



## Oxymetholone (Anadrol-50<sup>®</sup>) UTILIZATION MANAGEMENT CRITERIA

<b>DRUG CLASS:</b>	Anabolic Steroids
<b>Generic (Brand) Name:</b>	Oxymetholone (Anadrol-50) tablet 50 mg

### FDA-APPROVED INDICATIONS

For the treatment of anemias caused by deficient red cell production. Acquired or congenital aplastic anemias, myelofibrosis, and/or hypoplastic anemias caused by the administration of myelotoxic drugs often respond.

Oxymetholone should not replace other supportive measures, such as transfusion; correction of iron, folic acid, vitamin B<sub>12</sub>, or pyridoxine deficiency; antibacterial therapy; and the appropriate use of corticosteroids.

### COVERAGE AUTHORIZATION CRITERIA for oxymetholone (Anadrol-50):

#### Oxymetholone (Anadrol-50) is covered for the following:

- Anemias caused by deficient red cell production associated with the following conditions:
  - acquired aplastic anemia
  - congenital aplastic anemia
  - anemia of chronic renal failure
  - pure red cell aplasia
  - myelofibrosis
  - Fanconi's anemia
  - hypoplastic anemias caused by the administration of myelotoxic drugs, or myelosuppression due to chemotherapy
- HIV cachexia (unintentional weight loss of at least 10% of baseline weight, or body mass index (BMI) less than 20 kg/m<sup>2</sup>, not attributable to other causes, when optimal antiviral therapy has been instituted)
- Hereditary angioedema (C1 esterase inhibitor deficiency)

#### Oxymetholone (Anadrol-50) is not covered for the following conditions:

- Weight gain for cosmetic reasons
- To develop muscle mass in otherwise healthy patients

### BLACK BOX WARNINGS:

**Peliosis hepatis:** Peliosis hepatis, a condition in which liver and, sometimes, splenic tissue is replaced with blood-filled cysts, has occurred in patients receiving androgenic anabolic steroids. These cysts are sometimes present with minimal hepatic dysfunction and have been associated with liver failure. Often, they are not recognized until life-threatening liver failure or intra-

abdominal hemorrhage develops. Withdrawal of drug usually results in complete disappearance of lesions.

**Liver cell tumors:** Most often these tumors are benign and androgen-dependent, but fatal malignant tumors have occurred. Withdrawal of drug often results in regression or cessation of tumor progression. However, hepatic tumors associated with androgens or anabolic steroids are much more vascular than other hepatic tumors and may be silent until life-threatening, intra-abdominal hemorrhage develops.

**Blood lipid changes:** Blood lipid changes associated with increased risk of atherosclerosis are seen in patients treated with androgens and anabolic steroids. These changes include decreased high-density lipoprotein (HDL) and, sometimes, increased low-density lipoprotein (LDL). The changes may be very marked and could have a serious impact on the risk of atherosclerosis and coronary artery disease.

#### **DOSAGE:**

Adults and children: For anemia, 1 to 5 mg/kg daily. The usual effective dosage is 1 to 2 mg/kg daily, but higher dosages may be required. Response often is not immediate; give a minimum trial of 3 to 6 months.

#### **REFERENCES:**

Drug Facts and Comparisons eAnswers. Wolters Kluwer. Accessed December 2010.

Oxymetholone. DRUGDEX Evaluations. Micromedex 2.0. Thomson Reuters. December 2010.

Anadrol-50 (oxymetholone). Product Information. Alaven Pharmaceutical. 2006. [http://www.anadrol.com/Anadrol-50\(Rev.12-06\)-PI.pdf](http://www.anadrol.com/Anadrol-50(Rev.12-06)-PI.pdf)