



U.S. ANTI-DOPING AGENCY

# THERAPEUTIC USE EXEMPTION POLICY

Effective January 1, 2019

## 1. GENERAL PRINCIPLES

The United States Anti-Doping Agency (“USADA”) Policy for Therapeutic Use Exemptions (“USADA TUE Policy”) is based upon the relevant provisions of the World Anti-Doping Code (the “Code”) and the provisions of the World Anti-Doping Agency (“WADA”) International Standard for Therapeutic Use Exemptions (“ISTUE”) which are incorporated herein as if fully set forth. This Policy is informed by the following general principles which provide the context for the USADA TUE Policy.

It is each *Athlete’s* personal duty to ensure that no *Prohibited Substance* enters his or her body and no *Prohibited Method* is utilized. *Athletes* are responsible for any *Prohibited Substance* and/or its *Metabolites* or *Markers* found to be present in any *Sample(s)* they provide and/or *Prohibited Method* detected from the *Sample*. Source: *Code*, Article 2.2.1.

*Athletes* with documented medical conditions requiring the *Use* of a *Prohibited Substance* and/or a *Prohibited Method* must request a Therapeutic Use Exemption (“TUE”) from their International Federation or USADA.

All *Athletes* in the USADA *Registered Testing Pool* or Clean Athlete Program who require a TUE and who have not received one from their International Federation must contact USADA. USADA will recognize a valid TUE obtained from an *Athlete’s* International Federation.

For *Athletes* who are in their International Federation’s *Registered Testing Pool* or who intend to compete in an *International Event*, TUEs already granted by USADA, which meet the ISTUE criteria, must be recognized by the International Federation. If the International Federation determines that the TUE does not meet ISTUE criteria and so refuses to recognize it, the International Federation must promptly notify the *Athlete* and USADA of its determination. The *Athlete* or USADA shall then have twenty-one (21) days from such notification to refer the matter to WADA for review. *International-Level Athletes* who require a TUE and who have not received a TUE from USADA must obtain TUEs in accordance with the rules of their International Federation. Source: *Code*, Article 4.4.3.

For certain major *Events*, such as the Olympic Games and the Pan American Games, the *Major Event Organization* may require *Athletes* to apply to it for a TUE if they wish to *Use* a *Prohibited Substance* and/or *Prohibited Method* in connection with the *Event*. If a TUE is granted by the *Major Event Organization*, it will be effective for the duration of the *Event Period* only. TUEs already granted by an International Federation or USADA, which meet the ISTUE criteria, must be recognized by the *Major Event Organization*. If the *Major Event Organization* decides the TUE does not meet the ISTUE criteria and so refuses to recognize it, the *Major Event Organization* must promptly notify the *Athlete* of its determination. A decision by a *Major Event Organization* not to grant or recognize a TUE may be appealed by the *Athlete* exclusively to an independent body appointed by the *Major Event Organization* for that purpose. Source: *Code*, Article 4.4.4.

An application for a TUE will only be considered for retroactive approval where:

- a. Emergency treatment or treatment of an acute medical condition was necessary; or
  - b. Due to other exceptional circumstances, there was insufficient time or opportunity for the *Athlete* to submit, or for the TUEC to consider, an application for the TUE prior to *Sample* collection; or
  - c. It is agreed, by WADA and by the *Anti-Doping Organization* to whom the application for a retroactive TUE is or would be made, that fairness requires the grant of a retroactive TUE.
- . [Comment to (c): If WADA and/or the Anti-Doping Organization do not agree to the application of (c), that may not be challenged either as a defense to proceedings for an anti-doping rule violation, or by way of appeal, or otherwise.] (Source: WADA ISTUE 4.3(d))

Specific national rules for TUEs may be established for non-international-level or non-national-level competitors without being in conflict with the *Code*. Source: *Code*, *Athlete* definition.

**WARNING:** Because excretion rates for various substances vary between individuals, for substances which are prohibited only *In-Competition*, *Athletes* are advised to ensure sufficient time for any such substance to clear their body before participating in a *Competition* in order to avoid an anti-doping rule violation. Of course, discontinuance of a medication can also have adverse health consequences and should never be undertaken without consultation with the *Athlete's* physician and a full appreciation of the risks involved. The only completely safe method for an *International-Level Athlete* or a *National-Level Athlete* to Use a *Prohibited Substance* and/or a *Prohibited Method* without risking an anti-doping rule violation is to obtain a *TUE* prior to use.

