growth Factors, Related Substances and Mimetics

- Transforming growth factor-beta (TGF- β) signalling inhibitors are now included with their full rather than abbreviated name.
- IOX2 is added as an example of a hypoxia-inducible factor (HIF) activating agent.

S3. Beta-2 Agonists

- Inhaled vilanterol is now permitted up to the manufacturer's maximum recommended dose. The dose is expressed as the metered dose of 25 micrograms which is equivalent to a delivered dose of 22 micrograms.
- It is clarified that arformoterol and levosalbutamol are prohibited by adding them as examples.

S4. Hormone and Metabolic Modulators

- Sub-classes 4.2 and 4.3 were amalgamated to become anti-estrogenic substances (including selective estrogen receptor modulators (SERMs)). This clarification in terminology reflects that, for anti-doping purposes, all these substances act by a common mechanism of binding to estrogen receptors and blocking estrogen action. This clarification did not add or remove any substances from this category.

S5. Diuretics and Masking Agents

- The wording regarding the exception to allow the ophthalmic use of carbonic anhydrase inhibitors is clarified as "topical ophthalmic administration".

PROHIBITED METHODS

M2. Chemical and Physical Manipulation

- As explained above, M2.2 is changed from a non-Specified to a Specified Method.

SUBSTANCES AND METHODS PROHIBITED IN-COMPETITION

PROHIBITED SUBSTANCES

S6. Stimulants

- Examples of imidazole derivatives for topical use are added to the exceptions. These are brimonidine, clonazoline, fenoxazoline, indanazoline, naphazoline, oxymetazoline and xylometazoline.

S9. Glucocorticoids

- Additional examples of glucocorticoids are added to the List. The names of some existing examples are clarified to better reflect the active drug compound.
- As proposed in the draft 2021 Prohibited List circulated for consultation to stakeholders in May 2020, WADA's Executive Committee approved, at its 14-15 September 2020 meeting, prohibiting all injectable routes of administration of glucocorticoids during the **In-Competition period**. Examples of injectable routes of administration include: intravenous, intramuscular, periarticular, intra-articular, peritendinous, intratendinous, epidural, intrathecal, intrabursal, intralesional (e.g. intrakeloid), intradermal, and subcutaneous. However, in order to thoroughly and widely communicate the rule changes and to allow sufficient time for information and education, the Executive Committee decided to **introduce the prohibition of all injectable glucocorticoid routes and the implementation of the new rules on 1 January 2022**. This one-year period will allow, for example, Athletes and medical personnel to get a better understanding of the practical implementation of the washout periods, Laboratories to update their procedures to incorporate the revised and substance-specific new reporting

values, and sports authorities to develop educational tools for *Athletes*, medical and support personnel, addressing the safe use of glucocorticoids for clinical purposes in anti-doping.

P1. Beta-blockers

- Nebivolol was added as an example.

MONITORING PROGRAM

Beta-2 Agonists: In and Out-of-Competition:

- Any combination of beta-2 agonists was removed as the required prevalence data were obtained.
- Findings for salmeterol and vilanterol below the Minimum Reporting Level are included in the Monitoring Program to better monitor their therapeutic use vs risk of abuse.

* For further information on previous modifications and clarifications, please consult the *Prohibited List* Q & A at www.wada-ama.org/en/questions-answers/prohibited-list-qa.

NUTRITIONAL SUPPLEMENTS

- Extreme caution is recommended regarding dietary/nutritional supplement use, as its label may not declare a prohibited substance. A poorly labeled dietary supplement is not an adequate defense in a doping hearing.
- WADA is not involved in testing dietary/nutritional supplements and not even in any certification process.

CANNABIDIOL (CBD) OIL

- CBD is not prohibited; however some CBD oils and tinctures extracted from cannabis plants may also contain TCH and other cannabinoids that could result in a positive test for a prohibited cannabinoid.
- Please note that products, including foods and drinks, containing cannabinoids, are also prohibited as well as all synthetic cannabinoids that mimic the effects of TCH.

QUESTIONS AND ANSWERS ON THERAPEUTIC USE EXEMPTIONS

1. What is a Therapeutic Use Exemption (TUE)?

Athletes, like all others, may have illnesses or conditions that require them to take particular medications. If the medication an Athlete is required to take 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.

2. What are the criteria for granting a TUE?

As per [Article 4.2 of ISTUE](#), the 4 (four) following criterial must be met:

- The Athlete has a clear diagnosed medical condition which requires treatment using a prohibited substance or method;
- The therapeutic use of the substance will not, on the balance of probabilities, produce significant enhancement of performance;
- The prohibited substance or method is an indicated treatment for the medical condition, and there is no reasonable permitted therapeutic alternative, and
- The necessity to use that substance or method is not a consequence, wholly or in part, of the prior use (without a TUE), of a substance or method which was prohibited at the time of use.

3. Who grants TUEs?

Under the World Anti-Doping Code, WADA has issued an International Standard for TUEs. The standard states that all International Federations (IFs) and National Anti-Doping

Organizations (NADOs) must have a 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).

