AVEED®
(testosterone undecanoate) injection CIII
750 mg/3 mL

Benefits Investigation Form Instructions for Specialty Pharmacy

Within this guide you can find:

- Step-by-step instructions on how to fill out the Benefits Investigation Form for Specialty Pharmacy
- Key contact information for Specialty Pharmacy
- Access and reimbursement support through my**AVEED**, managed by Endo Advantage™

INDICATIONS AND USAGE

AVEED® (testosterone undecanoate) is indicated for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone.

- Primary hypogonadism (congenital or acquired): testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchiectomy, Klinefelter's syndrome, chemotherapy, or toxic damage from alcohol or heavy metals. These men usually have low serum testosterone concentrations and gonadotropins (follicle-stimulating hormone [FSH], luteinizing hormone [LH]) above the normal range.
- Hypogonadotropic hypogonadism (congenital or acquired): gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency or pituitary-hypothalamic injury from tumors, trauma, or radiation. These men have low testosterone serum concentrations but have gonadotropins in the normal or low range.

AVEED® should only be used in patients who require testosterone replacement therapy and in whom the benefits of the product outweigh the serious risks of pulmonary oil microembolism and anaphylaxis.

Limitations of use:

- Safety and efficacy of AVEED® in men with "age-related hypogonadism" have not been established.
- Safety and efficacy of AVEED® in males less than 18 years old have not been established.

IMPORTANT SAFETY INFORMATION about AVEED®

WARNING: 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 AVEED®, 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, AVEED® is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the AVEED® REMS Program.**

Please see Important Safety Information continued on next page.

Please click here for full Prescribing Information, including Boxed Warning and Medication Guide.

Instructions for Completing the Specialty Pharmacy section of the Benefits Investigation Form

- **Complete the entire Benefits Investigation Form** and fax it to 1-877-488-6701
- my**AVEED** will provide you with a summary of the patient's medical health plan, prescription pharmacy drug benefits, and the payor-designated specialty pharmacy contact information
- **PLEASE NOTE: Upon receipt of the benefits results, fax the AVEED® prescription and the Benefits Investigation Form to the designated Specialty Pharmacy associated with the patient's insurance plan**

Specialty Pharmacies	Phone	Fax
ALLIANCERX WALGREENS PRIME	888-347-3416	877-231-8302
CVS CAREMARK	800-360-0520, Ext 103-6990 (Opt 3, 2)	800-323-2445

- **Please let your patient know that the Specialty Pharmacy will be contacting him** prior to AVEED® being shipped to your office. You can also have your patient call the Specialty Pharmacy directly at the phone number provided above. The patient must pay copay (if any) and authorize shipment before the Specialty Pharmacy will ship the medication to your office
- **The Specialty Pharmacy Provider will contact your office to coordinate the AVEED® delivery. You can schedule the patient for injection at that time**
- **Be sure to offer the AVEED® Patient Savings Program. For more information, go to www.AveedUSA.com**

myAVEED Access and Reimbursement Support

For additional assistance, call 1-855-myAVEED (692-8333), 8am to 8pm ET.

- Contact patient health plan to verify medical and pharmacy benefit coverage and eligibility
- Claims appeals support
- Information about prior authorizations
- Questions about coding AVEED® on health plan claims
- Identify the Specialty Pharmacy associated with the patient's insurance

1 REQUESTED SERVICE
Please select Specialty Pharmacy and fill out the entire form.

2 PHYSICIAN INFORMATION
myAVEED will use this information to process the Benefits Investigation. The Specialty Pharmacy will manage the shipment of AVEED® to the address provided in this section.

3 PATIENT INFORMATION
myAVEED will use this information to research coverage for AVEED® and related procedures through medical and pharmacy benefits, and verify the need for prior authorization.

