



Preserving the integrity of competition. Inspiring true sport. Protecting the rights of athletes.

Dear Athlete,

The following two documents are provided to you to help you understand the Therapeutic Use Exemption (TUE) requirements to obtain a TUE for stimulants for ADD/ADHD.

The first document entitled "Documentation required to support a Therapeutic Use Exemption Application for Stimulants to treat ADD/ADHD" has been produced by USADA as a helpful checklist for athletes submitting TUEs. The items on this checklist are considered by USADA's Therapeutic Use Exemption Committee of Physicians (TUEC) to be very important in evaluating any application for the use of stimulants to manage ADD/ADHD.

The second document entitled "Medical Information to Support the Decisions of TUECs - ADHD" is published by the World Anti-doping Agency (WADA) as medical information to support the decisions of various Therapeutic Use Exemption Committees. This document is provided to you as a general guide for evaluating such applications. WADA's document is the minimum standard to which anti-doping agencies comply world-wide.

For further information concerning these documents or any other questions or concerns you might have, please contact the USADA TUE Department by email at tue@usada.org or by phone at 719-785-2045.

Sincerely,

Drug Reference Resource Department

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United States Anti-Doping Agency

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Documentation to support a Therapeutic Use Exemption Application for Stimulants to treat ADD/ADHD

Essential supporting documents

- A completed, and legible TUE application form
- A clinical record of the onset of symptoms, and copies of the consultation notes leading to the present diagnosis addressing the criteria set forth in the DSM IV or ICD-10.
- Other primary medical records, including medical progress notes, school special education evaluations, etc.
- Second expert opinions for diagnoses made in young adults, if available.
- Current mental status evaluation
- General medical history including other diagnoses and medications
- At least two reports describing behavior and symptoms in multiple realms, and over time (home, work, school, sport, athlete's own personal perspective, etc.). One report should be generated by the Athlete applying for the TUE. The other report should be by someone who knows the athlete well (a parent, teacher, supervisor, etc.).

Additional supporting documentation that may be useful (but are not essential)

- Standardized testing results. If they are available they may be submitted, but they are not essential. Similarly IQ testing is not required.
- Prior attempts to manage the condition with permitted medications. If trials have been conducted using atomoxetine or bupropion, this information is very useful and supportive of the TUE application. However, USADA will consider your TUE application in the absence of such a trial.
- Description of attempts at using behavior modification therapy.
- Family Psychiatric history

Duration: Any athlete on prolonged therapy with stimulant should provide evidence of annual review by a specialist in the management of ADD/ADHD.

Cautionary matters: Drugs to manage ADHD can have cardio-vascular side-effects. It is recommended that clinical parameters of this system (blood pressure, heart auscultation, ECG, etc.) are monitored and included in the TUE application.

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1. Medical Condition

ATTENTION DEFICIT HYPERACTIVITY DISORDER (ADHD) IN CHILDREN AND YOUNG ADULTS

Introduction

ADHD is the most common neurobehavioral disorder of childhood and amongst the most prevalent chronic health conditions affecting school-aged children. The core symptoms of ADHD include inattention, hyperactivity, and impulsivity. Children with ADHD may experience significant functional problems that may continue as they enter adolescence and adult life. Recent literature also suggests that ADHD may present for the first time in young adulthood.

2. Diagnosis

- A. Medical history

The diagnosis of ADHD is essentially a clinical diagnosis, frequently initiated by parents, teachers or other significant adults such as coaches and trainers who deal regularly with young people. However these early anecdotal suspicions must be established and confirmed by experienced clinicians. In most parts of the world these include paediatricians, child psychiatrists or clinical psychologists. Obviously a record of the onset of symptoms is required and the DSM-IV or ICD-10 criteria outlined in the following section must be met.

- B. Diagnostic criteria

These are in accordance with the DSM-IV criteria (see reference). The Connor scale has also shown utility in correlating the psychopathology in children with ADHD. (ref Journal of the American Academy of Child & Adolescent Psychiatry. 42(2):193-200, February 2003.)

Some recent research indicates that objective diagnosis by PET (Positron Emission Tomography) or SPECT (Single-photon Emission

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ADHD*

Computed Tomography) may be of possible diagnostic assistance in the near future.

When ADHD first appears at a young adult age, diagnostic confirmation demands a second expert opinion.

- C. Relevant medical information

See above.

3. Medical best practice treatment

- A. Name of prohibited substance

Stimulants form the basis of the treatment of ADHD and these may include short, intermediate and long acting methylphenidate, or dextroamphetamine.

- B. Route

Oral

- C. Frequency

Short-acting: 5-20 mg BID to TID
Intermediate acting: 20-40 mg QD
Extended release: 18-72 mg QD

- D. Recommended duration of treatment

It must be made clear that the treatment of ADHD is a long term treatment (possibly over years), but regular intermediate assessments every 3 to 4 months are useful. It is a mandatory requirement for any athlete on continued therapy with methylphenidate or dextroamphetamine to provide evidence of an annual review by a specialist in the management of ADHD (see above). Any change in therapy must constitute a renewed application for TUE.

4. Other non-prohibited alternative treatments?

Atomoxetine has been identified as a non-prohibited alternate treatment for some patients with ADHD. However this medication is not available in all countries. Where it is available there should be evidence that it has been tried as a therapeutic alternative. Otherwise, apart from some behaviour-modifying techniques, treatments with non-prohibited substances have not been shown to be effective.

5. Consequences to health if treatment is withheld

Untreated, true ADHD is widely recognized as having detrimental effects on the quality of life and psycho-social development of the patient. Psychiatric degradation is not excluded.

6. Treatment monitoring

Measures of treatment compliance together with target outcomes should be undertaken every 3 to 4 months by an experienced clinician.

7. TUE validity and recommended review process

The treatment will last as long as necessary, indicated by the instruments of clinical monitoring and specialist opinion mentioned above. Continued therapy with prohibited drugs must be justified by a full report. A TUE in a case of ADHD will not be granted for longer than 1 (one) year without adherence to strict review by a specialist in the field.

8. Any appropriate cautionary matters

Specialist opinion in the field of ADHD confirms that youngsters on prescribed medication frequently require their drugs more for behavioral control at school and in the home rather than for sports. It may be possible for the intake of a prohibited substance to be reduced or even stopped on the day of competition without disadvantaging an athlete and affecting the overall treatment. Drugs against ADHD can have some deleterious cardio-vascular side-effects. It is therefore strongly recommended to regularly (yearly) control usual clinical parameters of this organic system (blood pressure, heart auscultation, ECG.)

9. References

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