

Pharmacy Benefit Coverage Criteria



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Coverage Policy Number P0005

Oxymetholone

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Related Coverage Resources

INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Medical Necessity Criteria

Oxymetholone (Anadrol®) is considered medically necessary for the treatment of anemias caused by deficient red cell production including ANY of the following:

- Acquired aplastic anemia
- Congenital aplastic anemia
- Myelofibrosis or hypoplastic anemias due to the administration of myelotoxic drugs

Authorization is up to 12 months.

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy as applicable.

Oxymetholone (Anadrol) is considered experimental, investigational or unproven for any other indication.

Note: Receipt of sample product does not satisfy any criteria requirements for coverage.

FDA Approved Indications

FDA Approved Indication

Anadrol tablets are 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.

Anadrol tablets 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.

Recommended Dosing

FDA Recommended Dosing

The recommended daily dose in children and adults is 1-5 mg/kg body weight per day. The usual effective dose is 1-2 mg/kg/day but higher doses may be required, and the dose should be individualized. Response is not often immediate, and a minimum trial of three to six months should be given. Following remission, some patients may be maintained without the drug; others may be maintained on an established lower daily dosage. A continued maintenance dose is usually necessary in patients with congenital aplastic anemia.

Drug Availability

Supplied as tablets containing 50 mg oxymetholone.

Background

Professional Societies/Organizations

A guideline group representative of United Kingdom (UK)-based experts drafted recommendations for the diagnosis and management of aplastic anemia. Infection or uncontrolled bleeding should be treated first. Allogeneic bone marrow transplant (BMT) from a human leucocyte antigen (HLA)-identical sibling donor is the initial treatment of choice for newly diagnosed individuals with severe aplastic anemia. Immunosuppressive therapy is recommended for: individuals with non-severe aplastic anemia who are transfusion dependent, individuals with severe disease who are >40 years old, and younger individuals with severe disease who do not have an HLA-identical sibling donor. Standard immunosuppressive therapy recommended is a combination of antithymocyte globulin (ATG) and cyclosporine. Long term G-CSF, or other growth factors after ATF and cyclosporine is not recommended. Matched unrelated donor (MUD) BMT can be considered when an individual has severe disease, no matched sibling donor but a matched unrelated donor, is <50 years old (or 50-60 years old with good performance status) and has failed ATG in combination with cyclosporine. Oxymetholone is a treatment option for those individuals who have failed several courses of ATG in combination with cyclosporine, or in certain individuals where standard immunosuppressive treatment may not be an option. (Marsh, 2009)

Off Label Uses

AHFS Drug Information 2019 Edition does not have a monograph for oxymetholone.

References

1. Anadrol®-50 (package insert). Marietta, GA: Unimed Pharmaceuticals; September 2004.
2. Marsh JC, Ball SE, Cavenagh J, et al. Guidelines for the diagnosis and management of aplastic anaemia. Br J Haematol 2009; 147:43.
3. McEvoy GK, ed. 2019. AHFS Drug Information. Bethesda, MD: American Society of Health-System Pharmacists, Inc; 2018.

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