



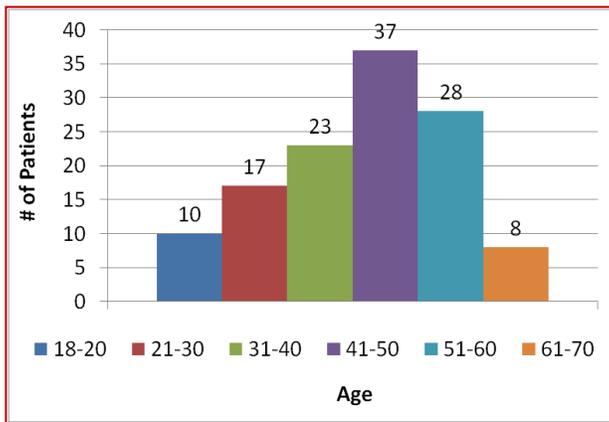
Transdermal Testosterone

Rationale for Drug Utilization Review (DUR) Project

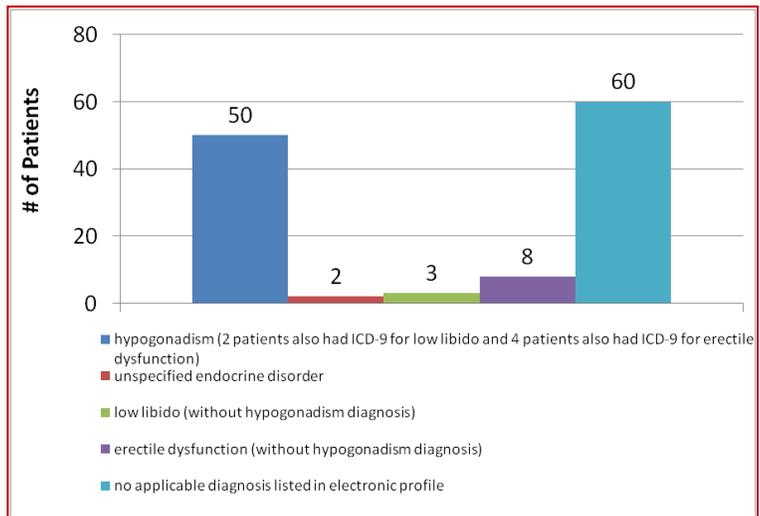
Idaho Medicaid's Pharmacy & Therapeutics (P&T) Committee recommended implementing therapeutic criteria for all drugs in the transdermal testosterone drug class, including requiring baseline serum testosterone levels.

Patient Selection

Patients with at least one paid claim for a transdermal testosterone product between June 1, 2010, and June 26, 2011, were evaluated (122 male patients, 1 female patient with one fill).



Patient Demographic – Number of Patients vs. Age of Patient



Patient Diagnoses

National Guideline

Testosterone Therapy in Adult Men with Androgen Deficiency Syndromes: An Endocrine Society Clinical Practice Guideline. *Journal of Clinical Endocrinology & Metabolism*, June 2010, Vol 95(6):2536-2559. This evidence based guideline was developed using the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) system to describe the strength of recommendations and the quality of the evidence.

DIAGNOSIS OF ANDROGEN DEFICIENCY IN MEN

1. Consistent symptoms and signs

Note: Idaho Medicaid does not authorize payment for medications for sexual dysfunction, so patient must be having other symptoms.

Specific Symptoms and Signs of Androgen Deficiency in Men

- As defined by the Endocrine Society
 - Incomplete or delayed sexual development, eunuchoidism
 - Reduced sexual desire (libido) and activity
 - Decreased spontaneous erections
 - Breast discomfort, gynecomastia
 - Loss of body (axillary and pubic) hair, reduced shaving
 - Very small (especially <5ml) or shrinking testes
 - Inability to father children, low or zero sperm count
 - Height loss, low trauma fracture, low bone mineral density
 - Hot flushes, sweats
 - Idaho Medicaid does not cover for the s/s underlined

Non-Specific Symptoms and Signs of Androgen Deficiency in Men

- As defined by the Endocrine Society
 - Decreased energy, motivation, initiative, and self-confidence
 - Feeling sad or blue, depressed mood, dysthymia
 - Poor concentration and memory
 - Sleep disturbance, increased sleepiness
 - Mild anemia (normochromic, normocytic)
 - Reduced muscle bulk and strength
 - Increased body fat, body mass index
 - Diminished physical or work performance
- As these symptoms/signs are quite non-specific, need to have in conjunction with at least one specific symptom/sign from above.



2. Unequivocally low serum testosterone level

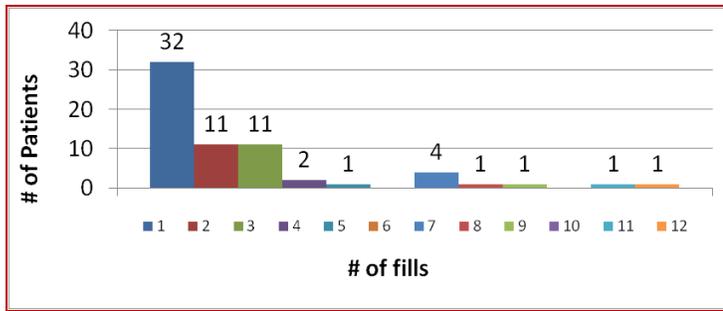
Defined as a morning level below the normal range as defined by the testing laboratory (the lower limit of normal testosterone is approximately 280-300ng/dl but may vary slightly between laboratories). Serum testosterone levels exhibit a circadian variation with peak values in the morning. Confirm low testosterone concentration in men with an initial testosterone level in the mildly hypogonadal range because 30% of such men have a normal testosterone level on repeat measurement.

Contra-indications to Testosterone Therapy

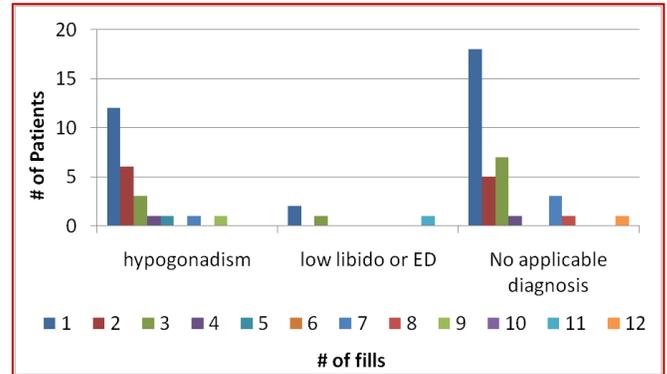
- Breast or prostate cancer
- Palpable prostate nodule or prostate-specific antigen (PSA) > 4ng/ml [or > 3ng/ml in African Americans or men with first degree relative with prostate cancer]
- Hematocrit > 50%
- Untreated severe obstructive sleep apnea
- Severe lower urinary tract symptoms
- Uncontrolled or poorly controlled heart failure

Duration of Therapy

For patients with a start and stop date within this study period (defined as first fill after July 1, 2010, and last fill prior to May 26, 2011).



Number of Patients vs. Number of Fills



Duration with Respect to Diagnosis

Therapeutic Criteria for Transdermal Testosterone will be implemented at the end of February 2012. Refer to new Prior Authorization form for additional information located at www.medicaidpharmacy.idaho.gov under PA forms.

Requirements for initial prior authorization:

1. Diagnosis of hypogonadism
2. At least one nonsexual dysfunction symptom of hypogonadism
3. Serum testosterone level below the lower limit of normal range

Initial approval will be for three months. Then a follow-up serum testosterone level will be required (should be in mid-normal range while on therapy). Subsequent approvals will be one year.

Requirements for prior authorization renewal:

1. Serum testosterone level while on therapy
2. Documentation that symptoms have responded to treatment
3. Documentation that patient is not experiencing adverse effects
4. Assessment of adherence to therapy