## 2. DEFINITIONS

A complete list of definitions from the *Code* and *ISTUE* which are relevant to this Policy can be found in Article 3 of the *ISTUE*. In addition, the definitions listed below have particular importance in applying this Policy. Throughout this Policy and as demonstrated in this Section below, terms defined in the *Code*<sup>[1]</sup> are written in italics, terms defined in the *ISTUE*<sup>[2]</sup> are underlined and terms specific to this **Policy** are in bold.

*Adverse Analytical Finding:* A report from a laboratory or other *WADA*-approved entity that, consistent with the International Standard for Laboratories and related Technical Documents, identifies in a *Sample* the presence of a *Prohibited Substance* or its *Metabolites* or *Markers* (including elevated quantities of endogenous substances) or evidence of the *Use of a Prohibited Method*.

*Athlete* [partial]: Any Person who competes in sport at the international level (as defined by each International Federation), or the national level (as defined by each *National Anti-Doping Organization*).

[USADA Comment to *Athlete* Definition: USADA has discretion to apply anti-doping rules to an *Athlete* who is neither an *International-Level Athlete* nor a *National-Level Athlete*, and thus to bring them within the definition of "*Athlete*" as defined in the USADA Protocol for Olympic and Paralympic Movement Testing.]

**Elite-Level National Championship:** An *Event* where *Athletes* or teams compete in an open category for a top national achievement award in any Olympic, Paralympic or Pan-American sport. (Note: Youth, Junior, Collegiate, Masters, Developmental and all Age-Category classifications are excluded.)

*Event:* A series of individual *Competitions* conducted together under one ruling body (e.g., the Olympic Games, FINA World Championships, or Pan American Games).

*Event Period:* The time between the beginning and end of an *Event*, as established by the ruling body of the *Event*.

*International Event:* An *Event* or *Competition* where the International Olympic Committee, the International Paralympic Committee, an International Federation, a *Major Event Organization*, or another international sport organization is the ruling body for the *Event* or appoints the technical officials for the *Event*.

*International-Level Athlete:* *Athletes* who compete in sport at the international level, as defined by each International Federation, consistent with the International Standard for Testing and Investigations<sup>[3]</sup>.

*Major Event Organizations:* The continental associations of *National Olympic Committees* and other international multisport organizations that function as the ruling body for any continental, regional or other *International Event*.

**NGB:** For purposes of the USADA TUE Policy, the term refers to National Governing Bodies of individual sports recognized by the United States Olympic Committee ("USOC"), Olympic Sport Organizations, Pan American Sport

[1] <https://www.wada-ama.org/en/resources/the-code/2015-world-anti-doping-code>.

[2] <https://www.wada-ama.org/en/resources/therapeutic-use-exemption-tue/international-standard-for-therapeutic-use-exemptions-istue>

[3] For purposes of this Policy, this will typically include *Athletes* designated by one or more International Federation as being within the *Registered Testing Pool* for the International Federation, or any *Athlete* planning to compete in an *International Event*.

Organizations and Paralympic Sport Organizations recognized by the USOC and High Performance Management Organizations that have contracts with the USOC to administer Paralympic Sport.

**National-Level Athlete:** For the purposes of the USADA TUE Policy, any *Athlete* who is in the USADA *Registered Testing Pool* or Clean Athlete Program, who is not also in the *Registered Testing Pool* of an International Federation or does not otherwise meet criteria to be considered an *International-Level Athlete*.

**Non-National Athlete:** For purposes of the USADA TUE Policy, any *Athlete* subject to the USADA Protocol for Olympic and Paralympic Movement Testing who is not an *International-Level Athlete* or an *Athlete* entered into an *International Event*, or is not a **National-Level Athlete**, and over whom USADA has authority to conduct results management in relation to an *Adverse Analytical Finding*, an *Atypical Finding* or other potential anti-doping rule violation.

*Prohibited List:* The List identifying the *Prohibited Substances* and *Prohibited Methods*.

