LOUISIANA BLUE

Select Inhaled Respiratory Agents

Policy # 00526
Original Effective Date: 01/01/2017
Current Effective Date: 04/01/2025

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Inhaled Corticosteroid Products

Based on review of available data, the Company may consider the inhaled corticosteroid products Aerospan®‡ (flunisolide), Alvesco®‡ (ciclesonide), Asmanex®‡ Twisthaler®‡ (mometasone furoate), Asmanex®‡ HFA (mometasone furoate), Armonair™‡ Respiclick®‡ (fluticasone propionate), Armonair Digihaler™‡ (fluticasone propionate), and branded generic Fluticasone Propionate HFA to be **eligible for coverage**** when the below patient selection criterion is met:

Patient Selection Criteria

Coverage eligibility will be considered for Aerospan (flunisolide), Alvesco (ciclesonide), Asmanex Twisthaler (mometasone furoate), Asmanex HFA (mometasone furoate), Armonair Respiclick (fluticasone propionate), Armonair Digihaler (fluticasone propionate), or branded generic Fluticasone Propionate HFA when the following criterion is met:

- There is clinical evidence or patient history that suggests the use of Arnuity™‡ Ellipta®‡ (fluticasone furoate), QVAR®‡ (beclomethasone dipropionate), or Pulmicort Flexhaler®‡ (budesonide) will be/was ineffective or will/did cause an adverse reaction to the patient; OR
- Patient is younger than 6 years of age AND requested drug is branded generic Fluticasone Propionate HFA.

When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of Aerospan (flunisolide), Alvesco (ciclesonide), Asmanex Twisthaler (mometasone furoate), Asmanex HFA (mometasone furoate), Armonair Respiclick (fluticasone propionate), Armonair Digihaler (fluticasone propionate), or branded generic Fluticasone Propionate HFA WITHOUT clinical evidence or patient history that suggests the use of Arnuity Ellipta (fluticasone furoate), QVAR (beclomethasone propionate), or Pulmicort Flexhaler (budesonide) will be/was ineffective or will/did cause an adverse reaction to the patient to be **not medically necessary.****

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- *Medical necessity criteria and guidelines are met.*

Inhaled Long Acting Beta Agonists (LABAs)

Based on review of available data, the Company may consider the inhaled long acting beta agonists Arcapta™‡ Neohaler™‡ (indacaterol) and Foradil®‡ Aerolizer®‡ (formoterol fumarate) to be **eligible for coverage**** when the below patient selection criterion is met:

Patient Selection Criteria

Coverage eligibility will be considered for Arcapta Neohaler (indacaterol) or Foradil Aerolizer (formoterol fumarate) when the following criterion is met:

- There is clinical evidence or patient history that suggests the use of Striverdi®‡ Respimat®‡ (olodaterol) or Serevent®‡ Diskus (salmeterol xinafoate) will be/was ineffective or will/did cause an adverse reaction to the patient.

When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of Arcapta Neohaler (indacaterol) or Foradil Aerolizer (formoterol fumarate) WITHOUT clinical evidence or patient history that suggests the use of Striverdi Respimat (olodaterol) or Serevent Diskus (salmeterol xinafoate) will be/was ineffective or will/did cause an adverse reaction to the patient to be **not medically necessary.****

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Nebulized Long Acting Chronic Obstructive Pulmonary Disease (COPD) Products

Based on review of available data, the Company may consider the nebulized long acting COPD products Brovana®‡ (arformoterol tartrate), generic arformoterol tartrate, Perforomist®‡ (formoterol fumarate), generic formoterol fumarate, Lonhala™‡ Magnair™‡ (glycopyrrolate), and Yupelri®‡ (revefenacin) to be **eligible for coverage**** when the below patient selection criteria are met:

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Coverage eligibility will be considered for Brovana (arformoterol tartrate), generic arformoterol tartrate, Perforomist (formoterol fumarate), generic formoterol fumarate, Lonhala Magnair (glycopyrrolate), or Yupelri (revefenacin) when the following criteria are met:

