

# Therapeutic Use Exemption (TUE) Beta-2 Agonist Application Form

A TUE application for the use of a terbutaline or vilanterol inhaler requires a medical file to confirm the diagnosis of asthma and/or its clinical variants. The medical file should include:

- A detailed medical history and clinical review
- Bronchodilator or Bronchoprovocation test results

For further information on how to submit a complete medical file use the diagnostic flow chart on page 2 of this application form.

Please complete all sections in BLOCK CAPITALS. Incomplete or illegible forms will be returned.

## 1. Athlete Information

**Surname:** \_\_\_\_\_ **First names:** \_\_\_\_\_

**Date of Birth (dd/mm/yy):** // **Gender (please tick):** Male  Female

**Address:** \_\_\_\_\_

**Post code:**

**Contact Tel (including dialling code):**

**Email:** \_\_\_\_\_

**Sport/Discipline:** \_\_\_\_\_ **Club:** \_\_\_\_\_

**National Governing Body:** \_\_\_\_\_ **Impairment category:** \_\_\_\_\_

### Level of competition (please tick one box as appropriate)

I am part of my International Federation's Registered Testing Pool

I am competing in an international competition

I am part of UK Anti-Doping's National Registered Testing Pool

I am competing at a national level event in my sport

Other  (please state level) \_\_\_\_\_

**Next competition the TUE is required for:** \_\_\_\_\_

**Competition date:** //

## 2. Previous Applications

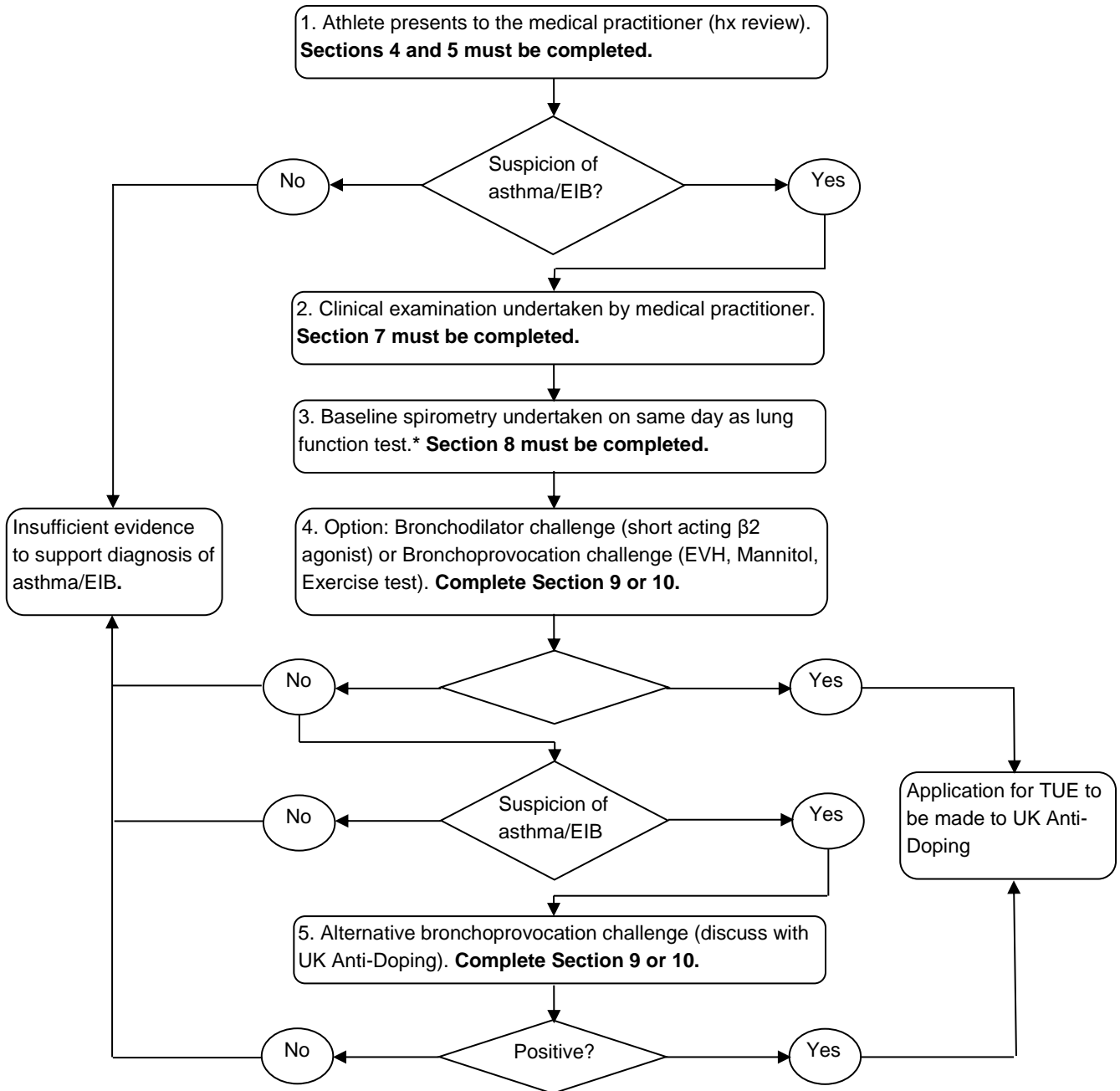
Have you submitted a previous TUE application? Yes  No

