BlueCross BlueShield Arizona

An Independent Licensee of the Blue Cross Blue Shield Association

PHARMACY COVERAGE GUIDELINE

Oxandrolone

This Pharmacy Coverage Guideline (PCG):
- Provides information about the reasons, basis, and information sources we use for coverage decisions
- Is not an opinion that a drug (collectively "Service") is clinically appropriate or inappropriate for a patient
- Is not a substitute for a provider's judgment (Provider and patient are responsible for all decisions about appropriateness of care)
- Is subject to all provisions e.g. (benefit coverage, limits, and exclusions) in the member's benefit plan; and
- Is subject to change as new information becomes available.

Scope
- This PCG applies to Commercial and Marketplace plans
- This PCG does not apply to the Federal Employee Program, Medicare Advantage, Medicaid or members of out-of-state Blue Cross and/or Blue Shield Plans

Instructions & Guidance
- To determine whether a member is eligible for the Service, read the entire PCG.
- This PCG is used for FDA approved indications including, but not limited to, a diagnosis and/or treatment with dosing, frequency, and duration.
- Use of a drug outside the FDA approved guidelines, refer to the appropriate Off-Label Use policy.
- The "Criteria" section outlines the factors and information we use to decide if the Service is medically necessary as defined in the Member's benefit plan.
- The "Description" section describes the Service.
- The "Definition" section defines certain words, terms or items within the policy and may include tables and charts.
- The "Resources" section lists the information and materials we considered in developing this PCG
- **We do not accept patient use of samples as evidence of an initial course of treatment, justification for continuation of therapy, or evidence of adequate trial and failure.**
- Information about medications that require precertification is available at www.azblue.com/pharmacy. You must fully complete the request form and provide chart notes, lab workup and any other supporting documentation. The prescribing provider must sign the form. Fax the form to BCBSAZ Pharmacy Management at (602) 864-3126 or email it to Pharmacyprecert@azblue.com.

Criteria:

- **Criteria for initial therapy:** Oxandrolone is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

  1. Prescriber is a physician specializing in the patient's diagnosis or is in consultation with an Endocrinologist, Surgeon, Trauma Specialist, Infectious Disease, Pediatrician, Bariatric Physician, or Nutritional Specialist depending upon indication or use

  2. A confirmed diagnosis of **ONE** of the following:
     a. To relieve bone pain from osteoporosis
     b. To offset protein catabolism from prolonged administration of corticosteroids
     c. For management of weight loss or maintenance of normal weight:
        i. As adjunctive therapy to promote weight gain after weight loss following extensive surgery, chronic infections, or severe trauma

3. **ALL** of the following **baseline tests** have been completed before initiation of treatment with continued monitoring as clinically appropriate:
    a. For pain from osteoporosis:
        i. T-score of -2.5 or worse
        ii. Baseline pain measure using a validated pain scale indicating severe pain
        iii. Pain significantly limits activities of daily living

    b. Protein catabolism from prolonged administration of corticosteroid:
        i. Uses at least 5 mg/day of prednisone or its equivalent for at least 3 months
        ii. Nutritional assessment using validated screening tool(s) that documents evidence of protein catabolism (Nutritional assessment must be submitted with request)

    c. For management of weight loss or maintenance of normal weight **BOTH** of the following:
        i. Suspected cause is **ONE** of the following:
            1. Reduced food intake or reduced absorption
            2. Underlying inflammation due to acute disease or injury or chronic disease
        ii. Presenting as **ONE** of the following:
            1. Documented unintentional weight loss of more than 5% of usual body weight over past 6 months
            2. Low body mass index of less than 20 (if less than 70 years of age) or less than 22 (if greater or equal to 70 years of age)

4. Documented failure, contraindication per FDA label, intolerance, or not a candidate to **ONE** the following:
    a. For pain from osteoporosis **BOTH** of the following:
        i. Individual uses as clinically appropriate standard osteoporosis medication (ex. bisphosphonates, teriparatide (generic or brand Forteo), abaloparatide (Tymlos), etc.)
        ii. Individual uses at least one pain reliever like acetaminophen, aspirin, ibuprofen, or naproxen

    b. Protein catabolism from prolonged administration of corticosteroid:
        i. Megestrol acetate

    c. For management of weight loss or maintenance of normal weight **BOTH** of the following:
        i. Megestrol acetate
        ii. Fail to gain or to maintain normal weight despite use of, as clinically appropriate, enteral or parenteral nutrition

