Pharmacy Medical Necessity Guidelines: Anabolic Steroids
Oxandrin (oxandrolone); Anadrol-50 (oxymetholone)

Effective: August 8, 2017

Prior Authorization Required ✓ Type of Review – Care Management
Not Covered Type of Review – Clinical Review ✓
Pharmacy (RX) or Medical (MED) Benefit RX Department to Review RXUM

This Pharmacy Medical Necessity Guidelines applies to the following:

Tufts Health Plan Commercial Plans
☐ Tufts Health Plan Commercial Plans – large group plans
☐ Tufts Health Plan Commercial Plans – small group and individual plans

Tufts Health Direct – Health Connector
☐ Tufts Health Together – A MassHealth Plan
☐ Tufts Health RITogether – A Rite Care + Rhody Health Partners Plan

Tufts Health Freedom Plan products
☐ Tufts Health Freedom Plan – large group plans
☐ Tufts Health Freedom Plan – small group plans

Fax Numbers:
RXUM: 617.673.0988

OVERVIEW

FDA-APPROVED INDICATIONS
Oxandrin (oxandrolone) is indicated
- For the relief of the bone pain frequently accompanying osteoporosis
- To offset the protein catabolism associated with prolonged administration of corticosteroids
- 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 maintain normal weight.

Anadrol-50 (oxymetholone) is indicated for the treatment of anemias caused by deficient red cell production. Acquired or congenital aplastic anemias, myelofibrosis, and/or hypoplastic anemias caused by the administration of myelotoxic drugs often respond. Oxymetholone should not replace other supportive measures, such as transfusion; correction of iron, folic acid, vitamin B₁₂, or pyridoxine deficiency; antibacterial therapy; and the appropriate use of corticosteroids.

COVERAGE GUIDELINES
The plan may authorize coverage of the anabolic steroids, oxandrolone or oxymetholone, for Members when the following criteria for a particular regimen are met and limitations do not apply:

For the coverage of oxandrolone
1. The medication will be used as adjunctive therapy for the promotion of appetite and weight gain in a setting of cachexia associated with extensive surgery, chronic infection, severe trauma, or AIDS wasting syndrome
   OR
2. The medication will be used to offset protein breakdown associated with prolonged corticosteroid use
   OR
3. The medication will be prescribed for the relief of bone pain associated with osteoporosis.

For the coverage of Anadrol-50 (oxymetholone)
1. The medication will be used for anemia caused by deficient red cell production, acquired or congenital aplastic anemia, or myelofibrosis and/or hypoplastic anemia caused by the administration of myelotoxic drugs.

LIMITATIONS
1. Coverage of oxandrolone is limited to a maximum daily dose of 20 mg per day for up to one month.
2. Coverage of oxymetholone is limited to a maximum daily dose of three tablets per day, based on a 1-2 mg/kg/day regimen, for up to a 6-month period.
3. Requests for brand-name products, which have AB-rated generics, will be reviewed according to Non-covered Medications criteria.
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REFERENCES

APPROVAL HISTORY
August 12, 2014: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:
- August 11, 2015: No changes
- January 1, 2016: Administrative change to rebranded template.
- August 9, 2016: Added limitation #3 "Requests for brand-name products, which have AB-rated generics, will be reviewed according to Brand Name criteria”
- April 11, 2017: Administrative update, adding Tufts Health RITogether to the template.
- August 8, 2017: No changes.

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION
Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. They are used in conjunction with a Member's benefit document and in coordination with the Member's physician(s). The plan makes coverage decisions on a case-by-case basis considering the individual Member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

This Pharmacy Medical Necessity Guideline does not apply to Uniformed Services Family Health Plan Members or to certain delegated service arrangements. Unless otherwise noted in the Member's benefit document or applicable Pharmacy Medical Necessity Guideline, Pharmacy Medical Necessity Guidelines do not apply to CareLinkSM Members. For self-insured plans, drug coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a coverage guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern. Applicable state or federal mandates will take precedence.

For Tufts Health Plan Medicare Preferred, please refer to Tufts Health Plan Medicare Preferred Prior Authorization Criteria.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to Member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.