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Coverage Policy Number **IP0496**

Oxandrolone

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Related Coverage Resources

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview

This policy supports medical necessity review for Oxandrolone.

Receipt of sample product does not satisfy any criteria requirements for coverage.

Medical Necessity Criteria

Oxandrolone is considered medically necessary when ONE of the following is met (1, 2, 3, 4, 5, or 6):

1. **For the management of protein catabolism associated with prolonged administration of corticosteroids**

2. **For the relief of the bone pain frequently accompanying osteoporosis**

3. **Adjunctive therapy to promote weight gain, following weight loss associated with ONE of the following (A, B, C or D):**
    A. Extensive surgery
    B. Chronic Infections
    C. Severe trauma
    D. Individuals, without definite pathophysiologic reasons, fail to gain or to maintain normal weight

4. **For the management of protein catabolism associated with burns/burn injury.** Individual has a documented inadequate response, contraindication or intolerance to a beta blocker.

5. **For the management of AIDS wasting and cachexia.**

6. **For the treatment of Turner's Syndrome or Ullrich-Turner Syndrome**

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Reauthorization Criteria

Oxandrolone is considered medically necessary for continued use when initial criteria are met AND there is documentation of beneficial response.

Authorization Duration

Initial approval duration: up to 12 months
Reauthorization approval duration: up to 12 months

Conditions Not Covered

Any other use is considered experimental, investigational or unproven, including the following (this list may not be all inclusive):

1. **Athletic Ability Enhancement**. Anabolic steroids are not FDA-approved for athletic performance enhancement or for body building in non-athletes. Federal law prohibits the distribution or dispensing of oxandrolone or related agents for non-FDA approved uses.

Background

OVERVIEW
Oxandrolone is an anabolic steroid which are synthetic derivatives of testosterone.[1,2] 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. They suppress the gonadotropic functions of the pituitary and may exert a direct effect upon the testes. Anabolic steroids have been reported to decrease high-density lipoproteins (HDL) and to sometimes increase low-density lipoproteins (LDL).[1,2] These levels revert to normal upon discontinuation of treatment.

Oxandrolone is classified as controlled substances and are listed in Schedule III (non-narcotic).[1,2] Oxandrolone is approved by the Food and Drug Administration (FDA) for 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, as adjunctive therapy to offset the protein catabolism associated with prolonged administration of corticosteroids, and for the relief of the bone pain

frequently accompanying osteoporosis.[1,2] Oxandrolone has been designated with orphan drug status for the following indications: HIV-associated wasting, Duchenne and Becker muscular dystrophy.[3]

Management of protein catabolism associated with burns/burn injury
Burns, especially severe burns, can cause a hypermetabolic response that can persist for months to years after the initial injury.[5,6] This persistent and profound catabolism can hinder rehabilitation efforts and hinder growth in children, including bone growth.[4,5] In a multicenter trial[7] 81 adult subjects with burns of 20% to 60% of total body surface area were given oxandrolone or placebo. The trial was stopped early due to the benefits noted with oxandrolone. The length of stay was shorter for patients given oxandrolone (31 days) compared with placebo (43 days).[7] Benefit in children with severe burns has also been documented.[8,9] In these studies, children experienced improved lean body mass, bone mineral content and muscle strength compared with controls, along with significant increases in height and weight.[8,9] Beta-blockers are the most effective anticatabolic treatment option for burn patients, however, studies have demonstrated efficacy with oxandrolone use in both adult and pediatric burn patients.[4-6]

AIDS wasting and cachexia
Oxandrolone has been studied alone and in combination with progressive exercise resistance in males with human immunodeficiency virus (HIV)-related wasting and in HIV-associated weight loss.[12,13] Average weight gain, and lean body mass, and body cell mass increased with oxandrolone use.[12-14]
Oxandrolone has an orphan drug designation from the FDA for adjunctive therapy for AIDS patients suffering from HIV-wasting syndrome.[5]

Turner's Syndrome or Ullrich-Turner Syndrome
Several studies over more than 15 years have demonstrated the safety and efficacy of oxandrolone use in combination with growth hormone for the management of short stature in girls with Turner's syndrome (or Ullrich-Turner syndrome).[15-18] Clinical practice guidelines on the care of girls and women with Turner Syndrome from proceedings of a multidisciplinary international conference sponsored by the National Institute of Child Health and Human Development (National Institutes of Health [NIH]) in April 2006 (published in 2007) state that consideration can be given to the administration of a nonaromatizable anabolic steroid such as oxandrolone in addition to growth hormone for girls with extreme short stature.[15] This guideline also notes that for girls below approximately 9 years of age therapy is usually started with growth hormone alone. Therapy should be continued until a satisfactory height is achieved or until the bone age is greater than or equal to 14 years and the patient's growth velocity has increased < 2.0 cm over the previous year.

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