



Oxandrolone (Oxandrin®) UTILIZATION MANAGEMENT CRITERIA

DRUG CLASS:	Anabolic Steroids
Generic (Brand) Name:	Oxandrolone (Oxandrin) tablets 2.5, 10 mg

FDA-APPROVED INDICATIONS:

- **Bone pain:** For the relief of the bone pain frequently accompanying osteoporosis.
- **Protein catabolism:** To offset the protein catabolism associated with prolonged administration of corticosteroids.
- **Weight gain:** 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 maintain normal weight.

COVERAGE AUTHORIZATION CRITERIA for oxandrolone (Oxandrin):

Oxandrolone (Oxandrin) is covered for the following conditions:

- Relief of bone pain accompanying osteoporosis
- Protein catabolism associated with chronic administration of corticosteroids
- Promotion of weight gain after weight loss
 - following extensive surgery;
 - chronic infections;
 - severe trauma;
 - in patients who otherwise fail to gain or maintain normal weight.
- HIV cachexia (unintentional weight loss of at least 10% of baseline weight, or body mass index (BMI) less than 20 kg/m², not attributable to other causes, when optimal antiviral therapy has been instituted)
- Alcoholic hepatitis
- Severe burns
- Hereditary angioedema (C1 esterase inhibitor deficiency)

Oxandrolone (Oxandrin) is not covered for the following conditions:

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

BLACK BOX WARNING:

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: 2.5 to 20 mg daily in 2 to 4 divided doses.

Children: Total daily dose is 0.1 mg/kg or less.

A course of therapy of 2 to 4 weeks is usually adequate. This may be repeated intermittently as indicated.

Higher doses may be used for some conditions.

REFERENCES:

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

Oxandrolone. DRUGDEX Evaluations. Micromedex 2.0. Thomson Reuters. October 2010.

Oxandrin (oxandrolone). Product Information. Savient Pharmaceuticals, Inc. 2005.
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