

Information for Athletes and Physicians regarding Therapeutic Use Exemptions for Beta-2 Agonists

Concerned about the increased use of Beta-2 agonists¹ by elite athletes, and the risks of using such medications long-term, the World Anti-Doping Agency has issued a new International Standard for Therapeutic Use Exemptions (2009)² that requires a medical file justifying the use of Beta-2 agonists. Information that would support your application includes:

History

- Symptoms suggesting airway obstruction with exercise
- Symptoms at rest and at night
- Allergies or atopic disorders especially seasonal or environmental allergies
- Identified triggering factors
- Childhood asthma
- Previous or current respiratory infection requiring beta-2 agonist treatment
- Previous results of RAST or skin prick testing if pertinent

Physical examination

- Exam findings emphasizing the respiratory system (pathway)
- Past pertinent exam findings (especially as related to initial diagnosis if available)

Spirometry and/or Bronchial Provocation Test Results

- Results of spirometry including forced expiratory volume in 1 second (FEV1) at rest AND in response to inhaled bronchodilator OR
- Results of bronchial provocation tests (eucapnic voluntary hyperpnea, exercise challenge, hypertonic saline, mannitol inhalation or methacholine challenge) with response to inhaled bronchodilator

Diagnosis

- Definitive diagnosis
- Differential diagnoses
- Associated diagnoses

Treatment

- Details of strategies to manage known contributing factors to asthma/EIB such as rhinitis, nasal congestion and allergies
- Attempts to manage symptoms with non-prohibited medications such as leukotriene receptor agonists, anticholinergics, sodium chromoglycate or theophyllines if appropriate

¹ For discussion of rationale for change in policy regarding Beta-2 Agonists, see "Asthma and the elite athlete: Summary of the International Olympic Committee's Consensus Conference, Lausanne Switzerland, January 22-24 2008" J Allergy Clin Immunol 2008;122:254-60.

² The World Anti-Doping Agency International Standard for Therapeutic Use Exemptions 2009 (http://www.wada-ama.org/rtecontent/document/TUE_Standard_2009_Final_031008.pdf)

In some instances, in order to produce test results that meet the criteria³ for the diagnosis of asthma as adopted by the World Anti-Doping Agency, an athlete *may* have to cease taking their asthma medications for a short time preceding the test. Cessation of medication should **ONLY** be done under the careful supervision of the attending physician. The athlete may wish to discuss this possibility with their physician prior to the office visit to determine if this is an appropriate approach.

In cases where athletes have **well controlled asthma** and record negative responses to all of the tests, but still seeking approval for the use of inhaled Beta-2 agonists, substantial medical justification will be required to demonstrate the absolute necessity for Beta-2 agonists. Such information may include evidence of emergency room attendance or admission into hospital for acute exacerbation of asthma, treatment with oral corticosteroids, and a thorough medical file containing ALL of the information listed above.

Please note: The US Anti-Doping Agency (in accordance with position statements by the IOC and WADA) recognizes the inherent risk of undertaking bronchial provocation tests, and the temporary cessation of medication that *may* be required to produce positive test results. For this reason, an advanced Therapeutic Use Exemption for Beta-2 agonists is only mandatory for athletes in the Registered Testing Pool of USADA or an International Sporting Federation, and for any athlete intending to compete at an event sanctioned by an International Sporting Federation regardless of whether they are in a registered testing pool⁴.

For athletes not in a registered testing pool, and not wishing to compete at an Internationally sanctioned event (non-national level athletes), you are only required to notify USADA in advance of your intention to use Beta-2 agonists through a Website Declaration on the USADA website (www.usada.org). However, according to WADA guidelines, any athlete may request an advance Therapeutic Use Exemption if they wish to do so. In the event of testing, you are also required to list the substance in the "Declaration of Use" section of the Doping Control Official Record at the time of collection.

³ For further information on WADA standard Therapeutic Use Exemption criteria please see the document entitled "Medical Information to Support the Decisions of TUECs- Asthma" published by the World Anti-Doping Agency on www.wada-ama.org

⁴ Please consult the document "USADA Policy for Therapeutic Use Exemptions and Declarations of Use" published www.usada.org.

****This form MUST accompany a TUE Application
for a Beta-2 Agonist****

PHYSICIAN- PLEASE COMPLETE

Please provide the following information to support this application for a Therapeutic Use Exemption for a Beta-2 agonist. Attach additional sheets as necessary.

- 1. Please attach a complete and comprehensive history of asthma and symptom management** (including the age of onset, severity of symptoms, identified triggering factors, hospital emergency department attendance for acute exacerbation of symptoms, history of treatment with oral corticosteroids, past physical exams and spirometry test results, specific information on coughing, wheezing, chest tightness during or post exercise etc. Attach additional sheets)

- 2. Please attach physical exam report with a focus on the respiratory system.**

- 3. Please comment on attempts to manage the asthma by non-prohibited medications** (such as leukotriene receptor antagonists, anticholinergics, sodium chromoglycate, or theophyllines. Please provide a clear statement why non-prohibited medications have not been effective or are otherwise inappropriate.)

- 4. Please note other considerations in the assessment of this patient's asthma** (i.e. other diagnoses, health concerns expressed by the athlete, parent etc.).

5. Spirometry and/or Bronchial Provocation Test Results (Select all that apply)⁵.

Has the patient had been on asthma medication in the days leading up to test(s)?

YES NO (if no, how long has patient been off medications? _____)

√	Test Type	WADA criteria for positive test	Please report test results with regard to fall in FEV1
	Spirometry: FEV1 Pre and Post Bronchodilator	12% increase in FEV1 post-bronchodilator	Please note % change in FEV1:
	Methacholine aerosol challenge	20% fall in FEV1; PC20<4mg/mL (tidal breathing technique-steroid naive)	Please note PD20 (µg) and/or PC20 (mg/mL) and % fall in FEV1:
	Mannitol Inhalation	15% fall in FEV1	FEV1 decrease of _____% in _____min.
	Eucapnic Voluntary Hyperpnea	10% fall in FEV1	FEV1 decrease of _____% in _____min.
	Hypertonic saline aerosol challenge	15% fall in FEV1	FEV1 decrease of _____% in _____min.
	Exercise challenge (field or laboratory)	10% fall in FEV1	FEV1 decrease of _____% in _____min Method of challenge: _____

7. According to the Therapeutic Use Exemption International Standard, Section 4, published Jan 2009 by the World Anti Doping Agency, the criteria for granting a Therapeutic Use Exemption are as follows:

4.2 The Athlete would experience a significant impairment to health if the prohibited substance were withheld in the course of treating an acute or chronic medical condition

4.3 The therapeutic use of the prohibited substance would produce no additional enhancement of performance other than that which might be anticipated by a return to a state of normal health following the treatment of a legitimate medical condition.

4.4 There is no reasonable therapeutic alternative to the use of the otherwise prohibited substance.

4.5 The necessity for the use of the otherwise prohibited substance cannot be a consequence, wholly or in part, of prior non-therapeutic use of any substance from the prohibited list.

In your opinion, does the asthma history and present health status of this patient meet the above criteria? Please Comment.

Signature _____

Date: _____

⁵ Test result criteria published www.wada-ama.org "Medical Information to Support the Decisions of TUECs-Asthma"