

USADA POLICY FOR THERAPEUTIC USE EXEMPTIONS AND DECLARATIONS OF USE

1) General Principles

USADA's Policy for Therapeutic Use Exemptions and Declarations of Use is based upon the relevant provisions of the World Anti-Doping Code (the "*Code*")¹ and the provisions of the World Anti-Doping Agency ("WADA") International Standard for TUEs ("IS TUE") which are incorporated herein as if fully set forth. This Policy is informed by the following general principles which provide the context for USADA's Policy.

It is each *Athlete's* personal duty to ensure that no *Prohibited Substance* enters his or her body. *Athletes* are responsible for any *Prohibited Substance* or its *Metabolites* or *Markers* found to be present in their *Samples*. **Source:** *Code*, Article 2.1.1.

Athletes with documented medical conditions requiring the use of a *Prohibited Substance* or a *Prohibited Method* must request a therapeutic use exemption ("*TUE*") from their International Federation ("IF") or USADA. For certain major competitions such as the Olympic Games and the Pan American Games TUEs must be sought directly from the event organizer and a USADA TUE or TUE from an IF will not be sufficient. **Source:** *Code*, Article 4.4.

Athletes who are in the IF's *Registered Testing Pool* or who intend to compete in an *International Event* may only obtain *TUEs* in accordance with the rules of their IF or the event organizer. **Source:** *Code*, Article 4.4.

Each IF shall publish a list of those *International Events* for which a *TUE* from the IF is required. **Source:** *Code*, Article 4.4.

All *Athletes* in the USADA *Registered Testing Pool* ("USADA RTP") who require a *TUE* and who have not gotten a *TUE* from their IF must contact USADA. USADA will recognize a valid *TUE* obtained from an *Athlete's* IF.

An application for a *TUE* will not be considered for retroactive approval (i.e., for approval after an *Adverse Analytical Finding* on a doping test) except in cases where:

- a. emergency treatment or treatment of an acute medical condition was necessary, or
- b. due to exceptional circumstances, there was insufficient time or opportunity for an applicant to submit, or a therapeutic use exemption committee ("*TUEC*") to consider, an application prior to doping control, or

¹ Capitalized and italicized terms have the meaning set forth in the Definitions Section of the World Anti-Doping Code or the International Standard for Therapeutic Use Exemptions.

- c. specific conditions pertaining to the use of a glucocorticosteroid or beta-2 agonist as set forth in IS TUE, Article 7.13 of applies. **Source:** IS TUE, Article 4.7.

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*, Definition of “*Athlete*.”

2) Definitions

A complete list of definitions from the *Code* and IS TUE which are relevant to this Policy can be found in Article 3 of the IS TUE. In addition, the following definitions have particular importance in applying this Policy:

- a) **Foreign Athlete:** For purposes of this Policy, a “Foreign Athlete” is an *Athlete* who is not a resident of the United States and is not either an International Level Athlete or a National Level Athlete as defined below.
- b) **International Event:** An *Event* where the International Olympic Committee, the International Paralympic Committee, an IF, a *Major Event Organization*, or another international sport organization is the ruling body for the *Event* or appoints the technical officials for the *Event*. Note: Pursuant to *Code* Article 4.4, each IF is required to publish a list of those *International Events* for which a *TUE* from the IF is required.
- c) **International-Level Athlete:** *Athletes* designated by one or more IFs as being within the *Registered Testing Pool* for an IF.
- d) **National Level Athlete:** For purposes of this Policy a “National Level Athlete” is any *Athlete* in the USADA RTP who is not in the *Registered Testing Pool* of an IF.
- e) **Non-National Level Athlete:** For purposes of this Policy a “Non-National Level Athlete” is any United States *Athlete* who is not an *International-Level Athlete* or an *Athlete* entered into an *International Event* and 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 rules violation.

3) National Level Athletes

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

- a) A National Level Athlete may apply to USADA for a *TUE* for any substance at any time, however, such applications must be complete and received by USADA at least twenty-one (21) days in advance of any use prohibited in sport.
- b) Except as specified below, retroactive approval of *TUE* applications will only be granted in accordance with the strict criteria set forth in the IS TUE.

WARNING: For substances which are prohibited only in-competition the athlete must ensure sufficient time for clearance from the body before the competition. Urine excretion rates for various substances vary between individuals and the *Athlete* must allow sufficient time to avoid an **anti-doping rules 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* without risking an anti-doping rule violation is to obtain a *TUE* prior to using a *Prohibited Substance* or *Prohibited Method*.