**Recreational Competitor:** For the purposes of the USADA TUE Policy, a **Non-National Athlete** who is not classified as a professional *Athlete* and who within the last 25 years (1) has not been in the USADA *Registered Testing Pool* or Clean Athlete Program, or the *Registered Testing Pool* of an International Federation; (2) has not represented the United States in an *International Event*; (3) has not won a national or regional level *Competition* in any sport; (4) has not finished first, second or third in an age group category of any *Event* sanctioned by an **NGB** in which fifty (50) or more competitors have been entered in that category in the sport in which they are presently competing; and (5) has not won more than five hundred dollars (500.00 USD) in prize money in an *Event* in the sport in which they are presently competing.

**Recreational Competitor TUE (or “RCTUE”):** A Therapeutic Use Exemption for use by a **Recreational Competitor** for substances and/or methods prohibited at all times or in *Competitions* where USADA anti-doping rules apply as defined by the USADA Protocol for Olympic and Paralympic Movement Testing, the USADA TUE Policy and as limited by the terms set forth in the certificate provided to an individual who has been granted an **RCTUE**.

*TUE:* Therapeutic Use Exemption, as described in [Code] Article 4.4.

Therapeutic Use Exemption Committee (or “TUEC”): The panel established by an *Anti-Doping Organization* to consider applications for *TUEs*.

### 3. POLICY FOR INTERNATIONAL-LEVEL ATHLETES

*International-Level Athletes* should submit new or renewal *TUE* applications to their International Federation for processing. USADA will assist *International-Level Athletes* in the USADA *Registered Testing Pool* or Clean Athlete Program by forwarding applications for *TUEs* if such requests for USADA assistance are made at least thirty (30) days in advance of the *Athlete’s Use* of the medication where prohibited in sport. USADA will make best efforts to expedite *TUE* requests made less than thirty (30) days in advance of the *Athlete’s* intended *Use* but can make no guarantees as to the responsiveness of the International Federation to such applications.

Where an *Athlete* already has a *TUE* granted by USADA for the substance or method in question, if that *TUE* meets the ISTUE criteria, then the International Federation must recognize it or promptly advise USADA and the *Athlete* of its reasons for refusing to recognize the *TUE*. Source: Code, Article 4.4.3.1.

According to the ISTUE, an International Federation decides whether or not to recognize the *TUE* as soon as possible, and usually (i.e., unless exceptional circumstances apply) within no more than twenty-one (21) days of receipt of a complete request for recognition. Source: ISTUE, Article 7.4.

#### 4. POLICY FOR NATIONAL-LEVEL ATHLETES

USADA will process *TUE* applications for **National-Level Athletes** in accordance with the ISTUE.

A **National-Level Athlete** may apply to USADA for a *TUE* for any *Prohibited Substance* and/or *Prohibited Method* at any time; however, such applications must be complete and received by USADA at least thirty (30) days in advance of any *Use* prohibited in sport. USADA will make best efforts to expedite *TUE* requests made less than thirty (30) days in advance of the *Athlete's* intended *Use* based on exceptional circumstances, but makes no guarantees regarding the processing of *TUE* applications under that timeframe.

*TUEs* will only be considered for retroactive approval for **National-Level Athletes** in accordance with the strict criteria set forth in the ISTUE and outlined in Section 1 of this Policy.

If a **National-Level Athlete** competes in an *International Event*, he or she may be required to submit a request for recognition of any *TUEs* granted by USADA or apply for a *TUE* from the relevant International Federation or *Major Event Organization* in advance of the *International Event*. It is the responsibility of every *Athlete* to investigate the applicable *TUE* requirements before competing in an *International Event*. If an International Federation chooses to test an *Athlete* who is not an *International-Level Athlete*, it must recognize a *TUE* granted to that *Athlete* by USADA. Source: Code Article 4.4.3.

#### 5. POLICY FOR NON-NATIONAL-LEVEL ATHLETES

- a. **Non-National Athletes** are required to obtain a *TUE* in advance for all substances and methods prohibited at all times (*In-* and *Out-of-Competition*) according to the *WADA Prohibited List*. **Non-National Athletes** are also required to apply for *TUEs* for all *Prohibited Substances* and/or *Prohibited Methods* in advance of competing in any *International Events* (including those taking place in the United States).