5. There are **NO** FDA-label contraindications, such as:
    a. Known or suspected carcinoma of the prostate or the male breast
    b. Carcinoma of the breast in female patient with hypercalcemia
    c. A woman of childbearing potential who is pregnant or may become pregnant
    d. Nephrosis or the nephrotic phase of nephritis
    e. Hypercalcemia
    f. Cholestatic hepatitis and jaundice
    g. Severe hepatic dysfunction

6. There are no significant interacting drugs

Initial approval duration: 1 month

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Oxandrolone

- **Criteria for continuation of coverage (renewal request):** Oxandrolone is considered ***medically necessary*** and will be approved when **ALL** the following criteria are met (**samples are not considered for continuation of therapy**):

  1. Individual continues to be seen by a physician specializing in the patient's diagnosis or is in consultation with an Endocrinologist, Surgeon, Trauma Specialist, Infectious Disease, Pediatrician, Bariatric Physician, or Nutritional Specialist depending upon indication or use

  2. Individual's condition has responded while on therapy with response defined as:
     a. Pain from osteoporosis:
        i. Significant decrease in pain from osteoporosis over baseline
        ii. Achieved and maintains most activities of daily living

     b. Protein catabolism from prolonged administration of corticosteroids:
        i. Continues to need at least 5 mg/day of prednisone or its equivalent
        ii. Improved nutritional assessment for protein catabolism over baseline

     c. For management of weight loss or maintenance of normal weight:
        i. Gained and maintains at least 15% of ideal body weight over baseline

  3. Individual has been adherent with the medication

  4. Individual has not developed any contraindications or other significant adverse drug effects that may exclude continued use
     a. Contraindications as listed in the criteria for initial therapy section
     b. Significant adverse effect such as:
        i. Peliosis hepatis
        ii. Liver cell tumors
        iii. Cholestatic hepatitis and jaundice
        iv. Osteolysis with hypercalcemia
        v. Virilization in a woman

  5. There are no significant interacting drugs

  Renewal duration: 6 months

- Criteria for a request for non-FDA use or indication, treatment with dosing, frequency, or duration outside the FDA-approved dosing, frequency, and duration, refer to one of the following Pharmacy Coverage Guideline:

  1. **Off-Label Use of Non-Cancer Medications**

  2. **Off-Label Use of Cancer Medications**

PHARMACY COVERAGE GUIDELINE

Oxandrolone

Description:

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.

Therapy with an anabolic steroid is considered adjunctive to and not a replacement for conventional therapy. The duration of therapy with oxandrolone will depend on the response of the patient and the possible appearance of adverse reactions. Therapy should be intermittent.

Oxandrolone is a synthetic derivative of testosterone, an anabolic steroid. Anabolic steroids suppress the gonadotropic functions of the pituitary and may exert a direct effect upon the testes. During exogenous administration of anabolic androgens, endogenous testosterone release is inhibited through inhibition of pituitary luteinizing hormone (LH). At large doses, spermatogenesis may be suppressed through feedback inhibition of pituitary follicle-stimulating hormone (FSH). Anabolic steroids have been reported to increase low-density lipoproteins and decrease high-density lipoproteins. These levels revert to normal on discontinuation of treatment.

Resources:

Oxandrolone product information, revised by Par Pharmaceutical, Inc. 12-2016. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed June 09, 2021.

Gupta R, Evans AT. Approach to the patient with unintentional weight loss. In: UpToDate, Elmore JG, Kunins L (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at http://uptodate.com. Accessed October 04, 2021.

Bruera E, Dev R. Assessment and management of anorexia and cachexia in palliative care. In: UpToDate, Smith TJ, Givens J, Savarese DMF (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at http://uptodate.com. Accessed October 04, 2021.

Ritchie C, Yukawa M.Geriatric nutrition: Nutritional issues in older adults. In: UpToDate, Schmader KE, Seres D, Givens J (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at http://uptodate.com. Accessed October 06, 2021.

Jensen GL, Cederholm T, Correia MITD, et al.: GLIM Criteria for the diagnosis of Malnutrition: A Consensus Report from the Global Clinical Nutrition Community. JPEN J Parenter Enteral Nutr 2019 Jan; 43 (1):32;40. Accessed October 06, 2021.