



## Prior Authorization Approval Criteria

**BiDil (isosorbide dinitrate 20 mg/hydralazine HCL 37.5 mg)**

<b>Generic name:</b>	Gamma interferon
<b>Brand name:</b>	Actimmune
<b>Medication class:</b>	Direct vasodilator
<b>FDA-approved uses:</b>	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.
<b>Available dosage form:</b>	Tablet containing 20 mg isosorbide dinitrate and 37.5 mg hydralazine hydrochloride.
<b>Usual dose range:</b>	1-2 tablets three times a day
<b>Duration of therapy:</b>	Indefinite

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

- 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 must have an inability (other than non-compliance) to use the individual agents (isosorbide and hydralazine) at the same time.

**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