Clinical Policy Title:	arformoterol tartrate
Policy Number:	RxA.33
Drug(s) Applied:	Brovana®
Original Policy Date:	02/07/2020
Last Review Date:	03/09/2021
Line of Business Policy Applies to:	All lines of business

Background

Arformoterol tartrate (Brovana®) is long-acting beta2 agonist (LABA). It is indicated for:

- Long-term, twice daily (morning and evening) administration in the maintenance treatment of bronchoconstriction in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and emphysema.

Limitation(s) of use: Brovana® is not indicated to treat asthma or acute deteriorations (e.g., acute bronchospasms) of COPD.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
Arformoterol tartrate (Brovana®)	COPD	One 15 mcg/2 mL vial inhaled via nebulizer every 12 hours	30 mcg/day

Dosage Forms

- Inhalation solution (unit-dose vial for nebulization): 15 mcg/2 mL

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

I. Initial Approval Criteria

A. Chronic Obstructive Pulmonary Disease (must meet all)**:**

1. Diagnosis of COPD;
2. Age 18 years of age or older;
3. Documentation supports inability to use inhaler devices;
4. Dose does not exceed 30 mcg per day (2 vials per day.

Approval Duration

Commercial: 12 months

Medicaid: 12 months

II. Continued Therapy Approval

A. Chronic Obstructive Pulmonary Disease (must meet all):

1. Member is currently receiving medication that has been authorized by RxAdvance or member has previously met initial approval criteria listed in this policy;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 30 mcg per day (2 vials per day).

Approval Duration
Commercial: 12 months
Medicaid: 12 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key
COPD: chronic obstructive pulmonary disease
FDA: Food and Drug Administration
LABA: long-acting $beta_2$ adrenergic agonist

APPENDIX B: Therapeutic Alternatives
Not applicable

APPENDIX C: Contraindications/Boxed Warnings

- Contraindication(s):
  - History of hypersensitivity to arformoterol, racemic formoterol or to any other components of this product;
  - All LABAs, including arformoterol, are contraindicated in patients with asthma without use of a long-term inhaled corticosteroid.

- Boxed Warning(s):
  - None.

APPENDIX D: General Information

- Brovana® helps the muscles around the airways in your lungs stay relaxed to prevent COPD symptoms, such as wheezing, coughing, chest tightness, and shortness of breath.
- In clinical studies, Brovana® was shown to improve lung function for up to 12 hours at a time. People in clinical studies reported that they used their rescue inhalers less often when taking Brovana®.
- Brovana® is taken with a nebulizer, which converts medicine into a fine, breathable mist.

References

1. Brovana Prescribing Information. Marlborough, MA: Sunovion Pharmaceuticals Inc.; May 2019. Available at http://www.brovana.com. Accessed January 29, 2021.
2. Global Initiative for Chronic Obstructive Lung Disease (GOLD): Global strategy for the diagnosis, management, and prevention of chronic obstructive pulmonary disease (2019 report). Available from: http://www.goldcopd.org/. Accessed January 29, 2021.
3. Arformoterol. Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI; 2019, December 19. Accessed with subscription at: http://www.micromedexsolutions.com. Accessed January 29, 2021.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	01/2020	02/07/2020
Policy was reviewed:	01/29/2021	03/09/2021

1) Clinical policy title was updated as “arformoterol tartrate”. 2) Line of business policies applies to All lines of business. 3) Continuation therapy criteria II.A.1. rephrased to “Member is currently receiving medication that has been authorized by RxAdvance or the member has met initial approval criteria listed in this policy.” 4) Appendix D was updated. 5) References were reviewed and updated.		