

Clinical Edit Criteria Proposal

Drug/Drug Class: Oxandrin® 10mg Tablets Clinical Edit
 Implementation Date: November 25, 2002
 Prepared for:
 Prepared by: Missouri Medicaid

New Criteria

Revision of Existing Criteria

Executive Summary

Purpose: Ensure appropriate utilization and control of Oxandrin 10mg Tablets.

Why was this Issue Selected:

Oxandrin® is indicated as adjunctive therapy to promote weight gain after weight loss following extensive surgery, chronic infections, or severe trauma in some patients who fail to gain or to maintain normal weight. Often this weight loss is without definite pathophysiologic reasons. This product is also indicated to offset the protein catabolism associated with prolonged administration of corticosteroids, and used for the relief of the bone pain associated with osteoporosis.

	Drug	Dosage Form	Cost per Dosage Form
Program-specific information:	• Oxandrin® Tablets	10mg tab	\$18.90 AWP
		2.5mg tab	\$5.57 AWP

Setting & Population: All patients.

Type of Criteria:

<input type="checkbox"/> Increased risk of ADE	<input type="checkbox"/> Non-Preferred Agent
<input checked="" type="checkbox"/> Appropriate Indications	<input type="checkbox"/>

Data Sources:

<input type="checkbox"/> Only administrative databases	<input checked="" type="checkbox"/> Databases + Prescriber-supplied
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Setting & Population

- Drug for review: Oxandrin® 10mg Tablets
- Age range: All ages
- Gender: Male and female

Approval Criteria

- Appropriate diagnosis – or inferred
 - Therapy to promote weight gain following:
 - Extensive Surgery
 - Chronic Infection
 - Severe Trauma
 - Therapy to offset protein catabolism associated with long-term use of corticosteroids
 - Treatment of bone pain associated with osteoporosis
- Therapy may be subject to review by a clinical consultant.

Denial Criteria

- Failure to meet approval criteria.

References:

1. Lippincott, Williams, Wilkins. PDR Electronic Library, Montvale NJ; 2002.
2. Facts and Comparisons, pg. 267 - 269; 2002.
3. USPDI, Micromedex; 2002.
4. Savient Pharmaceuticals, Inc. "Oxandrin.Com". 2004.

