



**Guidelines for the
International Standard for
Therapeutic Use Exemptions**

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Welcome to the International Standard for Therapeutic Use Exemptions Guidelines

Introduction

The International Standard for Therapeutic Use Exemptions (ISTUE) was created to provide a detailed, fair and understandable process for athletes, Anti-Doping Organizations (ADOs), physicians and Athlete Support Personnel (ASP) to follow when situations arise where, due to illness or medical condition, an athlete may require the use of substances or methods that are specifically included in the World Anti-Doping Agency (WADA) Prohibited List (List).

The Therapeutic Use Exemption (TUE) application process provides athletes with an opportunity to apply for a TUE when medical treatment is required involving the use of a prohibited substance or prohibited method. This process, protecting all clean athletes, promotes competition on a level playing field.

If a TUE is granted, an athlete may continue, or start to use, the otherwise prohibited substance or method while competing without resulting in an Anti-Doping Rule Violation (ADRV) and sanction, if applicable.

An athlete applying for a TUE must have a diagnosed medical condition, confirmed by relevant medical data that meet the ISTUE criteria for the grant of a TUE. This mandatory documentation, provided by the athlete's physician, must accompany the TUE application sent to the ADO. This information should be guided by the relevant [TUE Physician Guideline](#) and [Checklist](#). These guidelines and checklists cover common or challenging medical conditions that require TUE applications.

Scope

This ISTUE Guidelines (Guidelines) document takes athletes, ADOs, physicians and ASP through the TUE process, commencing with a clear understanding that only substances and methods included on the List require a TUE.

The Guidelines expand upon TUE-related matters in the World Anti-Doping Code (Code) and the ISTUE. Readers may be aware that some TUE topics addressed in the Code are not covered in the ISTUE, and vice versa. Code Article 4.4 describes the fundamentals of the TUE process for athletes, National Anti-Doping Organizations (NADOs), International Federations (IFs) and Major Event Organizations (MEOs) including such topics as jurisdiction, appeals and WADA reviews. The ISTUE covers the broader elements of the TUE process.

These Guidelines outline key ADO responsibilities, including support for athletes who need to make TUE applications, Therapeutic Use Exemption Committee (TUEC) decision-making guidelines, recognition of TUEs and communication of TUE decisions. Confidentiality provisions and the role of WADA in the review of TUE decisions are also addressed.

The Guidelines are intended to provide clarity and additional guidance to the Code and the ISTUE. Unlike the Code and ISTUE, the Guidelines are not a mandatory document. In the event of conflict between the Code and/or the ISTUE and the Guidelines, the Code and/or ISTUE (as applicable) must prevail.

How to use the Guidelines

How can you make the most of the Guidelines? The Guidelines are a support tool for ADOs, athletes, ASP and physicians. We understand that different organizations or people may have different needs, so we have designed the Guidelines into sections and chapters to help you navigate in a way that we hope works for you.

If you are new to TUEs or anti-doping, or if this is the first time your organization develops a TUE program, it might be helpful to read the Guidelines from start to finish and use the examples, figures and templates for your own work. Doing so will lead you through a logical process to develop your TUE program.

But, if you are seeking support on a particular item or article from the ISTUE, select the chapter that suits your needs and go directly to it. If more context is needed, look to other chapters for support.

If you want a snapshot of the content of the Guidelines, or need a quick refresher or reference guide, consult the summary to identify what chapters will best assist you in your work. And as you build, update or improve your TUE program, remember that in addition to these Guidelines, you can find on [ADEL](#) a suite of ISTUE resources to help you achieve your goals.

Resources and Documentation

The following resources are available on WADA's [website](#):

- ❖ [2021 World Anti-Doping Code](#)
- ❖ [International Standard for Therapeutic Use Exemptions](#)
- ❖ [The Prohibited List](#)
- ❖ [Questions and Answers on Therapeutic Use Exemptions](#)
- ❖ [TUE Physician Guidelines for various medical conditions](#)
- ❖ [TUE Checklists for different medical conditions](#)
- ❖ [Anti-Doping Education and Learning \(ADEL\) for Medical Professionals](#)
- ❖ [ADEL for Athletes \(Alpha\)](#)
- ❖ [Results Management, Hearings and Decisions Guidelines](#)

TUE Procedure Flowcharts

The following Flowcharts may be found within these guidelines:

- ❖ Lifecycle of a TUE
- ❖ Where should NLAs (or lower level athletes) apply?
- ❖ Retroactive ISTUE Article 4.3 TUE Flowchart
- ❖ NADO TUE Flowchart
- ❖ IF TUE Flowchart
- ❖ MEO TUE Flowchart

SECTION 1:

The Prohibited List

This section will provide background on WADA's Prohibited List, help you understand why substances and methods are included on the List and reinforce that TUEs are exemptions to allow one to use something included on the List for a therapeutic reason.



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It should be abundantly clear that TUEs provide exemptions for athletes to use and possess substances or methods that are on the List. Therefore, athletes, ASP and ADO managers should first verify if there is even a need for a TUE. To clarify, if a substance or method is not prohibited, then no TUE is necessary. Athletes may check if the substance is prohibited on WADA's website ([Prohibited List](#) & [ADEL](#)) or through national drug databases (if there is one available) via their NADOs. One example is Global DRO which was developed for a number of countries. Other countries have their own, such as [eirpharm.com](#) in Ireland.

After thorough consultation with experts and stakeholders, the List is updated every year and published on the WADA website on or before 1 October. The updated List then goes into effect on 1 January. Although the List can theoretically be updated at any time, in practice this almost never happens. Nevertheless, it is a wise practice for athletes and their ASP to check the List every time they are prescribed and before they start a treatment or use a medication.

It should also be noted that the List is harmonized across all sports, which means that every athlete should be aware that even if the substance or method would have no performance enhancing (PE) effect in their sport, it remains prohibited. Indeed, for substances or methods to be considered for addition to the List, two of the following three criteria should be present: has the potential to enhance or enhances sport performance; represents an actual or potential health risk to the athlete; violates the spirit of sport described in the introduction to the Code. The only exception to the harmonized List is Beta-blockers, which are prohibited in only specific sports and disciplines.

Some substances and methods are prohibited at all times while other substances are only prohibited in-competition. In cases where the substance is prohibited only in-competition and is used therapeutically out-of-competition, athletes may still need a TUE as the substance may be found in their system at the time of the competition. In these cases, a TUE might be needed. See the [Chapter 11](#) on retroactive TUEs, describing the opportunity to apply retroactively in those cases (ISTUE Article 4.1(e)). Athletes are strongly advised to always prepare a medical file if there is a therapeutic use for a prohibited substance or method close to a competition period, even if no advance TUE is necessary.

The TUE application process and criteria for the grant a TUE follow in Sections 2 and 3 of this document.

SECTION 2:

Applying for a TUE

This section follows an athlete's journey through the TUE process particularly ISTUE Articles 6.0 to 9.0. This will help facilitate the understanding of athletes' rights and responsibilities during the TUE application process.



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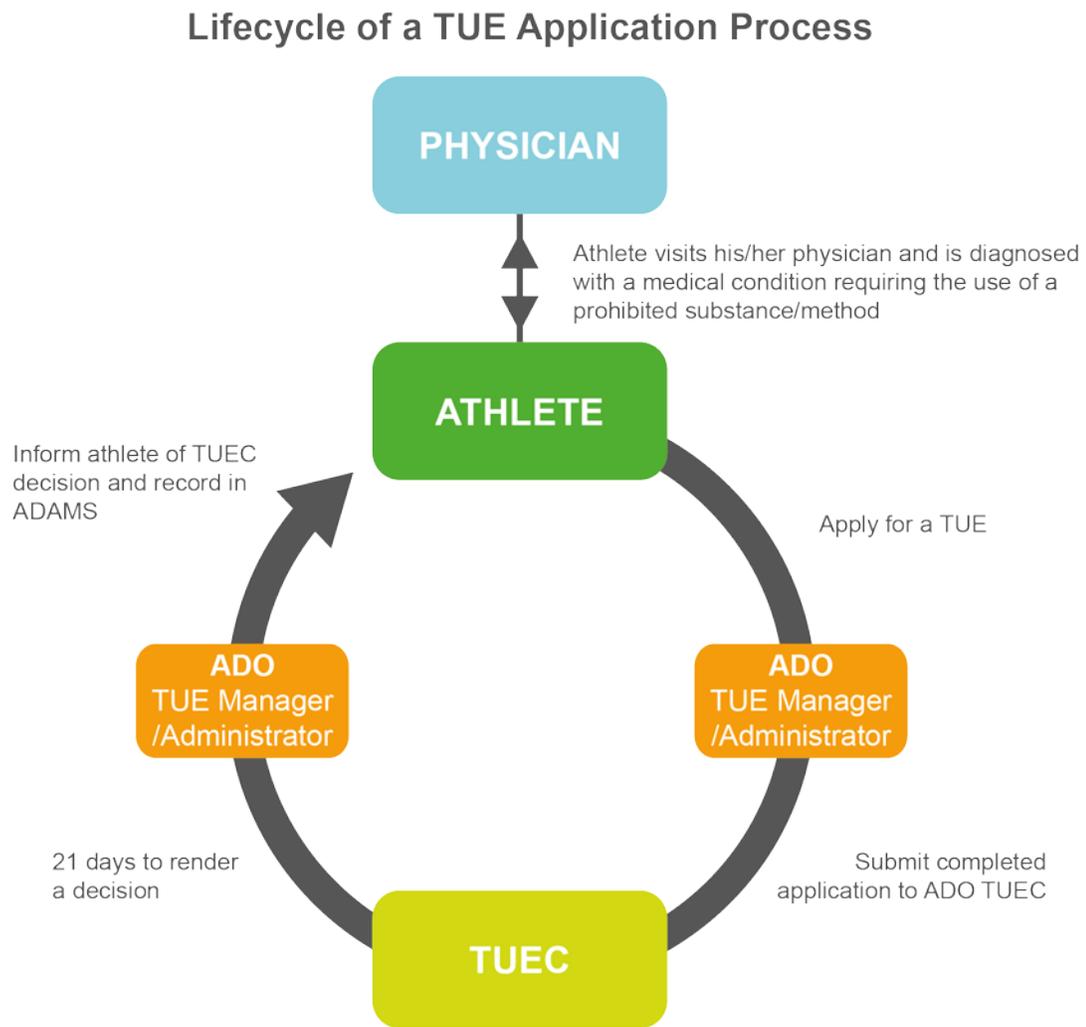
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If an athlete has a medical condition requiring treatment containing a prohibited substance or that constitutes a prohibited method included on the List, they must initiate the process of applying for a TUE as soon as possible. The lifecycle of a TUE process is illustrated below.

Figure 1:



*The ADO assumes a facilitator role between the athlete and the TUEC. ADO staff dealing with TUEs should not be involved in others areas which may create a conflict of interests. E.g. testing or intelligence.

CHAPTER 3:

When to apply for a TUE?

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Generally, athletes should apply for a TUE as soon as possible or when the need arises. However, some athletes may be able to apply retroactively, after they have provided a sample, and only if one of the exceptions listed in ISTUE Articles 4.1 or 4.3 apply.

1.0 For substances prohibited in-competition only

- ❖ Athletes should apply for a TUE at least 30 days before their next competition, unless it is an emergency or exceptional situation.
- ❖ If athletes know they will be taking a prohibited substance on a long-term basis, even if it is only prohibited in-competition, they should still apply as soon as possible to the appropriate ADO.

2.0 For substances prohibited at all times

- ❖ The TUE application must be submitted as soon as the medical condition requiring the use of a prohibited substance or prohibited method is diagnosed, or as soon as the athlete reaches a competitive level requiring advance application for a TUE.
- ❖ Some athletes who compete only at the national level or below may not be required or even allowed to apply in advance by their NADO. This will depend on the NADO's sport prioritization program and anti-doping rules. These athletes will be allowed to apply retroactively after they have provided a sample when subject to doping control. It is always important for athletes to first consult with their NADO (through their website for example) to see if they fall into this category.

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Where to apply for a TUE?

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The athlete should submit their TUE application to the relevant ADO via WADA's Anti-Doping Administration and Management System (ADAMS) or in paper format using the appropriate TUE application form. In the latter case, the ADO then enters the information in ADAMS.

Athletes may only apply to one ADO at a time for a TUE for the same medical condition. Further, athletes may not have more than one TUE for the same medical condition at the same time.

1.0 National-level athletes (NLAs)

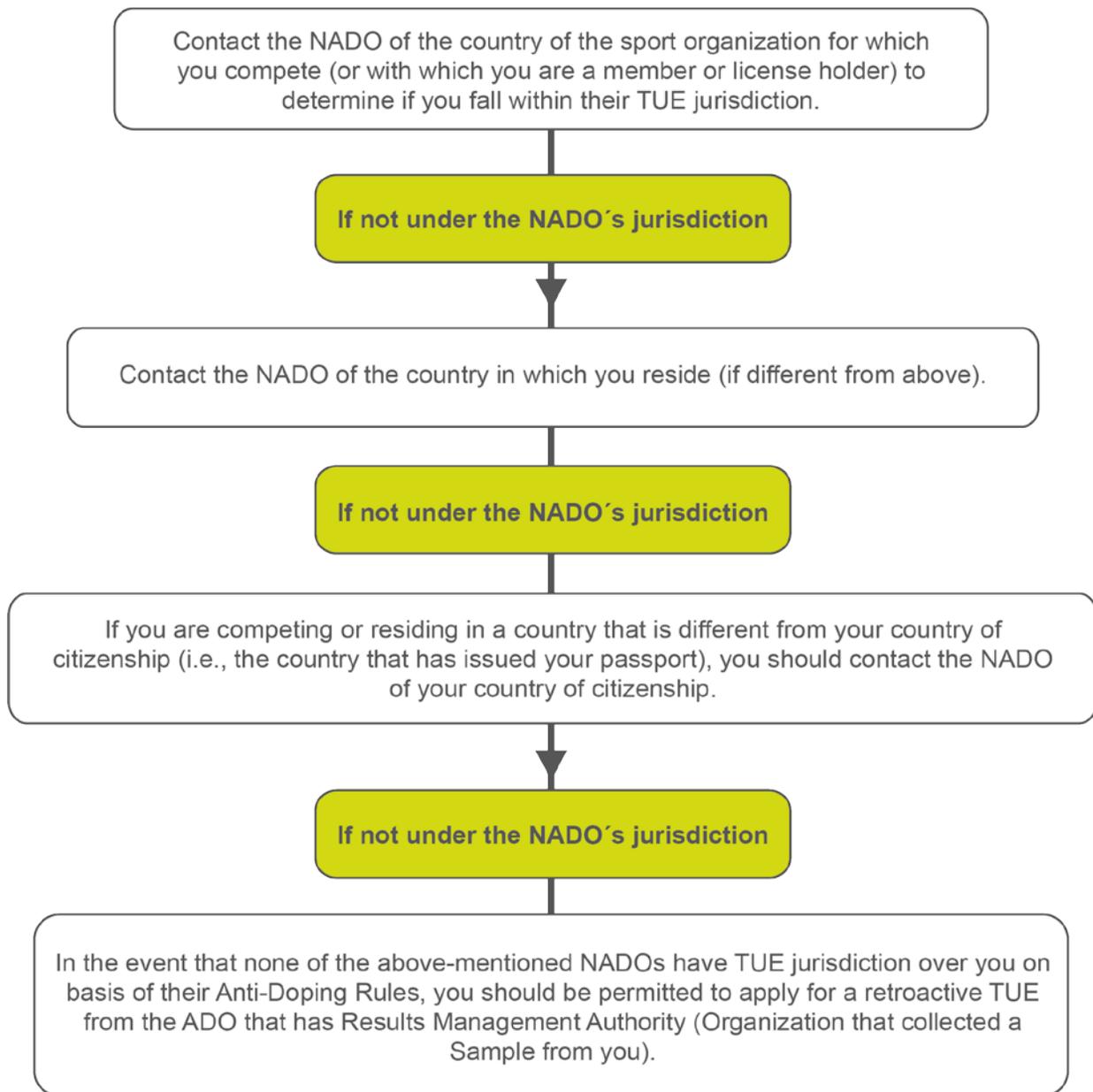
- ❖ NLAs must apply to their NADO for a TUE. NADOs decide which athletes are considered NLAs. However, since criteria may differ from one NADO to another, athletes are advised to contact their NADO if there is a need for clarification or confirmation. Please see Flowchart “Where should NLAs (or lower level athletes) apply?”, (Figure 2).

