

Protocol

Testosterone Implant Therapy For Men

Testing and Recommendations

- PSA, Testosterone, Sensitive estradiol, CBC, Hepatic profile, TSH (Lipid profile, FBS, HbA1C)
 - Optional (Do not order if it will not change therapy)
SHBG for calculated free androgen index (vs. free testosterone)
LH (young men under 45 years of age)
May consider HCG injections
- PSA
 - PSA < 1.0
 - Stable PSA < 2.5 or negative biopsy
 - Approval from Urologist
 - Trial of testosterone therapy (IM, SL or topical) with repeat PSA in 10-14 days (IM) or 3 months (SL/topical)
Treat if stable
- Estrogen
 - If Estradiol elevated* and *does not fit clinically*, REPEAT the test
 - Consider **Aromatase inhibitor (AI)** therapy if elevated Estradiol or history of prostate problems (see Ellem 2010)
Letrozole (Femara) 2.5 mg, ½ pill weekly
Anastrozole (Arimidex) 1 mg, ½ tablet twice weekly
Four, Testosterone (60 mg)-Anastrozole (4 mg) implants
16 mg dose SC anastrozole

ICD-9 codes; 257.8, 780.79, 259.9

Dosing

Testosterone pellet

- Average starting dose Testosterone 1200 mg. **i.e. 12, 100 mg pellets**
 - May increase dose on second insert
 - May want to treat with a higher dose if weight over 100 kg.

FU Testing

Treatment Levels

- Restore testosterone to upper limits of normal for young men
 - 900-1100 ng/dL *if* measured at month one
 - Check levels at week 4 if a patient has not responded to therapy
 - **Estradiol**, estrone, testosterone
- Maintain testosterone over 600 ng/dL
 - Every individual has their own threshold at which symptoms return
 - Symptoms are the best indicator of end organ response
 - Circadian release from the implants

- PSA, Testosterone, Estradiol and CBC prior to each reinsertion until stability of PSA and estradiol are established (12-18 months)
 - Treat elevated estradiol with AI therapy and lifestyle changes (diet, exercise, etc.)
 - Hemoglobin and Hct**
 - Donate blood for **Hb > 18, Hct > 51**
- Suppression of LH is expected and is an indication of adequacy of therapy
 - May give an aromatase inhibitor to prevent slight decrease in size of testicles (no data to support this)
- Clinical Follow up
 - Validated questionnaire (e.g. AMS) at baseline and when patient returns for second set of pellets
 - Optimal response, how they felt at their best
 - Waist circumference
 - Bone density if osteoporosis/osteopenia is an issue

*Estradiol levels and ranges vary between labs. *Depending on the lab*, consider treating Estradiol levels **> 30-35 pg/ml** on testosterone therapy. Recheck estradiol levels and discontinue aromatase inhibitor therapy when estradiol levels decline. Restart therapy if necessary. Four implants (16 mg Anastrozole) are suggested for testosterone doses of 1200 mg or greater.

Symptoms of elevated estradiol:

- Lack of effect from testosterone therapy
- Anxiety, irritability
- Weight gain, fat gain
- Fluid retention
- Breast enlargement, breast pain (gynecomastia)

** Testosterone may also **increase** the production of **red blood cells** (which is a normal function of testosterone) and a blood count will be followed. If the blood count elevates above normal, you may donate blood.

Patients with a history of treated prostate cancer should have 'Clearance' in writing from their urologist.