

## Therapeutic Use Exemptions

The NFL recognizes that within the list of prohibited substances there are medications that are appropriate for the treatment of specific medical conditions. For athletes who require the use of a prohibited substance to treat an appropriately diagnosed medical problem, a

Therapeutic Use Exemption (TUE) may be requested. In reviewing a TUE request, the Independent Administrator of the NFL Policy for Anabolic Steroids and Related Substances and the Medical Advisor for the Policy and Program for Substances of Abuse have sole discretion to require medical evidence beyond that normally necessary to initiate treatment by the medical community.

TUEs may be granted by the Independent Administrator and/or Medical Advisor after review of a player's TUE application. The TUE application should be filled out and submitted by the player's treating physician and should include all pertinent medical records documenting the diagnosis. After review of each case, the advisors may require further diagnostic testing or previous medical records, and/or may utilize the services of expert consultants. The advisors will have the final decision whether to grant a TUE.

The following general requirements apply to all TUE requests:

1. The medication must be necessary and indicated for treatment of the specific medical problem for which it has been requested;  
Acceptable alternative treatments with medications that are not prohibited were attempted but failed, or reasons for not prescribing these alternative treatments have been presented;
2. Appropriate evaluation has been completed and all medical records documenting the diagnosis have been submitted for review; and
3. The applicant may not begin use of the prohibited substance until after the TUE is granted.

Effective immediately, a TUE may be granted retroactively only if emergency use of the prohibited substance is necessary to avoid morbidity or mortality of disease or disorder. TUEs for draft-eligible players will continue to be reviewed and granted prior to or following pre-employment tests at Combine or during visits to individual team facilities.

In addition, specific requirements have been established and must be satisfied in order to obtain a TUE for the following conditions:

- ADD/ADHD
- male pattern baldness
- hypertension
- hormonal deficiency due to either primary or secondary hypogonadism and/or hypopituitarism.

**Any player who seeks to be treated by a physician with a prohibited substance for any condition must have that physician file a TUE application with the Independent Administrator. If a player tests positive for a prohibited substance without having been granted a TUE, this constitutes a positive test and will be referred for administrative action.**



## 2016 Therapeutic Use Exemption (TUEs) Application Form Please

print clearly or type all sections of this form

### Athlete Information

Name: \_\_\_\_\_ Date of Birth: \_\_\_\_\_

Team: \_\_\_\_\_ Position: \_\_\_\_\_

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

City: \_\_\_\_\_ State: \_\_\_\_\_ Zip: \_\_\_\_\_

Cell: \_\_\_\_\_ E-mail: \_\_\_\_\_

### Medical Information (Medical records must be included that document diagnosis & treatments)

Diagnosis: \_\_\_\_\_

Medication requested: Name (generic): \_\_\_\_\_

Dose: \_\_\_\_\_ Route: \_\_\_\_\_ Frequency: \_\_\_\_\_ Duration of treatment: \_\_\_\_\_

Alternative treatments with non-prohibited substances attempted: \_\_\_\_\_

\_\_\_\_\_  
\_\_\_\_\_

### Physician Information and Declaration

I certify that the above treatment is medically appropriate and that the use of alternate medication not on the prohibited list would be unsatisfactory for this condition.

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

Medical Specialty: \_\_\_\_\_

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

City: \_\_\_\_\_ State: \_\_\_\_\_ Zip: \_\_\_\_\_

Phone: \_\_\_\_\_ Fax: \_\_\_\_\_

E-mail: \_\_\_\_\_

Signature of Physician: \_\_\_\_\_ Date: \_\_\_\_\_

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#### **All TUE applications with documentation are to be sent to:**

John A. Lombardo, MD  
Independent Administrator of NFL Policy for  
Anabolic Steroids and Related Substances

mail: 1953 Lytham Road, Columbus, OH 43220  
fax: 614-442-0107  
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## NFL Requirements for Therapeutic Use Exemption (TUE):

### Attention Deficit and Attention Deficit Hyperactivity Disorders (ADD/ADHD)

ADD and ADHD are neurobehavioral disorders characterized by a persistent pattern of inattention and/or hyperactivity. To determine the diagnosis of ADD or ADHD, the medical evaluation must include:

1. Complete history, including interviews with player and preferably with family, associates, teachers, coaches or supervisors to establish behaviors;
2. Evaluation for co-morbidities, including laboratory tests, neurocognitive testing and appropriate screening tests (there is no one specific test which is diagnostic for ADD or ADHD) to determine the diagnosis and treatment plan; and
3. Establishment of DSM-IV or DSM-V (when available) criteria met by player for the diagnosis of ADD or ADHD through complete evaluation and use of a validated ADHD diagnostic rating scale (see below).