AVEED® (testosterone undecanoate) injection CIII 750 mg/3 mL

Benefits Investigation Form
Please fax this completed form to: 1-877-488-6701
Call us: 1-855-692-8333

Requested Service (please select one of the following)

☐ **Buy-and-Bill - Medical Benefits Investigation**
Step 1: Fill out left side of form, include Prescriber's signature in the Prescription Information section, and fax it to 1-877-488-6701.
For assistance with claim denial, partial payment, or prior authorization, please call 1-855-692-8333.

☑ **Specialty Pharmacy - Medical Benefits Investigation and Preferred Specialty Pharmacy**
Step 1: Fill out the entire form and fax it to 1-877-488-6701.
Step 2: Upon receipt of the benefits results, fax this form to the designated Specialty Pharmacy associated with the patient's insurance plan.

Physician Information

Physician Name	Dr. Jim Doe
Physician Specialty	Required
Practice Name	ABC Healthcare
Practice Ship-to Address	123 Any Street
City / State / ZIP	Any Town / AR / 12345
NPI # / DEA #	Required / Required
Tax ID # / State License #	Required / Required
Medicare PTAN	Required
AVEED® REMS Healthcare Provider Enrollment ID #	Required
AVEED® REMS Healthcare Setting Enrollment ID #	Required
Contact Person	Required
Contact Phone # / Fax #	123-456-7890 / 123-456-7890
Contact Email	office@healthcare.com

Patient Information

First Name / Last Name / MI	John / Smith / M
Address	123 Any Street
City / State / ZIP	Any Town / AR / 12345
Mobile Phone #	123-456-7890
May we contact you via text?	☑ Yes ☐ No
Alt. Phone #	123-456-7890
DOB	02/15/1970
	☑ Male ☐ Female

Attach copy, front and back, of all patient insurance cards (Medical and Pharmacy).

Primary Insurance	Insurance
Policy Holder / Group #	Name of Policy Holder / Required
Subscriber DOB	02/15/1970

Prescription Information*

ICD-10 / Other / Description	E 29.1 / EXX.X / If using "Other" include ICD-10 description
Drug Name and Strength	AVEED® 750 mg/3 mL
Directions/Sig	Inject 750 mg (3 mL) IM on day 1, second injection 4 weeks later, all subsequent injections every 10 weeks
Quantity Authorized (Numeric) / (Written) / Refills	1 / One / Three or 3

By signing this form, you are certifying that a) the described therapy above is medically necessary and b) you have received from the patient identified above, or his/her personal representative, the necessary authorization to release, in accordance with applicable federal and state privacy laws and regulations, referenced medical and/or other patient information relating to the need for AVEED® for the purpose of seeking information related to coverage for AVEED® and/or assisting in initiating or continuing AVEED®.

Manual Signature Required. No stamps or electronic signature — Date 05/08/2020

Prescriber Signature Required (no stamps)
***Please note regulations around transmission of prescriptions for controlled substances vary state by state.**

Clinical Information
Fax the completed form to the designated Specialty Pharmacy and include the following documents:
- Applicable chart notes
- Applicable laboratory results

Patient Authorization
By signing below, I authorize my healthcare providers, pharmacies, health plans and other programs that provide me with health benefits to disclose my personal health information (including medical records) and insurance information to Endo Pharmaceuticals Inc. and its representatives and agents (collectively, "Endo"), for Endo to use and disclose as may be necessary to assist in coordination of care, to assist in obtaining insurance coverage information and payment information for AVEED® (testosterone undecanoate), a prescription product distributed by Endo, to conduct reimbursement verifications, make referrals for payment assistance from charitable foundations, and provide me with educational and treatment support services, including treatment reminders and surveys about my treatment with AVEED®. I understand that the information to be disclosed hereunder, once shared with others, will not be protected by state and federal privacy laws, provided that it is used and disclosed solely for the purposes stated above.
I understand that my pharmacy provider may receive remuneration from Endo in exchange for health information and/or for therapy support services provided to me.
I understand that this authorization is voluntary and that if I do not sign it, my ability to obtain treatment from my physician or obtain insurance benefits will not be affected; however, I will not be eligible to receive the services described above. I understand that I may revoke this authorization at any time, to end further use and disclosure of my information, except to the extent that my information has been used or disclosed in reliance upon this authorization, or as permitted by law. I understand that if I choose to revoke this authorization, I must do so in writing to the following address:
myAVEED
400 Holiday Drive
Pittsburgh, PA 15220
I am entitled to a copy of this authorization. This authorization expires 5 years from the date signed below.

