Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	X

Oxandrin (oxandrolone)

Override(s)	Approval Duration
Prior Authorization	6 months

Medications
Oxandrin (oxandrolone)

APPROVAL CRITERIA

Requests for Oxandrin (oxandrolone) may be approved if the following criteria are met:

I. Individual is using as an adjunct to conventional therapy to promote weight gain after weight loss following one of the following:
   A. Extensive surgery; **OR**
   B. Chronic infections; **OR**
   C. Severe trauma;

OR

II. Individual is using as an adjunct to conventional therapy to promote weight gain or maintain a normal weight following weight loss from an unexplained pathophysiologic reason;

OR

III. Individual is using as an adjunct to conventional therapy to offset protein catabolism (such as, muscle wasting) associated with prolonged corticosteroid administration;

OR

IV. Individual is using as an adjunct to conventional therapy to relieve osteoporosis-related bone pain.

Oxandrin (oxandrolone) may not be approved for any of the following:

I. Known or suspected carcinoma of the prostate or breast in male individuals; **OR**
II. Carcinoma of the breast in females with hypercalcemia; **OR**
III. Individual is using to enhance athletic performance or physique; **OR**
IV. Individual has a diagnosis of nephrosis (nephrotic phase of nephritis); **OR**

Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	X

V. Individual has a diagnosis of hypercalcemia.

Note:
Oxandrin (oxandrolone) has black box warnings for the risk of peliosis hepatis, liver cell tumors, and blood lipid changes. Peliosis hepatis, a condition in which liver and sometimes splenic tissue is replaced with blood-filled cysts, and liver cell tumors have been reported in individuals receiving androgenic anabolic steroid therapy. These conditions can lead to life-threatening liver failure, intra-abdominal hemorrhage, or death. Withdrawal of the medication usually results in either complete disappearance of cysts or regression of or cessation of progression of tumors. Use may cause marked blood lipid changes that are known to be associated with an increased risk of atherosclerosis and coronary artery disease.

Key References:

1. Camacho PM, Petak SM, Binkley N, et al. American Association of Clinical Endocrinologists and American College of Endocrinology (AACE/ACE). Clinical Practice Guidelines for the Diagnosis and Treatment of Postmenopausal Osteoporosis. Endocrine Practice. 2020; 26(Suppl 1):1-46. Accessed on: May 13, 2020. 2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2020. URL: http://www.clinicalpharmacology.com. Updated periodically.
2. Cosman F, de Beur SJ, LeBoff MS, et al. National Osteoporosis Foundation (NOF). Clinician's Guide to Prevention and Treatment of Osteoporosis. Osteoporosis Int. 2014;25(8):1-25. Statement update 2017. Accessed on: May 13, 2020.
3. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed on: May 13, 2020.
4. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
5. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2020; Updated periodically.