- ❖ Note that some athletes may not be considered as NLAs and/or may be a low priority athlete for that particular NADO. They may not need to apply in advance for a TUE (ISTUE Article 4.1(c)). Athletes should consult the NADO rules or contact the NADO for clarification.

Where should NLAs (or lower level athletes) apply?

It should be noted that the Code and ISTUE allow each NADO to decide which athletes fall under their jurisdiction.

Figure 2:



2.0 International-level athletes (ILAs)

ILAs must apply for a TUE directly to their IF. IFs decide which athletes are considered as international level within their sport and are required to publish this information on their website either as:

- ❖ a list of athletes under their jurisdiction; or
- ❖ a notice that clearly sets out which athletes they consider international level and required to apply for a new TUE or request recognition of an existing NADO TUE.

If the athlete is still uncertain where to apply, they should contact their IF directly.

If an athlete changes level from national to international, it is their responsibility to alert or notify the IF if they already have a NADO TUE. The IF should then request access to the medical information from the NADO in order to evaluate and recognize (or not) the TUE. This step may not be necessary if the TUE is automatically recognized by the IF. The IF must publish a notice on their website, stating under which situations a TUE will be automatically recognized. See [Chapter 21](#) on automatic recognition. The athlete's NADO may assist them with this process.

Athletes who are not ILAs according to the rules of their IF, but who have a TUE granted by their NADO and who then compete in certain international event(s), will need their TUE to be recognized by the relevant IF before it can be considered valid at international level. It is recommended that IFs publish a list of the events on their website that require an athlete to seek recognition of their NADO TUE.

There may be occasions when a non-ILA is not required to apply in advance to their NADO for a TUE (according to the NADO rules). If this athlete decides to compete at an international event requiring advance TUE approval they should apply directly to the IF hosting the event unless they make an arrangement with the appropriate NADO to process the TUE. The IF must provide clear and concise guidance to the athlete as to where and when they should apply. There may be situations, particularly for large participation events, when the rules are such that lower level athletes will only be able to apply retroactively.

3.0 Recreational-level athletes (RLAs)

This is a new category of athlete as defined in the 2021 Code for athletes who do not compete at a high level. A RLA is defined by the relevant NADO but it cannot include an athlete who, within the five years prior to committing any ADRV:

- ❖ has been an ILA or NLA;
- ❖ represented any country in an international event in an open category;
- ❖ been included within any Registered Testing Pool (RTP) or other whereabouts information pool.

Athletes need to consult the applicable NADO rules or contact their NADO to see whether they are required to apply in advance for a TUE. Depending on the applicable rules and as per the ISTUE, a recreational athlete will be able to apply retroactively for a TUE in light of ISTUE Articles 4.1 (c) and 4.1 (d).

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What are the responsibilities of an athlete in submitting a TUE application?

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The athlete must inform/remind their doctor on each visit that they are an athlete as defined by their ADO and therefore subject to anti-doping rules.

1.0 Providing adequate medical information to the ADO

It is the athlete's responsibility to provide a completed TUE application containing adequate medical information to confirm the diagnosis to the ADO and the ADO TUEC. The athlete is strongly recommended to bring the TUE application form and the relevant [TUE Checklists](#) with them to their physician or have an electronic version readily accessible.



PROVIDING MEDICAL INFORMATION EXAMPLE

17-year-old male swimmer with suspected diabetes. Ideally, prior to his consultation with his physician, he will consult his ADO website where he will find the:

- ❖ TUE application form. This will be easily available to download from the applicable ADO's website or may be entered directly in ADAMS.
- ❖ A copy of the Diabetes TUE Checklist (see below, Figure 3). Note that the [TUE Checklists](#) for the most commonly seen conditions are available in many languages.

Figure 3: TUE Checklist for Diabetes (Insulin)



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CHECKLIST FOR THERAPEUTIC USE EXEMPTION (TUE)
APPLICATION: DIABETES
PROHIBITED SUBSTANCE: INSULIN

CHECKLIST FOR THERAPEUTIC USE EXEMPTION (TUE)
APPLICATION: DIABETES | PROHIBITED SUBSTANCE: INSULIN

This checklist is to guide the athlete and their physician on the requirements for a TUE application that will allow the TUEC to assess whether the relevant ISTUE criteria are met. Please note that the completed TUE application form alone is not sufficient; supporting documents **MUST** be provided. A completed application and checklist **DO NOT** guarantee the granting of a TUE. Conversely, in some situations a legitimate application may not include every element on the checklist.

TUE APPLICATION FORM MUST INCLUDE:	
All sections completed in legible handwriting	<input type="checkbox"/>
All information submitted in [language]	<input type="checkbox"/>
A signature from the applying physician	<input type="checkbox"/>
The Athlete's signature	<input type="checkbox"/>
MEDICAL REPORT SHOULD INCLUDE DETAILS OF:	
Medical history: symptoms, age at onset, course of disease, start of treatment, hypoglycaemia, diabetic ketoacidosis, diabetes-related complications (where applicable)	<input type="checkbox"/>
Interpretation of symptoms, signs and test results by physician	<input type="checkbox"/>
Diagnosis based on international criteria (fasting blood glucose/glucose tolerance test/ A1C or random blood glucose)	<input type="checkbox"/>
Type of insulin prescribed including dosage, frequency, administration route	<input type="checkbox"/>
DIAGNOSTIC TEST RESULTS SHOULD INCLUDE COPIES OF:	
Laboratory tests (e.g., A1C profile, blood glucose)	<input type="checkbox"/>
Oral glucose tolerance test results (if done)	<input type="checkbox"/>
ADDITIONAL INFORMATION INCLUDED:	
As per ADO specification	<input type="checkbox"/>

The athlete should work with their physician to fill out the TUE application form and collect the supporting documents listed on the TUE Checklist. It is important to ensure that the physician has correctly completed all the medical information, diagnosis, and medication details sections in the TUE application. It is also important that they sign and date the physician declaration. The athlete may choose to fax, mail or send all the information via secure email to the ADO who will enter the information into ADAMS. The athlete or physician may complete the form directly via ADAMS, if they have an account.

It is important for the athlete and their physician to be aware that a TUE application is only considered complete if it enables the TUEC to determine if the criteria set forth in the ISTUE (Article 4.2) are satisfied or not.

The following information must be included on/submitted with the TUE application form:

- ❖ the relevant diagnosis and medication details (prohibited substance/method name, dosage, route and frequency of administration, expiry date/duration of treatment);
- ❖ a declaration from the physician (including name, contact information and specialty); and
- ❖ supporting medical information (including comprehensive medical history, documentation from the original diagnosing physician(s) (where possible), results of relevant examinations, laboratory investigations and imaging studies, as applicable, as well as original medical reports or letters).

Athletes and treating physicians should refer to the [TUE Checklists](#) for more detailed explanations, whilst the [TUE Physician Guidelines](#) provide more in depth explanations of the requirements.

Athletes should keep a complete copy of the TUE application form, and of all materials and information submitted in support of that application. All appropriate medical information necessary for the TUEC to make a decision must be entered into ADAMS in either English or French. Ultimately it is the athlete's responsibility to provide these translations, but WADA recommends that ADOs assist their athletes.

TUE information must be entered in ADAMS in English or French. It is acceptable to provide a translated summary explaining the diagnosis, key elements of the clinical exams, medical tests and the treatment plan. It would not be acceptable to translate two lines from a physician stating the diagnosis and treatment. The summary should be prepared by either the treating physician or an ADO physician/staff member with an understanding of the case/condition. (See [Annex](#) for examples). WADA may, however, request further translations of the medical file, as necessary.

2.0 Dealing with incomplete applications

A TUE application will only be considered by the ADO TUEC following the receipt of a properly completed application form, accompanied by all relevant medical information. Incomplete applications will be returned by the ADO to the athlete for completion and re-submission. ADOs should clearly explain to athletes why their application was deemed incomplete.

3.0 Obtaining further information

The ADO TUEC may request additional information, examinations or imaging studies, or other information from the athlete or their physician, and/or involve other medical or scientific experts.

Similarly, when a WADA TUEC is reviewing a case, they may request additional information from the ADO and/or the athlete, including further studies, and/or involve other medical or scientific experts. However, a WADA TUEC may reverse a granted TUE without requesting further information, and the athlete would then have to re-apply for a TUE to the appropriate ADO. If the ADO has translated the athlete's file, the athlete will be given an opportunity to review the translation. Please see Section 7 for further information on WADA TUE reviews.

4.0 Starting medical treatment prior to the grant of a TUE

The TUE is valid, (from the effective date) once the athlete is notified by the ADO that the TUE has been granted.

Athletes who possess or use the prohibited substance(s) or prohibited method(s) prior to receiving this notification do so at their own risk. Such prior use or possession would constitute an ADRV in the event of denial of the TUE by the TUEC. However, in situations of a medical emergency or need for urgent treatment, an athlete should not jeopardize or risk their health and should be aware that they will, in such circumstances, be able to apply retroactively for a TUE. Such a TUE request is still subject to the criteria listed in ISTUE Article 4.2 (unless ISTUE Article 4.3 applies).

Athletes should verify if the substance or method they are using, or in possession of, is legal in the specific jurisdiction (e.g. country, state or province) where they compete or plan to compete. A TUE only grants permission to use and/or possess a prohibited substance or method while competing in sport. For example, cannabis or opioids are illegal in various states and countries and there may be serious legal consequences for transgressing those rules regardless of whether one was granted a TUE.

5.0 Costs involved in a TUE application

The athlete is responsible for all costs related to a TUE application, and for any supplemental information required by the TUEC.

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1.0 Processing of a TUE application

TUE applications are examined by the TUEC of the relevant ADO. In accordance with Article 6.9 of the ISTUE, the TUEC shall decide whether or not to grant the application as soon as possible, and usually (i.e., unless exceptional circumstances apply) within no more than 21 days of receipt of a complete application. Furthermore, the ADO must enter all the relevant information in ADAMS within 21 days from the date of the decision.

Following the assessment of the TUE application, a TUE certificate or a letter explaining to the athlete why the TUE was denied will be issued to the athlete (confirming any relevant reasons for the rejection decision or conditions associated with the granted TUE).

2.0 Validity of a TUE

- ❖ The TUEC assigns a start and end date to each TUE, upon which the TUE will expire automatically. The TUEC should use the WADA [TUE Physician Guidelines](#) to guide them in determining the duration. Athletes need to be aware of the duration of their TUE and be ready to re-apply well in advance before it expires.
- ❖ A TUE may be cancelled prior to its expiry if the athlete does not comply with any of the requirements or conditions imposed by the TUEC when it granted the TUE. For example, a TUEC may permit the use of testosterone under strict conditions, which may include submitting updated clinical test results to the ADO.
- ❖ An MEO TUE may only be granted for the duration of the MEO's event. If the athlete needs to continue using the prohibited substance or method and compete in sport, they will need to apply to the relevant ADO (i.e. their NADO or IF, as applicable) for a new TUE.

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What happens after a TUE is granted?

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1.0 Changes in the medical treatment

A TUE is granted for a specific dosage, frequency, route of administration and duration. Therefore, if there is a significant change to the conditions specified in the TUE, the athlete must contact their ADO to determine if they may simply provide the new information or are required to apply for a new TUE. It is recognized that for certain medical conditions, dosages may fluctuate, particularly during the early stages of treatment, e.g. for a condition such as insulin-dependent diabetes. The ADO may allow some flexibility of dosages but should note this in the conditions of the granted TUE. One should be aware that if an athlete returns an Adverse Analytical Finding (AAF) that is not compatible with the TUE, the athlete could be charged with an ADRV. For example, an athlete has a TUE for 10mg of substance X daily; however, the estimated concentration of the prohibited substance detected in their sample showed that they were taking far in excess of the approved dosage.

2.0 Renewing a TUE

Although not all tests or evaluations need necessarily be repeated, TUEs cannot be renewed without a new medical consultation and confirmation. The athlete must complete a new application signed by their physician. The athlete should reapply for the new TUE well in advance to allow sufficient time for a decision to be made on the application before the existing TUE expires. Automatic extension of a TUE is not allowed under any circumstances.

It may not be necessary to have an extensive re-evaluation, particularly for long-standing conditions. However, this is on a case-by-case basis and the athlete is advised to provide updated information rather than a brief note from a physician stating that the athlete should continue treatment. Although the athlete may receive a notification about an expiring TUE, it remains their responsibility to be aware and apply for a renewal of their TUE, when necessary.

If an athlete applies for a renewal of their TUE, the relevant medical information from the prior TUE(s) will be automatically be transferred to the new application by the ADO.

CHAPTER 8:

What happens if a TUE is denied?

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1.0 Explaining the reasons of denial

If a TUE application is denied, the TUEC is required to provide the athlete with an explanation of the reason(s) why the TUE was refused on each of the relevant ISTUE Article 4.2 criteria. A statement simply stating “ISTUE Article 4.2(c) (no reasonable alternative) was not met” is not sufficient. The TUEC should elaborate on how it reached its decision.

2.0 Missing medical information

If the TUE is denied because of a lack of medical tests and/or other information required to demonstrate the satisfaction of ISTUE Article 4.2 criteria, the matter should not be referred to the relevant national level appeal body, Court of Arbitration for Sport (CAS) or WADA. Instead, the file should be completed and re-submitted to the ADO. Athletes should contact their ADO for help and guidance

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Where to appeal a TUE decision?

