PRIOR AUTHORIZATION CRITERIA

DRUG CLASS	**ANABOLIC STEROIDS**
BRAND NAME* **(generic)**	**OXANDRIN** **(oxandrolone)**
Status: CVS Caremark Criteria	***Ref # 15-A***
Type: Initial Prior Authorization	***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

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

Compendial Uses

Cachexia associated with AIDS (HIV wasting)[2,3,4]

To enhance growth in patients with Turner Syndrome[3,5]

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

Oxandrin (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.[2,3,4] Oxandrin (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 Oxandrin 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. Oxandrin [package insert]. East Brunswick, NJ: Savient Pharmaceuticals, Inc.; January 2006.
2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Hudson, OH: Wolters Kluwer Clinical Drug Information, Inc. http://online.lexi.com/. Accessed May 2020.
3. Micromedex (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA. http://www.micromedexsolutions.com/. Accessed December 2019.
4. Orphan Products Designations and Approvals. Available at www.fda.gov/orphan/designat/alldes.rtf. Accessed December 2019.
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). Accessed December 2019.

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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
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)

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	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 - 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) Your request has been denied based on the information we have. [Short Description: No approvable diagnosis]
2.	Approve, 12 months	Deny	You do not meet the requirements of your plan. Your plan covers this drug when you are using it to enhance growth in Turner Syndrome. Your request has been denied based on the information we have. [Short Description: No approvable diagnosis]