Patient Signature / Date	Manual Signature Required. No stamps or electronic signature / 05/08/2020
Patient Printed Name	John Smith
Legal Representative / Date	Jane Smith / 05/08/2020
Relationship to Patient	Wife

Please see Important Safety Information on reverse.
Please see accompanying full Prescribing Information, including Boxed Warning.

endo pharmaceuticals an endo international company

Rx Only

MM-05498/May 2020 www.AveedUSA.com 1-800-462-ENDO (3636)

4 PRESCRIPTION INFORMATION
This section serves as your prescription for AVEED® and must be completed in its entirety, signed manually, and faxed to the designated Specialty Pharmacy associated with the patient's insurance. Regulations around transmission of prescriptions for controlled substances vary state by state. **Note:** Maintenance prescription: AVEED® 750 mg/3 mL. Dispense Qty: 1 vial, with 2 refills

5 CLINICAL INFORMATION
Fax the applicable chart notes and laboratory results with the Benefits Investigation Form.

6 PATIENT AUTHORIZATION
Patients should carefully read this section before signing the completed form.

7 Fax the form to 1-877-488-6701.

8 Upon receipt of the benefits results, fax this form to the designated Specialty Pharmacy associated with the patient's insurance plan.

IMPORTANT SAFETY INFORMATION about AVEED® (CONT)

CONTRAINDICATIONS

- Men with carcinoma of the breast or known or suspected carcinoma of the prostate.
- Women who are pregnant. Testosterone can cause virilization of the female fetus when administered to a pregnant woman.
- Men with known hypersensitivity to AVEED® or any of its ingredients (testosterone undecanoate, refined castor oil, benzyl benzoate).

Please see Important Safety Information continued on next page.

Please click here for full Prescribing Information, including Boxed Warning and Medication Guide.

AVEED® (testosterone undecanoate) injection CIII 750 mg/3 mL

Indications and Important Safety Information

INDICATIONS AND USAGE

AVEED® (testosterone undecanoate) is indicated for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone.

- Primary hypogonadism (congenital or acquired): testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchiectomy, Klinefelter's syndrome, chemotherapy, or toxic damage from alcohol or heavy metals. These men usually have low serum testosterone concentrations and gonadotropins (follicle-stimulating hormone [FSH], luteinizing hormone [LH]) above the normal range.
- Hypogonadotropic hypogonadism (congenital or acquired): gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency or pituitary-hypothalamic injury from tumors, trauma, or radiation. These men have low testosterone serum concentrations but have gonadotropins in the normal or low range.

AVEED® should only be used in patients who require testosterone replacement therapy and in whom the benefits of the product outweigh the serious risks of pulmonary oil microembolism and anaphylaxis.

Limitations of use:

- Safety and efficacy of AVEED® in men with "age-related hypogonadism" have not been established.
- Safety and efficacy of AVEED® in males less than 18 years old have not been established.

IMPORTANT SAFETY INFORMATION about AVEED®

WARNING: 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 AVEED®, 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, AVEED® is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the AVEED® REMS Program.**

CONTRAINDICATIONS

- Men with carcinoma of the breast or known or suspected carcinoma of the prostate.
- Women who are pregnant. Testosterone can cause virilization of the female fetus when administered to a pregnant woman.
- Men with known hypersensitivity to AVEED® or any of its ingredients (testosterone undecanoate, refined castor oil, benzyl benzoate).