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1.0 National-level athlete

If a NLA wishes to appeal a NADO TUEC decision, they would do so before the relevant national appeal body in their country. The NADO should guide the athlete through this process.

A NLA cannot appeal to CAS unless provided for within their NADO's rules. A national appeal body decision is final. However, WADA and the athlete's IF (and the International Olympic Committee or International Paralympic Committee, as and when applicable) have the right to appeal the national level appeal body's decision to CAS. WADA may review any TUE decision, at any time, on its own initiative.

A NLA can also request that WADA review the NADO TUEC's decision; however, WADA is not required to conduct such a review.

2.0 International-level athlete

An ILA may request that WADA review their refused TUE application. However, WADA is not obliged to review all TUE decisions and may do so at its discretion. There are cases where WADA must accept to review (see Section 7).

An ILA (or their NADO) may appeal an IF's TUE decision to the CAS if this decision is not reviewed by WADA or, if it is reviewed by WADA and the decision is not reversed on review.

It is important to note that in such cases, the decision being appealed by the athlete or the NADO is the IF's TUE decision.

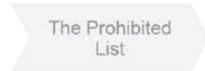
If WADA reviews any TUE decision and reverses it, WADA's decision may be appealed to CAS by the athlete, or the relevant NADO or IF.

CHAPTER 10:

How the athletes' personal information is dealt with throughout the TUE process

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1.0 Processing the athlete's information

When an athlete applies for a TUE, they are asked to provide health information to ADOs so they can determine, with the advice of health professionals, if the athlete can use a substance or method that would normally be prohibited in sport. This includes the diagnosis and medication details for the medical condition as well as supporting medical records, for example medical history, examination results, imaging studies, etc.

The athlete's ADO should provide them with complete details about the information needed for their application, how it will be used, and who will have access to it during the application process. The TUE Application Form provides a summary of this information.

When an athlete applies for a TUE, they may be asked by the ADO to confirm that they allow their physician to communicate additional health information to the members of the relevant TUEC if necessary. The TUEC members are physicians tasked with assessing TUE applications. Athletes can withdraw permission for their physician to release this information at any time. If the athlete does so, the TUE application or request for TUE recognition will be deemed withdrawn and will not be approved.

Once the TUE application is complete, if the athlete has an ADAMS account, they can submit it directly via this platform. The ADO may also allow submission via registered mail or a secure portal. When using email, it is recommended not to attach the application and supporting documents, instead WADA recommends the use of a secure file sharing system to safely share these documents. These systems allow the sharing of a link to a secure location where the athlete has uploaded their documents. These systems also allow athletes to set permissions for the link, for example, by requiring the recipient to authenticate themselves (e.g. with a password), only making the documents available for download for a limited period and notifying the athlete when they are downloaded. The athlete's ADO can also send an "upload link" by email if they use one of these systems. If these systems are not available, athletes should consider at least protecting their documents with a password that they can share separately with the ADO.

No matter how the athlete submitted their TUE application, it will be uploaded to ADAMS by the ADO so that it is available to WADA and other ADOs that need it to review and recognize the TUE.

More specifically:

- ❖ WADA needs access to complete TUE information in ADAMS to make sure TUEs are granted or rejected according to the rules of the Code and ISTUE. You can find out more about how WADA processes TUE information in the [ADAMS Privacy Policy](#);
- ❖ The athlete's NADO and IF need to know that the TUE was granted or rejected, and what it is for, so they know not to treat an AAF as an ADRV when it falls within the scope of the TUE;
- ❖ If an ADO needs to recognize the TUE, they should contact whoever granted it and request access to the medical file located under the "Diagnosis Information" tab in ADAMS; and
- ❖ If ADOs work with service providers to manage TUEs, it is possible they would also have access to the TUE information. The ADO should inform the athlete if this is the case.

To better understand how TUE information is handled within ADAMS, athletes can consult the response to [What information is collected in ADAMS and how is it used and shared?](#) in our [ADAMS Privacy and Security FAQs](#).

Outside of ADAMS, TUE applications will be assessed by individuals responsible for TUEs at ADOs and at WADA. It will also be assessed by the physicians who are part of the TUEC at the athlete's ADO and at WADA. Sometimes, other independent experts also need to be consulted to properly assess the application.

2.0 Protecting the athlete's information

ADOs are subject to strict confidentiality requirements with respect to an athlete's TUE information. All the information contained in a TUE application, including the supporting medical information, and any other information related to the evaluation of a TUE request must be handled in accordance with the principles of medical confidentiality.

Physicians who are members of a TUEC and any other experts consulted must be subject to confidentiality agreements. Physicians are also typically subject to a number of professional obligations to protect their patients' confidentiality.

Under the [International Standard for the Protection of Privacy and Personal Information \(ISPPPI\)](#), ADO staff must also sign confidentiality agreements, and the ADO must implement strong privacy and security measures to protect athlete's personal information. The ISPPPI requires ADOs to apply higher levels of security to TUE information, because of the sensitivity of this information.

Information about security in ADAMS can be found by consulting the response to [How is your information protected in ADAMS?](#) in our [ADAMS Privacy and Security FAQs](#).



Points to Remember

- ❖ Athletes should familiarize themselves with the Prohibited List and the TUE process.
- ❖ Athletes should reach out to their ADOs for help and guidance with the TUE process.
- ❖ WADA cautions athletes to ensure that their TUE supporting documentation is sufficient to meet the ISTUE criteria. A summary of medical information required, aimed at athletes and their physicians, can be found on the [WADA website \(TUE Checklists\)](#).
- ❖ Athletes should declare any medication or supplement that they are taking on their Doping Control Form.
- ❖ Athletes should be aware that there are certain situations in which a TUE may be applied for retroactively (see [Chapter 10](#)).

SECTION 3:

Obtaining a TUE

This section will support your understanding of Article 4.0 of the International Standard for TUEs. These are the key criteria that every person should know when applying for or evaluating a TUE. Hypothetical examples are included to provide extra clarification.



CHAPTER 11:

When may an athlete apply for a retroactive TUE (ISTUE Article 4.1)?

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While WADA encourages all athletes to apply in advance for a TUE, this is not always possible, especially when athletes require immediate medical treatment. The health and safety of the athlete is paramount, and no treatment should be withheld that would result in the athlete's health being compromised.

ISTUE Articles 4.1(a)-(e) cover a range of scenarios when an athlete may find themselves unable or not required to apply for a TUE in advance. A retroactive application submitted under Article 4.1 only allows the athlete the opportunity to apply for a TUE after starting to use the prohibited substance or method. In order to be granted a retroactive TUE in accordance with ISTUE Article 4.1, all the criteria set out in ISTUE Article 4.2 still need to be fulfilled.

Decisions regarding the retroactive criteria indicated in ISTUE Article 4.1 often involve assessing factors that are not purely medical. As such, they should be evaluated on a case-by-case basis by the relevant ADO and, when necessary, in consultation with a member(s) of their TUEC.

Retroactive TUE applications may be made in the following circumstances:

1.0 The retroactive application

- a) Emergency or urgent treatment of a medical condition was necessary.

The word 'urgent' was added to the new ISTUE as it is recognized that athletes may be prescribed medications or treatments and advised to begin immediately. While the situation may not be a true medical emergency, failure to start treatment immediately could put the athlete's health at risk.

ADOs should have internal procedures to expedite the evaluation and grant of TUEs for emergency situations, whenever possible.



EXAMPLE CASE 4.1 (a) – EMERGENCY TREATMENT

Background

- ❖ The athlete is a 28-year-old professional footballer.

Case Scenario

- ❖ Playing for his country in an international tournament.
- ❖ The tournament is held in the middle of summer and temperatures are extremely high.
- ❖ After the game the player is near collapse, with some clinical signs of dehydration, as well as hyperthermia.
- ❖ The team doctor administers an IV infusion of 1000ml (500ml NaCl +500ml Glucose) to the player in the dressing room, as well as treating him for hyperthermia.

Summary

- ❖ The team doctor may apply for a retroactive TUE under ISTUE Article 4.1(a).



EXAMPLE CASE 4.1 (a) – URGENT TREATMENT

Background

- ❖ 25-year-old endurance athlete.
- ❖ Documented history of asthma and severe pollen allergy since childhood.

Current Medication

- ❖ Inhaled fluticasone + formoterol
- ❖ Oral leukotriene antagonist
- ❖ Oral antihistamine
- ❖ Inhaled salbutamol + ipratropium bromide before exercise

Case Scenario

- ❖ Athlete competes in major games during high pollen season.
- ❖ Three days before their competition the athlete has an asthma flare-up necessitating urgent medical consultation.
- ❖ Increased use of inhaled salbutamol and introduction of oral prednisolone are advised by the attending physician.
- ❖ Athlete is selected for doping control and tests positive (i.e. returns an AAF) for both substances.

Summary

- ❖ The athlete may apply for retroactive TUE under Article 4.1(a) supported by medical files.

- b) Insufficient time, opportunity or other exceptional circumstances that prevented submission/consideration of a TUE application prior to sample collection.



EXAMPLE CASE 4.1 (b) – CASE 1

Background

- ❖ The athlete is a 20-year-old male sprinter.
- ❖ Diagnosed in childhood with Type 1 diabetes.

Current Medication

- ❖ Lantus Solostar 5IU daily
- ❖ Novorapid 2.5IU before main meal and when required

Case Scenario

- ❖ Athlete wins a college race, qualifying for national championships four days later.
- ❖ He has never competed at national level.
- ❖ NADO requires all athletes competing at national level to apply in advance for a TUE.
- ❖ Athlete is away from home, does not have immediate access to medical files and is unable to prepare a TUE application prior to event.
- ❖ Athlete competes, is tested and returns an AAF for insulin.

Summary

- ❖ The athlete may apply for a retroactive TUE under ISTUE Article 4.1(b).



EXAMPLE CASE 4.1 (b) – CASE 2

Background

- ❖ The athlete is a 27-year-old female swimmer.
- ❖ She was diagnosed with Ulcerative Colitis (UC) five years ago.

Current Medication

- ❖ Sulfasalazine 500mg three times a day
- ❖ Over the counter Probiotics

Case Scenario

- ❖ Four days before her national swim meet the athlete has a flare up of her UC.
- ❖ Her doctor prescribes her a 7-day course of prednisolone and the athlete applies for a TUE.
- ❖ The ADO received the athlete's application the day before the event and didn't submit it to their TUEC before she competed in her competition.
- ❖ She came third in her competition and was tested afterwards. She returned an AAF.

Summary

- ❖ The ADO processes the application as a retroactive TUE under ISTUE Article 4.1(b).

- c) Due to national level prioritization of certain sports, the athlete's NADO did not permit or require the athlete to apply for a prospective TUE.
- ❖ NADOs may prioritize certain sports due to resources or other legitimate reasons and thus not allow or require athletes competing in specific sports to apply for an advance TUE.
 - ❖ More guidance regarding this is usually included in the NADO anti-doping rules and guidance should also be available on the NADO's website.



EXAMPLE CASE 4.1 (c)

Background

- ❖ The athlete is a 30-year-old female ice hockey player.
- ❖ The athlete was previously diagnosed with polycystic ovary syndrome.

Current Medication

- ❖ Spironolactone 50mg once daily

Case Scenario

- ❖ While competing at national championships, she is tested and returns an AAF for spironolactone and its metabolites.
- ❖ In her country there are few ice hockey players, with football, rugby and athletics more popular.
- ❖ To prioritise resources, this particular NADO declares that national level ice hockey players do not require an in-advance TUE.

Summary

- ❖ The athlete may apply for a retroactive TUE under ISTUE Article 4.1(c).

- d) If an ADO chooses to collect a sample from an athlete who is not an ILA or NLA, and that athlete is using a prohibited substance or prohibited method for therapeutic reasons, the ADO must permit the athlete to apply for a retroactive TUE.
- ❖ Dependent on the ADO rules athletes competing below the national level may not be required and/or permitted to apply for a TUE in advance of the use of the prohibited substance or method.



EXAMPLE CASE 4.1 (d)

Background

- ❖ The athlete is a 17-year-old male shot-putter.
- ❖ He was diagnosed at age 7 with ADHD.

Current Medication

- ❖ Concerta 54mg every morning
- ❖ Ritalin 10mg once daily at 4pm

Case Scenario

- ❖ This young athlete competes at his first national championships and returns a surprising placed on the podium.
- ❖ He is selected for doping control and returns an AAF.

Summary

- ❖ The athlete was advised by their NADO to apply for a retroactive TUE under ISTUE Article 4.1(d).

- e) Out-of-competition use of a prohibited substance that is only prohibited in-competition.
- ❖ In certain situations, an athlete may require medical treatment out-of-competition, with a medication that contains a substance that is only prohibited in-competition. In these situations, the substance may still be found in sufficient quantities in the sample and there is a risk of an AAF when tested in-competition. In other words, the substance may still remain in the athlete's system and be detected during an anti-doping test days after its use.
 - ❖ If the athlete returns an AAF, in such a scenario, the ADO must allow the athlete the opportunity to apply for a retroactive TUE for the prohibited substance in question (where the athlete has not applied in advance). An example is the use of glucocorticoids (GCs) out-of-competition.

ISTUE Article 4.1(e) ensures that the athlete has the right to apply retroactively yet also removes the requirement for ADOs to assess advance TUE applications that are often not necessary.

Further elaborating on ISTUE Article 4.1(e); stopping the use or tapering some medications too rapidly could have adverse health consequences and should never be undertaken without consultation with the athlete's physician and a full appreciation of the risks involved.

For GCs new reporting thresholds with washout periods will be established in 2022 with the changes to prohibited routes of GC administration. Washout periods will assist athletes to determine whether they may return an in-competition AAF and whether an application for TUE would be necessary. Clearly, the closer to the end of the washout period, the more likely it will be that the GC reporting levels will be exceeded. Athletes taking any medication that may be prohibited should nevertheless be prepared to provide appropriate medical documentation as required. See [TUE Checklists](#) for the appropriate medical conditions.



EXAMPLE CASE 4.1 (e) – SCENARIO 1

Background

- ❖ The athlete is a 33-year-old male wheelchair basketball athlete.
- ❖ A week prior to the European Championships he is diagnosed with bronchitis.
- ❖ His doctor prescribes antibiotics and a course of prednisone due to finish the day before competition.

Medication

- ❖ Amoxicillin 500mg three times daily for 7 days
- ❖ Prednisolone 30mg in the morning for 5 days

Case Scenario

- ❖ He is tested in-competition and returns an AAF for prednisolone.

Summary

- ❖ The athlete may apply for a TUE under ISTUE Article 4.1(e).



EXAMPLE CASE 4.1 (e) – SCENARIO 2

Background

- ❖ 27-year-old male rugby athlete with a grade 2 AC sprain (shoulder separation).
- ❖ Athlete receives physical therapy, applies ice and takes NSAID.
- ❖ He stops training and misses two games.
- ❖ He wants to play in the following game but still has pain.
- ❖ Team doctor sends him to orthopedic surgeon who injects a GC into AC joint 36 hours prior to the next game.
- ❖ The athlete requests a medical note from the orthopedist, which he gives to his doctor, to put in his record.