The Anti-Doping Organisation applied to? UK Anti-Doping  Other (please state) \_\_\_\_\_

Decision: Approved  Declined

### 3. Medical File Requirements

The diagnostic flow chart below provides an outline of how to submit a complete medical file to UK Anti-Doping to confirm the diagnosis of asthma and/or its clinical variants.



**\*NB:** It is recommended that a bronchodilator challenge is the investigation of preference in athlete's with abnormal resting lung function ( $FEV_1 < 70\%$  predicted at baseline,  $FEV_1/FVC < 0.7$ ); a bronchodilator challenge should be considered if  $FEV_1$  is 70-80% predicted at baseline; a bronchodilator challenge is still an option but a bronchoprovocation challenge might be more suitable when  $FEV_1 > 80\%$  predicted at baseline.

**4. Retroactive Applications**

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Is this a retroactive application (has treatment already commenced)?

Yes  No  (if 'no', please go to section 5)

If yes, on what date did the treatment start? / /

If this is a retroactive application, please indicate the reason why:

- Emergency treatment or treatment of an acute medical condition was necessary
- Due to other exceptional circumstances, there was insufficient time or opportunity to submit an application prior to sample collection
- Advance application not required under applicable rules
- Other  Please state \_\_\_\_\_

**5. Medical History Report and Medication Details**

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Diagnosis (i.e. asthma, exercise induced asthma, exercise induced bronchoconstriction):

\_\_\_\_\_

Age of onset: \_\_\_\_\_

Symptoms experienced: (Please tick as appropriate)

- |   |  |  |
|---|--|--|
| Recurrent breathlessness <input type="checkbox"/>           | Coughing <input type="checkbox"/>                | Wheezing <input type="checkbox"/>        |
| Difficulty in breathing (dyspnoea) <input type="checkbox"/> | Excess mucus production <input type="checkbox"/> | Chest tightness <input type="checkbox"/> |

Other (please specify): \_\_\_\_\_

When are these symptoms experienced? \_\_\_\_\_

What environmental conditions trigger the above symptoms? (Please tick as appropriate)

- |  |  |  |
|--|--|--|
| Cold climate <input type="checkbox"/>  | Dry air <input type="checkbox"/>           | High pollen count <input type="checkbox"/> |
| Air pollution <input type="checkbox"/> | Altitude training <input type="checkbox"/> |  |

Other (please specify): \_\_\_\_\_

List all asthma medication used in the last three months (e.g. beclomethasone, mometasone)

\_\_\_\_\_

\_\_\_\_\_

Has the athlete any history of atopic disorders and/or childhood asthma?

\_\_\_\_\_

\_\_\_\_\_

Provide any details of any acute exacerbations of asthma including hospital department attendance/admission reports and/or previous treatment with oral glucocorticoids (please attach documents to confirm these details):

\_\_\_\_\_

\_\_\_\_\_

**Current asthma medication details (for which the TUE is required):**

| Generic name of Prohibited Substance(s) | Dose of administration | Route of administration | Frequency of administration | Maximum dosage permitted within 24 hours |
|---|------------------------|-------------------------|-----------------------------|--|
| 1.                                      | µg                     | Inhaled                 |                             | µg                                       |
| 2.                                      | µg                     | Inhaled                 |                             | µg                                       |
| 3.                                      | µg                     | Inhaled                 |                             | µg                                       |
| 4.                                      | µg                     | Inhaled                 |                             | µg                                       |

**Intended duration of treatment(s):** Once only  Emergency  Weeks/Months

Please specify duration: \_\_\_\_\_

**If a permitted medication can be used to treat the medical condition, please provide clinical justification for the requested use of the prohibited medication prescribed:**

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

**6. Notifying Medical Practitioner Details and Declaration**

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Name: \_\_\_\_\_

Qualifications: \_\_\_\_\_

Medical Speciality: \_\_\_\_\_

GMC Number: \_\_\_\_\_

Contact Tel.