WARNINGS AND PRECAUTIONS

- **Serious Pulmonary Oil Microembolism (POME) Reactions and Anaphylaxis**

  Serious POME reactions, involving cough, urge to cough, dyspnea, hyperhidrosis, throat tightening, chest pain, dizziness, and syncope, have been reported to occur during or immediately after the injection of intramuscular testosterone undecanoate 1000 mg (4 mL). The majority of these events lasted a few minutes and resolved with supportive measures; however, some lasted up to several hours and some required emergency care and/or hospitalization. To minimize the risk of intravascular injection of AVEED®, care should be taken to inject the preparation deeply into the gluteal muscle, being sure to follow the recommended procedure for intramuscular administration.

  In addition to serious POME reactions, episodes of anaphylaxis, including life-threatening reactions, have also been reported to occur following the injection of intramuscular testosterone undecanoate.

  Both serious POME reactions and anaphylaxis can occur after any injection of testosterone undecanoate during the course of therapy, including after the first dose. Patients with suspected hypersensitivity reactions to AVEED® should not be re-treated with AVEED®.

  Following each injection of AVEED®, observe patients in the healthcare setting for 30 minutes in order to provide appropriate medical treatment in the event of serious POME reactions and anaphylaxis.

Please click here for full Prescribing Information, including Boxed Warning and Medication Guide.

(Continued)

AVEED® (testosterone undecanoate) injection CIII
750 mg/3 mL

IMPORTANT SAFETY INFORMATION about AVEED® (CONT)

WARNINGS AND PRECAUTIONS (CONT)

- **AVEED® Risk Evaluation and Mitigation Strategy (REMS) Program**
  AVEED® is available only through a restricted program called the AVEED® REMS Program because of the risk of serious POME and anaphylaxis.

  Notable requirements of the AVEED® REMS Program include the following:

  - Healthcare providers who prescribe AVEED® must be certified with the REMS Program before ordering or dispensing AVEED®.
  - Healthcare settings must be certified with the REMS Program and have healthcare providers who are certified before ordering or dispensing AVEED®. Healthcare settings must have on-site access to equipment and personnel trained to manage serious POME and anaphylaxis.