Medication

- ❖ Betamethasone (Celestone) 1ml into the AC joint
- ❖ Paracetamol 500mg (Two taken four times a day)

Case Scenario

- ❖ The athlete plays and afterwards is subject to doping control returning an AAF for betamethasone.

Summary

- ❖ He may apply for a TUE under ISTUE Article 4.1(e).

For Retroactive TUEs 4.1 c-e:

- ❖ It is advisable that the athlete gathers relevant medical reports in advance, in case there is a need to apply for a retroactive TUE.
- ❖ WADA encourages any athlete to contact their ADO to discuss the retroactive process to better understand their rights and responsibilities.

CHAPTER 12:

Criteria for the grant of a TUE (ISTUE Article 4.2)

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Article 4.2 of the ISTUE sets out the key criteria that need to be satisfied for the grant of a TUE. TUECs will evaluate the medical information provided by the athlete and their physician to determine if they have, on the balance of probabilities, satisfied their burden of proof to fulfill all four criteria. The TUE will be granted only if all the conditions listed in ISTUE Article 4.2 are satisfied.

A “balance of probabilities” is a lower standard of proof than “comfortable satisfaction” and means that the TUEC is satisfied that it is more likely than not that the criterion was satisfied.

One of the two key purposes of the Code is:

To protect the athletes’ fundamental right to participate in doping-free sport and thus promote health, fairness and equality for athletes worldwide.

The four criteria are explored further below, followed by case examples:

1.0 Evaluating the ISTUE 4.2 criteria

- a) The prohibited substance or prohibited method in question is needed to treat a diagnosed medical condition supported by relevant clinical evidence.

In order to satisfy this condition, the athlete must demonstrate, on a balance of probabilities, that they have a true medical condition and, with their physician’s help, demonstrate that this medical condition requires the described treatment. It is not sufficient for their physician to simply provide the diagnosis. Instead, the TUECs evaluating TUE applications must be able to understand how the diagnosis was made. The details of the necessary documentation are described in the [TUE Physician Guidelines](#) and [TUE Checklists](#) for the different medical conditions and are available to download from the WADA website.

The use of a prohibited substance or prohibited method may be part of a necessary diagnostic investigation rather than a treatment. However, this should be a rare occurrence and will still require strong medical justification in support of the application (comment to ISTUE Article 4.2(a)). An example may be the adrenocorticotrophic hormone (ACTH) stimulation test used to diagnose adrenal insufficiency. It should be noted that “diagnostic investigations” would not include trials or studies of prohibited substances, such as testosterone.



EXAMPLE CASE 4.2 (a)

Background

- ❖ The athlete is a football (soccer) player who has made the U17 national team.
- ❖ He has a history of inattentiveness in school and talking during class.
- ❖ A consultation with his family physician suggests he may have Attention Deficit Hyperactivity Disorder (ADHD).
- ❖ The physician prescribes Adderall (amphetamine/dextroamphetamine), a stimulant medication.
- ❖ The athlete's behavior and academic performance significantly improve following initiation of treatment.
- ❖ Now selected for an U17 representative team, he undertakes on-line antidoping education, and realizes Adderall is on the List if taken in-competition.
- ❖ He applies for a TUE, with a letter from his physician reporting his history, and the effectiveness of the medication.

Considerations

- ❖ To satisfy ISTUE Article 4.2(a), the athlete must submit sufficient medical information to support the medication chosen to treat a correctly diagnosed medical condition.
- ❖ The [WADA TUE Physician Guidelines for ADHD](#) describe the information necessary to support a diagnosis of ADHD.
- ❖ In this case, the athlete has not submitted sufficient information to satisfy ISTUE Article 4.2(a). Specifically, he has not been seen by an appropriate medical specialist and he has not been subjected to the psychometric tests used to diagnose ADHD.
- ❖ The [TUE Checklists](#) are specifically designed for athletes and their treating physicians to inform them of the clinical details required for a TUE application.
- ❖ The athlete should take the checklist to his physician, who should then help arrange the necessary evaluations in order to be granted a TUE.



EXAMPLE CASE 4.2 (b)

Background

- ❖ The athlete is 29-year-old female archer, recently qualified for international competition.
- ❖ She takes a beta blocker to control high blood pressure, and is aware this is prohibited in the sport of archery, so she must apply for a TUE.
- ❖ She submits a TUE application clearly demonstrating her diagnosis of hypertension, with blood pressure readings off and on medications. Her application includes a full workup to rule out secondary causes.
- ❖ Despite trying alternatives, the combination of medication providing best control of her blood pressure is an angiotensin-converting enzyme (ACE) inhibitor, alpha-blocker and a beta-blocker.

Considerations

- ❖ The review of the athlete's application and the [TUE Physician Guidelines on Cardiovascular Conditions](#) indicate that there is good information to support the diagnosis, potential impairment to health if the medication was withheld, and no non-prohibited alternatives still to be tried.
- ❖ However, in order to satisfy ISTUE Article 4.2(b), the athlete must demonstrate that the medication will not, on balance of probabilities, produce any additional enhancement of performance beyond what might be anticipated by a return to the athlete's normal state of health following the treatment.
- ❖ The consideration in this specific example is that beta-blockers cause the heart rate to slow and may reduce tremor, thereby potentially enhancing performance in a precision sport such as archery. This may be a particular concern when athletes compete at a relatively high level.
- ❖ Note that in some cases, particularly for certain cardiac conditions, switching to a "reasonable" permitted alternative is not always a viable option. See the following ISTUE Article 4.2(c).

- c) The prohibited substance or prohibited method is an indicated treatment for the medical condition, and there is no reasonable permitted therapeutic alternative.

It is essential that the treatment provided must be indicated for the identified medical condition with clear justification in support of every TUE application.

WADA encourages the use of non-prohibited treatments where possible although it is not always necessary to try and fail alternatives before using the prohibited substance. With the help of experts, WADA has created guidance documents for several common conditions ([TUE Physician Guidelines](#)) to assist treating physicians and TUECs.

If the treating physician decides to prescribe a prohibited substance or method, they must clearly explain why that was the most appropriate treatment. Appropriate justification may include personal clinical experience, side effect profiles or, where appropriate, geographically-specific medical practice. In other cases, accessibility of specific medication or cost may be justifiable reasons. On occasion, opinions regarding valid and referenced medication may vary between countries. For example, medication registered in one country may not be available elsewhere, or its approval may be pending. Despite these matters, a clearly justified medical diagnosis is critical to the case.

Examples emphasizing 4.2 (c)



EXAMPLE CASE 4.2 (c) – EXAMPLE 1

Background

- ❖ A 26-year-old male basketball player was diagnosed with asthma as a child.
- ❖ Medical records include diagnostic spirometry and evidence of reversibility on beta-2 agonists. These tests conducted in childhood are repeated in adulthood.
- ❖ Player has been stable on terbutaline since childhood [S3. Beta-2 Agonists, Prohibited In- and out-of-competition plus an inhaled GC.]
- ❖ Player applies to IF TUEC for a TUE for terbutaline.
- ❖ Terbutaline is a commonly used beta-2 agonist in some countries.

Considerations

- ❖ Is the supporting medical evidence sufficient? Please refer to the WADA TUE [Physician Guideline on Asthma](#).
- ❖ Is the athlete stable on the medication; is it providing adequate therapeutic management of his condition?
- ❖ Each application should be assessed case-by-case.
- ❖ The athlete's health is paramount and switching from successful long-term treatments is not advisable.



EXAMPLE CASE 4.2 (c) – EXAMPLE 2

Background

- ❖ A 38-year-old female 5000m runner is diagnosed with fertility issues by a medical specialist.
- ❖ She is prescribed clomiphene for five days per month for three months.
- ❖ She applies to her IF for a TUE for clomiphene.

Considerations

- ❖ Is the supporting medical evidence sufficient? Please refer to the [WADA TUE Physician Guideline on infertility](#).
- ❖ Clomiphene is generally widely accessible and inexpensive.
- ❖ Clomiphene is generally not considered PE in women.
- ❖ Non-prohibited In Vitro Fertilization (IVF) treatments are expensive and not readily available in some countries.
- ❖ Common sense must prevail in this case.
- ❖ The TUEC must consider the whole picture, remembering the ISTUE and Code are to protect athletes and promote fair, inclusive sport.

- d) The necessity for the use of the prohibited substance or prohibited 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 such use.

The origin of this clause was that it was seen to be unfair if an athlete would request to use testosterone after long-term cheating with anabolic steroids that damaged their hypothalamic-pituitary-gonadal axis, or in other words, the long-term abuse shut down the natural production of testosterone. It would be very unlikely that this athlete would be granted a TUE for testosterone in that case. However, the use of methadone could be acceptable if the athlete was recovering from an opiate addiction.

2.0 Safety and legal considerations are not considered in the grant of a TUE

The grant of a TUE is based solely on consideration of the conditions set out in ISTUE Article 4.2. It enables the athlete to compete in sport while using a prohibited substance or method. It does not consider whether the prohibited substance or method is the most clinically appropriate or safe, or whether its use is legal in all jurisdictions.

For example, the use of narcotic analgesics and cannabinoids may be acceptable from a medical and TUE perspective, but the relevant sporting association may decide that, in certain situations, the use of narcotics and cannabinoids are an unacceptable safety risk to the athlete and/or other competitors. Sport safety issues are outside the realm of TUEs and anti-doping.

It is important to note that anti-doping authorities are not agents for law enforcement and do not carry the authority to grant athletes legal right to possess and carry illegal and/or controlled substances, such as narcotics and cannabinoids (and rarely some stimulants) across jurisdictional or international borders. It is the responsibility of the athlete to be aware of the law in the countries or jurisdictions in which they may be travelling.



Important to remember:

A TUE certificate does not grant the permission to possess a substance that is banned or illegal in a specific country or region.

CHAPTER 13:

When would it be manifestly unfair to deny a retroactive TUE (ISTUE Article 4.3)?

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1.0 Evaluating ISTUE Article 4.3 applications

In exceptional circumstances and notwithstanding the ISTUE Article 4.1 and 4.2 criteria, 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.

To be clear, the athlete may apply and possibly be granted a TUE under ISTUE Article 4.3 even if they have:

- ❖ fulfilled all the criteria in ISTUE 4.2, but not any of the retroactive conditions set out in ISTUE Article 4.1; or
- ❖ fulfilled at least one of the retroactive conditions in ISTUE Article 4.1, but not all the criteria in ISTUE Article 4.2

The application of ISTUE Article 4.3 should be used only for very rare cases and athletes should be aware of the high level of scrutiny involved with these applications.

ADOs should evaluate each ISTUE Article 4.3 application case-by-case. Often, cases may consist of factors other than those that are solely medical. For this reason, WADA recommends that these decisions be made in consultation with medical experts and relevant ADO staff (i.e. legal).

For the avoidance of doubt, retroactive approval may be granted under ISTUE Article 4.3 even if the conditions in ISTUE Article 4.2 are not met (although satisfaction of such conditions will be a relevant consideration). Other relevant factors might include the reasons why the athlete did not apply in advance; the athlete's level and experience; whether the athlete declared the use of the substance or method on the Doping Control Form; or the recent expiration of the athlete's TUE.

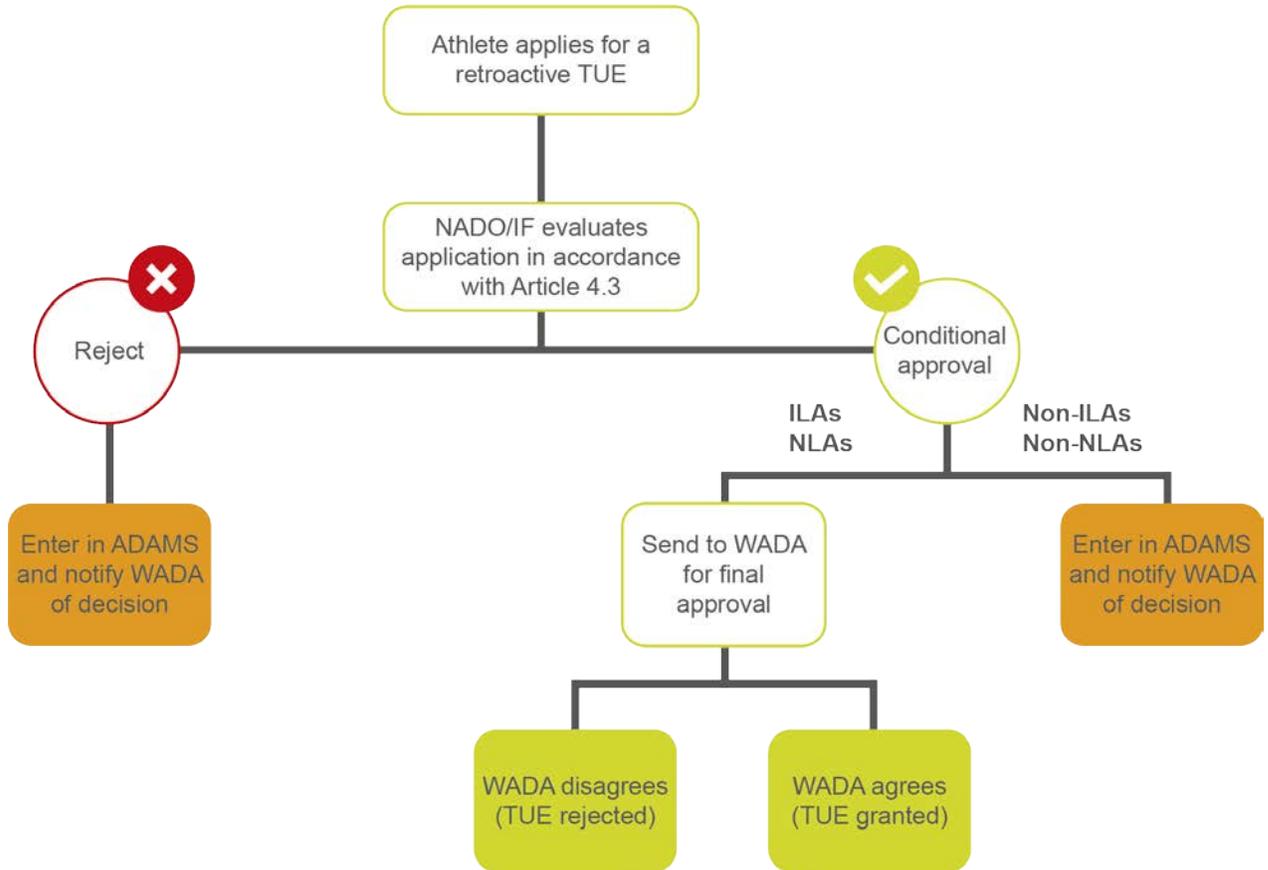
2.0 ISTUE Article 4.3 Process

For ILAs and NLAs, an ADO may grant an athlete's TUE under ISTUE Article 4.3 only after obtaining WADA's approval. The ADO must first evaluate the case, reach a decision and inform WADA. If WADA agrees with the ADO's decision, the TUE will be granted; however, if WADA disagrees, the TUE will not be granted. If the ADO rejects the application, they are still required to record this decision in ADAMS and inform WADA of its decision.

