MVP Health Care Medical Policy

Medicare Part B: Male Hypogonadism

Type of Policy:	**Medical Therapy**
Prior Approval Date:	**N/A**
Approval Date:	**02/01/2025**
Effective Date:	**04/01/2025**
Related Policies:	**Medicare Part B Drug Therapy**

Refer to the MVP website for the Medicare Part D formulary for drugs that may covered under the Part D benefit.

- **Please refer to relevant CMS LCDs/NCDs/Policy Articles for most up to date Medicare Part B guidance if available.**

Codes Requiring Prior Authorization (covered under the medical benefit).

J3145 Aveed (Testosterone undecanoate 750mg/3ml)

Codes Requiring Prior Authorization (covered under the medical benefit) when quantity limits are exceeded. Quantities greater than 10 pellets.

J3490 Testopel (Testosterone pellet, 75 mg)

Overview

Endogenous androgens such as testosterone, are responsible for the normal growth and development of the male sex organs and for maintenance of secondary sex characteristics. Male hypogonadism results from insufficient secretion of testosterone and is characterized by low serum testosterone concentrations (normal range of serum total testosterone is 300-1000 ng/dL). Signs and symptoms associated with male hypogonadism include erectile dysfunction and decreased sexual desire, fatigue and loss of energy, mood depression, regression of secondary sexual characteristics and osteoporosis. Individuals with HIV and on high dose glucocorticoids may experience hypogonadism and may benefit from testosterone therapy.

Indications/Criteria

The following criteria must be met for coverage of **Aveed**:

- Member has coverage under Medicare Part B and meets the criteria for a not usually self-administered, physician administered Medicare Part B covered drug **AND**
- Biologically Male; **AND**
- Early morning serum testosterone level below the lower limit of normal range for healthy young men established in the laboratory (200 to 400 ng/dL) prior to start of therapy. The target of therapy should be the mid-normal range of serum total testosterone; **AND**
- Confirmation of early morning serum total testosterone level **on a separate occasion** OR if the patient is suspected to have alterations in sex hormone-binding globulin (SHBG) measurement below the lower limit of normal established in the laboratory of early morning free testosterone (=50 pg/mL measured by equilibrium dialysis or =65 pg/mL for calculated) or bioavailable testosterone using an accurate and reliable assay. Conditions associated with alterations in SHBG concentration include moderate obesity, nephritic syndrome, hypothyroidism, acromegaly, diabetes mellitus, aging, hepatic cirrhosis and hepatitis, hyperthyroidism, HIV disease, polymorphisms in the SHBG gene, or use of glucocorticoids, progestins, and androgenic steroids, anticonvulsants, and estrogens; **AND**
- Consistent (daily) signs and symptoms of testosterone deficiency**.** Specific symptoms must be provided with each request. (i.e. incomplete or delayed sexual development, eunuchoidism, loss of body (axillary and pubic) hair significant muscle loss or fatigue interfering with activities of daily living, breast discomfort, gynecomastia, very small testes (especially 6mL), low trauma fracture, low bone mineral density); **AND**
- Documentation of:
    - Baseline hematocrit below 48%. For reauthorization of coverage repeat annually.
    - Baseline PSA level prior to initiation of testosterone therapy in men 40 years of age or older. For reauthorization of coverage repeat PSA level at 3-12 months, and then in accordance with prostate cancer screening guidelines; **AND**

Initial approval will be for **12 months**.

Extension of therapy will be for **12 months** will be provided if documentation identifies continued benefit including improvement in symptoms and an increase in serum testosterone levels to within normal limits (if used for testosterone deficiency).

Exclusions

- Indication, age, dose, frequency of dosing, and/or duration of therapy outside of FDA approved package labeling.
- Enhancement of athletic ability or for bodybuilding beyond what is required for activities of daily living
- Hematocrit >48% (>50% for men living at high altitude)
- Metastatic prostate cancer
- Breast cancer
- PSA > 4 ng/ml (>3 ng/ml in individuals at high risk for prostate cancer, such as African Americans or men with first-degree relatives who have prostate cancer)
- Uncontrolled or poorly controlled congestive heart failure
- Untreated severe obstructive sleep apnea
- Severe lower urinary tract symptoms associated with benign prostatic hypertrophy as indicated by AUA/IPSS score > 19
- Myocardial infarction or stroke within the last six months
- Thrombophilia
- Unevaluated prostate nodule or induration
- Desire for fertility in the near term
- Requests for therapy to increase serum total testosterone level above mid-normal range
- Testosterone implant pellets 87.5mg, 100mg, 200mg are excluded from coverage
- Age-related hypogonadism

References

1. AACE Hypogonadism Task Force. American Association of Clinical Endocrinologists medical guidelines for clinical practice for the evaluation and treatment of hypogonadism in adult male patients. Endocrine Practice Vol 8 No. 6 November/December 2002.
2. Bhasin S, Cunningham GR, Hayes FJ, et al. Testosterone therapy in adult men with androgen deficiency syndromes: an endocrine society clinical practice guideline. J Clin Endocrinol Metab. 2010 Jun;95(6):2536-59.

3. Bhasin S, Brito JP, Cunningham GR, et al. Testosterone therapy in men with hypogonadism: An endocrine society clinical practice guideline. J Clin Endocrinol Metab. 2018 May;103(5):1715-1744.
4. Testopel (testosterone pellets) package insert. Malvern, PA: Endo Pharmaceuticals Inc.; 2024 Mar.
5. Aveed (testosterone undecanoate) package insert. Malvern, PA. Endo Pharmaceuticals Inc.; 2021 Aug.