



**Aveed**  
**Aveed (testosterone undecanoate) J3145**  
**Prior Authorization Request**  
**Medicare Part B Form**

Instructions: \* Indicates required information – Form may be returned if required information is not provided. Please fax this request to the appropriate fax number listed at the bottom of the page.

<input type="checkbox"/>	<b>Standard Request– (72 Hours)</b>	<input type="checkbox"/>	<b>Urgent Request</b> (standard time frame could place the member's life, health or ability in serious jeopardy)
Date Requested _____			
Requestor _____ Clinic name: _____ Phone _____ / Fax _____			

**MEMBER INFORMATION**

\*Name: \_\_\_\_\_ \*ID#: \_\_\_\_\_ \*DOB: \_\_\_\_\_

**PRESCRIBER INFORMATION**

\*Name: \_\_\_\_\_  MD  FNP  DO  NP  PA \*Phone: \_\_\_\_\_

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

**DISPENSING PROVIDER / ADMINISTRATION INFORMATION**

\*Name: \_\_\_\_\_ Phone: \_\_\_\_\_

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

**PROCEDURE / PRODUCT INFORMATION**

HCPC Code	Name of Drug	Dose (Wt: _____ kg Ht: _____ )	Frequency	End Date if known

Self-administered       Provider-administered       Home Infusion

Chart notes attached. **Other important information:** \_\_\_\_\_

**Diagnosis: ICD10:** \_\_\_\_\_ **Description:** \_\_\_\_\_

Provider attests the diagnosis provided is an FDA-Approved indication for this drug

**CLINICAL INFORMATION**

**New Start or Initial Request: (Clinical documentation required for all requests)**

**Hypogonadal (Testosterone Deficiency) Associated with Structural or Genetic Etiologies**

- Patient is male 18 years or older AND
- Confirmed diagnosis of hypogonadism associated with structural or genetic etiologies (e.g., Klinefelter syndrome, pituitary tumors, Kallmann syndrome, hypothalamic injury) AND
- Laboratory confirmation:
  - Two separate morning (8-10am) serum testosterone levels below 300 ng/dL AND
  - Confirmed abnormalities in luteinizing hormone (LH) and/or follicle-stimulating hormone (FSH) consistent with hypogonadotropic or hypergonadotropic hypogonadism AND
- Documentation that patient has been informed of and enrolled in the Aveed REMS program AND
- Prescriber is certified in the Aveed REMS program AND
- Patient will receive injections in a healthcare setting with ability to monitor for 30 minutes post-injection for pulmonary oil microembolism (POME) and anaphylaxis

**Gender Dysphoria (transgender male)**

- Individual has a diagnosis of gender dysphoria/incongruence (WPATH 2022, Hembree 2017); AND
- Individual has experienced puberty to at least Tanner Stage 2; AND
- Individual fulfills the DSM V criteria for gender dysphoria (American Psychiatric Association 2013); AND
- Individual has (early) pubertal changes that have resulted in an increase of their gender dysphoria AND
- Individual does not suffer from a comorbidity that interferes with the diagnostic work-up or treatment AND
- Individual has psychological and social support before and during treatment AND
- Individual has demonstrated knowledge and understanding of the expected risks and outcomes of hormone therapy.

If not, please provide **clinical rationale** for formulary exception: \_\_\_\_\_  
\_\_\_\_\_

**Continuation Requests: (Clinical documentation required for all requests)**

- Patient had an **adequate response** or **significant improvement** while on this medication.
- Medical record documentation of positive response is included

If not, please provide clinical rationale for continuing this medication: \_\_\_\_\_  
\_\_\_\_\_

**ACKNOWLEDGEMENT**

**Request By (Signature Required):** \_\_\_\_\_ **Date:** \_\_\_\_ / \_\_\_\_ / \_\_\_\_

Any person who knowingly files a request for authorization of coverage of a medical procedure or service with the intent to injure, defraud or deceive any insurance company by providing materially false information or conceals material information for the purpose of misleading, commits a fraudulent insurance act, which is a crime and subjects such person to criminal and civil penalties. **THIS AUTHORIZATION IS NOT A GUARANTEE OF PAYMENT.** PAYMENT IS BASED ON BENEFITS IN EFFECT AT THE TIME OF SERVICE, MEMBER ELIGIBILITY AND MEDICAL NECESSITY.

## Prior Authorization Group – Aved Prior Authorization

### Drug Name(s):

**AVEED**

**TESTOSTERONE UNDECANOATE**

### Criteria for approval of Non-Formulary/Preferred Drug:

1. Prescribed for an approved FDA diagnosis (as listed below):
2. Member does not have any clinically relevant contraindications, or CMS/Plan exclusions, to the requested drug.
  - If the member meets all these criteria, they may be approved by the Plan for the requested drug.
  - Quantity limits and Tiering will be determined by the Plan.
  - Continuation Requests: Provider must verify continued clinical benefit in confirmatory trial(s).

### Exclusion Criteria:

**N/A**

### Prescriber Restrictions:

**Hematologist or other related specialist**

### Coverage Duration:

**Approval will be for 6 months**

### FDA Indications:

**Aved**

- Male hypogonadism

### Off-Label Uses:

- Gender dysphoria - Transgender male (Class IIa Recommendation; Effective)

### Age Restrictions:

The safety and effectiveness of testosterone undecanoate IM have not been established in pediatric patients younger than 18 years

### Other Clinical Consideration:

#### **Intramuscular (Solution)**

- Serious Pulmonary Oil Microembolism (POME) Reactions and Anaphylaxis: Serious POME reactions, involving urge to cough, dyspnea, throat tightening, chest pain, dizziness, and syncope; and episodes of anaphylaxis, including life-threatening reactions, have been reported to occur during or immediately after the administration of testosterone undecanoate injection. These reactions can occur after any injection of testosterone undecanoate during the course of therapy, including after the first dose.
- Following each injection of testosterone undecanoate, observe patients in the healthcare setting for 30 minutes in order to provide appropriate medical treatment in the event of serious POME reactions or anaphylaxis.
- Because of the risks of serious POME reactions and anaphylaxis, testosterone undecanoate is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the Aved(R) REMS Program

### Resources:

[https://www.micromedexsolutions.com/micromedex2/librarian/CS/2A5CD3/ND\\_PR/evidencexpert/ND\\_P/evidencexpert/DOPLICATI/ONSHIELDSYNC/CDA418/ND\\_PG/evidencexpert/ND\\_B/evidencexpert/ND\\_AppProduct/evidencexpert/ND\\_T/evidencexpert/PFActionId/evidencexpert.GoToDashboard?docId=923826&contentSetId=100&title=Testosterone+Undecanoate&servicesTitle=Testosterone+Undecanoate&brandName=Aved&UserMdxSearchTerm=Aved#](https://www.micromedexsolutions.com/micromedex2/librarian/CS/2A5CD3/ND_PR/evidencexpert/ND_P/evidencexpert/DOPLICATI/ONSHIELDSYNC/CDA418/ND_PG/evidencexpert/ND_B/evidencexpert/ND_AppProduct/evidencexpert/ND_T/evidencexpert/PFActionId/evidencexpert.GoToDashboard?docId=923826&contentSetId=100&title=Testosterone+Undecanoate&servicesTitle=Testosterone+Undecanoate&brandName=Aved&UserMdxSearchTerm=Aved#)