Any decision made by WADA and/or the ADO under ISTUE Article 4.3 may not be challenged as a defense to proceedings for an ADRV or by way of an appeal or otherwise. In other words, these decisions are final and not appealable.

For athletes who are not ILAs or NLAs, an ADO may grant an athlete's TUE under ISTUE Article 4.3 without consulting WADA; however, WADA may at any time review any ADO decision and may, in its absolute discretion, agree with or reverse the decision. The ADO's decision to grant/reject the athlete's application must be recorded in ADAMS.

Figure 4: Flowchart of ISTUE Article 4.3 Decision Process



3.0 Examples Cases



EXAMPLE CASE 4.3 – CASE 1 Athlete with Growth Hormone Deficiency (GHD)

Background

- ❖ The athlete is an 18-year-old male Alpine skier.
- ❖ It is his first time on the circuit after qualifying through youth ranks.
- ❖ Following his promotion to the tour, the athlete spoke with his team physician. This physician reassured the athlete that he would send in the necessary files to obtain a TUE. The athlete believed that he had a valid TUE in place authorizing him to complete while taking medication for his Growth Hormone Deficiency.

Anti-Doping Test

- ❖ The athlete was 17 years old at the time and had his first anti-doping test.
- ❖ He provided a urine sample, declaring “Growth Hormone” use on the Doping Control Form.
- ❖ The lab results returned an AAF for hGH (S2), a substance included on the Prohibited List.

Relevant Medical History and Interactions with his Physician

- ❖ The athlete was diagnosed with short stature by a specialist at age 13 and had extensive medical justification to warrant treatment.
- ❖ The treatment was stopped after his 18th birthday.
- ❖ Investigations revealed that there were several emails exchanged with the physician corroborating the facts described by the athlete.
- ❖ The physician admitted his fault in failing to file the TUE application.

Extent of Prior Anti-Doping Education

- ❖ The athlete claims no prior anti-doping education either at youth level or since turning professional.

- ❖ He admits to limited awareness of the TUE process from his previous attendance at Youth World Games.
- ❖ The IF confirmed that they had not provided anti-doping education to the athlete.

Considerations

- ❖ Was there enough evidence to corroborate his story that his physician would take care of the TUE?
- ❖ Is there any evidence to prove that the athlete has received any anti-doping education, in particular on TUEs?
- ❖ While the physician was at fault, athletes remain responsible for what they take.
- ❖ Did the athlete declare the use of the substance on their DCF?
- ❖ Did the athlete provide sufficient medical evidence to justify a TUE?
- ❖ Has this athlete committed an ADRV deserving a sanction?
- ❖ Should the team physician be considered liable in any way?
- ❖ The entire picture needs to be considered in order to determine if it would be manifestly unfair for the athlete to be denied a TUE.



EXAMPLE CASE 4.3 – CASE 2 Athlete traveling to high altitude

Background

- ❖ A female marathon athlete traveled to South America to compete.
- ❖ The city in which she was competing was 239m above sea level.
- ❖ The athlete competed and wins the event. She is tested in-competition by the local NADO and does not return an AAF.
- ❖ Post-competition, the athlete visited a national park which is at around 4000m elevation.
- ❖ Her physician prescribed her acetazolamide as an altitude sickness prophylaxis.
- ❖ The athlete was concerned about a use violation and asks her home NADO if she needs to apply for a TUE.
- ❖ The NADO requests the medical information but advised that a retroactive TUE, under ISTUE Article 4.3, could be granted if she used or returned an AAF for the prohibited substance.

Considerations

- ❖ Prophylactic treatment for acute mountain sickness and potential cerebral and pulmonary edema is rare and challenging.
- ❖ While an intelligent ascent and descent plan should be implemented, practical considerations may be such that this does not always occur.
- ❖ Acetazolamide is recognized as the only evidence based prophylactic treatment for acute mountain sickness.
- ❖ The ADOs and TUECs need to use their best judgement and assess these situations case-by-case.
- ❖ WADA will have final oversight of the case.

Why did the athlete not apply in advance?

The athlete's application would have had difficulty fulfilling ISTUE Article 4.2(a) – She was using the medication for a prophylactic treatment therefore she did not have a diagnosed medical condition. Under ISTUE Article 4.3 the athlete may be granted a TUE even if all of the ISTUE Article 4.2(a-d) criteria are not fulfilled but they should be taken into consideration.



EXAMPLE CASE 4.3 – CASE 3

Athlete with ADHD

Background

- ❖ The athlete is a 20-year-old male snowboarder.
- ❖ He was diagnosed with Attention Deficit Hyperactivity Disorder (ADHD) by a consultant psychiatrist at the age of 17.
- ❖ The diagnosis fulfilled the DSM-5 criteria and was confirmed via diagnostic schedules/rating scales and a psychiatric assessment.
- ❖ He was treated with methylphenidate 20mg daily (S6. Stimulants, prohibited in-competition only).

Scenario

- ❖ The athlete has been a NLA since the age of 18.
- ❖ He applied for and was granted a TUE for one year expiring on 31 January.
- ❖ On 7 February the athlete competed in an event where he was subject to doping control.
- ❖ The athlete returned an AAF for methylphenidate.
- ❖ The athlete declared the use of methylphenidate on the DCF.
- ❖ On 10 February the athlete applied for a retroactive TUE under ISTUE Article 4.3.
- ❖ He had started the re-application for a new TUE on 17 January, meeting with his new physician but forgot to send the application to the NADO, due to his competition and travel schedule.
- ❖ The athlete's TUE expired 10 days before he sent in his application for a new TUE.
- ❖ There was no dosage change in the new application.

Considerations

- ❖ The first step should be to answer the following:
 - “Should the athlete be allowed to apply for a retroactive TUE?”
 - In this case, the only possible applicable retroactive article is 4.3
- ❖ An assessment of the circumstances surrounding the failure to re-apply for a TUE prospectively should first be made by the NADO. For example:
 - The recent expiration of the athlete's TUE.
 - The athlete was relatively new to the anti-doping process; had a documented medical condition; and did not note the administrative deadline.
 - The athlete declared the substance on the DCF.

- ❖ In this case, all the 4.2 criteria have been fulfilled.
- ❖ Overall, would it be manifestly unfair for the athlete to be denied a TUE and be sanctioned?

SECTION 4:

Responsibilities of ADOs

This section will support ADOs by addressing all articles of the ISTUE to help you ensure every person in your organization understands and is able to comply with the requirements of your TUE program. Creating a highly functional TUE process with trained staff is key to the success of your TUE program.



CHAPTER 14:

How should ADOs deal with TUE applications?

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1.0 Establishing a TUE process

ADOs must establish a process to receive and evaluate TUEs. This begins with informing and educating their athletes about what a TUE is, and the process to apply for one when necessary. It is the duty of the ADO to help and guide the athlete through the process. ADOs need to clearly define in their anti-doping rules which athletes fall under their jurisdiction so that athletes understand to which organization they must apply for a TUE and if they are required to apply prospectively. ADOs must also publish details of that process by (at a minimum) posting the information in a conspicuous place on its website and sending the information to WADA. WADA recommends that this information be updated at least annually.

2.0 Setting up internal procedures

The ADO needs to set up a system to receive TUE applications in a safe and confidential manner and must communicate the preferred process to their athletes. The ADO should assign to an internal staff member(s) the duties of receiving athlete requests and questions. Once the application is received the TUE manager/assigned staff member should assess the athlete's application to determine if the athlete is under their jurisdiction, if the athlete actually requires a TUE and if the athlete is required to apply in advance. Next the TUE manager/assigned staff member should assess the athlete's TUE application, double checking that the athlete has correctly filled out the necessary details and provided a complete medical file. The [TUE Checklists](#) may be a useful tool for this assessment.

If the application is incomplete, WADA recommends that the ADO inform the athlete in writing and guide them on what is necessary to complete the application. Once the TUE manager/assigned staff member is satisfied the athlete has provided a complete application, it should be sent to their TUEC for a decision. The TUEC shall render its decision as soon as possible, and, usually, unless there are exceptional circumstances, within no more than 21 days of receipt of a complete TUE application (or request for recognition, where applicable).

After the TUEC has made their decision, the ADO TUE manager/assigned staff member must promptly inform the athlete in writing. They must also enter the decision in ADAMS within 21 days so that it is available for WADA and other ADOs.

If the TUE has been granted, the decision should specify the approved substance or method, the dosage(s), frequency, route of administration, the duration of the TUE (and, if different, the duration of prescribed treatment), and any conditions imposed in connection with the TUE.

If the TUE is not granted, the ADO TUE manager/assigned staff member must inform the athlete in writing of the reasons for the denial of the application including what elements of the ISTUE Article 4.2 criteria were not satisfied and why. The ADO should also inform the athlete of the appeal or review process (as applicable).

To assess TUE applications, ADOs may operate in different manners, some may have a permanent TUEC while others may rapidly set up TUECs for each individual case, depending on the expertise and availability

of the experts in their pool. The fulfilment of the retroactive conditions (ISTUE Articles 4.1 and 4.3) may be determined by the ADO in consultation with a member(s) of the TUEC. For further information, see Section 3.

While IFs/MEOs may choose to recognize pre-existing TUEs automatically, there must be a mechanism for athletes participating in an IF or MEO event to obtain a new TUE if the need arises. It is up to each IF/MEO whether it sets up its own TUEC for this purpose or outsources the task by agreement to a third party (such as the International Testing Agency (ITA)).

3.0 Updating the TUE application form

ADOs are required to update their TUE application form based on WADA's template, which is available [here](#). The template may be modified by ADOs to include additional requests for information, but no sections or items may be removed. The TUE application form may be translated into other languages by ADOs, but the English or French text must remain on the form.

4.0 Meeting deadlines

An athlete who has not received a response regarding their TUE application within 21 days of the date of the submission of the complete application, or prior to an event, as applicable, should contact the ADO to enquire about the status of their TUE application.

Unless there are exceptional circumstances, the ADO must render a decision within a reasonable period on a TUE application submitted in due form, which is usually within 21 days of receipt of a complete application. If the ADO is unable to meet this deadline, and the athlete is unable to receive information or an update from their ADO, they may contact WADA for assistance.

An ADO's failure to render a decision within a reasonable time on a complete application is considered a denial of the application and will trigger the athlete's right to seek a review or file an appeal, depending on the circumstances (Code Article 4.4.9).

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ADOs involved in the TUE process

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1.0 NADOs

NADOs are organizations designated by each country as the primary authority with responsibility to adopt and implement national anti-doping rules, carry out anti-doping education, plan tests and conduct results management at the national level. They may also test athletes from other countries who are competing or training within that nation's borders.

To help ease the burden of work on NADOs, they may identify low priority sports in which athletes may not be required to apply in advance for a TUE. However, this should be clearly communicated to athletes via the NADO's website. (see comment to ISTUE Article 5.1)

When a NADO grants a TUE, it must warn the athlete in writing that:

- ❖ The TUE is valid at the national level only.
- ❖ If the athlete becomes an ILA or competes in an international event, that TUE will not be valid for those purposes unless it is recognized by the relevant IF or MEO. The NADO should help the athlete to determine when they need to submit the TUE to an IF or MEO for recognition and should guide and support the athlete through the recognition process.

When a NLA has a TUE granted by their NADO, it is valid only at the national level, both in and out-of-competition. However, that TUE is valid at the national level on a global basis and does not need to be formally recognized by other NADOs (see hypothetical case below). If the athlete is competing consistently over a long period of time in another country, or decides to move on a permanent basis, the new NADO may have authority over the athlete for anti-doping purposes. Re-applying to the new NADO should not be necessary unless the athlete has permanently relocated to a new country and the TUE has expired or been withdrawn for any reason. The two NADOs can decide on who has jurisdiction over the athlete's TUE. In the event of a conflict, WADA will decide. As a reminder, in order to understand jurisdiction, see the principles in [Chapter 3](#) applicable to cases where athletes apply for the first time.



Hypothetical Case:

- ❖ The athlete is a 38-year-old South African cricket player diagnosed with hypertension and treated with a number of anti-hypertensive drugs including hydrochlorothiazide 25mg daily.
- ❖ He was granted a four-year TUE by the South African NADO (SAIDS).
- ❖ A year into his TUE, he receives a three-month contract to play in the Indian Premier League, after which he will join a team in the UK for a further 3 months before returning to South Africa.

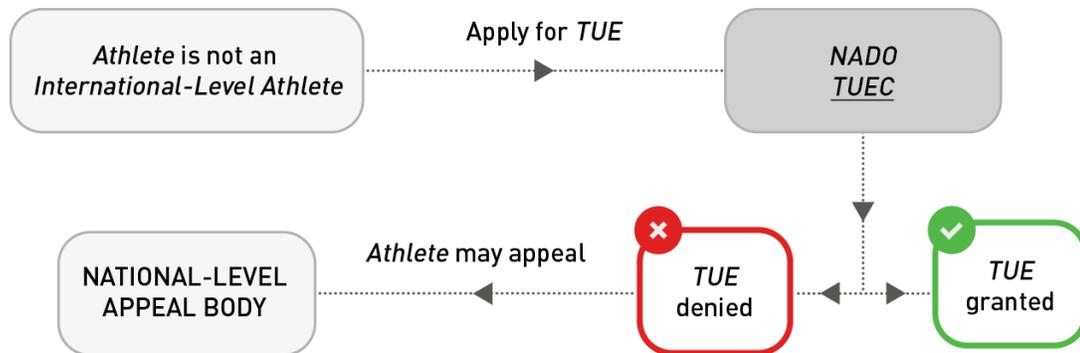
Discussion:

- ❖ The athlete's national level TUE will be valid on a global basis for national level events or below in any country.
- ❖ If the athlete was considered an international level athlete by the IF (as defined in their rules and on their website) then the athlete should apply for recognition to the IF.
- ❖ What if the athlete moved to compete in the UK, on a more permanent basis, and then needed to reapply for his TUE because it had expired?
- ❖ At this point, the athlete should follow the rules on "Where should NLAs (or lower level athletes) apply", in Chapter 3 (Flowchart Figure 2).
- ❖ This would mean that the athlete should apply to UKAD¹.
- ❖ The athlete could continue with SAIDS¹, if SAIDS agrees to evaluate the TUE and UKAD agrees to allow this.
- ❖ If there is a dispute over who has jurisdiction over the athlete, WADA will decide.