- For all requested products: There is clinical evidence or patient history that suggests the use of TWO of the following preferred bronchodilating agents for COPD: generic fluticasone propionate/salmeterol diskus^, Wixela™‡ Inhub^ (fluticasone propionate/salmeterol), Serevent Diskus (salmeterol xinafoate), Spiriva®‡ Respimat®‡ (tiotropium bromide), Spiriva HandiHaler®‡ (tiotropium bromide), Anoro®‡ Ellipta (umeclidinium/vilanterol), Stiolto®‡ Respimat (tiotropium bromide/olodaterol), Striverdi Respimat (olodaterol), Incruse®‡ Ellipta (umeclidinium), Symbicort®‡ (budesonide/formoterol fumarate dihydrate), or generic budesonide/formoterol fumarate dihydrate (Breyna, budesonide/formoterol fumarate dihydrate) will be/was ineffective or will/did cause an adverse reaction to the patient; AND
- If the request is for Brovana (arformoterol tartrate) or Perforomist (formoterol fumarate), the following criterion must ALSO be met: There is clinical evidence or patient history that suggests the use of the generic equivalent product (arformoterol for Brovana requests or formoterol for Perforomist requests) will be/was ineffective or will/did cause an adverse reaction to the patient.

^*Note that the use of more than one generic equivalent of Advair®‡ Diskus only counts as one product*

When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of Brovana (arformoterol tartrate), generic arformoterol tartrate, Perforomist (formoterol fumarate), generic formoterol fumarate, Lonhala Magnair (glycopyrrolate), or Yupelri (revefenacin) WITHOUT clinical evidence or patient history that suggests the use of TWO of the following preferred bronchodilating agents for COPD: generic fluticasone propionate/salmeterol diskus, Wixela Inhub (fluticasone propionate/salmeterol), Serevent Diskus (salmeterol xinafoate), Spiriva Respimat (tiotropium bromide), Spiriva HandiHaler (tiotropium bromide), Anoro Ellipta (umeclidinium/vilanterol), Stiolto Respimat (tiotropium bromide/olodaterol), Striverdi Respimat (olodaterol), Incruse Ellipta (umeclidinium), Symbicort (budesonide/formoterol fumarate dihydrate), or generic budesonide/formoterol fumarate dihydrate (Breyna, budesonide/formoterol fumarate dihydrate) will be/was ineffective or will/did cause an adverse reaction to the patient to be **not medically necessary.****

Based on review of available data, the Company considers the use of Brovana (arformoterol tartrate), or Perforomist (formoterol fumarate) WITHOUT clinical evidence or patient history that suggests the use of the generic equivalent product (arformoterol for Brovana requests or formoterol for Perforomist requests) will be/was ineffective or will/did cause an adverse reaction to the patient to be **not medically necessary.****

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- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Inhaled Corticosteroid/Long Acting Beta Agonist Combination Products (ICS/LABAs)

Based on review of available data, the Company may consider the inhaled corticosteroid/long acting beta agonist combination products AirDuo™‡ Respiclick (fluticasone propionate/salmeterol), AirDuo Digihaler (fluticasone propionate/salmeterol), Advair Diskus (fluticasone propionate/salmeterol), branded generic Fluticasone furoate/Vilanterol, and branded generic Fluticasone propionate/Salmeterol HFA to be **eligible for coverage**** when the below patient selection criterion is met:

Patient Selection Criteria

Coverage eligibility will be considered for AirDuo Respiclick (fluticasone propionate/salmeterol), AirDuo Digihaler (fluticasone propionate/salmeterol), Advair Diskus (fluticasone propionate/salmeterol), branded generic Fluticasone furoate/Vilanterol, or branded generic Fluticasone propionate/Salmeterol HFA when the following criterion is met:

- There is clinical evidence or patient history that suggests the use of generic fluticasone propionate/salmeterol diskus, Wixela Inhub (fluticasone propionate/salmeterol), Advair HFA (fluticasone propionate/salmeterol), Breo®‡ Ellipta (fluticasone furoate/vilanterol), the branded generic Fluticasone Propionate/Salmeterol (branded generic of AirDuo Respiclick), Dulera®‡ (mometasone furoate/formoterol furoate), or generic budesonide/formoterol fumarate dihydrate (Breyna, budesonide/formoterol fumarate dihydrate) will be/was ineffective or will/did cause an adverse reaction to the patient.

When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of AirDuo Respiclick (fluticasone propionate/salmeterol), AirDuo Digihaler (fluticasone propionate/salmeterol), Advair Diskus (fluticasone propionate/salmeterol), branded generic Fluticasone furoate/Vilanterol, or branded generic Fluticasone propionate/Salmeterol HFA WITHOUT clinical evidence or patient history that suggests the use of generic fluticasone propionate/salmeterol diskus, Wixela Inhub (fluticasone propionate/salmeterol), Advair HFA (fluticasone propionate/salmeterol), Breo Ellipta (fluticasone furoate/vilanterol), the branded generic Fluticasone Propionate/Salmeterol (branded generic of AirDuo Respiclick), Dulera (mometasone furoate/formoterol furoate), or generic budesonide/formoterol fumarate dihydrate (Breyna, budesonide/formoterol fumarate dihydrate) will be/was ineffective or will/did cause an adverse reaction to the patient to be **not medically necessary.****

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- *Medical necessity criteria and guidelines are met.*

Inhaled Long Acting Antimuscarinic Agents (LAMAs)

Based on review of available data, the Company may consider the inhaled long acting antimuscarinic agents Tudorza®‡ Pressair®‡ (aclidinium bromide) and Seebri™‡ Neohaler (glycopyrrolate) to be **eligible for coverage**** when the below patient selection criterion is met:

Patient Selection Criteria

Coverage eligibility will be considered for Tudorza Pressair (aclidinium bromide) or Seebri Neohaler (glycopyrrolate) when the following criterion is met:

- There is clinical evidence or patient history that suggests the use of Spiriva Respimat (tiotropium bromide), Spiriva HandiHaler (tiotropium bromide), or Incruse Ellipta (umeclidinium) will be/was ineffective or will/did cause an adverse reaction to the patient.

When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of Tudorza Pressair (aclidinium bromide) or Seebri Neohaler (glycopyrrolate) WITHOUT clinical evidence or patient history that suggests the use of Spiriva Respimat (tiotropium bromide), Spiriva HandiHaler (tiotropium bromide), or Incruse Ellipta (umeclidinium) will be/was ineffective or will/did cause an adverse reaction to the patient to be **not medically necessary.****

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Inhaled Long Acting Antimuscarinic Agent/Long Acting Beta Agonist Combination Products (LAMA/LABAs)

Based on review of available data, the Company may consider the inhaled long acting antimuscarinic agent/long acting beta agonist combination products Bevespi Aerosphere™‡ (glycopyrrolate/formoterol fumarate), Utibron™‡ Neohaler (indacaterol/glycopyrrolate), and Duaklir®‡ Pressair (aclidinium/formoterol fumarate) to be **eligible for coverage**** when the below patient selection criterion is met:

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Patient Selection Criteria
Coverage eligibility will be considered for Bevespi Aerosphere (glycopyrrolate/formoterol fumarate), Utibron Neohaler (indacaterol/glycopyrrolate), or Duaklir Pressair (aclidinium/formoterol fumarate) when the following criterion is met:

- There is clinical evidence or patient history that suggests the use of Anoro Ellipta (umeclidinium/vilanterol) or Stiolto Respimat (tiotropium bromide/olodaterol) will be/was ineffective or will/did cause an adverse reaction to the patient.