IFs and NADOs, through their TUECs, are then responsible for granting or declining such applications.

WADA does not accept TUE Applications from Athletes.

4. Where should an Athlete submit a TUE Application?

If you are an [international level Athlete](#) or if you are entered in an international event for which a TUE issued by your International Federation (IF) is required, you must submit your TUE Application to your IF via WADA's Anti-Doping Administration and Management System (ADAMS). If you are a national level Athlete you must submit your TUE Application to your National Anti-Doping Organization (NADO). It is the Athlete's responsibility to provide a complete TUE application containing adequate medical information to confirm the diagnosis.

Please note that your NADO's TUE is only valid at national level and you must submit a request for recognition to the FIVB.

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

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 of 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 organizations that function as the ruling body for any continental, regional, or other international event (e.g. IOC, IPC, FISU).

5. What is WADA's role regarding TUEs?

WADA's role in the TUE process is two-pronged. First, the Agency, through its TUE Committee (TUEC), has the right to monitor and review any TUE granted by a federation or anti-doping organization and, pursuant to such review, to uphold or 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. WADA is not obliged to review all cases and Athletes may appeal their denial to national review bodies or to CAS. There are certain cases, such as a discrepancy between an IF and NADO, where WADA must review TUE decisions.

6. How can an Athlete apply for a TUE?

The FIVB encourages Athletes to submit their TUE applications via ADAMS, together with the required medical information. Otherwise, please download the TUE Application Form (M-8 Form) and once duly completed and signed, send it together with the required medical file to medical@fivb.com.

Any TUE for substances prohibited in-competition shall be requested at least 30 days before the competition, unless one of the exceptions on retroactive TUEs apply.

The TUE application must be submitted in legible capital letters or typing.

The medical file must include:

- A comprehensive medical history, including documentation from the original diagnosing physician(s), if possible;
- The results of all examinations, laboratory investigations and imaging studies relevant to the application.

7. Can an Athlete get a retroactive TUE?

Athletes may only apply for a retroactive TUE if:

- An emergency or urgent treatment is required;
- There was insufficient time, opportunity or other exceptional circumstances that prevented the submission of a TUE application before getting tested;
- It concerns a lower-level Athlete who is not under the FIVB jurisdiction or NADO and was tested;
- Athlete was tested positive after using a substance out-of-competition that is only prohibited In-Competition (for instance, glucocorticoids).

If, considering the purpose of the Code, it would be manifestly unfair not to grant a retroactive TUE, the Athlete may be granted retroactive approval for a TUE of a prohibited substance or method. This unique retroactive TUE will only be granted with the prior approval of WADA, which can in the use of its absolute discretion agree with or reject the FIVB TUEC decision.

8. What happens if an Athlete is granted a TUE?

TUEs are granted for a specific medication with a defined dosage, frequency and route of administration. They are also granted for a specific period of time and do expire. The Athlete needs to comply with all the treatment conditions outlined in the TUE Application.

Using a prohibited substance or method without a TUE could result in an Anti-Doping Rule Violation.

9. NADO TUE Recognition

If you wish to participate in an International Event (i.e. an event where the FIVB is the ruling body) and you have been granted a TUE by your National Anti-Doping Organization (NADO), you must, prior to such participation, obtain recognition from the FIVB TUEC. If that TUE meets the criteria set out in Section 4.4.2.1 of the Medical & Anti-Doping Regulations, then the FIVB TUEC shall recognize it.

10. What can an Athlete do if WADA reverses the original decision granting him/her a TUE?

The Athlete or the respective NADO/IF can appeal to the Court of Arbitration for Sport (CAS) for a final decision.

11. 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 medication being used and that you specify that a TUE has been granted. If you have easy access to a copy of the TUE Approval form, it is preferable but not mandatory that you show it to the doping control official.

12. 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 review 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 proves satisfactory, the result of your test will be recorded as negative.

13. What can an Athlete do if his/her TUE is denied or not recognized by the granting authority?

If the TUE is rejected:

- If a national level Athlete wishes to appeal a NADO TUEC decision, they would do so before the relevant national appeal body in their country. If no such body is in place and available at the time of the appeal, the Athlete has a right to appeal to CAS. The NADO should guide the Athlete through this process.
- An international level Athlete may request that WADA review their refused TUE application. WADA is not obliged to review all TUE decisions but may do so at their discretion (ISTUE 8.3; Code Article 4.4.6).

There are two situations where WADA must review (mandatory review), assuming the Athlete or the NADO makes a request to WADA (Code Article 4.4.6):

- If an IF refuses to recognize a NADO TUE;
- If a NADO disagrees with an IF's decision to grant a TUE.

If the TUE is not recognized by an IF:

- The international-level Athlete and/or their NADO may refer the non-recognition to WADA for review.
- An international-level Athlete may also appeal an IF's decision to the Court of Arbitration of Sport if this decision is not reviewed by WADA.