¹ All examples included in these Guidelines are fictional. Countries have been included in this example to facilitate understanding

Figure 5: NADO TUE Flowchart

When a TUE is denied by the NADO, the athlete may appeal exclusively to the national level appeal body.



The rules for such appeal shall respect the following principles:

- ❖ a timely hearing;
- ❖ a fair, impartial, and operationally and institutionally independent hearing panel;
- ❖ the right to be represented by counsel at the athlete’s own expense; and
- ❖ a timely, written, reasoned decision.

If no such body as described above is in place and available at the time of the appeal, the athlete has a right to appeal to CAS

Although the Code does not specify that national appeal bodies need to be formed by a group of physicians, such as a TUEC, it is advisable that these review panels for TUEs include physicians.

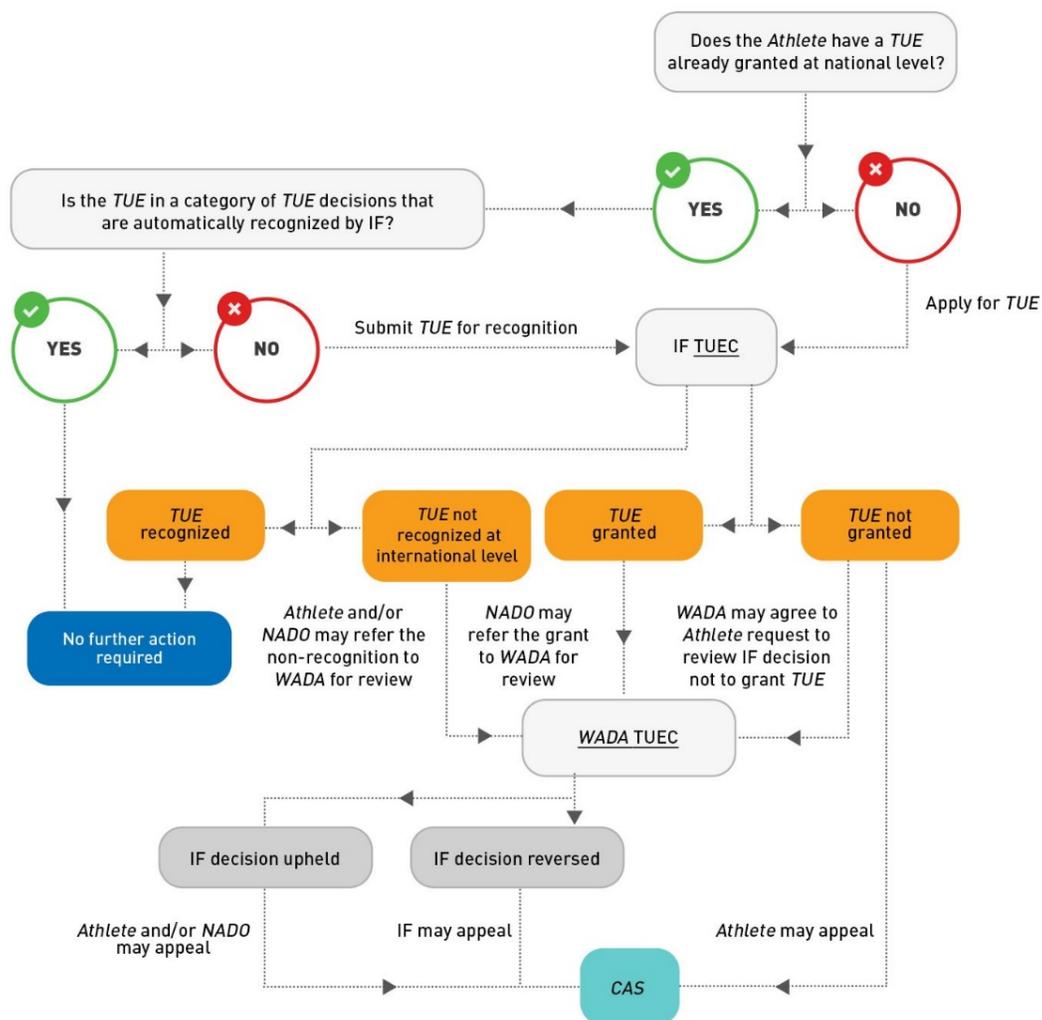
2.0 International Federation

Anti-doping activities required of IFs by the Code include, amongst other things, conducting in-competition and out-of-competition testing, providing education programs and, where appropriate, sanctioning those who commit ADRVs.

ILAs should apply directly to their IFs for a TUE. IFs must establish a clear process for athletes to apply to their organization for a TUE, which must be published on their website.

The IF should also help an athlete to determine when they need to submit a NADO TUE for recognition and should guide the athlete through the recognition process. See Section 6 for more on recognition. The IFs should not require the athlete to submit a new application if all the information has already been entered in ADAMS. IFs should set out clearly which athletes under their jurisdiction (e.g. for which international events) require recognition of their TUE.

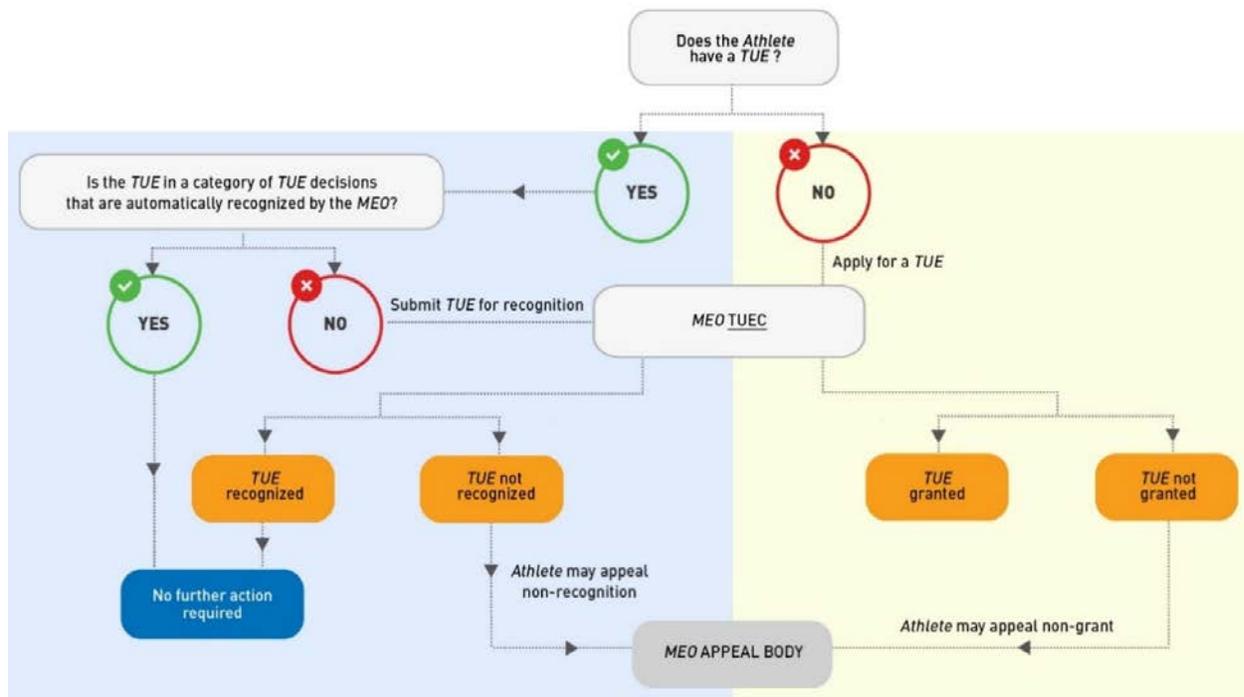
Figure 6: IF TUE Flowchart.



3.0 Major Event Organizers (MEOs)

The TUE process of MEOs functions in many ways like those of an IF, but they either grant or recognize TUEs solely for the duration of their event. The MEO may recognize IF or NADO TUEs. While a MEO may choose to recognize pre-existing TUEs automatically, there must be a mechanism for athletes participating in the event to obtain a new TUE if the need arises. It is up to each MEO whether it sets up its own TUEC for this purpose or outsources the task by agreement to a delegated third party. The aim in each case should be to ensure that athletes competing in such events can easily apply and rapidly receive a decision on their TUE application.

Figure 7: MEO TUE Flowchart



4.0 Regional Anti-Doping Organizations (RADOs)

WADA created the RADO program to strengthen under-resourced NADOs and National Olympic Committees (NOCs) acting as NADOs. Further information and links to the different RADO websites can be found on the [WADA website](#).

Each RADO should have their TUE process described on their website and make their TUE application form available to download for the athletes.

RADO TUEs are equivalent to NADO TUEs and are:

- ❖ valid at the national level only; and
- ❖ if the athlete becomes an ILA or competes in an international event, the TUE will not be valid for those purposes unless it is recognized by the relevant IF or MEO.

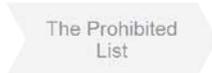
If an athlete's application is denied by the RADO TUEC, the athlete may appeal the decision to the appeal body as described in the applicable anti-doping rules.

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How should ADOs guide athletes?

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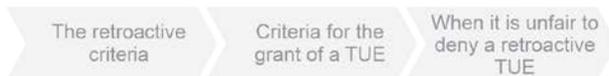
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1.0 Providing information after a TUE is denied

When an ADO decides to reject an athlete's TUE application or request for recognition, it must provide them with the reason(s) for the denial. In addition, they should also inform the athlete of their right to appeal or seek a review and should guide the athlete through the process.

If the denial is due to the application lacking a critical piece of information, or new relevant information or test results, the file should be completed and resubmitted. If the denial is due to other reasons, NLAs may appeal the decision to the relevant national appeal body and ILAs may request that WADA review the relevant IF's decision. However, WADA is not obligated to review every TUE decision. If WADA declines to review a TUE decision in relation to an ILA, or if it does review the decision but does not reverse it, the ILA may appeal to the CAS (Code Article 4.4.7). Athletes may also appeal any WADA decision to reverse a TUE decision to the CAS.

If an MEO decides not to recognize a TUE granted by the athlete's NADO or IF, the athlete may appeal this decision to the independent appeal body established by the MEO. If there is no appeal or the appeal is unsuccessful, the TUE is not valid for the MEO's event, but remains valid outside the event.

If an IF decides not to recognize a NADO TUE, and if the matter is not referred to WADA for review, the athlete's NADO needs to assess whether the original TUE granted by that NADO should nevertheless remain valid for national level competition and out-of-competition testing (provided that the athlete ceases to be an ILA and does not participate in international level competition)

For information on WADA reviews please see Section 7.

2.0 Educating on the TUE process

In accordance with the Code (Article 18.2) and the [International Standard for Education](#) (ISE Article 5.2), ADOs must establish an educational program to include 'Use of medications and TUEs'. This must be available publicly on the ADO website.

The ADO is required to identify an education pool, similar to an RTP. It is mandatory for the ADO's RTP athletes and athletes returning from a sanction to be included in this education pool. WADA suggests ADOs consider the inclusion of all other athletes, especially those who are subject to their anti-doping rules. ADOs must explain why athletes subject to anti-doping rules have been excluded from this education pool and how this will be addressed in the future. Communication between ADOs and its athletes regarding education and TUEs is essential to improving athletes' knowledge and compliance with the TUE process.

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1.0 Implementing strict confidentiality for TUE information

Collection, storage, processing, disclosure, and retention of personal information by ADOs and WADA during the TUE process must comply with ISPPPI criteria. All the information contained in a TUE application, including the supporting medical information, and any other information related to the evaluation of a TUE request must be handled in accordance with the principles of medical confidentiality. This information must only be used to evaluate a TUE application, or in the context of ADRV investigations and proceedings.

The ISPPPI specifically requires ADOs to apply higher levels of security to TUE information due to the sensitivity of this information (ISPPPI Article 9.2), and to regularly assess the proportionality and risks associated with the processing of TUE information (ISPPPI Article 9.6). Through this assessment, ADOs should also determine if any measures could mitigate the identified risks and implement these measures.

In practice, WADA recommends that TUE manager(s)/ assigned staff member(s) at ADOs formulate a strategy to enhance the management of their TUE process and identify the following:

- ❖ The types of personal information collected;
- ❖ How this information is collected, and who it is collected from;
- ❖ How and when the individual the personal information relates to was informed of the processing of their personal information for TUE purposes;
- ❖ Why this type of personal information is needed (i.e., what is it used for)?
- ❖ With whom the personal information will be shared with?
- ❖ How is it shared?
- ❖ Where and how is the personal information stored?
- ❖ When and how is personal information deleted once it is no longer needed?
- ❖ What safeguards exist to protect the personal information?
- ❖ Throughout the process, what systems or tools are used to process the personal information?

The answers to these questions should be documented in a record of processing, as required under the ISPPPI (Article 4.4).

Then, TUE manager(s)/ assigned staff member(s), ideally with the assistance of the ADO's privacy manager, should assess the process and determine if any additional measures should be implemented to protect TUE information.

Consider the following questions:

- ❖ Are athletes provided with sufficient information to understand how their TUE information will be handled by signatories, TUECs, WADA and other experts?
 - For guidance, see "Providing a privacy notice to athletes" below.
- ❖ Do athletes understand the steps they should take to protect their TUE application and supporting documents (e.g. not sending unencrypted documents by email)?
- ❖ Which staff have access to TUE information? Do these staff members require full access to fulfill their duties? Can some staff fulfill their duties with only limited TUE information?
- ❖ Is access to TUE information limited and controlled in each system where this information is stored or processed (e.g. internal documents, ADAMS, internal document management systems, etc.)?
- ❖ Is personal information deleted from each of these systems in accordance with [ISPPPI Annex A \(TUE module\)](#)?
- ❖ What authentication requirements (e.g. passwords, 2-Factor Authentication, etc.) exist for each of these systems?
- ❖ When personal information is shared, is it protected with encryption and access controls?
 - For guidance on sharing information with TUECs, see [Conflict of Interest](#) and [Confidentiality for TUEC physicians](#).
- ❖ Have all recipients of personal information signed confidentiality agreements, or are they subject to statutory confidentiality obligations?

ADOs should document their assessment and implement the identified mitigation measures. This process should be regularly repeated to ensure TUE information is kept strictly confidential throughout the TUE process.

2.0 Providing a privacy notice to athletes

Before collecting personal information or obtaining consent from an athlete, the ADO must communicate the information set out in [ISPPPI Article 7.1](#) to the athlete. This information is essentially the same information ADOs should document as part of the assessment of their TUE process described above.

An athlete applying for a TUE or for TUE recognition must be specifically informed by the ADO that:

- a) All information pertaining to the application will be transmitted to all TUEC members authorized to review the file and, as required, other independent medical or scientific experts,

as well as all necessary staff (including WADA staff) involved in the management, review or appeal of TUE applications;

- b) The athlete must authorize their physician(s) to release health information deemed necessary to review the application to a TUEC upon request;
- c) The athlete may withdraw this authorization at any time by informing the relevant physician and the ADO that the TUEC is no longer permitted to obtain health information directly from their physician;
- d) The consequence of withdrawing this authorization will be the withdrawal of the application without approval/recognition; and
- e) The decision on the application will be made available to all ADOs with testing authority and/or Results Management Authority (RMA) over the athlete.

