Prior Authorization Criteria for the Use of Anabolic Steroids

Drugs Addressed in this Policy include all testosterone-like products categorized as anabolic steroids which include:

- oxandrolone (Oxandrin®)
- oxymetholone (Anadrol®-50)

FDA-Approved Indications:

- Acquired aplastic anemia (oxymetholone)
- Anemia of chronic renal failure (oxymetholone)
- Myelosuppression induced by cancer chemotherapy (oxymetholone)
- Fanconi's anemia (oxymetholone)
- Pure red cell aplasia (oxymetholone)

- 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 bone pain frequently accompanying osteoporosis (oxandrolone)

Background:
Oxandrolone and oxymetholone have Black Box Warnings for peliosis hepatitis, liver cell tumors, blood lipid changes which could result in serious risk of atherosclerosis and coronary artery disease. Both oxandrolone and oxymetholone are classified as pregnancy category X. Of note, anabolic steroids are synthetic derivatives of testosterone anabolic steroids and are not indicated for male contraception.
Approval Criteria:
When a benefit, oxandrolone or oxymetholone will be approved for the following treatment conditions:

I. Oxandrolone (Oxandrin®)
   When a benefit, oxandrolone will be approved for the following treatment conditions:
   A. As adjunctive therapy in stimulating weight gain in men or women with recent significant weight loss following surgery or due to severe illness, chronic infection, or severe trauma
   B. As adjunctive therapy to offset protein catabolism associated with prolonged administration of corticosteroids
   C. The relief of bone pain associated with osteoporosis after trial and failure of two federal legend drugs used to treat osteoporosis

II. Oxymetholone (Anadrol®-50)
   When a benefit, oxymetholone will be approved for the following treatment conditions:
   A. Acquired aplastic anemia
   B. Fanconi’s Anemia (ICD-9 284.09) (ICD-10 D61.09)
   C. Pure red cell aplasia (ICD-9) (ICD-10 D60.0, D60.1, D60.8, D60.9)
   D. Anemia of chronic renal failure after failure of erythropoiesis stimulating agents (ICD-9 285.21) (ICD-10 D63.1)
   E. Myelosuppression induced by antineoplastic therapies.

Duration of Authorization:

- If approved, up to a lifetime authorization may be granted.

References: