



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

ATHLETES & PRESCRIBING PHYSICIANS PLEASE READ

USADA can grant a Therapeutic Use Exemption (TUE) in compliance with the World Anti-Doping Agency International Standard for TUEs. The TUE application process is thorough and designed to balance the need to provide athletes access to critical medication while protecting the rights of clean athletes to compete on a level playing field.

Included in this document is a checklist of items necessary for a complete TUE Application and the WADA Guidelines used to evaluate TUE Applications for your specific condition. (Please be aware that the TUE Committee may ask for additional information while evaluating TUE Applications). It is important that the TUE Application include all the documentation outlined in the checklist below. Please reference the included guidelines for details related to types of diagnoses, specific laboratory tests, and more.

TUE APPLICATION CHECKLIST – RENAL TRANSPLANTATION

- Complete and legible TUE Application form
- Copies of all relevant examinations and clinical notes from the original diagnosis through present
 - Including documented decline in renal function and the surgical report from the renal transplant
- Copies of all laboratory results/reports related to the diagnosis (please see the guidelines for specific results to include)
- A statement from the physician explaining why the Prohibited Substance is needed
 - Please explain why permitted alternative treatments were not effective or not appropriate/indicated for treatment

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RENAL TRANSPLANTATION (SECONDARY TO END-STAGE RENAL DISEASE)

1. Medical Condition

The aetiology of the end-stage renal disease necessitating transplantation must be well documented with confirmation by the attending surgeon and renal physician. Although uncommon in elite athletes, recent cases of renal transplantation in high-profiled athletes have been reported.

2. Diagnosis

- The diagnosis of end-stage renal disease must be accompanied by an appropriate history of documented decline in renal function confirmed by a renal physician.
- A report from the treating surgeon including surgical procedures must also be provided.
- It is necessary to provide the history of declining renal function and associated evidence that the criteria for renal transplantation have been met. This may be provided by the family physician with appropriate endorsement from a registered nephrologist.

3. Good Medical Practice

In the management of post-transplant patients, it is possible that combination therapy may be required including the use of:

1. Glucocorticoids (GCs)
2. Beta-Blockers
3. Diuretics
4. Erythropoietin (EPO) or agents stimulating EPO release (ESA in different forms such CERA and pegylated forms)
5. Hypoxia-inducible factor (HIF) proyl-hydroxylase inhibitors. These are orally available agents (GSK 1278863 and FG 2216) that upregulate the transcription of EPO gene and hence increase production of EPO and which are currently in phase 2 & 3 clinical studies.

4. Route of administration

All agents should be administered orally with the exception of erythropoietin either intravenously or via subcutaneous injection.

5. Frequency of administration

Daily doses of GCs (5-10mg daily for maintenance), beta-blockers, diuretics and EPO in accordance with current guidelines (see references). For EPO the current guidelines recommend a haemoglobin of 120g/L.

6. Recommended duration of treatment

The treatment is life-long with recommended annual review by a renal physician.

7. Other non-prohibited alternative treatments

Following renal transplantation, there is no other appropriate, non-prohibited treatment available.

8. Consequences to health if treatment is withheld

Given that the criteria for renal transplantation have been met, the consequences of withholding prescribed treatment from these individuals will impact significantly upon the function of the transplanted kidney as well as the health of that individual. This applies to immunosuppressive therapy (GCs) and cardiovascular medications (including Beta-blockers).

Most renal transplant recipients will present a history of hypertension secondary to chronic renal disease. Untreated, hypertension appears to be linked to reduced long-term graft and patient survival. Thus, anti-hypertensive therapy, including diuretics, where indicated is essential.

In cases where moderate graft impairment is confirmed, patients may require EPO supplementation due to reduced EPO production. EPO therapy is indicated as per guidelines for the management of anaemia associated with chronic kidney disease.

9. Treatment monitoring

Routine assessment of renal function including monitoring of blood pressure will be at the discretion of the renal physician. Haematological and biochemical parameters are routinely measured, so a record of values are readily available to detect any unexpected changes.

10. TUE validity and recommended review process

Lifetime therapy in accordance with clinical status and an annual review is acceptable. Any changes to the therapeutic regime involving prohibited agents should be well documented and endorsed by a renal physician and form the basis of a revised TUE.

At annual review, athletes on EPO should have blood tests including Hb, Hematocrit, RBC count, Reticulocyte count. Values for these parameters over the preceding 12 months should be provided to detect any unexpected changes.

The recommended validity of a TUE for a case of renal transplantation is 10 years, with an annual review required to revalidate, as described above.

11. Any appropriate cautionary matters

Renal transplantation in elite athletes is not a common occurrence. However there are documented contemporary cases and the consistent application of best practice guidelines is essential.

12. References

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