Email: \_\_\_\_\_

Practice stamp / address:

I certify that the above-mentioned substance(s) for the above named athlete has been/are to be administered as the correct treatment for the above named medical condition. I further certify that the use of alternative medications not on the Prohibited List would be unsatisfactory for the treatment of the above named medical condition.

If the athlete is under 18 and I have not notified the athlete's parent/guardian, this is because I consider the athlete to be competent to give consent to treatment.

I understand that my details will be held on an anti-doping database and will be accessible by the athlete, their National Governing Body, their International Federation, UK Anti-Doping, and the World Anti-Doping Agency in order to allow them to administer the anti-doping programme.

Signature of medical practitioner: \_\_\_\_\_ Date:   /   /

**If the athlete is under 18 does the athlete's parent/guardian know about this treatment?**

Yes  No

**Are the relevant medical reports and examination/test results attached?**

Yes  No

**7. Clinical Examination**

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**Clinical examination findings with specific focus on the respiratory system were:**

Normal  Abnormal

Please specify any abnormal findings: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

### 8. Baseline Spirometry

Date: / /  Best Baseline FEV<sub>1</sub> \_\_\_\_\_ L (must be within 5% of second best FEV<sub>1</sub>)

**NB:** The application will not be reviewed unless the data for at least two flow loops are presented in the table below and that the best baseline FEV<sub>1</sub> is within 5% of the second best FEV<sub>1</sub>. Further flow loops are required if the best baseline FEV<sub>1</sub> value is not within 5% of second best FEV<sub>1</sub> value at baseline.

|                                 | FEV <sub>1</sub> (L) | FVC (L) | FEV <sub>1</sub> /FVC (%) | FEF <sub>25-75</sub> (L·s <sup>-1</sup> ) |
|---------------------------------|----------------------|---------|---------------------------|---|
| <b>1<sup>st</sup> Flow Loop</b> |                      |         |                           |   |
| <b>% Predicted</b>              |                      |         |                           |   |
| <b>2<sup>nd</sup> Flow Loop</b> |                      |         |                           |   |
| <b>% Predicted</b>              |                      |         |                           |   |
| <b>3<sup>rd</sup> Flow Loop</b> |                      |         |                           |   |

Abbreviations: **FEV<sub>1</sub>**, Forced Expiratory Volume in one second; **FVC**, Forced Vital Capacity; **FEF<sub>25-75</sub>**, Forced Expiratory Flow between 25-75% of vital capacity; **L**, Litres; **L·s<sup>-1</sup>**, Litres per second.

### 9. Bronchodilator Challenge

If chosen as the test to confirm asthma, please complete this section and attach an electronic printout of test results if available.

**NB:** The application will not be reviewed unless duplicate FEV<sub>1</sub> measurements are presented in the table below. Duplicate FEV<sub>1</sub> values must also agree within 5% and 150ml of each other to confirm reproducibility of the best FEV<sub>1</sub> value measured.

Date of challenge: / /  Bronchodilator and dose used: \_\_\_\_\_

| Time post-test | FEV <sub>1</sub> Post BD dose (L) |             | % difference from baseline FEV <sub>1</sub> (using best of duplicate) | FVC Post BD dose (L) |             | % difference from baseline FVC (using best of duplicate) |
|----------------|-----------------------------------|-------------|---|----------------------|-------------|--|
|                | Duplicate 1                       | Duplicate 2 |   | Duplicate 1          | Duplicate 2 |  |
| min            |                                   |             |   |                      |             |  |
| min            |                                   |             |   |                      |             |  |

Technician Name and Contact Details: \_\_\_\_\_

Comments (optional): \_\_\_\_\_

**10. Bronchoprovocation Challenge**

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If chosen to confirm asthma, please provide a summary of the test results below and attach either:

- Electronic printout of spirometry results and flow volume loop tracing; or
- A bronchoprovocation data collection worksheet (NB: Worksheets can be found on the UK Anti-Doping website if the centre completing the challenge does not have their own)

**NB:** The application will not be reviewed unless duplicate FEV<sub>1</sub> measurements are taken at each time point.

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**EVH** – Fall in FEV<sub>1</sub> at two consecutive time points:

Time point 1: \_\_\_\_\_ min    Best FEV<sub>1</sub> value at time point: \_\_\_\_\_ L    FEV<sub>1</sub> fall from baseline: \_\_\_\_\_ %

