

ATHLETES & PRESCRIBING PHYSICIANS PLEASE READ

Intravenous (IV) injections and infusions are administered to athletes under various circumstances and to treat numerous conditions. The goal of these guidelines is to clarify the situations where an athlete might require a Therapeutic Use Exemption (TUE) for an IV and what documentation should be provided if a TUE is indicated.

For treatment in response to an emergency, **please consider the athlete's health first** – all the decisions about medical care are between the athlete and their physician. During a medical emergency, athletes are not required to notify USADA prior to receiving treatment.

PLEASE DO NOT WAIT FOR TUE APPROVAL BEFORE RECEIVING EMERGENCY TREATMENT

Step 1: <u>Determine if the substance(s) administered in the IV infusion or injection is/are prohibited.</u>

• The status of substances/medications can be found at <u>GlobalDRO.com</u>. Once you are aware of the status for each substance in the IV, proceed to the next step.

Step 2: <u>Determine if the type of IV infusion or injection received or intended is prohibited.</u>

- Intravenous infusions and intravenous injections of any substance containing more than 100 milliliters in less than a 12-hour period are prohibited, unless it is administered legitimately during the course of hospital treatments, surgical procedures, or clinical diagnostic investigations.
 - IV infusions provided outside of a hospital including, but not limited to, on-site event medical services, ambulatory treatment, outpatient clinics, doctors' or medical offices, home visits, mobile IV clinics, boutique IV clinics, etc., <u>ALL</u> require a TUE.
- If the substance that is administered is prohibited, a TUE is necessary for this substance regardless of the infusion or injection volume.
- Infusions or injections are permitted if the infused/injected substance is not on the Prohibited List **AND** the total volume of fluid administered does not exceed 100 mL per 12-hour period.

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Step 3: <u>Finally, determine what information is required for your TUE Application.</u>

TUE Applications for IV Infusions typically fall into one of four categories:

- 1. General IVs (heat stroke, dehydration, etc.)
- 2. IV Iron Infusions (iron deficiency, anemia, blood loss, etc.)
- 3. IV Infusions for Gastrointestinal Disease (ulcerative colitis, Crohn's disease, IBS, etc.)
- 4. Emergency/Surgery/Procedural IVs

On the following pages, you will find information and guidelines on preparing TUE Application packets for each of the four categories. If your condition does not fall into one of the specified categories, please check to see if your condition has its own TUE Application Guidelines Document. If you have any further questions or concerns, please contact the USADA TUE Department at <u>tue@usada.org</u> or 719-785-2045.

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CATEGORY 1 – GENERAL IV ADMINISTRATION

This category comprises IVs administered for acute medical conditions including, but not limited to, dehydration, heat stroke, bacterial infections, viral infections, etc.

CATEGORY 1 - TUE APPLICATION CHECKLIST

- □ Complete and legible TUE Application form
- Copies of all relevant examinations and clinical notes related to the medical condition
- □ Copies of all laboratory results/reports related to the medical condition, if applicable
- □ A statement from the physician explaining why an IV infusion is needed
 - Please explain why permitted alternative treatments such as small volume injections, oral rehydration, etc. were not effective or not appropriate/indicated for treatment
- □ KEY NOTE: Please specify the <u>TOTAL VOLUME</u> of liquid administered via the IV infusion and/or injection (amount of the active substance <u>AND</u> amount of saline or other fluid). If possible, please include the amount of time required to administer the IV infusion and/or injection.

CATEGORY 2 – IV IRON INFUSIONS

This category comprises IVs administered to treat medical conditions including, but not limited to, iron deficiency, iron deficiency anemia, blood loss, etc.

CATEGORY 2 - TUE APPLICATION CHECKLIST

- □ Complete and legible TUE Application form
- □ Copies of all relevant examinations and clinical notes related to the medical condition
- □ Copies of all laboratory results/reports related to the medical condition
 - The athlete's blood results should be able to demonstrate a consistent iron deficiency (i.e., multiple lab results should be provided)
 - Iron absorption test results, if applicable

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- □ A statement from the physician explaining why oral iron supplementation or a small volume (less than 100mL) IV iron infusions/injections were not effective or appropriate.
 - It is highly unlikely that an IV Iron TUE Application will be approved if the athlete has not undergone a trial of oral iron supplementation.
- KEY NOTE: Please specify the <u>TOTAL VOLUME</u> of liquid administered via the IV infusion and/or injection (amount of the active substance <u>AND</u> amount of saline or other fluid). If possible, please include the amount of time required to administer the IV infusion and/or injection.

CATEGORY 3 – IV INFUSIONS for CHRONIC GASTROINTESTINAL DISEASE

PLEASE ALSO REVIEW THE GUIDELINES DOCUMENT FOR IRRITABLE BOWEL SYNDROME

This category comprises IVs administered to treat medical conditions including, but not limited to, ulcerative colitis, Crohn's disease, IBS, etc.

CATEGORY 3 - TUE APPLICATION CHECKLIST

- □ Complete and legible TUE Application form
- □ Copies of all relevant examinations and clinical notes related to the medical condition
- □ Copies of all laboratory results/reports related to the medical condition
 - Endoscopy or colonoscopy results, if applicable
- □ A statement from the physician explaining why other routes of administration or other methods of treatment were not effective or appropriate.
 - Please explain why permitted alternative treatments were not effective or not appropriate/indicated for treatment
- □ KEY NOTE: Please specify the <u>TOTAL VOLUME</u> of liquid administered via the IV infusion and/or injection (amount of the active substance <u>AND</u> amount of saline or other fluid). If possible, please include the amount of time required to administer the IV infusion and/or injection.
- □ **KEY NOTE:** If the athlete requires multiple IV infusions and/or injections over a period of time, please specify the intended treatment regimen (e.g. one IV infusion every 3 months), and location of treatment (e.g. at home administered by a visiting nurse, in an outpatient clinic)

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CATEGORY 4 – SURGICAL or PROCEDURAL IV ADMINISTRATION

This category comprises IVs administered during surgical procedures (planned or emergency) and clinical diagnostic/investigative procedures.

CATEGORY 4 - TUE APPLICATION CHECKLIST

- □ Complete and legible TUE Application form
- Copies of all relevant examinations and clinical notes related to the medical condition
 - Please include the surgical report including the substances utilized for general anesthesia (if applicable)

□ Copies of all laboratory results/reports related to the medical condition, if applicable

- □ A statement from the physician explaining why the intravenous infusion is needed
 - Please explain why permitted alternative treatments were not effective or not appropriate/indicated for treatment
- □ KEY NOTE: Please specify the <u>TOTAL VOLUME</u> of liquid administered via the IV infusion and/or injection (amount of the active substance <u>AND</u> amount of saline or other fluid). If possible, please include the amount of time required to administer the IV infusion and/or injection.