AvMed HEALTH PLANS

# *Title: arformoterol (Brovana) Or formoterol (Perforomist)*

| **Origination:** 08/22/07 | **Revised:** 10/08/09 | **Annual Review:** 12/15/11 |
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## **Purpose:**

To provide guidelines and criteria for the review and decision determination of requests for medications that requires prior authorization.

## **Background Information:**

### *Medication Summary*

- Brovana (arformoterol tartrate) and Perforomist (formoterol) Inhalation Solutions are indicated for long-term maintenance treatment of bronchoconstriction in chronic obstructive pulmonary disease (COPD), including chronic bronchitis and emphysema. Both medications are administered twice daily (in the morning and evening) via nebulizer.
- Brovana (arformoterol tartrate) and Perforomist (formoterol) are NOT indicated for use in asthma.

### *Exclusions*

- Member with history of hypersensitivity to arformoterol, formoterol, or any other components of the product.

### *Reference Statement*

- Guidelines are compiled from available US Food and Drug Administration (FDA) approved indications, general practice guidelines, and/or evidence-based uses established through phase III clinical studies without published conflicting data. Only clinical studies published in their entirety in reputable peer-reviewed journals will be evaluated.

### *Eligibility Criteria*

- Member must be eligible and have applicable benefit coverage (i.e., self-injectable rider) within the specified date(s) of service.
- Prior authorization requests that do not meet clinical criteria in this Procedure will be forwarded to a Clinical Pharmacist for review.

# *Title: arformoterol (Brovana) Or formoterol (Perforomist)*

**Procedure:**

1.0 Request for *initial therapy* with Brovana or Perforomist for **maintenance treatment** of **chronic obstructive pulmonary disease (COPD)** requires documentation from the Member's medical records maintained by the requesting independent practitioner verifying the following:

1.1 Diagnosis of COPD by **one (1)** of the following:

1.1.1 Presence of signs and symptoms of COPD including, but not limited to the following:

1.1.1.1 Chronic cough;

1.1.1.2 Increased sputum production;

1.1.1.3 Dyspnea (shortness of breath);

1.1.1.4 History of exposure to risk factors for disease (ex. tobacco smoke, occupational dust and chemicals); **AND**

1.1.2 Pulmonary function tests showing reduced FEV1 (<80% predicted), FVC (<70% predicted), or FEV1/FVC ratio less than 70%;

**AND**

1.2 Documented improper use of metered-dose inhalers that could not be corrected by use of spacers, masks, or additional instruction on technique; **OR**

1.2 Documented failure of formoterol (Foradil) MDI therapy; **OR**

1.2 Documented side effects or contraindication to the use of formoterol (Foradil) MDI that would not be expected with Brovana or Perforomist;

1.3 If Member meets criteria, initial therapy with Brovana or Perforomist may be approved for up to six (6) months.

2.0 Request for *continuation therapy* beyond initial authorization period for COPD requires documentation from the Member's medical records maintained by the requesting independent practitioner verifying the following:

2.1 Reduction in Member's signs and symptoms (ex. decreased cough and sputum production, decreased shortness of breath, improvement in pulmonary function tests [PFTs] from baseline); **AND**

2.2 Tolerance to therapy as evidenced by lack of documented side effects;

2.3 If Member meets criteria, Brovana or Perforomist may be approved for one (1) year.

**References:**

***Title:* arformoterol (Brovana) Or formoterol (Perforomist)**


1. Brovana (arformoterol), Package Insert, Sepracor, Inc Marlborough, MA. August 2008.

2. Perforomist (formoterol fumarate), Package Insert, Dey L.P, Napa, CA, 2008.

3. Global Initiative for Chronic Obstructive Lung Disease. Global strategy for diagnosis, management, and prevention of chronic obstructive pulmonary disease, 2008. [Online] cited [2009 Sep 30].


**Disclaimer Information:**

Prior Authorization criteria are developed to determine coverage for AvMed Health Plans' benefits, and are published to provide a better understanding of the basis upon which coverage decisions are made. AvMed Health Plans makes coverage decisions based on the Member's benefit plan contract and these criteria. This guideline sets forth concise clinical coverage criteria which have been developed from a review of current literature, policies of the FDA and other government agencies, and other appropriate references, in consultation and with approval from practicing physicians who are members of AvMed's Pharmacy and Therapeutic committee. Treating providers are solely responsible for the medical advice and treatment of Members. This guideline may be updated and therefore is subject to change. The use of these criteria is neither a guarantee of payment nor a final prediction of how specific claim(s) will be adjudicated.