



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
- Patient cannot use 2 separate medications at the same time (isosorbide and hydralazine).

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