

IFBB GUIDELINES FOR THERAPEUTIC USE EXEMPTION PROCEDURES

OBTAINING A TUE

Athletes may have illnesses or conditions that require them to take medications or undergo procedures. If the medication or method an Athlete is required to use to treat an illness or condition is prohibited as per the World Anti-Doping Agency's (WADA) <u>Prohibited List</u>, a TUE may give that Athlete the authorization to use that substance or method while competing without invoking an anti-doping rule violation (ADRV) and applicable sanction. Applications for TUEs are evaluated by a panel of physicians, the TUE Committee (TUEC).

If the Athlete needs to Use a Prohibited Substance or Prohibited Method for Therapeutic reasons, he/she must apply for and obtain a TUE prior to Using or Possessing the substance or method in question.

The Athlete may apply retroactively for a TUE to IFBB if one of any of the following exceptions applies:

- a) Emergency or urgent treatment of a medical condition was necessary;
- b) There was insufficient time, opportunity or other exceptional circumstances that prevented the Athlete from submitting (or the TUEC to consider) an application for the TUE prior to Sample collection;
- c) Due to national level prioritization of certain sports, the Athlete's National Anti-Doping Organization did not permit or require the Athlete to apply for a prospective TUE;
- d) If the IFBB Anti-Doping Commission chooses to collect a Sample from an Athlete who is not an International-Level Athlete or National-Level Athlete, and that Athlete is Using a Prohibited Substance or Prohibited Method for Therapeutic reasons, the IFBB ADC must permit the Athlete to apply for a retroactive TUE; or
- e) The Athlete Used Out-of-Competition, for Therapeutic reasons, a Prohibited Substance that is only prohibited In-Competition.

An Athlete may be granted a TUE if he/she can show, on the balance of probabilities, that each of the following conditions is met:

a) The Prohibited Substance or Prohibited Method in question is needed to treat a diagnosed medical condition supported by relevant clinical evidence.

Important note: The Use of the Prohibited Substance or Prohibited Method may be part of a necessary diagnostic investigation rather than a treatment per se.

b) The Therapeutic Use of the Prohibited Substance or Prohibited Method will not, on the 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 of the medical condition.

c) The Prohibited Substance or Prohibited Method is an indicated treatment for the medical condition, and there is no reasonable permitted Therapeutic alternative.

Important note: The physician must explain why the treatment chosen was the most appropriate, e.g. based on experience, side-effect profiles or other medical justifications, including, where applicable, geographically specific medical practice, and the ability to access the medication. Further, it is not always necessary to try and fail alternatives before using the Prohibited Substance or Prohibited Method.

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.

Important note: The granting of a TUE is based solely on consideration of the conditions set out in Article 4.2. of the World Anti-Doping Code (WADC). It does not consider whether the Prohibited Substance or Prohibited Method is the most clinically appropriate or safe, or whether its use is legal in all jurisdictions.

In exceptional circumstances the Athlete may apply for and be granted retroactive approval for their Therapeutic Use of a Prohibited Substance or Prohibited Method if, considering the purpose of the Code, it would be manifestly unfair not to grant a retroactive TUE. The IFBB ADC may grant an Athlete's application for a retroactive TUE for International-Level Athletes and National-Level Athletes only with the prior approval of WADA. All decisions, whether granting or denying a TUE, must be reported through ADAMS.

For the avoidance of doubt, when a National Anti-Doping Organization grants a TUE to an Athlete, that TUE is valid at national level on a global basis and does not need to be formally recognized by other National Anti-Doping Organizations (for example, if an Athlete is granted a TUE by their National Anti-Doping Organization and then trains or competes in the country of another National Anti-Doping Organization, that TUE will be valid if the Athlete is then tested by such other National Anti-Doping Organization).

THE NOTICE

IFBB will publish and will keep updated a notice that sets out clearly:

- (1) which Athletes under its jurisdiction are required to apply to it for a TUE, and when;
- (2) which TUE decisions of other Anti-Doping Organizations it will automatically recognize in lieu of such application; and
- (3) which TUE decisions of other Anti-Doping Organizations will have to be submitted to it for recognition.



The following charts show the steps to be followed to grant a TUE:

Chart for TUE procedure if Athlete is not an International-Level Athlete when need for TUE arises:

When the Athlete is not an International-Level Athlete and the need for TUE arises, he/she should apply for a TUE to the National Anti-Doping Organization (NADO) TUEC, then:

- a) The TUE can be granted; or
- b) The TUE can be denied.

