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## Anabolic Steroids Prior Authorization Criteria

Brand	generic	Dosage Form
Anadrol <sup>®</sup> -50	oxymetholone	oral tablet
Winstrol <sup>®</sup> <sup>a</sup>	stanozolol	oral tablet
Oxandrin <sup>®</sup>	oxandrolone <sup>b</sup>	oral tablet

a – discontinued by manufacturer; will be removed from program when inactivated in claims database

b – available as generic; included in prior authorization program

### FDA APPROVED INDICATIONS<sup>1-4</sup>

Anadrol-50<sup>®</sup> (oxymetholone) is indicated in the treatment of anemias caused by deficient red cell production. Acquired aplastic anemia, congenital aplastic anemia, myelofibrosis and the hypoplastic anemias due to the administration of myelotoxic drugs often respond.<sup>1</sup>

Winstrol<sup>®</sup> (stanozolol) is indicated prophylactically to decrease the frequency and severity of attacks of hereditary angioedema. Given the serious potential adverse reactions, patients should be placed on the lowest possible effective dose.<sup>2</sup>

Oxandrin<sup>®</sup> (oxandrolone) is indicated as adjunctive therapy to promote weight gain after weight loss following extensive surgery, chronic infections, or severe trauma, and in some patients who without definite pathophysiologic reasons fail to gain or to maintain normal weight, to offset the protein catabolism associated with prolonged administration of corticosteroids, and for the relief of the bone pain frequently accompanying osteoporosis.<sup>3,4</sup>

### RATIONALE FOR SELECTING ANABOLIC STEROIDS FOR PRIOR AUTHORIZATION

The intent of the Prior Authorization (PA) criteria for anabolic steroids is to ensure that patients are appropriately selected and treated for an appropriate indication according to parameters defined in product labeling and/or clinical evidence and/or guidelines. This policy does not address testosterone replacement for testosterone deficiency or hypogonadism.

Anabolic steroids may be considered **medically necessary** for the following conditions:<sup>1-5</sup>

- Treatment of anemias caused by deficient red cell production including but not limited to acquired aplastic anemia, congenital aplastic anemia, myelofibrosis and hypoplastic anemia due to the administration of myelotoxic drugs
- Treatment of hereditary angioedema
- Adjunctive therapy to promote weight gain after involuntary weight loss following extensive surgery, chronic infections, or severe trauma
- To promote weight gain in patient who without definite pathophysiologic reasons fail to gain or to maintain weight
- To counterbalance protein catabolism associated with chronic corticosteroid administration
- To relieve osteoporosis-related bone pain

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.

Anabolic steroids (Anadrol-50 or oxymetholone) should not be used to replace other supportive measures such as transfusions, correction of iron, folic acid and vitamin B<sub>12</sub> or pyridoxine deficiency, antibacterial therapy and the appropriate use of corticosteroids. Response to steroids is typically not immediate and a minimal trial of three to six months should be given. Maintenance, following remissions, should be individualized to the patient and should be at the lowest possible dose.<sup>1</sup>

Anabolic steroids (Winstrol or stanozolol) are indicated prophylactically to decrease the frequency and severity of attacks of hereditary angioedema. Given the serious potential adverse reactions, patients should be placed on the lowest possible effective dose.<sup>2</sup>

Anabolic steroids (Oxandrin or oxandrolone) are indicated as adjunctive therapy to promote weight gain after weight loss following extensive surgery, chronic infections, or severe trauma, and in some patients who without definite pathophysiologic reasons fail to gain or to maintain normal weight, to offset the protein catabolism associated with prolonged administration of corticosteroids, and for the relief of the bone pain frequently accompanying osteoporosis.. Generally, wasting is a diagnosis of exclusion and the weight loss should be evaluated as a clinical problem. A general approach should include identifying weight loss and characterizing changes in body composition, searching for treatable causes and treatment. General causes of weight loss may include hypermetabolism, malabsorption, decreased oral intake or hypogonadism.<sup>3,4</sup>

