



## Prior Authorization Approval Criteria

### *Ranexa (ranolazine)*

<b>Generic name:</b>	Ranolazine
<b>Brand name:</b>	Ranexa
<b>Medication class:</b>	antianginal agent
<b>FDA-approved uses:</b>	chronic stable angina
<b>Available dosage forms:</b>	1000mg and 500mg tablets
<b>Usual dose:</b>	Initiate at 500mg twice a day and may increase to 1000mg twice a day.
<b>Approximate monthly cost:</b> (based on AWP 2010)	\$241.80/month for 500mg bid \$397.20/month for 1000mg bid
<b>Duration of therapy:</b>	Indefinite

**Criteria for use** (*bullet points below are all inclusive unless otherwise noted*):

- The indicated diagnosis (including any applicable labs and /or tests) and medication usage must be supported by documentation from the patient's medical records.
- Used as add on therapy for patients who remained symptomatic despite treatment with the maximum dose of combined anti-anginal therapy such as; nitrates, beta-blockers, and calcium channel blockers.
- Unable to take full doses of conventional angina drugs due to low blood pressure and heart rate.
- Blood pressure must be adequately controlled at 130/80 or less.

**Caution:**

- Increase risk of arrhythmias

**Monitoring:**

- Baseline and follow-up ECG's to evaluate Ranexa's effect of QT interval

**Contraindication:**

- Hepatic impairment (Child-Pugh Classes A and B).
- Combined administration with other drugs that are strong inhibitors of CYP3A including ketoconazole, itraconazole, clarithromycin, nefazodone, nelfinavir, ritonavir, indinavir, and saquinavir.
- Combined administration with other drugs that are inducers of CYP3A including rifampin, rifabutin, rifapentin, phenobarbital, phenytoin, carbamazepine, and St. John's wort.

**Not approved if:**

- Patient does not meet the above stated criteria
- Patient has any contraindications to the use of Ranexa

**Special considerations:**

- Patients have about 1 less angina episode per week.
- Ranolazine is less effective in women than in men.
- Doesn't lower blood pressure or heart rate like the others.
- Not for initial therapy because it can increase QT interval.
- If patient needs a calcium channel blocker (CCB) with ranolazine, amlodipine is recommended over other CCB's since it does not inhibit CYP3A4.

FCHP Pharmacy and Therapeutics Committee approval: \_\_\_\_\_

Date: \_\_\_\_\_

Adopted: 09/13/06

Updated: 09/08/10