THERAPEUTIC USE EXEMPTION POLICY

U.S. ANTI-DOPING AGENCY

Effective JANUARY 1, 2018
(Revised June 21, 2018)
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 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[1] are written in italics, terms defined in the ISTUE[2] 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[3].

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


[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, 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 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 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; 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 Athlete 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[4].

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

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, 2018.