Except for **Recreational Competitor *TUEs*** as described below, *TUEs* for **Non-National Athletes** will be obtained in the same manner as for **National-Level Athletes**. **Non-National Athletes** will only be granted by a TUEC in strict accordance with the ISTUE and *WADA Medical Information to Support the Decisions of TUECs*. Any **Non-National Athlete** who is a member or license-holder of an **NGB** and chooses to *Use* a substance that is prohibited at all times without prior *TUE* approval risks an anti-doping rule violation, even when not competing.

USADA will not consider disclosure of *Use* of a *Prohibited Substance* and/or a *Prohibited Method* in the **Non-National Athlete's** *TUE* application and supporting medical file to be an anti-doping rule violation, so long as (1) the **Non-National Athlete** refrains from competing while his or her *TUE* application is being considered; (2) the **Non-National Athlete** does not have an adverse analytical finding for a *Prohibited Substance* and/or a *Prohibited Method*; and (3) USADA does not have an independent basis for investigating the **Non-National Athlete**. Nothing in this section limits any rights listed in Article 13.2.3 the parties may have to review and act on information in a **Non-National Athlete's** *TUE* application. In the event a **Non-National Athlete** receives a *TUE* denial, further use of a *Prohibited Substance* and/or *Prohibited Method* will be considered an anti-doping rule violation.

For a **Non-National Athlete** who has a first *Adverse Analytical Finding* caused by the *Use*, and/or declaration of *Use* at the time of testing, of a *Prohibited Substance* and/or *Prohibited Method* and who is able to satisfy the criteria set forth in Sections 5.b-d below, USADA may determine that the **Non-National Athlete** has not committed an anti-doping rule violation if the *Adverse Analytical Finding*

or the **Non-National Athlete's** potential anti-doping rule violation resulted from the **Non-National Athlete's** Use of one or more of the following:

1. Substances or methods prohibited only *In-Competition* or prohibited by particular sports;
  2. Substances in the class of "Diuretics and Other Masking Agents;"
  3. All inhaled Beta-2 agonists;
  4. Insulin where the *Athlete* can demonstrate diagnosis of insulin-dependent diabetes;
  5. Selective estrogen receptor modulators (SERMs) where the female *Athlete* can demonstrate use due to a diagnosis and treatment of breast or other cancers;
  6. Clomiphene where the female *Athlete* can demonstrate use due to treatment of infertility;
  7. An IV infusion or injection of a non-prohibited substance greater than 100mL per any 12 hour period for rehydration; and
  8. Medically-supervised plasmapheresis as a plasma donor (reintroduction of any quantity of additional blood or blood components remains prohibited, e.g., blood transfusions).
- b. Subject to the provisions of Sections 5.c. below, **Non-National Athletes** who have a first *Adverse Analytical Finding* caused by the *Use*, and/or declaration of *Use* at the time of testing, of a *Prohibited Substance and/or Prohibited Method* will not have committed an anti-doping rule violation for substances or methods outlined in Section 5.a.1-8, so long as:
1. With respect to an IV infusion or injection of a non-prohibited substance greater than 100mL per 12 hour period:
    - i. The **Non-National Athlete** is able to demonstrate to USADA's satisfaction that they were unaware of the scope of the restrictions on the use of IVs and injections set forth in the *Prohibited List*.
    - ii. The **Non-National Athlete** is able to demonstrate that the IV infusion or injection was undertaken for rehydration purposes or was medically-supervised plasmapheresis as a plasma donor.
    - iii. Disclosure on a **Non-National Athlete's** doping control form or voluntary cooperation with USADA's investigation shall be considered strong evidence that can lead to the conclusion that a **Non-National Athlete** was unaware of the scope of the restrictions on the use of IVs or injections in the *Prohibited List*, that the substance injected or infused did not contain a *Prohibited Substance*, and/or that the purpose of the IV or injection was for rehydration.
  2. With respect to a first *Adverse Analytical Finding*, and/or declaration of *Use* at the time of testing, for a substance or method listed in Section 5.a.1-6,
    - i. The **Non-National Athlete** has a legitimate medical condition diagnosed by a licensed physician which was thoroughly documented, and the prescribed *Use* is consistent with an appropriate treatment plan in his or her medical records prior to the date of *Sample* collection;
    - ii. The **Non-National Athlete** has a prescription signed by a licensed physician prior to *Sample* collection consistent with the *Adverse Analytical Finding*;