If the TUE is denied, the Athlete may appeal to the National-Level Appeal Body, as the chart below:

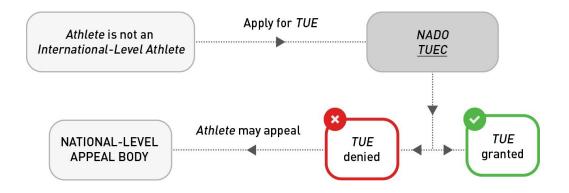


Chart for TUE procedure if Athlete is an International-Level Athlete (and so subject to the International Federation's TUE requirements) when need for TUE arises:

If the Athlete already has a TUE granted at National level, he/she should confirm if the TUE is in the category of TUE decisions that are automatically recognized by IFBB:

- 1) If the TUE is in the category of the TUE decisions, no further action is required;
- 2) If the TUE is not in the category of TUE decisions, the Athlete may submit a TUE for recognition to the IFBB TUEC, then the TUE can be:
 - a) Recognized;
 - b) Not recognized at International Level.

If the TUE is not recognized at International Level, the Athlete and/or NADO may refer the non-recognition to WADA review. Also, the NADO may refer the grant to WADA for review. WADA may agree to the Athlete request to review the IFBB decision not to grant the TUE. Therefore, WADA TUEC shall reverse or upheld the IFBB decision. If the



decision is upheld the athlete or NADO may appeal; If the decision is reversed, IFBB may appeal; Both of them may appeal to CAS (Court of Arbitration for Sport).

- 3) If the Athlete doesn't have a TUE already granted at National level, the first step is applying for a TUE to the IFBB TUEC, then:
 - a) The IFBB TUEC may grant the TUE; or
 - b) The IFBB may do not grant the TUE.

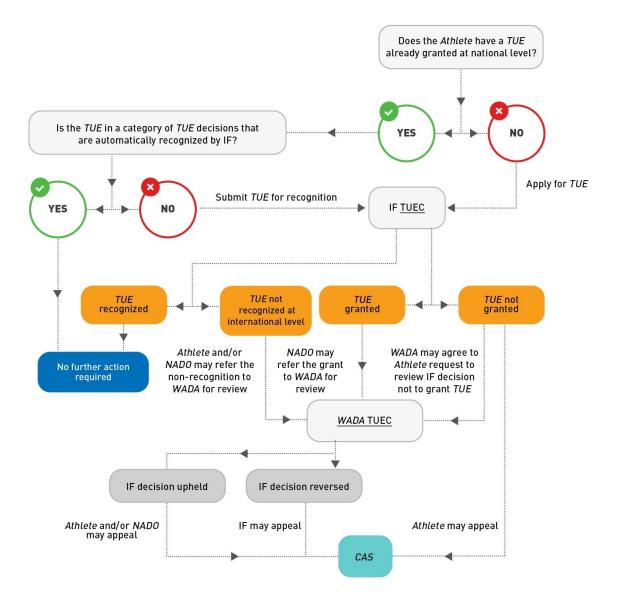
If the TUE is denied, the Athlete may request to review this decision to the WADA TUEC. The WADA TUEC may agree to the Athlete request to review IFBB decision to not granting the TUE. Therefore, WADA TUEC may reverse or upheld the IFBB's decision:

- a) If the decision is upheld, the Athlete and/or NADO may appeal;
- b) If the decision is reversed, IFBB may appeal.

Both of them may appeal to the CAS (Court of Arbitration for Sport).

The following chart shows the steps to be followed:





TUE APPLICATION PROCESS

The Athlete who needs a TUE should apply as soon as possible. For substances prohibited In-Competition only, the Athlete should apply for a TUE at least thirty (30) days before their next Competition, unless it is an emergency or exceptional situation.

IFBB encourages to submit TUE applications via ADAMS, together with the required medical information. If the Athlete doesn't have an ADAMS account, he/she should contact the IFBB to have the account set up and for technical support, contact the ADAMS Helpdesk:

- North America: 1 866 922 3267
- International: +1 514 904 8800



The Athlete should apply to IFBB using the TUE application form provided, the <u>IFBB's</u> <u>TUE Application Form</u> and once duly completed and signed, send it together with the required medical file to <u>headquarters@ifbb.com</u>

• The form must be signed by the treating physician and accompanied by a comprehensive medical history, including documentation from the original diagnosing physician(s) (where possible) and the results of all examinations, laboratory investigations and imaging studies relevant to the application.

Important note: To assist the Athlete and his/her doctor in providing the correct medical documentation, we suggest consulting the WADA's <u>Checklists for TUE</u> <u>applications</u> for guidance and support, and <u>Medical Information to Support the</u> <u>Decisions of TUECs</u> for guidance on specific common medical conditions, treatments, substances, etc.

