



Clinical Edit Criteria Proposal

Drug/Drug Class: **Ranexa[®] (Ranolazine) Clinical Edit**
 Date: **June 30, 2011**
 Prepared for:
 Prepared by: **MO HealthNet**

New Criteria

Revision of Existing Criteria

Executive Summary

Purpose: To ensure appropriate utilization and control of Ranexa[®] (Ranolazine extended release tablets).

Why was this Issue Selected: Ranexa[®] is a branded drug product containing Ranolazine indicated for the treatment of chronic angina. Roughly 6.3 million Americans are estimated to experience angina. The prevalence of angina rises with an increase in age. This product represents the first new pharmaceutical approach to treat angina in more than 20 years in the United States. Ranexa may produce changes in the electrocardiogram (QT_c interval prolongation); therefore it should be reserved for use in patients as a combination therapy with another antianginal drug. Myocardial ischemia and symptoms of angina occur when there is a deficit of oxygen supply relative to oxygen demand. The focus of therapy has been to correct this imbalance by providing therapy which alters hemodynamic variables such as lowering of blood pressure, lowering of heart rate, and coronary vasodilation which improves myocardial oxygen supply. Ranexa improves diastolic relaxation to reduce myocardial workload and reduces resistance to coronary blood flow and thus reduces myocardial ischemia.

Program-specific information:	Drug	Cost/Month (WAC)
	Ranexa 500mg Tabs	\$165.00
	Ranexa 1000mg Tabs	\$331.20

Setting & Population: Patients 18 years of age and older

Type of Criteria:

Increased risk of ADE **Non-Preferred Agent**

Appropriate Indications **Other:**

Data Sources: Only administrative databases

Databases + Prescriber-supplied

Setting & Population

- Age range: Patients 18 years of age and older
- Gender: males and females

Approval Criteria

- Documented electrocardiogram (EKG) prior to therapy initiation
- Patient is 18 years of age or older
- **Concomitant therapy with one of the following:**
 - calcium channel blocker
 - beta blocker
 - ACE inhibitor
 - angiotensin receptor blocker
 - nitrates.
- **Patients taking diltiazem, verapamil or cyclosporine the dose of Ranexa is limited to 500 mg twice daily.**

Denial Criteria

- Claims for patients under 18 years of age (require clinical consultant review)
- Lack of adequate initial therapeutic intervention with a reference products (calcium channel blocker, beta blocker, ACE inhibitor, angiotensin receptor blocker or nitrates)
- **Patients with clinically significant hepatic impairment**
- **Concurrent use of products in contraindicated therapeutic classes**
 - **CYP3A and P-gp inducers**
 - Rifampin, rifabutin, rifapentin, phenobarbital, phenytoin, carbamazepine, St. John's wort
 - CYP3A inhibitors (potent)
 - Ketoconazole, macrolides, protease inhibitors
 - **Drugs transported by P-gp**
 - Digoxin
 - Drugs metabolized by CYP2D6
 - Tricyclic antidepressants, thioridazine, ziprasidone
 - Drugs that prolong QT_c interval
 - Quinidine, sotalol, erythromycin, Tikosyn



Required Documentation

Laboratory results:

MedWatch form:

Progress notes:

Disposition of Edit

- **Denial:** Edit 682 “Clinical Edit”

References

1. Lippincott, Williams, Wilkins. PDR Electronic Library, Montvale NJ; 2010.
2. Facts and Comparisons; 2010.
3. USPDI, Micromedex, 2010.
4. Gilead Sciences, Inc.; “Ranexa Package Insert”, Foster City, CA, 94404; 2010