- iii. The **Non-National Athlete**, at his or her own expense, promptly undergoes any additional medical examination and testing requested by USADA, including, but not limited to, seeing particular physicians which may be designated by USADA; and
- iv. The facts and circumstances of the case put to rest any reasonable suspicion that the **Non-National Athlete** used the substance for the purpose of enhancing his or her performance. Inclusion of the *Prohibited Substance* and/or *Prohibited Method* in the “Declaration of Use” section on a Doping Control Official Record shall be considered strong evidence that the *Use* of the substance or method was not intended to enhance performance.

**NOTE:** If the **Non-National Athlete** intends to compete further in any *Event* or *Competition* that may be drug tested by USADA or any other *Code Signatory*, he or she must apply for and be granted a *TUE* for any *Prohibited Substance* and/or *Prohibited Method* in advance of participating in any further *Event* or *Competition*.

- c. **Non-National Athletes** who have a first *Adverse Analytical Finding* resulting from the *Use* of a medication shall remain liable for an anti-doping violation if: they have previously been included in the USADA *Registered Testing Pool* or Clean Athlete Program; they have previously been included in an International Federation *Registered Testing Pool*; they are a current recipient of USOC funding; the *Adverse Analytical Finding* results from a *Sample* collected at an **Elite-Level National Championship** at which they placed in the top three; or the *Adverse Analytical Finding* results from a *Sample* collected at an *International Event* or at an individually contested event which immediately results in National Team selection for an Olympic, Paralympic, Pan- or Para-Pan American Games, including the Youth Olympic Games (e.g., any Olympic Trials named event).
- d. **Non-National Athletes** who have once had an *Adverse Analytical Finding* caused by the *Use* of any *Prohibited Substance* and/or *Prohibited Method* shall be liable for an anti-doping rule violation for any future positive drug test or finding of any *Prohibited Substance* and/or *Prohibited Method* unless they have applied for and been granted a *TUE* for the substance or method in accordance with the ISTUE and this Policy.
- e. **Non-National Athletes** who have had their *TUE* denied by a TUEC will have their denied application reviewed for a **Recreational Competitor TUE**, which may be granted where USADA determines in its sole discretion that the following conditions have been met:
  - 1. The **Non-National Athlete** is a **Recreational Competitor** as defined by the USADA TUE Policy.
  - 2. The **Recreational Competitor** has submitted a completed *TUE* application and complied with all follow up requests for information, medical records and additional testing made by USADA at USADA’s discretion and as may be set forth in the ISTUE and *WADA Medical Information to Support the Decisions of TUECs* or subsequent guidance document issued by WADA.
  - 3. The *TUE* application was denied by USADA’s TUEC on the ground that the **Recreational Competitor** has been unable to meet their burden of satisfying the requirements set forth in the ISTUE and *WADA Medical Information to Support the Decisions of TUECs*; however, the evidence submitted by the **Recreational Competitor** establishes the treatment of a properly diagnosed, substantial and continuing health condition through the *Use* of a *Prohibited Substance* and/or *Prohibited Method* is within the acceptable standard of clinical care, and the inability to meet the requirements set forth in the ISTUE and *WADA Medical Information to Support the Decisions of TUECs* is not the result of failure by the **Recreational Competitor** to undergo adequate testing or diagnostic workups, the failure to acquire and submit adequate documentation, or the prior *Use*

of a *Prohibited Substance* and/or *Prohibited Method*.