- The Athlete should keep a complete copy of the TUE application form and of all materials and information submitted in support of that application.
- Also, the Athlete may not apply to more than one (1) Anti-Doping Organization for a TUE for the Use of the same Prohibited Substance or Prohibited Method for the same medical condition. Nor may an Athlete have more than one (1) TUE at a time for the Use of the same Prohibited Substance or Prohibited Method for the same medical condition (and any such new TUE will supersede the previous TUE, which should be cancelled by the relevant Anti-Doping Organization).
- A TUE application will only be considered by the TUEC following the receipt of a properly completed application form, accompanied by all relevant documents. Incomplete applications will be returned to the Athlete for completion and resubmission.
- The TUEC may request from the Athlete or their physician any additional information, examinations or imaging studies, or other information that it deems necessary in order to consider the Athlete's application; and/or it may seek the assistance of such other medical or scientific experts as it deems appropriate.
- Any costs incurred by the Athlete in making the TUE application and in supplementing it as required by the TUEC are the responsibility of the Athlete.
- 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 twenty-one (21) days of receipt of a complete application. Where a TUE application is made in a reasonable time prior to an Event, the TUEC must use its best endeavors to issue its decision before the start of the Event.
- The TUEC's decision must be communicated in writing to the Athlete and must be made available to WADA and to other Anti-Doping Organizations via ADAMS.



- Each TUE will have a specified duration, as decided by the TUEC, at the end of which the TUE will expire automatically. If the Athlete needs to continue to Use the Prohibited Substance or Prohibited Method after the expiry date, he/she must submit an application for a new TUE well in advance of that expiry date, so that there is sufficient time for a decision to be made on the application before the expiry date.
- A TUE will be withdrawn prior to expiry if the Athlete does not promptly comply with any requirements or conditions imposed by the IFBB ADC granting the TUE. Alternatively, a TUE may be reversed upon review by WADA or on appeal.
- Where an Adverse Analytical Finding is issued shortly after a TUE for the Prohibited Substance in question has expired or has been withdrawn or reversed, the IFBB ADC that is conducting the initial review of the Adverse Analytical Finding, shall consider whether the finding is consistent with Use of the Prohibited Substance prior to the expiry, withdrawal or reversal of the TUE. If so, such Use (and any resulting presence of the Prohibited Substance in the Athlete's Sample) is not an anti-doping rule violation.
- In the event that, after their TUE is granted, the Athlete requires a materially different dosage, frequency, route or duration of Administration of the Prohibited Substance or Prohibited Method to that specified in the TUE, he/she must contact the IFBB, who will then determine whether the Athlete needs to apply for a new TUE. If the presence, Use, Possession or Administration of the Prohibited Substance or Prohibited Method is not consistent with the terms of the TUE granted, the fact that the Athlete has the TUE will not prevent the finding of an anti-doping rule violation.

Important note: It is recognized that for certain medical conditions, dosages may fluctuate, particularly during the early stages of the establishment of a treatment regime or for a condition such as insulin-dependent diabetes. Such potential fluctuations should be accounted for in the TUE. However, in the event of a change that is not accounted for in the TUE, the Athlete must contact the IFBB ADC to determine whether a new TUE is required

TUE RECOGNITION PROCESS

The Code (in the Article 4.4) requires Anti-Doping Organizations to recognize TUEs granted by other Anti-Doping Organizations that satisfy all the necessary conditions. Therefore, if an Athlete who becomes subject to the TUE requirements of an International Federation or Major Event Organization already has a TUE, he/she should not submit an application for a new TUE to the International Federation or Major Event Organization. Instead:



- a) The IFBB ADC or Major Event Organization may publish notice that it will automatically recognize TUE decisions (or certain categories of such decisions, e.g., those made by specified Anti-Doping Organizations, or those relating to particular Prohibited Substances). If the Athlete's TUE falls into a category of TUEs that are automatically recognized in this way at the time the TUE is granted, he/she does not need to take any further action.
- b) In the absence of the automatic recognition, the Athlete shall submit a request for recognition of the TUE to IFBB or Major Event Organization in question, either via ADAMS or as otherwise specified by IFBB or Major Event Organization. The request should be accompanied by a copy of the TUE and the original TUE application form and supporting materials;
- Incomplete requests for recognition of a TUE will be returned to the Athlete for completion and re-submission. In addition, the TUEC may request from the Athlete or their physician any additional information, examinations or imaging studies, or other information that it deems necessary in order to consider the Athlete's request for recognition of the TUE; and/or it may seek the assistance of such other medical or scientific experts as it deems appropriate;
- Any costs incurred by the Athlete in making the request for recognition of the TUE and in supplementing it as required by the TUEC are the responsibility of the Athlete;
- The TUEC shall decide whether or not to recognize the TUE as soon as possible, and usually (unless exceptional circumstances apply) within no more than twentyone (21) days of receipt of a complete request for recognition. Where the request is made a reasonable time prior to an Event, the TUEC must use its best endeavors to issue its decision before the start of the Event.
- The TUEC's decision will be notified in writing to the Athlete and will be made available to WADA and to other Anti-Doping Organizations via ADAMS. A decision not to recognize a TUE must include an explanation of the reason(s) for the non-recognition.
- If IFBB chooses to test an Athlete who is not an International-Level Athlete, it must recognize a TUE granted by that Athlete's National Anti-Doping Organization unless the Athlete is required to apply for recognition of the TUE, i.e. because the Athlete is competing in an International Event.

