

PRIOR AUTHORIZATION CRITERIA

BRAND NAME
(generic)

(oxandrolone)

Status: CVS Caremark Criteria
Type: Initial Prior Authorization

POLICY

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

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).