4. Use of the *Prohibited Substance* and/or *Prohibited Method* by the **Recreational Competitor** is highly unlikely to produce any additional enhancement of performance beyond what might be reasonably anticipated by a return to the individual's normal state of health they would have had without the substantial and continuing health condition.
- f. As with any *TUE*, to ensure no performance enhancing benefit is gained through the Use of a *Prohibited Substance* and/or *Prohibited Method*, the **RCTUE** may include conditions, which may include but are not limited to:
1. Minimum requirements for follow-up testing;
  2. Routine clinical monitoring, including repeat testing, evaluation or examination and reporting at USADA's request;
  3. The **Recreational Competitor** remaining accessible and submitting whereabouts information to USADA for follow-up testing during the period his or her **RCTUE** is in place;
  4. The **Recreational Competitor** maintaining physiological levels of the *Prohibited Substance* and/or its *Metabolites* or *Markers* and/or use of a *Prohibited Method* within clinically acceptable therapeutic ranges to limit any therapeutic benefit to a return to a normal state of health;
  5. Limitations on the *Competitions* for which the *TUE* may be used, including a proviso that the *TUE* may be revoked in the future for certain *Competitions*; and/or
  6. Limitation on the Use of the *Prohibited Substance* and/or *Prohibited Method* during *Competition* or within a fixed period of time in advance of *Competition*.
- g. A **Recreational Competitor TUE** granted by USADA is only valid for the time period specified in the **RCTUE** certificate and expires immediately if the individual who has received the **RCTUE** ceases to be a **Recreational Competitor**. An **RCTUE** granted by USADA shall not be valid for *International Events* or National Championships unless expressly recognized as a valid *TUE* by the relevant International Federation or *WADA*.
- h. A **Recreational Competitor TUE** granted by USADA may be revoked by USADA upon adequate notice to the **Recreational Competitor** in the event an **NGB**, International Federation, *WADA* or other sports organization demonstrates with compelling evidence that the **RCTUE** has resulted in or is likely to result in an unfair competitive advantage over fellow competitors by the **Recreational Competitor**.

## 6. APPEAL

*International-Level Athletes* may appeal a *TUE* denial to *WADA* or *CAS* according to applicable rules and instructions set forth in the *Code*, *ISTUE* and *WADA TUE Guidelines*<sup>[4]</sup>.

In the case of any *TUE* denial, an *Athlete* will be provided a detailed explanation as to why their *TUE* application did not meet the *ISTUE* criteria. Any *Athlete* may request further information about a denial, and may request a medical review from USADA by contacting USADA in writing. In response to a request for medical review USADA may: (a) determine whether an **RCTUE** may be appropriate, (b) determine whether additional information should be submitted by the *Athlete*, (c) determine whether additional testing should be required of the *Athlete*, (d) request written authorization from the *Athlete* to contact the *Athlete's* physician(s) or other healthcare providers and/or

[4] <https://www.wada-ama.org/en/resources/therapeutic-use-exemption-tue/international-standard-for-therapeutic-use-exemptions-istue>.



obtain information from the physician(s) or healthcare provider(s), (e) request that the *Athlete* explain any aspect of his application, file or request that is unclear, (f) inform the *Athlete* that no further review of the current *TUE* application will be made but that a further application may be made if additional information is included in the application, (g) re-submit the application to another TUEC, (h) inform the *Athlete* in writing that no further action will be taken on his *TUE* application at this time, or (i) any combination of the foregoing.

If a **National-Level Athlete** or a **Non-National Athlete**, who has submitted a complete *TUE* application and all appropriate and requested documentation, is not satisfied by USADA's *TUE* decision, and if a medical review of USADA's *TUE* decision has been requested and has not, within twenty-one (21) days of the request for review, resulted in the granting of a *TUE*, the **National-Level Athlete** or **Non-National Athlete** may appeal USADA's *TUE* decision through a request for arbitration pursuant to the USADA Protocol for Olympic and Paralympic Movement Testing. Any request for a medical review of a USADA decision denying a *TUE* to a **National-Level Athlete** or **Non-National Athlete** must be made within ten (10) days of the denial by USADA. Any request for arbitration must be filed within twenty-one (21) days of USADA's refusal to reverse a *TUE* denial upon the **National-Level Athlete's** or **Non-National Athlete's** request for medical review of the *TUE* decision.

If a **Recreational Competitor** who receives an **RCTUE** desires to compete in any *Competition* not covered by the **RCTUE** they must timely submit a new *TUE* application in accordance with the applicable deadlines for submission of an application for *TUE*.

**RCTUE** decisions may not be appealed.

## **7. EFFECTIVE DATE**

The effective date of this USADA *TUE* Policy shall be January 1, 2019.