

PRIOR AUTHORIZATION CRITERIA

BRAND NAME*
(generic)

(oxandrolone)

Status: CVS Caremark Criteria
Type: Initial Prior Authorization

Ref # 15-A
Ref # 320-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

Oxandrolone tablets are 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 corticosteroids, and for the relief of bone pain frequently accompanying osteoporosis.

Compendial Uses

Cachexia associated with AIDS (HIV wasting)²⁻⁴

To enhance growth in patients with Turner Syndrome³⁻⁵

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) As adjunctive therapy to promote weight gain after weight loss following extensive surgery, chronic infections or severe trauma, B) To offset the protein catabolism associated with prolonged administration of corticosteroids, C) For the relief of bone pain accompanying osteoporosis, D) Cachexia associated with acquired immunodeficiency syndrome (AIDS) (human immunodeficiency virus [HIV] wasting)

OR

- The requested drug is being prescribed to enhance growth in patients with Turner Syndrome

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. Oxandrolone 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 corticosteroids, and for the relief of bone pain frequently accompanying osteoporosis.¹

Oxandrolone has been effective in promoting weight gain in patients with AIDS-related wasting and has been given an Orphan Drug designation for AIDS patients suffering from HIV-wasting syndrome.²⁻⁴ Oxandrolone is also recommended as concomitant therapy with growth hormone for the treatment of short stature associated with Turner Syndrome.³⁻⁵

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.² Although oxandrolone is indicated in as adjunctive therapy to promote weight gain after weight loss in some patients who without definite pathophysiologic reasons fail to gain or to maintain normal weight, this criteria will not allow coverage of this unspecified indication due to its potential for misuse and abuse.

For the FDA approved indications, the duration of therapy with oxandrolone will depend on the response of the patient and the possible appearance of adverse reactions. A course of therapy of 2 to 4 weeks is usually adequate. This may be repeated intermittently as indicated.¹ For HIV-associated wasting, continuous administration for 3 to 4 months has been evaluated.² Therefore, the duration of approval will be 6 months for these indications. For Turner Syndrome, oxandrolone has been given for 1 to 2 years in trials as monotherapy and 3 to 5 years in trials as combination therapy.³ Therefore, the duration of approval for Turner Syndrome will be 12 months.

REFERENCES

1. Oxandrolone [package insert]. Hunt Valley, MD: Upsher-Smith Laboratories, LLC; June 2020.
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. Orphan Products Designations and Approvals. Available at <https://www.fda.gov/media/76409/download>. Accessed December 2020.
5. Gravholt CH, Andersen NH, Conway GS, et al. Clinical practice guidelines for the care of girls and women with Turner syndrome: proceedings from the 2016 Cincinnati International Turner Syndrome Meeting. *Eur J Endocrinol*. 2017;177(3):G1–G170. Available at: <http://www.eje-online.org/content/177/3/G1.full>. (Endorsed on September 2017 by the American Academy of Pediatrics. *Pediatrics*. 2017;140(5): e20172626).

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; (SF) 02/2015; (KM) 02/2016; (MS) 02/2017; (RP/DS) 02/2018, (RP) 12/2018 (no clinical changes), (JK) 12/2019 (removed MDC designation from title/document, added extensive surgery and severe trauma as approvable diagnoses in 320-A, put 15-A and 320-A on same document); 05/2020 (off-cycle increase of DOA for Turner Syndrome); 12/2020 (Updated document title, removed brand)
 Reviewed: Medical Affairs (MM) 09/2004, 10/2005, 10/2006; (WF) 09/2007, 09/2008, 09/2009; (KP) 09/2010, 06/2011, 11/2011, 06/2012; (SES) 06/2013; (KP) 02/2014 (MCM) 02/2015; (MC) 02/2016; (ME) 02/2017; (AN) 02/2018; (DNC) 12/2018; (CHART) 01/02/2020; (CHART) 05/21/2020; (CHART) 12/31/2020
 External Review: 02/2004; 10/2004, 02/2007, 04/2008, 02/2009, 12/2009, 2/16/2011, 10/2011, 10/2012, 08/2013, 06/2014, 06/2015, 06/2016, 04/2017, 04/2018, 02/2019, 02/2020, 06/2020 (FYI), 04/2021

CRITERIA FOR APPROVAL

- | | | | |
|---|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----|----|
| 1 | Is the requested drug being prescribed for any of the following: A) As adjunctive therapy to promote weight gain after weight loss following extensive surgery, chronic infections or severe trauma, B) To offset the protein catabolism associated with prolonged administration of corticosteroids, C) For the relief of bone pain accompanying osteoporosis, D) Cachexia associated with acquired immunodeficiency syndrome (AIDS) (human immunodeficiency virus [HIV] wasting)?
[If yes, then no further questions.] | Yes | No |
| 2 | Is the requested drug being prescribed to enhance growth in patients with Turner Syndrome? | Yes | No |

Mapping Instructions (15-A, 320-A)

	Yes	No	DENIAL REASONS – DO NOT USE FOR MEDICARE PART D
1.	Approve, 6 Months	Go to 2	
2.	Approve, 12 months	Deny	You do not meet the requirements of your plan. Your plan covers this drug when you are using it for any of the following: - As adjunctive therapy to promote weight gain after weight loss following extensive surgery, chronic infections or severe trauma

			<ul style="list-style-type: none"> - To offset the protein catabolism associated with prolonged use of corticosteroids - For the relief of bone pain accompanying osteoporosis - Cachexia associated with AIDS (HIV wasting) - To enhance growth in Turner Syndrome. <p>Your request has been denied based on the information we have.</p> <p>[Short Description: No approvable diagnosis]</p>
--	--	--	------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------