#### Initial TUE application

As a reminder, all TUE applications must be sent to the Independent Administrator prior to the initiation of treatment.

The following specific requirements must be satisfied in order to grant a TUE for ADD or ADHD:

1. Evaluation within the last 3 years by a psychiatrist, other physician who has specialized in the treatment of ADD and ADHD or a knowledgeable physician working with a psychologist who works in this area;
2. Pertinent and current history, physical examination and testing, which must be reported including:
  - a. Complete history and physical examination, which must include a thorough neurological evaluation, including a thorough and complete concussion history with appropriate brain imaging if indicated and any neuropsychological testing performed to distinguish between post concussive symptoms and ADHD;
  - b. The presence or absence of other mental health disorders should be established via longitudinal clinical psychiatric history
  - c. Any evaluation or testing for medical and mental health co-morbidities (hypothyroidism, depression, etc.), including laboratory tests, imaging studies or neuropsychological testing (does not replace longitudinal psychiatric or concussion history);
  - d. ADD/ADHD comprehensive diagnostic scale (**symptom scales are not acceptable**) assessing symptoms and impairment used to support the diagnosis of ADD or ADHD, including:
    - i. Conners Adult ADHD diagnostic inventory (CAADID); or
    - ii. Adult ADHD Clinician Diagnostic Scale (ACDS) v1.2; or
    - iii. Barkley Diagnostic Scale with Barkley Impairment Scales;
    - iv. Diagnostic Interview for ADHD in adults (DIVA 2.0); and
  - e. Additional testing as indicated by clinical evaluation.
3. All available records from previous evaluations that document diagnosis, including any previous test results, previous treatments that have been attempted (include doses and duration of treatment) and the results of such treatment trials;
4. Specification of the DSM-IV criteria that are present to diagnose ADD/ADHD; and 5. Management plan, to include:
  - a. Medication prescribed, including dosage and frequency of medication; Treatment with non-prohibited substances should be included;
  - b. Mechanism to be used to document treatment effectiveness (e.g., the use of rating scales, such as the World Health Organization's Adult ADHD Self Report Scale (ASRS v1.1). Symptom Checklist can be given before beginning treatment and at follow-up visits). **These symptom scales can be used for documentation of treatment but not for diagnosis.**
  - c. Further testing or treatment of co-morbidities; and
  - d. Plans for follow-up visits.
6. Completed 2014 TUE application form.

Additionally, it is **strongly suggested in all cases, and required if there is any question that the player may have a learning disability**, that the initial TUE application include the following:

1. Neurocognitive testing for learning disabilities, including:
  - i. Wechsler Adult Intelligence Scale-III;
  - ii. Wechsler Individual Achievement Test-II or Woodcock Johnson Tests of Cognitive Abilities – III;
  - iii. Specific tests of executive function and impulse control; and
  - iv. Appropriate testing to assess learning disabilities as indicated in clinical history.
2. Verification of the symptoms and behaviors by another person, e.g., a family member, coach, teacher, supervisor or school records. An evaluation by a second expert clinician would also suffice.

#### **Annual renewal**

All TUEs for ADD/ADHD require an annual renewal. The following must be submitted annually prior to July 1, 2014:

1. Documentation of all follow-up visits (minimum of 2), including symptoms, efficacy of treatment and treatment of co-morbid conditions. The most recent follow-up visit must take place within 60 days of the TUE renewal application;
2. Results of any pertinent testing that was completed during the previous year, including the mechanism used to document treatment effectiveness (e.g., rating scales such as the World Health Organization's Adult ADHD Self Report Scale (ASRS v1.1)); and
3. Treatment plan for the coming year, including medication(s) prescribed, tests ordered and plans for follow-up visits.
4. Completed 2014 TUE application form.

**A full evaluation must be performed every three (3) years.**

## **NFL Requirements for Therapeutic Use Exemption (TUE):**

### **Diuretics in the Treatment of Hypertension**

Systemic hypertension is the most common cardiovascular condition observed in competitive athletes and is defined as a having a blood pressure measurement above 140/90 on two separate occasions. There are many factors or conditions which affect blood pressure including excess body weight, excess sodium intake, renal disease, sleep apnea and other diseases. In addition, certain medications and foods can cause elevated blood pressure including, non-steroidal anti-inflammatory medication, stimulants, corticosteroids, anti-depressant medication and alcohol. Lifestyle, medications and presence of causative diseases should be included in the evaluation and treatment of an individual with hypertension. The use of diuretics as part of the treatment of NFL players with hypertension requires a TUE.

#### **Initial TUE application**

As a reminder, all TUE applications must be sent to the Independent Administrator prior to the initiation of treatment.

