**MEDICATION POLICY:**
# Oxandrin®

**Generic Name:** Oxandrolone

**Therapeutic Class or Brand Name:** Oxandrin®

**Applicable Drugs (if Therapeutic Class):** N/A

**GPI Code:** 2320004000

**Preferred:** Oxandrolone tablets (generic)

**Non-preferred:** Oxandrin® tablets

**Date of Origin:** 2/1/2013

**Date Last Reviewed / Revised:** 2/9/2019

## Prior Authorization Criteria

(May be considered medically necessary when criteria I through II are met)

I. Documented diagnosis of one of the following conditions A through C:

   A. Used 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.

   B. Therapy to offset protein catabolism associated with long-term use of corticosteroids.

   C. Treatment of bone pain associated with osteoporosis.

II. Non-preferred products (i.e. Oxandrin® tablets) require a documented clinical reason containing details as to why generic oxandrolone is not appropriate or is contraindicated.

## Exclusion Criteria

- Known or suspected carcinoma of the prostate or the male breast.
- Carcinoma of the breast in females with hypercalcemia.
- Pregnancy.
- Nephrosis, the nephrotic phase of nephritis.
- Hypercalcemia.

## Other Criteria

- N/A

## Quantity / Days Supply Restrictions

- The total daily adult dose is 2.5mg to 20mg given in 2 to 4 divided doses. For children the total daily dose is ≤ 0.1mg per kg or ≤ 0.045mg per lb. The quantity is limited to a maximum of a 30 day supply per fill.

## Approval Length

- **Authorization:** 3 months.

- **Re-Authorization:** An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and that the medication is effective by documenting maintenance or an increase in total body weight.

## APPENDIX

N/A

## REFERENCES

1. https://medicaid.utah.gov/pharmacy/priorauthorization/pdf/Oxandrin.pdf .
2. http://www.fchp.org/~/media/Files/FCHP/Imported/Oxandrin_oxandrolone.pdf.ashx .
3. NPS.
4. http://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=F622616E-4C11-4149-BF00-5EA5CE97800B .

## HISTORICAL TRACKING OF CHANGES MADE TO POLICY

| Date | Notes/Changes |
|---|---|
| 2/6/2019 | 1. Policy reviewed: no changes made. |
| 1/4/2018 | 1. Policy reviewed: no changes made. |
| 10/9/2016 | 1. **Changed** "N/A" **to** "Preferred: Oxandrolone tablets (generic); Non-Preferred: Oxandrin® tablets" **following Applicable Drugs**.<br>2. **Added** "II. Non-preferred products (i.e. Oxandrin® tablets) require a documented clinical reason containing details as to why generic oxandrolone is not appropriate or is contraindicated" **under Prior Authorization Criteria**.<br>3. **Removed** "http://www.connecticare.com/provider/PDFs/Pharmacy/Oxandrin.pdf" **from References** (link no longer valid). |
| 7/28/2015 | 1. **Changed** "A. Used as an adjunctive therapy to promote weight gain after weight loss following one of the following listed below as 1, 2 or 3: 1. Extensive Surgery, 2. Chronic Infection, 3. Severe Trauma" **to** "A. Used 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" **under Prior Authorization Criteria**.<br>2. **Changed** "Nephritis" **to** "Nephrosis, the nephrotic phase of nephritis" **under Exclusion Criteria**.<br>3. **Updated** "http://www.health.utah.gov/medicaid/pharmacy/priorauthorization/pdf/Oxandrin.pdf" **to** "https://medicaid.utah.gov/pharmacy/priorauthorization/pdf/Oxandrin.pdf" **and** "http://www.savientpharma.com/pdf/PI%20005429_Oxandrin12.pdf" **to** "http://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=F622616E-4C11-4149-BF00-5EA5CE97800B" **under References**. |

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|---|---|
| 1/27/2014 | 1. **Adapted policy to new format.**<br>2. **Changed Prior Authorization Criteria from:**<br>"Documented diagnosis of Adult onset - AIDS Wasting indication only; Body Mass Index < 20. Must provide current weight, height, and BMI; Patient must be taking an antiretroviral medication, and this needs to be documented; Patient must be maintaining a nutritional intake; Minimum age requirement: 19 years old"<br>**to:**<br>"Documented diagnosis of one of the following conditions A through C: A. Used as an adjunctive therapy to promote weight gain after weight loss following one of the following listed below as 1, 2 or 3: 1. Extensive Surgery, Chronic Infection, Severe Trauma; B. Therapy to offset protein catabolism associated with long-term use of corticosteroids; C. Treatment of bone pain associated with osteoporosis".<br>3. **Added** "Known or suspected carcinoma of the prostate or the male breast; Carcinoma of the breast in females with hypercalcemia; Pregnancy; Nephritis; Hypercalcemia" **to Exclusion Criteria**.<br>4. **Changed Quantity/Days Supply Restrictions from** "120 tablets per 30 days" **to** "The total daily adult dose is 2.5mg to 20mg given in 2 to 4 divided doses. For children the total daily dose is ≤ 0.1mg per kg or ≤ 0.045mg per lb. The quantity is limited to a maximum of a 30 day supply per fill'.<br>5. **Changed Authorization under Approval Length from** "Initially approved for a 60 day trial. After the 60 day trial: If weight is maintained or has increased, an additional 4 months will be authorized. If weight has not maintained, Oxandrin® is no longer authorized - patient may need to advance to Growth Hormone" **to** "3 months".<br>6. **Changed Re-Authorization under Approval Length from** "6 Months. If weight is maintained or has increased, the patient may remain on Oxandrin®. Submit previous weight and current weight. All initial criteria remain effective" **to** "An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and that the medication is effective by documenting maintenance or an increase in total body weight".<br>7. **Updated references** to include Connecticare policy, fchp policy, and package insert. |