  Further information is available at www.AveedREMS.com or call 1-855-755-0494.
- **Worsening of Benign Prostatic Hyperplasia (BPH) and Potential Risk of Prostate Cancer -** Patients with BPH treated with androgens are at an increased risk of worsening of signs and symptoms of BPH. Monitor patients with BPH for worsening signs and symptoms. Patients treated with androgens may be at an increased risk for prostate cancer. Evaluate patients for prostate cancer prior to initiating and during treatment with androgens.
- **Polycythemia -** Increases in hematocrit, reflective of increases in red blood cell mass, may require discontinuation of testosterone. Check hematocrit prior to initiating testosterone treatment. It would be appropriate to re-evaluate the hematocrit 3 to 6 months after starting testosterone treatment, and then annually. If hematocrit becomes elevated, stop therapy until hematocrit decreases to an acceptable level. An increase in red blood cell mass may increase the risk of thromboembolic events.
- **Venous Thromboembolism (VTE) -** There have been postmarketing reports of venous thromboembolic events, including deep vein thrombosis (DVT) and pulmonary embolism (PE), in patients using testosterone products, such as AVEED®. Evaluate patients who report symptoms of pain, edema, warmth and erythema in the lower extremity for DVT and those who present with acute shortness of breath for PE. If a venous thromboembolic event is suspected, discontinue treatment with AVEED® and initiate appropriate workup and management.
- **Cardiovascular Risk -** Some postmarketing studies have shown an increased risk of major adverse cardiovascular events (MACE) with use of testosterone replacement therapy. Patients should be informed of this possible risk when deciding to use or to continue to use AVEED®.
- **Abuse of Testosterone and Monitoring of Serum Testosterone Concentrations -** Testosterone has been subject to abuse, typically at doses higher than recommended for the approved indication and in combination with other anabolic steroids. Anabolic androgenic steroid abuse can lead to serious cardiovascular and psychiatric adverse reactions. If testosterone abuse is suspected, check serum testosterone concentrations to ensure that they are within therapeutic range. However, testosterone levels may be in the normal or subnormal range in men abusing synthetic testosterone derivatives. Counsel patients concerning the serious adverse reactions associated with abuse of testosterone and anabolic androgenic steroids. Conversely, consider the possibility of testosterone and androgenic steroid abuse in suspected patients who present with serious cardiovascular or psychiatric adverse events.
- **Use in Women -** Due to lack of controlled evaluations in women and potential virilizing effects, AVEED® is not indicated for use in women.
- **Potential for Adverse Effects on Spermatogenesis -** With large doses of exogenous androgens, including AVEED®, spermatogenesis may be suppressed through feedback inhibition of pituitary follicle-stimulating hormone (FSH) which could possibly lead to adverse effects on semen parameters including sperm count.
- **Hepatic Adverse Effects -** Prolonged use of high doses of orally active 17-alpha-alkyl androgens (e.g., methyltestosterone) has been associated with serious hepatic adverse effects (peliosis hepatis, hepatic neoplasms, cholestatic hepatitis, and jaundice). Peliosis hepatis can be a life-threatening or fatal complication. Long-term therapy with intramuscular testosterone enanthate, which elevates blood levels for prolonged periods, has produced multiple hepatic adenomas. AVEED® is not known to produce these adverse effects. Nonetheless, patients should be instructed to report any signs or symptoms of hepatic dysfunction (e.g., jaundice). If these occur, promptly discontinue AVEED® while the cause is evaluated.
- **Edema -** Androgens, including AVEED®, may promote retention of sodium and water. Edema with or without congestive heart failure may be a serious complication in patients with preexisting cardiac, renal, or hepatic disease. In addition to discontinuation of the drug, diuretic therapy may be required.
- **Gynecomastia -** Gynecomastia occasionally develops and occasionally persists in patients being treated for hypogonadism.
- **Sleep Apnea -** The treatment of hypogonadal men with testosterone products may potentiate sleep apnea in some patients, especially those with risk factors such as obesity or chronic lung diseases.
- **Lipids -** Changes in serum lipid profile may require dose adjustment of lipid lowering drugs or discontinuation of testosterone therapy.
- **Hypercalcemia -** Androgens, including AVEED®, should be used with caution in cancer patients at risk of hypercalcemia (and associated hypercalciuria). Regular monitoring of serum calcium concentrations is recommended in these patients.
- **Decreased Thyroxine-binding Globulin -** Androgens, including AVEED®, may decrease concentrations of thyroxine-binding globulin, resulting in decreased total T4 serum concentrations and increased resin uptake of T3 and T4. Free thyroid hormone concentrations remain unchanged, however, and there is no clinical evidence of thyroid dysfunction.
- **Laboratory Monitoring -** Monitor prostatic specific antigen (PSA), hemoglobin, hematocrit, and lipid concentrations at the start of treatment and periodically thereafter.

Please click here for full Prescribing Information, including Boxed Warning and Medication Guide.

(Continued)

AVEED®
(testosterone undecanoate) injection CIII
750 mg/3 mL

IMPORTANT SAFETY INFORMATION about AVEED® (CONT)

ADVERSE REACTIONS

AVEED® was evaluated in an 84-week clinical study using a dose regimen of 750 mg (3 mL) at initiation, at 4 weeks, and every 10 weeks thereafter in 153 hypogonadal men. The most commonly reported adverse reactions (≥2%) were: acne, injection site pain, prostate specific antigen increased, hypogonadism, estradiol increased, fatigue, irritability, hemoglobin increased, insomnia, and mood swings.

In the 84-week clinical trial, 7 patients (4.6%) discontinued treatment because of adverse reactions. Adverse reactions leading to discontinuation included: hematocrit increased, estradiol increased, prostatic specific antigen increased, prostate cancer, mood swings, prostatic dysplasia, acne, and deep vein thrombosis.

- **Postmarketing Experience**
  Pulmonary Oil Microembolism (POME) and Anaphylaxis
  Serious pulmonary oil microembolism (POME) reactions, involving cough, urge to cough, dyspnea, hyperhidrosis, throat tightening, chest pain, dizziness, and syncope, have been reported to occur during or immediately after the injection of intramuscular testosterone undecanoate 1000 mg (4 mL) in post-approval use outside the United States.

  In addition to serious POME reactions, episodes of anaphylaxis, including life-threatening reactions, have also been reported to occur following the injection of intramuscular testosterone undecanoate in post-approval use outside of the United States.

DRUG INTERACTIONS

- **Insulin -** Changes in insulin sensitivity or glycemic control may occur in patients treated with androgens. In diabetic patients, the metabolic effects of androgens may decrease blood glucose and, therefore, may necessitate a decrease in the dose of anti-diabetic medication.
- **Oral Anticoagulants -** Changes in anticoagulant activity may be seen with androgens, therefore, more frequent monitoring of international normalized ratio (INR) and prothrombin time are recommended in patients taking warfarin, especially at the initiation and termination of androgen therapy.
- **Corticosteroids -** The concurrent use of testosterone with corticosteroids may result in increased fluid retention and requires careful monitoring, particularly in patients with cardiac, renal or hepatic disease.

USE IN SPECIFIC POPULATIONS

- **Geriatric Use -** There have not been sufficient numbers of geriatric patients in controlled clinical studies with AVEED® to determine whether efficacy or safety in those over 65 years of age differs from younger subjects. There are insufficient long-term safety data in geriatric patients to assess the potential risks of cardiovascular disease and prostate cancer.
- **Infertility -** Spermatogenesis may be suppressed and reduced fertility is observed in some men taking testosterone replacement therapy.

DRUG ABUSE AND DEPENDENCE

AVEED® contains testosterone undecanoate, a Schedule III controlled substance in the Controlled Substances Act.

- Abuse and misuse of testosterone are seen in male and female adults and adolescents. Testosterone, often in combination with other anabolic androgenic steroids, may be abused by athletes and bodybuilders.
- Serious adverse reactions have been reported in individuals who abuse anabolic androgenic steroids, and include cardiac arrest, myocardial infarction, hypertrophic cardiomyopathy, congestive heart failure, cerebrovascular accident, hepatotoxicity, and serious psychiatric manifestations, including major depression, mania, paranoia, psychosis, delusions, hallucinations, hostility, and aggression.
- The following adverse reactions have been reported in men: transient ischemic attacks, convulsions, hypomania, irritability, dyslipidemia, testicular atrophy, subfertility, and infertility.
- The following adverse reactions have been reported in women: hirsutism, virilization, deepening of voice, clitoral enlargement, breast atrophy, male pattern baldness, and menstrual irregularities.
- The following adverse reactions have been reported in male and female adolescents: premature closure of bony epiphyses with termination of growth, and precocious puberty.
- Withdrawal symptoms can be experienced upon abrupt discontinuation in patients with addiction. Withdrawal symptoms include depressed mood, major depression, fatigue, craving, restlessness, irritability, anorexia, insomnia, decreased libido, and hypogonadotropic hypogonadism. Drug dependence in individuals using approved doses for approved indications have not been documented.

Please click here for full Prescribing Information, including Boxed Warning and Medication Guide.

AVEED®
(testosterone undecanoate) injection CIII
750 mg/3 mL

endo pharmaceuticals
an endo international company

Rx Only

MM-05502/May 2020 www.AveedUSA.com 1-800-462-ENDO (3636)