



An Independent Licensee of the Blue Cross Blue Shield Association

PHARMACY COVERAGE GUIDELINES
SECTION: DRUGS

ORIGINAL EFFECTIVE DATE: 11/18/2021
LAST REVIEW DATE:
LAST CRITERIA REVISION DATE:
ARCHIVE DATE:

Oxandrolone

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Pharmacy Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Pharmacy Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Pharmacy Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Pharmacy Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

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This Pharmacy Coverage Guideline does not apply to FEP or other states' Blues Plans.

Information about medications that require precertification is available at www.azblue.com/pharmacy.

Some large (100+) benefit plan groups may customize certain benefits, including adding or deleting precertification requirements.

All applicable benefit plan provisions apply, e.g., waiting periods, limitations, exclusions, waivers and benefit maximums.

Precertification for medication(s) or product(s) indicated in this guideline requires completion of the [request form](#) in its entirety with the chart notes as documentation. **All requested data must be provided.** Once completed the form must be signed by the prescribing provider and faxed back to BCBSAZ Pharmacy Management at (602) 864-3126 or emailed to Pharmacyprecert@azblue.com. **Incomplete forms or forms without the chart notes will be returned.**

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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. **ONE** of the following 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
 - ii. **For plans with a weight loss benefit**, as adjunctive therapy in some patients who without definite pathophysiologic reasons fail to gain or to maintain normal weight
 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.)



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- 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

➤ **Criteria for continuation of coverage (renewal request):** Oxandrolone is considered *medically necessary* and will be approved when **ALL** of the following criteria are met:

- 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
 - a. Response is defined as:
 - i. Pain from osteoporosis:
 - 1. Significant decrease in pain from osteoporosis over baseline
 - 2. Achieved and maintains most activities of daily living
 - ii. Protein catabolism from prolonged administration of corticosteroids:
 - 1. Continues to need at least 5 mg/day of prednisone or its equivalent
 - 2. Improved nutritional assessment for protein catabolism over baseline
 - iii. For management of weight loss or maintenance of normal weight:
 - 1. Gained and maintains at least 15% of ideal body weight over baseline
- 3. Individual has been adherent with the medication

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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 a Non-Cancer Medications**
 2. **Off-Label Use of a Cancer Medication for the Treatment of Cancer without a Specific Coverage Guideline**

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.



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Resources:

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

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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.

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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.
