PRIOR AUTHORIZATION CRITERIA

BRAND NAME*
(generic)

ANADROL-50
(oxymetholone)

Status: CVS Caremark Criteria
Type: Initial Prior Authorization ***Ref # 1087-A***

** Drugs that are listed in the target drug box include both brand and generic and all dosage forms and strengths unless otherwise stated. OTC products are not included unless otherwise stated.*

FDA-APPROVED INDICATIONS

Anadrol-50 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-50 Tablets 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.

Compendial Uses
Cachexia associated with AIDS (HIV wasting)[3]

COVERAGE CRITERIA

The requested drug will be covered with prior authorization when the following criteria are met:

- The requested drug is being prescribed for any of the following: A) Anemia due to deficient red cell production, (e.g., acquired aplastic anemia, congenital aplastic anemia, myelofibrosis, the hypoplastic anemias due to the administration of myelotoxic drugs, Fanconi's anemia), B) Cachexia associated with acquired immunodeficiency syndrome (AIDS) (human immunodeficiency virus [HIV] wasting)

RATIONALE

The intent of the criteria is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. Anadrol-50 (oxymetholone) 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]

Fanconi's anemia is categorized under the FDA-approved indication.[3] Additionally, oxymetholone produced significant gains in lean body mass and body cell mass in HIV patients with wasting.[3]

Androgens have been misused and abused by athletes, bodybuilders, weight lifters, and others to enhance athletic performance or physique. Following review of data from published literature and case reports in October 2016, the FDA concluded that misuse and abuse of androgens are associated with serious adverse cardiovascular, hepatic, endocrine, and mental health effects.[4]

The manufacturer states that response is not often immediate, and a minimum trial of three to six months should be given.[1] Therefore, the duration of approval will be 6 months.

REFERENCES

1. Anadrol-50 [package insert]. Marietta, GA: Alaven Pharmaceuticals LLC; December 2006.
2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Hudson, OH: Wolters Kluwer Clinical Drug Information, Inc. http://online.lexi.com/. Accessed December 2020.

3. Micromedex (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA. http://www.micromedexsolutions.com/. Accessed December 2020.
4. Food and Drug Administration. Testosterone and other anabolic androgenic steroids (AAS): FDA statement – risks associated with abuse and dependence. Silver Spring, MD; 2016 Oct 25. Available at: https://wayback.archive-it.org/7993/20170111133941/http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm526151.htm. Accessed December 2020.

Written by:	UM Development (GP)
Date Written:	8/1997
Revised:	(LS) 12/1998; (MG) 12/2002, 12/2003; (TM) 09/2004; (MC) 10/2005; (MG) 10/2006(2); (NB) 07/2007; (CT) 09/2007; (AM) 09/2008; (CT) 09/2009; (MS) 09/2010, 06/2011, 11/2011, 03/2012; (PL) 06/2012; (CT) 06/2013, 12/2013 (split Anadrol-50 and Oxandrin into separate criteria), 02/2014; (RP) 02/2015; (MS) 02/2016, 02/2017; (DS) 02/2018; (RP) 12/2018 (no clinical changes), (JK) 12/2019 (no clinical changes, removed MDC designation from title/document), 12/2020 (Updated document title)
Reviewed:	CRC 01/2004; CDPR/Medical Affairs 09/2004, 10/2005, 10/2006; (WF) 07/2007, 09/2007, 09/2008, 09/2009; (KP) 09/2010, 06/2011, 11/2011, 06/2012; (SES) 06/2013; (KP) 02/2014; (SES) 02/2015; (DC) 02/2016; (ME) 02/2017; (AN) 02/2018; (DNC) 12/2018; (CHART) 01/02/2020; (CHART) 12/31/2020 External Review: 04/2008, 02/2009, 12/2009, 1/2011, 10/2011, 10/2012, 08/2013, 06/2014, 06/2015, 06/2016, 04/2017, 04/2018, 02/2019, 02/2020, 04/2021

CRITERIA FOR APPROVAL

1	Is the requested drug being prescribed for any of the following: A) Anemia due to deficient red cell production, (e.g., acquired aplastic anemia, congenital aplastic anemia, myelofibrosis, the hypoplastic anemias due to the administration of myelotoxic drugs, Fanconi's anemia), B) Cachexia associated with acquired immunodeficiency syndrome (AIDS) (human immunodeficiency virus [HIV] wasting)?	Yes	No

Guidelines for Approval	
Duration of Approval **6 Months**	
Set 1	
Yes to question(s)	**No to question(s)**
1	None

Mapping Instructions			
	Yes	**No**	**DENIAL REASONS – DO NOT USE FOR MEDICARE PART D**
1.	Approve, 6 months	Deny	You do not meet the requirements of your plan. Your plan covers this drug when you have any of these conditions: - Anemia due to deficient red-cell production, (e.g., acquired aplastic anemia, congenital aplastic anemia, myelofibrosis, hypoplastic anemias due to the administration of myelotoxic drugs, Fanconi's anemia) - Cachexia associated with AIDS (HIV-wasting) Your request has been denied based on the information we have. [Short Description: No approvable diagnosis]