14. Where can an Athlete appeal a decision made by WADA?

A decision by WADA to reverse or uphold a TUE decision may be appealed by the Athlete, the NADO and/or the IF affected, exclusively to CAS.

15. Will the information on the Athlete's TUE Application remain confidential?

Athletes concerned about confidentiality should note that all the information processed during the TUE application, including the supporting medical information and any other information related to the evaluation of his/her TUE request, is kept strictly confidential and treated in accordance with the International Standard for the Protection of Privacy and Personal Information, as per the Athlete's Declaration contained in the ADAMS TUE and in the TUE Application Form. The TUE Application will be kept strictly confidential as medical data. All members of the TUEC and any authorized recipients of an Athlete TUE request are subject to a professional or contractual confidentiality obligation.

16. 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. For more information, please check the links below:

- [International Standard for TUEs \(ISTUE\)](#)

- [WADA Q&A on Therapeutic Use Exemptions](#)
- [WADA Checklists for TUE Applications](#)
- [WADA Guidelines for the 2021 ISTUE](#)
- [WADA Anti-Doping Education and Learning \(ADEL\)](#)

17. Should Athletes declare all medications (prescription or otherwise) on the Doping Control Form at the time of doping control?

Yes. Athletes are advised to declare all medications and other substances that are being taken or have been taken in the previous seven days.

ADAMS TUE QUICK REFERENCE FOR ATHLETES



How to enter a TUE in ADAMS?

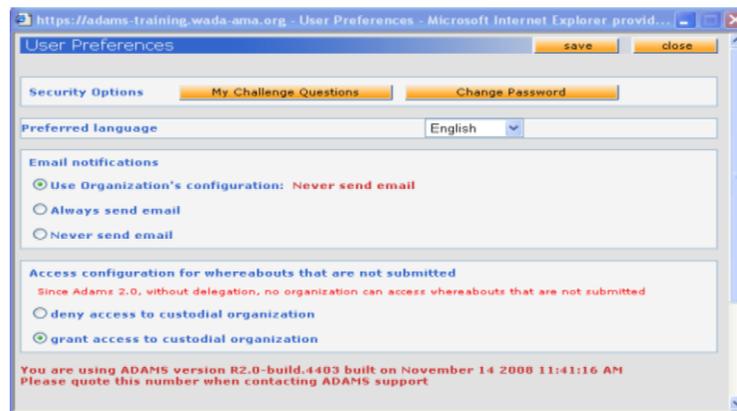
1. Request username and password from your ADO for you and/or your doctor
Send an email to your International Federation (IF) or National Anti-Doping Organization (NADO) depending on your RTP level. The message must include your doctor name and contact details including email address
2. Log into ADAMS on the Internet
 - Make sure that your pop-up blocker is disabled
 - Go to <http://adams.wada-ama.org>
 - Enter your new username and password
 - Click [login]
 - When you log in for the first time, an information form will appear.
 - Read the statement
 - Type your password to indicate your acknowledgment

- Click [Accept]



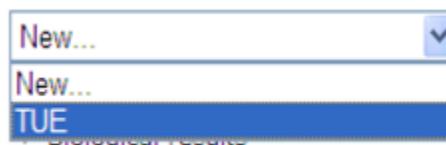
3. Update your Profile and set your Preferences

- Click [My Profile] for updating your profile if required
- To set your Preferences click on your name displayed at the right top in the header on the Home page
- Adjust your Password, select your Language, indicate whether you want to receive notifications on your email address (as set in your profile) if desired
- Click [Save] to save your modifications



4. Open your TUE form

- Expand the **New** drop down and select TUE:



- Complete the mandatory fields (with *)
 - RTP information
 - physician details
 - diagnosis
 - medication
 - attachment (Medical file **in English**: medical report confirming condition)



The screenshot shows a web form titled "Athlete TUE" with a "Submit Application" button in the top right corner. The form contains the following sections:

- Provide information in red text with a red asterisk:**
- STEP 1: IDENTIFY YOUR SPORT AND IF APPLICABLE, THE EXERCISES (TUE):** Specify the event if it is relevant or required by your sporting organization. Select the Sporting Organization to which you are applying for the TUE. Select national federations by your sporting organization if you are a national level athlete or apply to your National Anti-Doping Organization (NADO) and if you are an international level athlete you apply to your International Federation. You must specify the Registered Testing Pool you belong to.
- Sport:** A dropdown menu.
- Event:** A dropdown menu.
- Identifying Organization:** A dropdown menu.
- Registered Testing Pool:** A list of checkboxes:
 - I am part of an International Federation Registered Testing Pool
 - I am part of a National Anti-Doping Organization Testing Pool
 - I am participating in an international event for which a TUE is granted pursuant to the International Federation's rules or required
 - None of the above
- Need a competition card code:** A text input field.

- Save, review your information
- The save option is a draft only available to you.
- You will not be able to modify any data once you submit your application.
- Your IF and NADO will only see your TUE application once you submit your application.
- Click **Submit Application**