SmartPA Criteria Proposal

Drug/Drug Class:	Oxandrin Clinical Edit
First Implementation Date:	November 25, 2002
Proposed Date:	September 16, 2021
Prepared for:	MO HealthNet
Prepared by:	MO HealthNet/Conduent
Criteria Status:	☒Existing Criteria ☐Revision of Existing Criteria ☐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 7-1-2020 to 6-30-2021			
Drug	**Claims**	**Spend**	**Avg Spend per Claim**
OXANDROLONE 2.5 MG TABLET	57	$17,126.19	$300.45
OXANDROLONE 10 MG TABLET	4	$1,789.55	$447.38

Type of Criteria:
☐ **Increased risk of ADE**
☒ **Appropriate Indications**
☐ **Preferred Drug List**
☒ **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**

- 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:		Progress Notes:	
MedWatch Form:		Other:	X

Disposition of Edit

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

Default Approval Period

30 days

References

- Oxandrin® (oxandrolone tablets) [package insert]. East Brunswick, NJ: Savient Pharmaceuticals, Inc.; January 2006.
- Facts & Comparisons. Oxandrolone Oral. Accessed August 9, 2021.
- Clinical Pharmacology. Oxandrolone. Accessed August 9, 2021.