

Clinical Edit Criteria Proposal

Drug/Drug Class: Raniclor[®] Chewable Tablets Clinical Edit
 Implementation Date: January 12, 2005
 Prepared for:
 Prepared by: Missouri Medicaid

New Criteria

Revision of Existing Criteria

Executive Summary

Purpose: Ensure appropriate utilization and control of Raniclor[®] (cefaclor chewable tablets).

Why was this Issue Selected:

This product is the first chewable cephalosporin tablet on the market and is available in 125mg, 187mg, 250mg, and 375mg strengths. This chewable antibiotic features twice a day or three times a day dosing regimens. The new dosage form offers an alternative to oral suspensions or capsules, and provides ease of dosing in patients that have difficulty swallowing capsules. Indications for this dosage form are no different than cefaclor capsules and suspensions. Compared to suspensions, the chewable tablet dosage form increases cost of therapy by 25% – 50%.

| Program-specific information: | Drug | Dosage Form | Cost per Dosage Form |
|-------------------------------|--------------------------------|-------------|----------------------|
| • | Raniclor [®] Chewtabs | 125mg tab | \$39.64 AWP |
| | | 187mg tab | \$39.64 AWP |
| | | 250mg tab | \$70.72 AWP |
| | | 375mg tab | \$70.72 AWP |

Setting & Population: All patients.

Type of Criteria:

Increased risk of ADE

Appropriate Indications

Non-Preferred Agent

Data Sources: Only administrative databases

Databases + Prescriber-supplied

Setting & Population

- Drug for review: Raniclor[®] 125mg, 187mg, 250mg, and 375mg (cefaclor chewable tablets)
- Age range: All ages
- Gender: Male and female

Approval Criteria

Patient is unable to take oral suspension or capsules due to:

- Allergy to ingredients in suspension, or capsules, or
- Documented ADE/ADR to cefaclor oral suspension, or capsules, or
- Trial of cefaclor suspension, or capsules, in the past 45 days.

Denial Criteria

- Failure to meet approval criteria.

References:

1. Lippincott, Williams, Wilkins. PDR Electronic Library, Montvale NJ; 2004.
2. Facts and Comparisons, pg. 1239 - 1245; 2004.
3. USPDI, Micromedex; 2004.

