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

Effective: July 20, 2020

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

These pharmacy medical necessity guidelines apply to the following:

Commercial Products

☐ Tufts Health Plan Commercial products – large group plans
☐ Tufts Health Plan Commercial products – small group and individual plans
☐ Tufts Health Freedom Plan products – large group plans
☐ Tufts Health Freedom Plan products – small group plans
- CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Tufts Health Public Plans Products

☐ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product)
☐ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans
☒ Tufts Health RITogether – A Rhode Island Medicaid Plan

Fax Numbers:
RXUM: 617.673.0988

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

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.

Oxandrolone has been studied in patients with hereditary angioedema (HAE). The Plan will approve requests for oxandrolone for patients with a diagnosis of HAE.

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 B_{12}, 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 member has a diagnosis of hereditary angioedema (HAE)

OR

2. 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

3. The medication will be used to offset protein breakdown associated with prolonged corticosteroid use

OR

4. 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.

CODES

None

REFERENCES

1. Anadrol-50 [package insert]. Marietta, GA: Unimed Pharmaceuticals; September 2004.
2. Oxandrolone [package insert]. Corona, CA: Watson Laboratories, Inc.; February 2006.

APPROVAL HISTORY

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

Subsequent endorsement date(s) and changes made:

1. August 11, 2015: No changes
2. January 1, 2016: Administrative change to rebranded template.
3. August 9, 2016: Added limitation #3 "Requests for brand-name products, which have AB-rated generics, will be reviewed according to Brand Name criteria"
4. April 11, 2017: Administrative update. Effective 6/1/2017, Medical Necessity Guideline applies to Tufts Health RITogether.
5. August 8, 2017: No changes.
6. August 7, 2018: No changes.
7. June 11, 2019: Administrative changes made to template.
8. May 12, 2020: No changes.
9. July 14, 2020: Updated MNG to include language allowing for approval of oxandrolone for the diagnosis of hereditary angioedema (HAE).

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. 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.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

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.