

5.30.062

Section:	Prescription Drugs	Effective Date:	April 1, 2024
Subsection:	Endocrine and Metabolic Drugs	Original Policy Date:	April 12, 2019
Subject:	Anabolic Steroids	Page:	1 of 4

Last Review Date: March 8, 2024

Anabolic Steroids

Description

Anadrol-50 (oxymetholone), Oxandrin (oxandrolone)

Background

Anabolic steroids are synthetic derivatives of testosterone. Nitrogen balance is improved with anabolic agents but only when there is sufficient intake of calories and protein. Anadrol-50 (oxymetholone) enhances the production and urinary excretion of erythropoietin in patients with anemias due to bone marrow failure and often stimulates erythropoiesis in anemias due to deficient red cell production (1-2).

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 (1-2).

Regulatory Status

FDA-approved indications:

1. Anadrol-50 is indicated in the treatment of anemias caused by deficient red cell production. Acquired aplastic anemia, congenital aplastic anemia, myelofibrosis and the hypoplastic anemias due to the administration of myelotoxic drugs often respond (1).
2. Oxandrin 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

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corticosteroids, and for the relief of the bone pain frequently accompanying osteoporosis (2).

Anabolic steroids have boxed warnings for peliosis hepatitis, a condition in which liver and sometimes splenic tissue is replaced with blood-filled cysts. These cysts are sometimes present with minimal hepatic dysfunction, but at other times they have been associated with liver failure. They are often not recognized until life-threatening liver failure or intra-abdominal hemorrhage develops (1-2).

Anabolic steroids also have boxed warnings for liver cell tumors and blood lipid changes. The tumors are most often benign and androgen-dependent, but fatal malignant tumors have been reported. The blood lipid changes may include decreased high-density lipoprotein and sometimes increased low density lipoprotein. The changes may be very marked and could have a serious impact on the risk of atherosclerosis and coronary artery disease (1-2).

Androgenic anabolic steroid therapy should be used very cautiously in children and only by specialists who are aware of the effects on bone maturation (1-2).

Related policies

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Anabolic steroids may be considered **medically necessary** if the conditions indicated below are met.

Anabolic steroids may be considered **investigational** for all other indications.

Prior-Approval Requirements

Diagnosis

Anadrol only:

Patient must have the following:

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1. Anemia due to deficient red-cell production (e.g., acquired aplastic anemia, congenital aplastic anemia, myelofibrosis, or the hypoplastic anemias due to the administration of myelotoxic drugs)

Oxandrin only:

Patient must have **ONE** of the following:

1. Promote weight gain after weight loss due to chronic infections, extensive surgery, or severe trauma
 - a. Used as adjunctive therapy
2. To offset the protein catabolism associated with prolonged administration of corticosteroids
3. Bone pain accompanying osteoporosis

AND the following for **ALL** drugs:

1. Prescriber agrees to monitor for peliosis hepatitis, liver cell tumors, and blood lipid changes

Prior-Approval *Renewal* Requirements

Same as above

Policy Guidelines

Pre-PA Allowance

None

Prior-Approval Limits

Duration 6 months

Prior-Approval *Renewal* Limits

Same as above

Rationale

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Summary

Anabolic steroids are synthetic derivatives of testosterone. Nitrogen balance is improved with anabolic agents but only when there is sufficient intake of calories and protein. Anadrol-50 (oxymetholone) enhances the production and urinary excretion of erythropoietin in patients with anemias due to bone marrow failure and often stimulates erythropoiesis in anemias due to deficient red cell production. Androgenic anabolic steroid therapy should be used very cautiously in children and only by specialists who are aware of the effects on bone maturation (1-2).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Anabolic Steroids while maintaining optimal therapeutic outcomes.

References

1. Anadrol-50 [package insert]. Marietta, GA: Alaven Pharmaceutical LLC; October 2012.
2. Oxandrin [package insert]. Greenville, NC: DSM Pharmaceuticals, Inc.; April 2007.

Policy History

Date	Action
April 2019	Addition to PA
June 2019	Annual review
December 2020	Annual review
March 2021	Annual review
March 2022	Annual review
March 2023	Annual review. Changed policy number to 5.30.062
September 2023	Annual review
March 2024	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 8, 2024 and is effective on April 1, 2024.