

Commercial/Healthcare Exchange PA Criteria

Effective: April 30, 2020

Prior Authorization: Oxandrolone

Products Affected: Oxandrin (oxandrolone) oral tablets, oxandrolone oral tablets

Medication Description:

Anabolic steroids are synthetic derivatives of testosterone. Certain clinical effects and adverse reactions demonstrate the androgenic properties of this class of drugs. Complete dissociation of anabolic and androgenic effects has not been achieved. The actions of anabolic steroids are therefore similar to those of male sex hormones with the possibility of causing serious disturbances of growth and sexual development if given to young children. Anabolic steroids suppress the gonadotropic functions of the pituitary and may exert a direct effect upon the testes.

Covered Uses:

1. 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
2. To offset the protein catabolism associated with prolonged administration of corticosteroids
3. The relief of bone pain frequently accompanying osteoporosis

Exclusion Criteria:

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
4. Nephrosis, the nephrotic phase of nephritis
5. Hypercalcemia

Required Medical Information:

1. Diagnosis
2. Medical history

Age Restrictions: N/A

Prescriber Restrictions: N/A

Coverage Duration: 3 months

Other Criteria:

- A. Patient is using requested medication as adjunctive therapy to promote weight gain after weight loss in one of the following:
 - i. Extensive surgery; **OR**
 - ii. Chronic infections; **OR**
 - iii. Severe trauma; **OR**

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- iv. Failure to gain or maintain normal weight with no pathophysiological reason; **OR**
- B. Patient is using requested medication to offset the protein catabolism associated with prolonged administration of corticosteroids; **OR**
- C. Patient is using the requested medication for the relief of bone pain accompanying osteoporosis.

References:

Oxandrin Prescribing Information. Savient Pharmaceuticals, Inc. U.S. National Library of Medicine, National Institutes of Health, DailyMed. Accessed April 30, 2020.

Policy Revision history

| Rev # | Type of Change | Summary of Change | Sections Affected | Date |
|--------------|-----------------------|--------------------------|--------------------------|-------------|
| 1 | New Policy | New Policy | All | 4/30/2020 |

