## Criteria Based Consultation Prescribing Program CRITERIA FOR DRUG COVERAGE

## **Testosterone undecanoate (Aveed)**

Non-formulary **Testosterone undecanoate** (Aveed) will be covered on the prescription drug benefit when the following criteria are met:

- 1. Two documented unequivocally low early morning testosterone levels (clearly below the lowest normal reference range of the assay used). The testosterone levels should have been drawn BEFORE testosterone treatment was started or 3 months AFTER testosterone treatment was discontinued,
  - -AND-
- Diagnosis of primary or secondary hypogonadism (decreased functional activity of the testes) on problem list from documented gonadotropins [reproductive/sexual hormones: luteinizing hormone (LH), prolactin & follicle stimulating hormone (FSH)],
   -AND-
- Consider DRE and PSA for men with higher risk for prostate cancer aged between 40 and 50; If over age 50: digital rectal exam (DRE) and prostate-specific antigen (PSA) in last 12 months, -AND-
- **4.** Recent (last 12 months) Hematocrit (blood test that measures the percent of red blood cells) less than 50%,
  - -AND-
- 5. Adequate trial (3 months) of injectable testosterone (enanthate or cypionate) AND testosterone topical gel 1% (generic Androgel packets),
  - -OR-
- 6. Intolerance or hypersensitivity with injectable testosterone (enanthate or cypionate) AND testosterone topical gel 1% (generic Androgel packets),
   -OR-
- Patient has <u>female to male</u> Gender Dysphoria (a condition in which someone feels their gender identity does not match their biological sex)
   -AND-
- 8. Adequate trial (3 months) of injectable testosterone (enanthate or cypionate) AND testosterone topical gel 1% (generic Androgel packets),
  -OR-
- 9. Intolerance or hypersensitivity with injectable testosterone (enanthate or cypionate) AND testosterone topical gel 1% (generic Androgel packets),
   -OR-
- **10.** Short course prescribed by Pediatric Endocrinologist to invoke puberty or prior to genital surgery, or long-term puberty hormonal therapy

