

SmartPA Criteria Proposal

Drug/Drug Class:	Oxandrin Clinical Edit
First Implementation Date:	November 25, 2002
Proposed Date:	June 16, 2022
Prepared for:	MO HealthNet
Prepared by:	MO HealthNet/Conduent
Criteria Status:	<input checked="" type="checkbox"/> Existing Criteria <input type="checkbox"/> Revision of Existing Criteria <input type="checkbox"/> New Criteria

Executive Summary

Purpose: Ensure appropriate utilization and control of Oxandrin® (oxandrolone)

Why Issue Selected: Oxandrin® is an oral tablet formulation of the anabolic steroid oxandrolone. It was FDA approved in 1964 and became a Schedule III controlled substance in 1991. Oxandrin is indicated as adjunctive therapy to promote weight gain after weight loss following extensive surgery, chronic infections, or severe trauma or in patients who fail to gain or maintain normal weight without definite pathophysiologic reasons. It is also indicated to offset the protein catabolism associated with prolonged administration of corticosteroids and for the relief of the bone pain frequently accompanying osteoporosis. Due to the specific approved indications, MO HealthNet will impose clinical criteria to ensure appropriate utilization of Oxandrin.

Program-Specific Information:	Date Range FFS 4-1-2021 to 3-31-2022			
	Drug	Claims	Spend	Avg Spend per Claim
	OXANDROLONE 2.5 MG TABLET	55	\$13,141.55	\$238.93
	OXANDROLONE 10 MG TABLET	5	\$2,597.57	\$519.51

Type of Criteria: Increased risk of ADE Preferred Drug List
 Appropriate Indications Clinical Edit

Data Sources: Only Administrative Databases Databases + Prescriber-Supplied

Setting & Population

- Drug class for review: Oxandrin® (oxandrolone)
- Age range: All appropriate MO HealthNet participants

Approval Criteria

- Diagnosis of bone pain associated with osteoporosis **OR**
- Diagnosis of protein catabolism associated with chronic corticosteroids **OR**
- To promote weight gain:
 - Documented history of extensive surgery, chronic infection, or severe trauma **OR**

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- Documented failure to gain or maintain at least 90% of ideal body weight due to underlying disease state (ex. COPD or AIDS) **OR**
- Approval based on clinical consultant review

Denial Criteria

- Therapy will be denied if all approval criteria are not met
- Participant is currently pregnant

Required Documentation

Laboratory Results:
MedWatch Form:

Progress Notes:
Other:

X

Disposition of Edit

Denial: Exception code "0682" (Clinical Edit)
Rule Type: CE

Default Approval Period

30 days

References

- Facts & Comparisons. Oxandrolone Oral. Accessed May 6, 2022.
- Clinical Pharmacology. Oxandrolone. Accessed May 6, 2022.