All ADOs must provide this minimum privacy notice to athletes applying for a TUE, regardless of their legal ground for processing the related personal information. Where the ADO is relying on the athlete's consent for the processing of TUE-related personal information, ADOs must obtain written and express confirmation from the athlete that they consent to the processing described in the ADO's notice. The WADA [TUE Application Form](#) template contains a short-form privacy notice accompanied by a signed declaration, which is designed to enable ADOs to meet this obligation, including those ADOs relying on consent for the personal information processing. Because the TUE application form provides limited space to describe all the related processing of personal information, ADOs are encouraged to supplement this short privacy notice with a more fulsome description of their processing activities. This can be done by including a hyperlink to the ADOs general privacy policy, or to FAQs or other documents created to describe the TUE process to athletes.

Where to find help?

For general guidance on the ISPPPI, ADOs can consult the [Guidelines for Privacy](#) and many other resources on ADEL. For assistance conducting a risk assessment, ADOs are encouraged to use the template [Risk Assessment Form](#). Help on drafting a privacy notice for the TUE application form and other privacy notices is available in the form of a TUE application form template and other WADA privacy notice templates. Finally, ADOs can learn more about implementing appropriate security measures by listening to the webinar on Cyber Essentials for ADOs available on ADEL. For help reviewing ADAMS access permissions and processes, ADOs can reach out to the ADAMS support team at adams@wada-ama.org or to one of WADA's TUE managers.

SECTION 5:

TUE Committees (TUECs)

This section will support ADOs with Articles 4.0 to 9.0 of the ISTUE by helping establish TUECs, provide support to your TUECs and identify resources that can support you along the way.



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Setting up a TUEC

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1.0 Composition of a TUEC

A TUEC should be composed of at least three physicians, where one member acts as the chairperson. Members should have a sound knowledge of clinical, sports and exercise medicine. Furthermore, whenever appropriate, the TUEC should include, or seek the opinion of, a physician with an expertise related to the athlete's condition. For example, a testosterone case should be evaluated with the help of an appropriate endocrinologist. It may also be necessary to seek the appropriate expertise for applications involving athletes with impairments whereby the expert should have experience in the care and treatment of such athletes.

2.0 Composition of a MEO TUEC

The TUEC chairperson should appoint an ad hoc TUEC composed of a minimum of three physicians from amongst the MEO's TUEC pool of members to ensure that athletes competing at the MEO's event are able to obtain TUEs quickly and efficiently before and during the event.

3.0 Conflict of interest and confidentiality for TUEC physicians

To ensure impartiality of decisions, TUEC members must sign a conflict of interest and confidentiality declaration. The [TUEC Confidentiality Declaration](#) template is available on WADA's website.

Where the TUEC members require advice from external independent experts on a particular case, the TUEC must notify the ADO, and the ADO must ensure that such experts are bound by confidentiality requirements either through their professional order or by contract. The same applies to the extent the ADO needs to consult an external legal expert regarding a particular case.

The ADOs should provide the TUEC members (and any other independent experts) with the minimum amount of personal information (if any) required to evaluate the TUE.

The ADO should also provide instructions to TUEC members for the secure transmission of information between ADO and the TUEC or between the TUEC and other experts. As mentioned above, ADO and TUEC members should first remove any unnecessary personal information from their communications. In addition, encryption and access controls should be used to protect any confidential information that is transmitted (for example, file sharing systems allow the user to require the recipient to authenticate themselves - e.g., with a password, to only make documents available for download for a limited period, and to notify the user of any accesses or downloads by the recipient).

TUEC members should treat all confidential information received as they would treat the medical information of their own patients. This includes ensuring appropriate security safeguards have been implemented to protect this information and ensuring clinical records and other data are only retained as long as needed to complete the assessment and comply with regulatory and professional obligations. After the retention period has lapsed, TUE information should be securely destroyed by the TUEC member.

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How does a TUEC function?

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1.0 General TUEC procedure

The ADO TUEC normally operates based on consensus, led by the TUEC Chair. In the event of a divergence of opinion or disagreement concerning a decision or a follow-up action, the majority prevails.

The TUEC must render its decision as soon as possible, and, usually, unless there are exceptional circumstances, within no more than 21 days of receipt of a complete TUE application (or request for recognition, where applicable). Where a TUE application is made within a reasonable time prior to an event, the TUEC must use its best endeavors to issue its decision prior to the start of the event.

2.0 Evaluating the TUE and reporting back to the ADO

The TUECs should refer to the [TUE Physician Guidelines](#) and [Checklists](#) for guidance when reviewing TUE applications or requests for recognition and making decisions.

A TUE application is deemed complete if it enables the TUEC to determine if the criteria set forth in ISTUE Article 4.2 or 4.3 are satisfied. The TUEC may request additional information, examinations, tests, imaging studies, etc., from the athlete or their physician, and/or involve other medical experts.

The TUEC may grant a retroactive TUE only if it meets the criteria set forth in the ISTUE Article 4.0

For retroactive TUE applications under ISTUE Article 4.3 involving ILAs or NLAs, WADA's agreement must be sought before the TUE may be granted.² For such applications, a three-member TUEC is often not required; however, WADA recommends that the ADO consults with at least one medical expert (member of their TUEC pool) when assessing these applications.

The TUEC must provide reasons why a decision was made to deny or not recognize a TUE.

² ADOs may assess and grant ISTUE Article 4.3 TUEs to sub-national level athletes without consulting WADA.

3.0 Determining TUE duration

TUE duration should be decided on a case by case basis although the [TUE Physician Guidelines](#) provides recommendations in this area. The chart below is a summary of the recommendations extracted from the individual guidelines for your convenience. Note that TUE duration is **not** a criterion on which an ADO can refuse to recognize a TUE that is granted based on the ISTUE Article 4.2 criteria.

The maximum TUE duration of 10 years is based on the requirements for data retention by the [ISPPPI](#).

MEDICAL CONDITION	SUBSTANCES / METHOD	RECOMMENDED DURATIONS
ADHD	Stimulants – e.g. methylphenidate	12 months for a new diagnosis. Up to 4 years for those with a diagnosis made more than 12 months previously on a stable dose of medication.
Adrenal Insufficiency Primary	Glucocorticoids	10 years in case of primary insufficiency, pituitary disease or surgery
Adrenal Insufficiency Secondary	Glucocorticoids	4-12 weeks
Anaphylaxis	Stimulants and glucocorticoids: 1. Epinephrine (adrenaline) 2. Systemic glucocorticoids: hydrocortisone or methylprednisolone	Most patients respond to 1-2 doses. TUE for epinephrine for athletes at risk of future anaphylaxis; up to 5 years but notify every time used
Androgen Deficiency / Male Hypogonadism – Primary or Secondary	Testosterone or human Chorionic Gonadotropin (hCG)	4 years but regular monitoring by ADO imperative
Asthma	1. Beta-2 agonists 2. Glucocorticoids	Beta-2 agonists: 4 years Glucocorticoids: up to 12 months
Cardiovascular Conditions: Arterial Hypertension	1. Diuretics 2. Beta-blockers	Up to 4 years for arterial hypertension Up to 10 years for congenital LQTS

MEDICAL CONDITION	SUBSTANCES / METHOD	RECOMMENDED DURATIONS
Diabetes Mellitus – Type 1	Insulin	First granted TUE should not exceed a 1-year duration. All future TUEs can have a validity of up to 10 years
Female-to-Male (FtM) Transgender Athletes	Testosterone	10 years
Growth Hormone Deficiency (adult)	hGH	8 years if genetic, congenital, or hypothalamic-pituitary structural abnormality 2 years if due to brain trauma or irradiation
Growth Hormone Deficiency (child & adolescent)	hGH	8 years if genetic, congenital, or hypothalamic-pituitary structural abnormality 4 years if due to brain trauma or irradiation
Infertility / Polycystic Ovarian Syndrome (PCO)	1. Clomiphene 2. Spironolactone	Infertility: 2 years PCO: 10 years
Inflammatory Bowel Disease	Glucocorticoids	4 years
Intravenous Infusion	Administration of i.v. fluids	Single medical episode
Intrinsic Sleep Disorders	Stimulants e.g. Modafinil, methylphenidate and dexamphetamine	4 years with annual review by a specialist physician
Musculoskeletal Conditions	1. Glucocorticoids 2. Narcotics	Both GC and narcotics should be as short as possible, days to weeks. There are certain cases of chronic pain where duration of glucocorticoids and narcotics may be longer.
Pain Management	1. Narcotics 2. Cannabinoids	Acute pain: (e.g. post-op) a period of days to a week Chronic pain: 1 to 4 years

MEDICAL CONDITION	SUBSTANCES / METHOD	RECOMMENDED DURATIONS
Renal Transplantation	<ol style="list-style-type: none"> 1. Glucocorticoids 2. Beta-Blockers 3. Diuretics 4. Erythropoietin (EPO) 	10 years (if on EPO, regular monitoring of blood parameters & specialist review)
Sinusitis	<ol style="list-style-type: none"> 1. Glucocorticoids 2. Pseudoephedrine 	Days to weeks

SECTION 6:

TUE recognition process

This section will support ADOs with Article 7.0 of the ISTUE by guiding you through the recognition process, maximizing your efforts and minimizing duplication.



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General principles of TUE recognition

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1.0 Dealing with the recognition process

TUE recognition seeks to reduce the burden and work for both the athlete and the ADO. Instead of requiring the athlete to complete a new TUE application when they change level (i.e., when they move from NLA to ILA) or if they compete in an international event under the authority of either an IF or a MEO, the higher level ADO may simply recognize (or not) the TUE that the athlete has already been granted.

The ADO should evaluate the TUE based solely on the ISTUE Article 4.2 criteria before recognizing/not recognizing it. To further decrease the burden, MEOs or IFs may decide to automatically recognize certain TUE decisions (please see below: automatic recognition).

In general, NLAs or below apply directly to their NADO for a TUE and ILAs apply directly to their IF. If a NLA competes in an IF sanctioned event for which a TUE is required (as determined and communicated by the IF), the athlete will need to request recognition of their NADO granted TUE by the IF. In cases where such recognition is not required, and the IF chooses to test an athlete who is not an ILA, it must recognize a TUE granted by that athlete's NADO.

An athlete who needs a new TUE while competing at a major event must apply directly to the MEO. However, if an athlete already has a TUE granted by the NADO or IF, they would request the MEO to recognize the TUE, unless there is automatic recognition. It is important to note that TUEs recognized or granted by MEOs are only valid for the duration of the MEO's event.

The ADO must determine if the athlete is under their jurisdiction before recognizing the TUE. If the IF recognizes a TUE because the athlete has moved up to the international level (and satisfies the definition of ILA), the athlete's TUE becomes an IF TUE and will remain valid for international events until it expires.

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1.0 Standard recognition process

When necessary, the athlete is responsible for requesting their IF and/or MEO to recognize their approved NADO TUE.³ However, the NADO should provide some assistance to the athlete with this process. Once the request is made to the IF or MEO, they will contact the NADO or IF (as applicable) to obtain access to the athlete's medical files in ADAMS to determine if the TUE satisfies all the ISTUE Article 4.2 criteria.

The IF or MEO should render a decision as soon as possible and usually, unless there are exceptional circumstances, within 21 days of receipt of the complete recognition request. The IF or MEO should promptly inform the athlete once a decision is reached and shall record the decision in ADAMS within 21 days of receipt of the decision. If the IF fails to reach a decision within the appropriate period or decides to reject the recognition request, its access to the athlete's medical information in ADAMS will be removed. This access control serves to protect athlete's medical information by minimizing access to what is necessary for the TUE recognition process, in accordance with ISPPPI Article 5. Therefore, access should be granted to an ADO only if recognition is necessary.

When making a request for recognition to their IF or MEO, the athlete is essentially re-submitting their NADO or IF TUE application. The IF or MEO should accordingly set up a TUEC to evaluate the application as described earlier in Section 4 and 5. Although the ISTUE recommends a panel of at least three physicians, the IF or MEO may, at its discretion, use a single member TUEC for certain recognition evaluations. These decisions should be made case-by-case and only for low risk substances in the particular sport.

For example, a badminton player applies to get her TUE for insulin recognized by her IF. She was diagnosed with type 1 diabetes in early childhood. The Chair of the IF TUEC physician pool reviews her extensive medical file and decides that this case does not warrant a full 3-member panel review. They make a record of this when formally recognizing the TUE in ADAMS.

If the IF decides not to recognize a TUE granted by the NADO, it must provide the reasons for its decision in writing to the athlete and their NADO. It should be noted that the duration of a TUE is not an ISTUE criterion and therefore a TUEC should **not** refuse to recognize a TUE based on a disagreement on duration. The athlete or their NADO will have 21 days from the notification of the decision to refer the matter to WADA for review. During WADA's review, the NADO TUE is valid for national level competition and out-of-competition testing only.

If the athlete and/or NADO decide not to refer the matter to WADA, the NADO must determine whether the original TUE that it granted should remain valid for national level competition and out-of-competition testing. Pending the NADO's decision, the TUE remains valid **only** for national level competition and all out-of-competition testing (Code Article 4.4.3.1).

³ An athlete may also be required to submit a TUE granted by their IF to an MEO for recognition pursuant to Code Article 4.4.4.2.

In the rare case that an athlete needs a TUE from two IFs (e.g. biathlon and Nordic skiing), they should apply to both IFs independently. Refusal of the TUE by one IF would not negate the TUE for other sports or levels. However, the athlete may request a review or WADA may initiate a review.

If an MEO refuses to recognize an athlete's TUE, granted by either their NADO or IF, the athlete may appeal that decision to the independent body established or appointed by the MEO. The athlete's TUE remains valid for all competitions outside of the major event.

2.0 Automatic recognition process

Automatic recognition further expedites the process of ensuring that the TUE in place is accepted as an athlete progresses to higher competitive levels. In that respect, IFs and MEOs may decide to automatically recognize TUE decisions (or certain categories of TUE decisions e.g. from certain ADOs or relating to certain substances). Information about any such automatic recognition should be published on the ADO's website and sent to WADA and NADOs (WADA recommends that this list be updated annually). Automatic recognition is especially helpful for athletes who suddenly become international level or qualify for an international/major event and may not otherwise have their TUE recognized in time.

The IF or MEO will have access to the athlete's medical information in ADAMS for any TUE they automatically recognize. The automatic recognition process is contingent upon the use of ADAMS.

IFs and MEOs should verify if the athlete falls under their jurisdiction before recognizing a TUE (i.e. becomes an ILA or qualifies to compete at an international event). Once the athlete with a NADO TUE falls under the IF's or MEO's jurisdiction, the IF or MEO must finalize the recognition in ADAMS, provided the NADO TUE falls within those automatically recognized.

