

Therapeutic Use Exemption Guidelines | Diabetes Mellitus

Introduction

This guidance document outlines the medical evidence required to support Therapeutic Use Exemption (TUE) applications for the use of insulins to treat type 1 or type 2 diabetes. The guidance covers the medical evidence required to support i. an initial TUE application (that is, first-time requests for a TUE); and ii. renewal applications.

A. Required medical evidence to support first-time applications

1. TUE Application Form

A TUE application form must be completed; application forms can be downloaded from the [UKAD website](#).

NB. Section 4 of the application form (page 2) must correctly state the daily dosing regimen of each type of insulin prescribed in units (as opposed to concentrations). Where the dose per administration is variable, the range (in units) should be stated. Please see the below table for examples of how medication details should be recorded on the application form.

Prohibited substance(s)	Dose and units of administration	Route of administration	Frequency of administration
1. e.g. <i>Insulin detemir (Levemir)</i>	18 – 24 IU	<i>Subcutaneous</i>	<i>Twice daily</i>
2. e.g. <i>Insulin aspart (NovoRapid)</i>	12 – 16 IU	<i>Subcutaneous</i>	<i>With meals, three times per day</i>

2. Medical History

Details of the athlete's clinical history must be submitted with the application. The clinical history must include the following information:

- Initial diagnosis letters
- Blood test results confirming the diagnosis.

3. Annual Diabetes Clinic Review Letter

Where the condition is not newly diagnosed, a copy of the most recent annual diabetes clinic review letter must be submitted to demonstrate that clinical monitoring is occurring. The review letter must contain the following information:

- Confirmation of the ongoing treatment plan
- Most recent HbA1c (glycated haemoglobin) blood test results.

Please note that first-time applications will not be considered unless the above components are enclosed within the application.

B. Required medical evidence to support renewal applications

1. TUE Application Form

A new TUE application form must be completed to support a TUE renewal request.

2. Annual Diabetes Clinic Review Letter

An annual clinic review letter from the doctor overseeing the treatment (i.e. Endocrinologist, Diabetes Specialist Nurse, or General Practitioner) must be submitted with the application. The review letter must contain the following information:

- Summary of annual review findings from the diabetes clinic appointment
- Confirmation of the ongoing treatment plan.

3. Blood Test Results

A copy of the athlete's latest HbA1c blood test results must be submitted.

Please note that renewal applications will not be considered unless the above components are enclosed within the application.

Contact Us

For further information, please contact the UKAD Science and Medicine Team at tue@ukad.org.uk.