



## Prior Authorization Approval Criteria

### *Anadrol-50 (oxymetholone)*

<b>Generic name:</b>	Oxymetholone
<b>Brand name:</b>	Anadrol-50
<b>Medication class:</b>	Anabolic steroid
<b>FDA-approved uses:</b>	Treatment of anemias caused by deficient red blood cell production. Acquired aplastic anemia, congenital aplastic anemia, myelofibrosis and the hypoplastic anemias due to administration of myelotoxic drugs often respond.
<b>Usual dose range:</b>	Children and adults: 1-5 mg/kg body weight per day
<b>Duration of therapy:</b>	Response is often not immediate, and a minimum trial of three to six months should be given. Some patients may be maintained without the drug after remission; others may be maintained on an established lower daily dosage.

**Criteria for use** (*bullet points below are all inclusive unless otherwise noted*):

- Clinically diagnosed anemia caused by deficient red blood cell production, including, but not limited to, acquired aplastic anemia, congenital aplastic anemia, myelofibrosis and the hypoplastic anemia due to administration of myelotoxic drugs.
- Must not be used as a replacement of other supportive measures such as transfusion, correction of iron, folic acid, vitamin B12 or pyridoxine deficiency, antibacterial therapy and the appropriate use of corticosteroids.

**Contraindications:**

- Known or suspected carcinoma of the prostate or the male breast.
- Carcinoma of the breast in females with hypercalcemia (anabolic steroids stimulate osteolytic bone resorption).
- Pregnancy (Pregnancy Category X)
- Nephrosis
- Hypersensitivity to the drug
- Severe hepatic dysfunction

**Not approved if:**

- Patient has any contraindications to Anadrol-50
- Patient does not meet above criteria
- Being used to enhance athletic performance. Anabolic steroids are considered **not medically necessary** to increase muscle strength or muscle size to enhance performance. Performance enhancement is not considered to be the treatment of a disease or injury.

**Note:**

- May cause peliosis hepatis, liver cell tumors, and blood lipid changes
- May stunt bone growth in children

- May increase half-life of S-warfarin from 26 hours to 48 hours. Bioavailability is also increased. Warfarin dose may need to be decreased significantly (80% to 85%). Monitoring is necessary for oral anticoagulants.
- May inhibit metabolism of oral hypoglycemic agents.
- In patients with edema, concomitant administration with adrenal cortical steroids or ACTH may increase edema.
- Monitoring: Liver function tests, cholesterol profile, hemoglobin/hematocrit; in children: radiographs of left wrist every 6 months; adult females: signs of virilization, and urine and serum calcium in women with breast cancer.

FCHP Pharmacy and Therapeutics Committee approval: \_\_\_\_\_

Date: \_\_\_\_\_

Adopted: 9/12/07