Prior Authorization Approval Criteria

BiDil (isosorbide dinitrate 20 mg/hydralazine HCl 37.5 mg)

- Generic name: isosorbide dinitrate/hydralazine HCl
- Brand name: BiDil
- Medication class: Direct vasodilator
- FDA-approved uses: Treatment of heart failure as an adjunct to standard therapy in self-identified African-American patients to improve survival, to prolong time to hospitalization for heart failure, and to improve patient-reported functional status.
- Available dosage form: Tablet containing 20 mg isosorbide dinitrate and 37.5 mg hydralazine hydrochloride.
- Usual dose range: 1-2 tablets three times a day
- Duration of therapy: 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.
- Clinically diagnosed heart failure
- Patient must be self-identify as black/African-American
- Not to be used as monotherapy; must use some other treatment for heart failure

Contraindication: Allergy to organic nitrates.

Not approved if:
- Patient does not meet the above stated criteria
- Patient has any contraindications to the use of BiDil
- Patient is not African-American

FCHP Pharmacy and Therapeutics Committee approval: __________________________

Date: ______________________

Adopted: 10/12/05