4) International Level Athletes

USADA's TUE Policy does not apply to *International-Level Athletes*. USADA will assist *International-Level Athletes* in the USADA RTP with forwarding applications for *TUEs* if such requests for USADA assistance are made at least 21 days in advance of the *Athlete's Use* of the medication where prohibited in sport.

Some IFs have granted USADA authority to process *TUEs* for *International-Level Athletes* who are U.S. citizens; USADA will process their *TUE* applications in accordance with the rules of the IF and the IS TUE.

WARNING: If a National Level Athlete competes in an *International Event* they may be required to obtain a TUE in advance from the relevant IF. It is the responsibility of every *Athlete* to investigate the applicable TUE requirements before competing in an *International Event*.

5) Non-National Level Athletes

- a) Non-National Level Athletes are required to obtain an advance TUE for substances prohibited at all times (both in- and out-of-competition), with the exception of a **first** AAF caused by one or more of the:
 - i) substances prohibited only in-competition,
 - ii) the class of "Diuretics and Other Masking Agents",
 - iii) Beta-2 agonists, and
 - iv) glucocorticosteroids (by local injection, inhalation, or topical use) where the Athlete can comply with the requirements set forth in section 5(b).

TUEs will be obtained in the same manner as for National Level Athletes as set forth in Section 3 above.

- b) Non-National Level Athletes who have a **first** AAF caused by the *Use* of a medication will not have committed an anti-doping rules violation for substances outlined in Section 5 a) i – iv above if the rules below are followed.

- i) For substances prohibited only in-competition and substances within the class of “Diuretics and Other Masking Agents.”
 - (1) The *Athlete* has a medical condition which was well documented in his or her medical records prior to the date of the collection and testing at issue and the medication was declared on the Declaration of Use section of their Doping Control Official Record (DCOR).
 - (2) The *Athlete*, at the *Athlete’s* 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.
 - (3) The facts and circumstances of the case put to rest any reasonable suspicion that the *Athlete* used the substance for the purpose of enhancing the *Athlete’s* performance. Completing the “Declaration of Use” section on the DCOR shall be considered strong proof that the use of the substance was not intended to enhance performance.
 - (4) If the *Athlete* intends to compete further in any *Event* or *Competition* that may be drug tested by USADA the *Athlete* must use his or her best efforts to apply for a *TUE* in advance of any further *Event* or *Competition*.
 - (5) Non-National Level Athletes who have once had an *AAF* caused by the use of a any substance shall be liable for an anti-doping rules violation for any future positive drug test unless they:
 - (a) have applied for and been granted a *TUE* for the substance in accordance with the IS TUE; or
 - (b) have complied with the “Declaration of Use” process in the DCOR for glucocorticosteroids set forth below under the section for National Level Athletes; or
 - (c) qualify for the retroactive *TUE* process for inhaled beta-2 agonists as set forth below.
- ii) For rules on the Beta-2 agonists and glucocorticosteroids administered by local injection or inhalation see below.

6) Beta-2 agonists and Glucocorticosteroids

Special rules apply to the use of Beta-2 agonists and Glucocorticosteroids, as follows:

- a) **Inhaled beta-2 agonists [Albuterol (also known as salbutamol), salmeterol, formoterol or terbutaline]**
 - i) ***International-Level Athletes* or other level *Athletes* who will compete in an *International Event*** - must get advance TUE approval. The request must include pulmonary function testing (PFT) for use of all inhaled beta-2

agonists. The minimal requirements for a TUE for beta-2 agonists are set forth in Annex 1 to the IS TUE. Note: An IF or *International Event* organizing committee may have approval authority for TUEs for beta-2 agonists.

- ii) **National Level Athletes not wishing to compete in an *International Event***
 - (1) In order to avoid the potential for an anti-doping rule violation due to an incomplete medical file all National Level Athletes who use or intend to use a beta-2 agonist should seek TUE approval more than twenty-one (21) days in advance. The minimal requirements for a TUE for beta-2 agonists include a pulmonary function test and are set forth in Annex 1 to the IS TUE.
 - (2) USADA will consider a retroactive *TUE* for these substances if a National Level Athlete receives an *Adverse Analytical Finding* (“*AAF*”) for one of these substances provided that:
 - (a) the Athlete listed the substance in the “Declaration of Use” section on the DCOR at the time of collection and
 - (b) the *Athlete* provided USADA advance notice of *Use* of the substance through a Website Declaration on the USADA website and
 - (c) the *Athlete* produces to USADA a complete medical file satisfying the requirements of Annex 1 to the IS TUE within fourteen (14) days after notification to the National Level Athlete of the *AAF* on the A sample.
 - (3) No retroactive *TUE* will be granted if the requirements of Annex 1 are not met. Therefore, failure to obtain an advance TUE for a beta-2 agonist and reliance on the retroactive *TUE* process will put the *Athlete* at risk for an anti-doping rule violation.