Anabolic steroids are contraindicated in the following situations:<sup>1-5</sup>

1. Known or suspected carcinoma of the prostate or the male breast
2. Carcinoma of the breast in females with hypercalcemia (androgenic anabolic steroids may stimulate osteolytic bone resorption)
3. Pregnancy (possible masculinization of the fetus).
  - Oxandrolone has been shown to cause embryotoxicity, fetotoxicity, infertility, and masculinization of female animal offspring when given in doses 9 times the human dose
  - Oxymetholone can cause fetal harm when administered to pregnancy women.
4. Nephrosis, the nephritic phase of nephritis
5. Hypercalcemia
6. Severe hepatic dysfunction
7. Severe renal dysfunction

For all indications, the use of anabolic steroids may be associated with serious adverse reactions. The development of peliosis hepatitis, liver cell tumors and blood lipid and atherosclerosis changes occur with a frequency to preclude use except in those with significant and severe weight loss. Anabolic steroids may cause pulmonary edema, with or without congestive heart failure. They should be used with extreme caution in patients with cardiac, renal or hepatic disease, epilepsy, migraine or other conditions that may be aggravated by fluid retention.<sup>1-5</sup>

Anabolic steroids are controlled substances (category III) as defined by Federal regulations and are subject to restrictions common to scheduled drugs.<sup>1-4</sup>

## PRIOR AUTHORIZATION CRITERIA FOR APPROVAL

### **Anabolic Steroids**

#### **Initial Evaluation**

1. What is the diagnosis?
  - a. Anemia
  - b. Weight loss following extensive surgery, severe trauma, or chronic infection
  - c. Hereditary angioedema
  - d. Duchenne muscular dystrophy or Becker's muscular dystrophy
  - e. Turner's syndrome
  - f. Chronic pain from osteoporosis
  - g. Long-term administration of corticosteroids
  - h. OtherIf a, continue to 2; If b, continue to 3; If c, d, e, f, or g, continue to 5. If h, deny.
2. Does patient have a hematocrit (Hct) value <30%?  
If yes, continue to 5. If no, deny.
3. Does patient have significant weight loss defined by BMI\* value < 20 or 7.5% unintentional loss of weight over 6 months?  
\* BMI = [(wt in lbs) ÷ (ht in inches)<sup>2</sup>] x 703  
If yes, continue to 4. If no, deny.
4. Has the patient's weight loss been evaluated and treatable causes ruled out?  
If yes, continue to 5. If no, deny.
5. Does the patient have a history of liver disease, renal disease, hyperlipidemia, coronary artery disease, or atherosclerosis?  
If yes, deny. If no, approve for 6 months.

#### **CONCLUSION**

The anabolic steroids are indicated in the treatment of anemias, hereditary angioedema, or involuntary weight loss (following extensive surgery, chronic infections, or severe trauma). They may be used to promote weight gain in patients who without definite pathophysiologic reasons fail to gain or to maintain weight, to counterbalance protein catabolism associated with chronic corticosteroid administration, or to relieve osteoporosis-related bone pain. Anabolic steroids are considered not medically necessary to increase muscle strength or muscle size to enhance performance. The PA criteria for Anadrol-50 (oxymetholone), Oxandrin (oxandrolone), and Winstrol (stanozolol) provide an approval mechanism for patients for whom anabolic steroids are medically necessary.

#### **REFERENCES**

1. Anadrol-50 Prescribing Information. Alaven Pharmaceutical, June 2006.
2. Winstrol Prescribing Information. Facts and Comparisons, online version 2005.
3. Oxandrin Prescribing Information. Savient Pharmaceuticals, Inc. January 2006.
4. Oxandrolone Prescribing Information. Sandoz Inc., December 2006; Upsher-Smith Laboratories, Inc, November 2006.
5. Clinical Pharmacology Drug Monographs: Oxandrolone, Oxymetholone, Stanozolol. Available at: <http://cpip.gsm.com> Accessed December 5, 2007.

#### **Document History**

Client Specific criteria BCBSIL 11/2004

Client Specific criteria approved by HCSC Corporate Clinical Committee 11/2006

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Annual Review Client Specific criteria approved by HCSC Corporate Clinical Committee 12/2007