It remains the responsibility of the athlete to check the IF/MEO's website or contact them directly to find out if their TUE falls into the category (or categories) of decisions automatically recognized.

IFs and MEOs should carefully decide from which ADOs and/or for which substances or methods, they will automatically recognize the TUE decisions. An internal process should be created to help with these decisions. WADA recommends creating a good communication network with ADOs as a first step in the process. Deciding on the categories of prohibited substance(s) or methods that an IF or MEO will automatically recognize will be very specific to every sport and IF or MEO. WADA recommends careful consultation with physicians and experts in the field before reaching a final decision.

SECTION 7:

WADA TUE reviews

This section will support you with Article 8.0 of the ISTUE by guiding you through the WADA TUE review process.



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1.0 Describing a WADA TUE review

A WADA TUE review is a process where WADA establishes a WADA TUEC to evaluate a TUE decision referred to them by an athlete or an ADO. The process of requesting WADA to review a TUE is identical for athletes and ADOs. There are different scenarios when an athlete or ADO may request a WADA TUE review (described below). WADA may also decide in its discretion to review any ADO decision.

2.0 Requesting a WADA TUE review

An athlete may request that WADA review a TUE application that was denied by their ADO. WADA is not, however, obliged to review all TUE decisions, but may do so at their discretion (ISTUE 8.3; Code Article 4.4.6).

Any decision by WADA not to refer a TUE decision to the WADA TUEC is final and may not be appealed. However, the original TUE decision may still be appealed to the appeal body designated in the applicable anti-doping rules.

3.0 Mandatory WADA TUE reviews

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
 - Once an IF refuses to recognize a TUE, the athlete or the NADO have 21 days from the notification to refer the matter to WADA for review.
- ❖ If a NADO disagrees with an IF's decision to grant a TUE
 - IFs must notify the athlete's NADO when they grant a TUE. The NADO then has 21 days from this notification to refer the decision to WADA for review.

WADA may refer the decision back to the IF or the NADO, as applicable:

- for clarification, e.g. if the reasons are not clearly set out in the decision; and/or
- for re-consideration, e.g. if the TUE was only denied because medical tests or other information required to demonstrate satisfaction of the ISTUE Article 4.2 conditions were missing.

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The following describes the process when WADA reviews a TUE decision (ISTUE Article 8):

- ❖ For mandatory reviews, WADA generally will not charge a fee; however, whichever ADO 'loses' the review may be asked to reimburse the application fees and/or the payment of the costs incurred.
- ❖ For non-mandatory review, if WADA accepts the athlete's request, they will be asked to make a payment of \$500 US as an administrative fee.
- ❖ For reviews that WADA initiated, WADA may require the ADO that made the initial decision to pay the costs incurred by WADA in respect of that review, if the TUE is reversed.
- ❖ TUE review requests must be submitted to WADA in writing and should contain all of the information sent during the initial submission (i.e., the complete file), along with the initial decision issued and the explanation provided by the ADO regarding why the TUE was not granted or recognized. The athlete or ADO should confirm what documents were part of their initial TUE application.
- ❖ When submitting a request for a review, the athlete must notify the ADO whose decision they are appealing. If the request is made by an ADO on behalf of the athlete, then the athlete must also be included.
- ❖ In cases where a review is not mandatory, WADA will inform the requesting party whether or not the TUE decision will be reviewed by the WADA TUEC.
- ❖ WADA will commence its review upon receipt of payment (where applicable) and all the necessary documentation.
- ❖ WADA will set up a WADA TUEC, which will review the case and render a decision. The original grant/denial of the TUE will remain in effect until the WADA TUEC reaches a decision.
- ❖ The WADA TUEC will evaluate the case based on the information provided in the original application. If the athlete has new information, such as medical tests, then they should reapply to the relevant ADO.
 - A WADA TUEC may, at its discretion, request additional information, which may be considered as part of the TUE review.

- ❖ The WADA TUEC may obtain the assistance of other medical or scientific experts as it deems appropriate.
- ❖ WADA will communicate the reasoned decision of the WADA TUEC promptly to the athlete and to their NADO, IF, and (if applicable) the MEO.
- ❖ If, following its review, a TUE is granted by the WADA TUEC, it will come into effect in accordance with the conditions outlined by the WADA TUEC.
- ❖ If, following its review, a TUE is reversed by the WADA TUEC, the ADO whose decision is reversed must reflect the status change in ADAMS.

Additional comments

- ❖ Any TUE decision by an IF (or NADO where it has agreed to consider the application on behalf of an IF) that is not reviewed by WADA, or that is reviewed by WADA but is not reversed upon review, may be appealed by the athlete and/or the athlete's NADO, exclusively to CAS.
- ❖ In such cases, the decision being appealed is the IF's TUE decision, not WADA's decision not to review the TUE decision or (having reviewed it) not to reverse the TUE decision
- ❖ A decision by WADA to reverse a TUE decision may be appealed by the athlete, the NADO and/or the IF affected, exclusively to CAS. Unless the CAS orders otherwise, WADA's decision remains in effect until the CAS renders a final decision.
- ❖ The time to appeal the TUE decision does not begin to run until the date that WADA communicates its decision (Comment to Code Article 4.4.7).

The request and information for WADA to review may be sent by a secure on-line method or by registered mail at the following address:

WADA Medical Department
World Anti-Doping Agency
800, Square Victoria
Montreal, H4Z 1B7, QC Canada

The email address to enquire and/or send the request for review is:
medical@wada-ama.org

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The review procedure does not suspend the initial decision, which remains in effect throughout the duration of the review until the WADA TUEC issues its decision. However, if the athlete had been granted a TUE by a NADO that was not recognized by an IF, then the TUE would only be valid at a national level competition and for out-of-competition testing, pending WADA's review, but not for international level competition (Code Article 4.4.3).

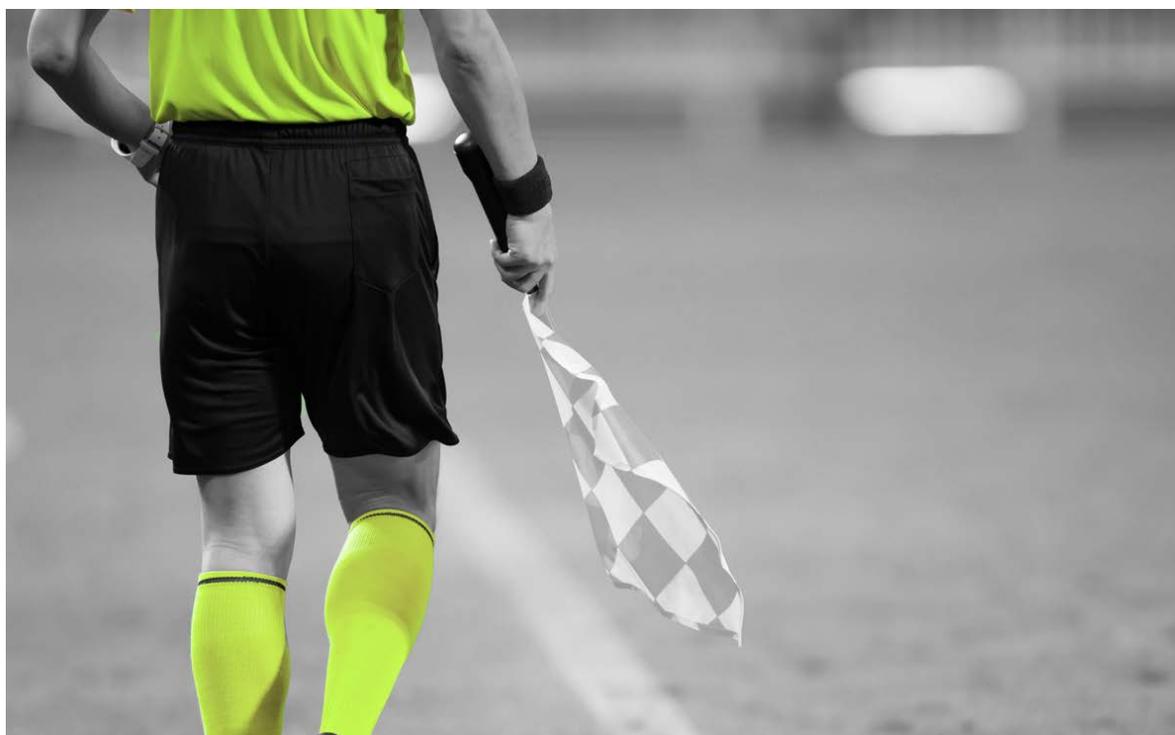
If the TUE was granted by an IF and referred to WADA for review by the athlete's NADO, the TUE remains valid for international level competition and out-of-competition testing, but is not valid for national level competition, pending WADA's review.

If the WADA TUEC reverses the initial decision and grants the TUE, the athlete may start to use the substance or method according to the TUE granted by the WADA TUEC. The TUE will be valid at both the national and international level. Conversely, if the WADA TUEC considers that the TUE should not be granted, it will not be valid at any level

SECTION 8:

TUES and ADAMS

This section will make you aware of the key functionalities in ADAMS associated with the TUE process.



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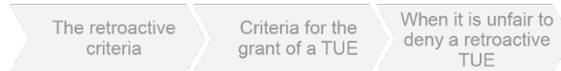
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What is ADAMS

ADAMS is a web-based system designed in strict compliance with the Code to assist stakeholders and WADA in their anti-doping operations.

As a central clearinghouse for doping control testing data and results management decisions, ADAMS allows for data entry, reporting, sharing, and storage in a highly secure environment, with access restricted to relevant authorized parties.

The ADAMS TUE management module provides the following services:

- ❖ Online submission of TUE applications by
 - athletes;
 - athlete physicians; and
 - ADOs to TUEC physicians.
- ❖ Online management of TUE applications
- ❖ Notification of receipt to athletes
- ❖ Notification of refusal to grant a TUE to athletes
- ❖ Dispatch of TUE certificates to athletes
- ❖ Online notification of the expiry/change in status of a TUE to relevant parties
- ❖ Sharing of information relating to the TUE with all relevant parties
- ❖ Recognition by IF of TUE granted by NADOs
- ❖ Link between TUEs and AAFs
- ❖ Search function and printing of reports.
 - A new TUE module is being developed in ADAMS Next Gen.

Annex

TUE Applications – Translation of Medical Information:

TUE information must be entered in ADAMS in English or French in accordance with ISTUE Article 5.5. It is acceptable to provide a translated summary explaining the diagnosis, key elements of the clinical exams, medical tests and the treatment plan. It would not be sufficient to translate two lines from a physician stating the diagnosis and treatment. The summary should be prepared by either the treating physician or an ADO physician/staff with an understanding of the case/condition. WADA may, however, request further translation of some or all of the medical file, as necessary.

A complete translation summary should provide enough information to help the TUEC physician understand how the diagnosis was made.

Examples of good translation summaries:



EXAMPLE 1

The athlete is a 25-year-old male triathlete requiring Andriol (testosterone) 40mg p.o. daily, diagnosed with secondary hypogonadism. Past medical history includes delayed sexual development, testicular volume of 11 mL at age 20, and a Tanner scale IV. No history of testicular injuries, decreased energy, mood, and depression and no gynecomastia.

Most recent Lab results on 25 June 2020 as follows:

- ❖ Serum total testosterone 1.5 nmol/L (9.9-52.4)
- ❖ FSH = 14.7 mIU/mL (1.5 – 12.4)
- ❖ LH = 4.2 mIU/mL (1.7 – 8.6)
- ❖ TSH = 0.689 mIU/mL (0.45-4.5)
- ❖ Estradiol = 20.9 pg/mL (7.6-42.6)
- ❖ Prolactin = 8.5 ng/mL (4.0-15.2)

❖ Semen analysis – 0 viable spermatozoa

All labs were drawn at 8 am. An MRI of pituitary showed adenoma (see imaging attached and letter from endocrinologist). The pathology is organic in nature. Functional causes were ruled out – no overtraining (training schedule provided), no obesity.

Further untranslated documents were uploaded in ADAMS.



EXAMPLE 2

The athlete is a 29-year-old male tennis player diagnosed with asthma at age 10. History of rhinitis, atopy and seasonal allergies. Diagnostic work up was repeated at age 21 to confirm the diagnosis of asthma by a respiratory physician. The athlete was twice admitted to a hospital this year for acute exacerbations during training sessions. At age 24, spirometry was done again demonstrating the following (please see the attached graphs included with this TUE applications):

	Spirometry	Interpretation
Baseline	EV1 = 3.24 (76% predicted) FVC = 4.82 (91% predicted) FEV1/FVC ratio = 0.67	Reduced Normal Slightly reduced
Post Bronchodilator	FEV1 = 4.17 (+930 ml and 29%)	Significant reversibility

Spirometry reveals a mild degree of obstruction that was highly responsive (highly reversible) to salbutamol. This reversibility and clinical history are indicative of asthma and is confirmed by spirometry. Airway responsiveness test was performed by methacholine challenge.

Athlete is using Advair 250/25 mcg diskus (fluticasone/formoterol) and salbutamol prn. During his match, he had severe symptoms of shortness of breath consistent an asthma attack. Oral prednisone 50mg p.o. was administered and the athlete was brought to the hospital where his asthma symptoms of wheezing and shortness of breath subsided.

Examples of inadequate translation summaries:



EXAMPLE 3

The athlete is a 25-year-old male long jumper diagnosed with hypogonadotropic hypogonadism. There is no permitted alternative therapy and he needs testosterone 40mg p.o. daily. He was diagnosed by an endocrinologist. He is doing very well on his medication.



EXAMPLE 4

Diagnosis: ADHD (since childhood): The athlete was diagnosed with ADHD at age 11 by her pediatrician. She is treated with 54-72 mg Concerta (methylphenidate extended release) daily. See the prescription that is attached to this application.

Glossary

A

ADAMS	Anti-Doping Administration & Management System
ADHD	Attention Deficit Hyperactivity Disorder
ADO	Anti-Doping Organization
ADRV	Anti-Doping Rule Violation
ASP	Athlete Support Personnel
AAF	Adverse Analytical Finding
ACTH	Adrenocorticotrophic hormone
ADEL	Anti-Doping Education and Learning

C

CAS	Court of Arbitration for Sport
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G

GC	Glucocorticoid
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I

ISTUE	International Standard for Therapeutic Use Exemptions
ITA	International Testing Agency
IF	International Federation
ILA	International-Level Athlete
ISPPPI	International Standard for the Protection of Privacy and Personal Information

M

MEOs	Major Event Organizations
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N

NLA	National-Level Athlete
NADO	National Anti-Doping Organization

P

List Prohibited List

PE Performance Enhancing

R

RTP Registered Testing Pool

RMA Results Management Authority

RLA Recreational-Level Athlete

T

TUEC Therapeutic Use Exemption Committee

TUE Therapeutic Use Exemption

W

WADA World Anti-Doping Agency