REVIEW OF TUE DECISIONS BY WADA

The Code provides that WADA, in certain cases, must review TUE decisions of International Federations:



- Each request for review must be submitted to WADA in writing and must be accompanied by payment of the application fee established by WADA, as well as copies of all of the information specified in Article 6.4 (or, in the case of review of a TUE denial, all of the information that the Athlete submitted in connection with the original TUE application). In addition, the request must be copied to the IFBB ADC.
- Where the request is for review of a TUE decision that WADA is not obliged to review, WADA shall advise the Athlete as soon as practicable following receipt of the request whether or not it will review the TUE decision. Any decision by WADA not to review the TUE decision is final and may not be appealed. However, the TUE decision may still be appealable.
- WADA shall reverse any grant of a TUE that does not comply with the Article 4.1 and 4.2 conditions (as applicable). Where the TUE reversed was a prospective TUE (rather than a retroactive TUE), such reversal shall take effect upon the date specified by WADA (which shall not be earlier than the date of WADA's notification to the Athlete). The reversal shall not apply retroactively and the Athlete's results prior to such notification shall not be Disqualified. Where the TUE reversed was a retroactive TUE, however, the reversal shall also be retroactive.
- WADA shall reverse any denial of a TUE where the TUE application met the necessary conditions, i.e., it shall grant the TUE.
- Where WADA reviews a decision of IFBB that has been referred to it (i.e., a mandatory review), it may require whichever Anti-Doping Organization "loses" the review (i.e., the Anti-Doping Organization whose view it does not uphold): (a) to reimburse the application fee to the party that referred the decision to WADA (if applicable); and/or
 (b) to pay the costs incurred by WADA in respect of that review, to the extent they

(b) to pay the costs incurred by WADA in respect of that review, to the extent they are not covered by the application fee.

- Where WADA reverses a TUE decision that WADA has decided in its discretion to review, WADA may require the Anti-Doping Organization that made the decision to pay the costs incurred by WADA in respect of that review.
- If applicable, WADA shall communicate the reasoned decision of the WADA TUEC promptly to the Athlete and to their National Anti-Doping Organization and International Federation (and, if applicable, the Major Event Organization).

CONFIDENTIALITY OF INFORMATION

All the information contained in a TUE application, including the supporting medical information and any other information related to the evaluation of the TUE request is kept strictly confidential and treated in accordance with the Athlete's Declaration contained in



the ADAMS TUE process and in the IFBB's TUE Application Form. All members of the TUEC and any other authorized recipients of the TUE request and related information (as described in the Athlete's Declaration) are subject to a professional or contractual confidentiality obligation.

The IFBB Anti-Doping Commission will communicate in writing the following information to Athletes in connection with an Athlete's application for the grant or recognition of a TUE:

- All information pertaining to the application will be transmitted to members of all TUECs with authority to review the file and, as required, other independent medical or scientific experts, and to 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 to any relevant TUEC upon request any health information that any such TUEC deems necessary in order to consider and determine the Athlete's application; and
- c) The decision on the application will be made available to all Anti-Doping Organizations with Testing authority and/or Results Management authority over the Athlete.

Important note: Where Anti-Doping Organizations are relying upon the Athlete's consent to Process Personal Information in connection with the TUE process, the Athlete applying for the grant or recognition of a TUE shall provide written and explicit consent to the foregoing.

- The TUE application shall be dealt with in accordance with the principles of strict medical confidentiality. The members of all relevant TUECs, any consulted independent experts and the relevant staff of IFBB Anti-Doping Commission will conduct all the activities relating to the process in strict confidence and shall sign appropriate confidentiality agreements. In particular, the following information are confidential:
 - a) All medical information provided by the Athlete and physician(s) involved in the Athlete's care; and
 - b) All details of the application, including the name of the physician(s) involved in the process.
- Should the Athlete wish to revoke the right of a TUEC to obtain any health information on their behalf, the Athlete shall notify their physician in writing of such revocation; provided that, as a result of that revocation, the Athlete's application for a TUE or for recognition of an existing TUE will be deemed withdrawn without approval/recognition having been granted.
- Anti-Doping Organizations shall only use information submitted by an Athlete in connection with a TUE application to evaluate the application and in the context of potential anti-doping rule violation investigations and proceedings