The following specific requirements must be satisfied in order to grant a TUE for the use of diuretics for hypertension:

1. History and physical examination with blood pressure measured on at least two independent occasions with an adequate sized cuff;
2. Laboratory testing must include:
  - a. 12 lead electrocardiogram
  - b. Urinalysis
  - c. Electrolytes including Calcium
  - d. BUN/Creatinine
  - e. Urinalysis
3. Testing as indicated including:
  - a. 24 hour urine for protein and creatinine
  - b. Renal imaging
  - c. Echocardiography
  - d. EKG stress testing
4. Management plan including:
  - a. Treatments previously attempted including lifestyle modification and medication (including dose, frequency and duration of trial of treatment). Trial with a non-prohibited substance (e.g. ACE-I, ARB, calcium channel blocker, etc) is required before the use of a diuretic will be approved.
  - b. Medication suggested with dose, route and frequency
  - c. Plan for monitoring including frequency of visits and follow-up testing

#### **Annual Renewal**

All TUEs for hypertension require annual renewal. The following must be submitted prior to July 1:

1. Documentation of all follow-up visits including effect of treatment, adverse effects and results of all laboratory tests. The latest visit should be within 60 days of renewal; and
2. Management plan for the year, including:
  - a. Medication suggested with dose, route and frequency
  - b. Plan for monitoring including frequency of visits and follow-up testing.

## NFL Requirements for Therapeutic Use Exemption (TUE):

### Hypogonadism

Hypogonadism is the absent or decreased function of the testes resulting in decreased production of testosterone and/or decreased production of spermatozoa. Hypogonadism can be primary, a problem in the testes with etiologies such as Klinefelter's syndrome, Leydig cell aplasia, bilateral anorchia, testicular infection, trauma, etc. Hypogonadism can also be secondary with normal testes but lack of the stimulatory signals (gonadatropic hormones LH and/or FSH). Examples of the medical conditions or treatments that may cause

hypogonadotropic hypogonadism include isolated LH deficiency, hypopituitarism due to tumor, infection or trauma, medications, etc.

Previous use of exogenous androgens may result in decreased pituitary and/or gonadal function and TUE is not indicated for this condition. Additionally, low normal levels of gonadal hormones and/or gonadotropins are not indications for granting a TUE for hypogonadism.

#### **Initial TUE application**

As a reminder, all TUE applications must be sent to the Independent Administrator prior to the initiation of treatment. Additionally because expanded drug testing is required during evaluation process (see below), the Independent Administrator should be notified when diagnosis is being considered.

The following specific requirements must be satisfied in order to grant a TUE for hypogonadism:

1. History and physical examination performed by an endocrinologist and all medical records which document the diagnosis;
2. Laboratory testing must include:
  - a. Free (dialysis method) and Total testosterone drawn before 10 AM – repeated 3 times over 4 weeks
  - b. LH and FSH – drawn with testosterone each time
  - c. Sex hormone binding globulin (SHBG)
  - d. TSH and free T4
  - e. Estradiol
  - f. Prolactin
  - g. IGF-1
3. If clinically indicated, testing must include:
  - a. Testicular imaging
  - b. Semen analysis
4. If hypogonadotropic hypogonadism is the presumptive diagnosis, then stimulation testing and imaging must be performed including:
  - a. Glucagon stimulation test or GHRH for GHG
  - b. HCG stimulation test
  - c. MRI of brain with pituitary (sella) cuts with and without contrast
5. Drug testing under the NFL Policy on Anabolic Steroids and Related Substances to coincide with the administration of repeated tests for testosterone (to be arranged through the Independent Administrator)
6. Management plan including:
  - a. Medication suggested with dose, route and frequency and who will be administering medication
  - b. Regular testing of serum hormone levels (Free and total testosterone, LH, FSH) with levels not exceeding therapeutic range. Results must be sent to Independent Administrator who may at his sole discretion require additional testing of the player's hormonal level on 24 hour notice; and
  - c. Regular visits and plans for re-evaluation (e.g. trial off medication with testing)

**All players granted a TUE for hypogonadism will be subject to expanded testing under the Policy during the year.**

### **Annual Renewal**

All TUEs for hypogonadism require annual renewal. The following must be submitted prior to July 1:

1. Documentation of all follow-up visits including effect of treatment, adverse effects and results of all laboratory tests (latest test must be within 60 days of application);
2. Results of a re-evaluation following removal from the medication with adequate washout period (4-6 weeks) or medical justification why re-evaluation need not be performed.
3. Management plan for the year to include:
  - a. Medication suggested with dose, route and frequency and who will be administering medication
  - b. Regular testing of hormone levels (Free and total testosterone, LH, FSH)
  - c. Regular visits and plans for re-evaluation (e.g. trial off medication with testing)