



Prior Authorization Approval Criteria

Brovana (arformoterol)

Generic name:	Arformoterol
Brand name:	Brovana
Medication class:	Long-actins beta-2 agonist
FDA-approved uses:	Long term maintenance treatment of bronchoconstriction in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and emphysema.
Available dosage forms:	Inhalation solution for use by nebulization. 15 mcg of arformoterol as 2 ml of a sterile solution in cartons of 30 or 60 unit-doses (individually pouched vials).
Usual dose range:	15 mcg administered twice daily by nebulization. Doses greater than 30 mcg per day is not recommended.
Duration of therapy:	Indefinite
Cost (based on AWP 2007):	\$350.00 for 15 mcg twice daily per month

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

- Clinically diagnosed COPD.
- Failed or intolerant to Foradil (formoterol).
- Failed or intolerant to Serevent (salmeterol).

OR

- Patient unable to use an inhaler.

Caution:

- The drug compatibility, efficacy, and safety of Brovana when mixed with other drugs in a nebulizer have not been established.

Contraindications:

- Patients with a history of hypersensitivity to arformoterol, racemic formoterol or to any other components of this product.

Not approved if:

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

Special considerations:

- Must be stored refrigerated in individual unit-dose, low-density polyethylene (LDPE) vials sealed in single foil pouches, and should be used immediately after opening. Unopened foil pouches may be stored at room temperature for up to 6 weeks, at which point any unused product must be discarded.

- Brovana safety and efficacy has only been established in clinical trials when administered using the PARI LC PLUS nebulizers and PARI DURA-NEB 3000 compressors. The safety and efficacy of Brovana when administered using other nebulizer systems has not been established.
- Arformoterol is the (R, R)-enantiomer of formoterol (Foradil).
- One study compared 3 doses of arformoterol to placebo and to salmeterol metered-dose inhaler. Mean percentage change from baseline FEV-1 over 12 weeks was +16.9% for arformoterol, +6% for placebo and +17.4% for salmeterol. Clinically meaningful improvements in dyspnea at 12 weeks were 57-62% for arformoterol, 37% for placebo and 50% for salmeterol. Exacerbation frequency was similar in all groups. There were no significant differences between groups in improvements in the 6-minute walk test.
- Brovana does not offer clinical advantages beyond offering options to patients who cannot use dry powder inhalers.

Some inhaled drugs for maintenance treatment of COPD (Medical Letter, July 2, 2007):

<i>Drug</i>	<i>Formulation</i>	<i>Delivery device</i>	<i>Daily dosage</i>	<i>Cost¹</i>
Long-acting beta-2 agonists				
Salmeterol (Serevent Diskus)	Powder 50 mcg/blister	DPI	50 mcg bid	\$120.27
Formoterol (Foradil Aerolizer)	Powder 12 mcg/capsule	DPI	12 mcg bid	\$117.90
Formoterol (Perforomist)	Solution 20 mcg/2 mL	Nebulizer	20 mcg bid	N/A
Arformoterol (Brovana)	Solution 15 mcg/2 mL	Nebulizer	15 mcg bid	\$350.00 ²
Long-acting anticholinergic				
Tiotropium – Spiriva	Powder 18 mcg/cap	DPI	18 mcg once	\$134.33
Corticosteroid/beta-2 agonist combinations				
Fluticasone/salmeterol (Advair Diskus)	Powder 100/50 mcg 250/50 mcg; 500/50 mcg blister ³	DPI	1 inhalation bid	\$185.22
Advair HFA ⁴	Suspension 45, 115, 230 mcg/21 mcg	MDI	2 inhalations BID	\$159.02 \$270.29
Budesonide/formoterol (Symbicort) ⁴	Powder 80 or 160 mcg 4.5 mcg	DPI	2 inhalations BID	\$165.65 \$189.34 ⁵

DPI = Dry powder inhaler, MDI = Metered dose inhaler, N/A = Price not yet available.

1. Cost for 30 days' treatment, according to AWP listings in Red Book 2007.

2. Wholesale acquisition cost, according to the manufacturer.

3. Only the 250/50 mcg dose is FDA-approved for use in COPD.

4. Only approved for treatment of asthma.

5. Cost according to AWP listings in Price Alert, June 15, 2007.

FCHP Pharmacy and Therapeutics Committee approval: _____

Date: _____

Adopted: 09/12/07