IMPORTANT NOTE: A retroactive *TUE* process may not be available for *Athletes* participating in an *International Event*. *Athletes* competing in an *International Event* must consult the rules of the relevant IF and of the International Event organizing committee to determine whether advance *TUE* approval of asthma medications is required regardless of whether the *Athlete* is considered an *International-Level Athlete*, a National Level *Athlete*, a Non-National Level *Athlete* or a Foreign *Athlete* under this Policy.

- iii) **Non-National Level Athletes not competing in an *International Event* -**
 - (1) Non-National Level Athletes who have a first *AAF* caused by the use of an inhaled beta-2 agonist medication will not have committed an anti-doping rules violation if the medication was declared in the “Declaration of Use” in the DCOR at the time of collection.
 - (2) The general rule for Non-National Level Athletes set forth in Section 5(b)above, that an *AAF* for designated substances will not result in an anti-doping rules violation if 5(b)(i)(5)(a), (b) or (c) is met, applies to a first *AAF* caused by an inhaled beta-2 agonist.
 - (3) A medical file must be provided within 14 days of the *AAF* to document the use of the inhaled beta-2 agonist.

b) Glucocorticosteroids used by inhalation, and non-systemic routes (including intraarticular, periarticular, peritendinous, epidural, and intradermal injection and topical application):

International-Level Athletes, National Level Athletes and All Athletes competing in an International Event - requires advance submission of a Website Declaration at www.usada.org (for transmission to WADA through ADAMS) and completion of the “Declaration of Use” section of the DCOR by the *Athlete* at the time of doping control. In addition, the Athlete must declare the *Use* of the substance during any subsequent *Out-of-Competition* or *In-Competition* drug test within three months of the use of the substance.

Note: The Website Declaration must be made electronically at the time the *Use* starts via the secure website access provided by USADA and in advance of any *Competition* or *Event* in which the *Athlete* will participate. The information provided to USADA must include the diagnosis, the name of the substance, the dose to be taken, and the name and contact details of the physician. USADA will provide this information to WADA.

- i) **Non-National Level Athletes not competing in an International Event** - The general rule for Non-National Level Athletes set forth in Section 5(b) above, that an *AAF* will not result in an anti-doping rules violation if 5(b)(i)(5)(a), (b) or (c) is met, applies to a first *AAF* caused by glucocorticosteroids used by non-systemic and inhaled routes. Thereafter, a Non-National Level athlete must follow the declaration of use process set forth in section 5(b) above.
 - ii) **Topical application of glucocorticosteroids** – glucocorticosteroids used by topical (including nasal, ophthalmic, dermal, otic, phonophoresis and iontophoresis) means are permitted and do not require a TUE or Website Declaration; however, the medication must be listed on the “Declaration of Use” section of the DCOR.
- 7) **Important Note Regarding a Transition Period for Expiration of ATUEs:**
The following rules apply to the Abbreviated TUEs previously accepted by USADA; however, some IFs may have different rules. Through December 31, 2008, an abbreviated therapeutic use exemption (“ATUE”) process was available for certain uses of glucocorticosteroids and beta-2 agonists. Effective January 1, 2009, the ATUE process has been discontinued. ATUEs accepted by USADA prior to December 31, 2008, are governed by the WADA 2005 TUE Standard and will expire upon the earlier of:
- (1) December 31, 2009
 - (2) the expiration date set forth on the ATUE certificate, or
 - (3) the date on which the ATUE is cancelled by the competent TUEC of the IF following review in accordance with Article 8.6 of the 2005 TUE Standard.

Important Note: These transition rules apply only to ATUEs granted by USADA. For ATUEs granted by an IF, please contact the approving IF for their transition rules.

8) **Effective Date**

This USADA TUE Policy shall go into effect on January 1, 2009. This Policy shall not apply retrospectively to matters pending before January 1, 2009 except as provided in Article 25 of the *Code*.