Time point 2: \_\_\_\_\_ min    Best FEV<sub>1</sub> value at time point: \_\_\_\_\_ L    FEV<sub>1</sub> fall from baseline: \_\_\_\_\_ %

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**Exercise** – Fall in FEV<sub>1</sub> at two consecutive time points:

Time point 1: \_\_\_\_\_ min    Best FEV<sub>1</sub> value at time point: \_\_\_\_\_ L    FEV<sub>1</sub> fall from baseline: \_\_\_\_\_ %

Time point 2: \_\_\_\_\_ min    Best FEV<sub>1</sub> value at time point: \_\_\_\_\_ L    FEV<sub>1</sub> fall from baseline: \_\_\_\_\_ %

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**Mannitol** – True baseline FEV<sub>1</sub> following 0mg mannitol dose: \_\_\_\_\_ L

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PD15: \_\_\_\_\_ mg FEV<sub>1</sub> value at dose that induced a > or = 15% fall: \_\_\_\_\_ L FEV<sub>1</sub> fall from true baseline: \_\_\_\_\_ %

FEV<sub>1</sub> value at dose prior to 15% fall: \_\_\_\_\_ L    Dose: \_\_\_\_\_ mg    FEV<sub>1</sub> fall from true baseline: \_\_\_\_\_ %

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A 10% incremental fall in FEV<sub>1</sub> between doses: \_\_\_\_\_ mg (dose 1) and \_\_\_\_\_ mg (dose 2)

FEV<sub>1</sub> fall from true baseline at dose 1 \_\_\_\_\_ L \_\_\_\_\_ % and FEV<sub>1</sub> fall from true baseline 2 \_\_\_\_\_ L \_\_\_\_\_ %

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Date of challenge:   /   /      Comments (optional): \_\_\_\_\_

Technician Name and Contact details: \_\_\_\_\_

### 11. Athlete's Declaration

I certify that the information provided under Section 1 of this TUE application form is accurate and that I am requesting approval to use a substance or method on the World Anti-Doping Code (Code) Prohibited List. I authorise the release of personal medical information related to this application to the National Anti-Doping Organisation (NADO, namely UK Anti-Doping) as well as to the World Anti-Doping Agency (WADA) staff, to the NADO's Therapeutic Use Exemption Committee (TUEC) and to other Anti-Doping Organisations (ADO) under the provisions of the Code and the anti-doping rules of my sport.

I understand and agree that:

- My TUE data will only be used to allow the above organisations to administer the anti-doping programme in accordance with the Code International Standard for TUEs;
- My TUE data will be collected by the NADO who shall be principally responsible for ensuring the protection of this data. The NADO will use the Anti-Doping Administration and Management System (ADAMS) to store, process and manage my data, including its disclosure to authorised recipients;
- My TUE data, or part of it, will be made accessible to authorised ADOs (for instance, designated NADOs, the International or National Federation of my Sport, and WADA);
- My TUE data may have to be shared with other independent medical and/or scientific experts, and all necessary staff involved in the management, review or appeals of TUEs if applicable;
- Persons or parties receiving my information may be located outside of the country where I reside. In some other countries data protection and privacy laws may not be equivalent to those in my own country;
- I may have certain rights under applicable laws in relation to my TUE data, including rights to access and/or correct and inaccurate data; and
- To the extent that I have any concerns about the processing of my TUE data I may consult with the NADO and/or WADA as appropriate.

#### Withdrawal of Consent

I understand that if I ever wish to revoke the right of the NADO and authorised ADOs (designated NADOs, the International or National Federation of my Sport, and WADA) to access my TUE information, I must notify my medical practitioner and the NADO in writing of that fact.

#### Authorisation and Consent

By signing this form I expressly consent to the use of my TUE data as set out above.

**Athlete's signature:** \_\_\_\_\_ **Date:**   /   /

**Parent/guardian signature:** \_\_\_\_\_ **Date:**   /   /

If the athlete is under 18 and is not deemed to be competent to give their consent to the treatment or has an impairment preventing him/her to sign this form, a parent or guardian shall sign together with or on behalf of the athlete).

**I would like the decision to be sent to (please tick one box as appropriate):**

**My postal address**  **My e-mail address**  **The notifying medical practitioner**

Mark as confidential and submit the completed form to UK Anti-Doping and keep a copy for your records.

**Address:** TUE, UK Anti-Doping, Fleetbank House, 2-6 Salisbury Square, London, EC4Y 8AE

**Confidential fax:** 0800 298 3362 **e-mail:** tue@ukad.org.uk