When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of Bevespi Aerosphere (glycopyrrolate/formoterol fumarate), Utibron Neohaler (indacaterol/glycopyrrolate), or Duaklir Pressair (aclidinium/formoterol fumarate) WITHOUT clinical evidence or patient history that suggests the use of Anoro Ellipta (umeclidinium/vilanterol) or Stiolto Respimat (tiotropium bromide/olodaterol) will be/was ineffective or will/did cause an adverse reaction to the patient to be **not medically necessary.****

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Inhaled Short Acting Beta Agonists (SABAs)

Based on review of available data, the Company may consider the short acting beta agonists Proventil®‡ HFA (albuterol sulfate), Xopenex®‡ HFA (levalbuterol tartrate), ProAir®‡ Digihaler (albuterol sulfate), branded generic Levalbuterol HFA, branded generic Albuterol HFA, and ProAir HFA (albuterol sulfate) to be **eligible for coverage**** when the below patient selection criterion is met:

Patient Selection Criteria
Coverage eligibility will be considered for Proventil HFA (albuterol sulfate), Xopenex HFA (levalbuterol tartrate), ProAir Digihaler (albuterol sulfate), branded generic Levalbuterol HFA, branded generic Albuterol HFA, or ProAir HFA (albuterol sulfate) when the following criterion is met:

- There is clinical evidence or patient history that suggests the use of ProAir RespiClick (albuterol sulfate), Ventolin®‡ HFA (albuterol sulfate), or generic albuterol sulfate HFA will be/was ineffective or will/did cause an adverse reaction to the patient.

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When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of Proventil HFA (albuterol sulfate), Xopenex HFA (levalbuterol tartrate), ProAir Digihaler (albuterol sulfate), branded generic Levalbuterol HFA, branded generic Albuterol HFA, or ProAir HFA (albuterol sulfate) WITHOUT clinical evidence or patient history that suggests the use of ProAir RespiClick (albuterol sulfate), Ventolin HFA (albuterol sulfate), or generic albuterol sulfate HFA will be/was ineffective or will/did cause an adverse reaction to the patient to be **not medically necessary.****

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Inhaled Short Acting Beta Agonists/ Inhaled Corticosteroid Combination Products (SABAs/ICS)

Based on review of available data, the Company may consider the short acting beta agonists/inhaled corticosteroid combination product Airsupra™‡ (albuterol sulfate/budesonide), to be **eligible for coverage**** when the below patient selection criterion is met:

Patient Selection Criteria

Coverage eligibility will be considered for Airsupra (albuterol sulfate/budesonide) when the following criterion is met:

- There is clinical evidence or patient history that suggests the use of ProAir RespiClick (albuterol sulfate), Ventolin HFA (albuterol sulfate), or generic albuterol sulfate HFA AND Arnuity Ellipta (fluticasone furoate), QVAR (beclomethasone dipropionate), or Pulmicort Flexhaler (budesonide) will be/was ineffective or will/did cause an adverse reaction to the patient.

When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of Airsupra (albuterol/budesonide) WITHOUT clinical evidence or patient history that suggests the use of ProAir RespiClick (albuterol sulfate), Ventolin HFA (albuterol sulfate), or generic albuterol sulfate HFA AND Arnuity Ellipta (fluticasone furoate), QVAR (beclomethasone dipropionate), or Pulmicort Flexhaler (budesonide) will be/was ineffective or will/did cause an adverse reaction to the patient to be **not medically necessary.****

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Schematic

Class	Non-Preferred Products	Preferred Products
Inhaled Corticosteroids (ICS)	Aerospan Alvesco Asmanex Twisthaler Asmanex HFA Armonair Respiclick Armonair Digihaler Branded Generic Fluticasone Propionate HFA	Arnuity Ellipta QVAR Pulimcort Flexhaler
Inhaled Long Acting Beta Agonists (LABAs)	Arcapta Neohaler Foradil Aerolizer	Striverdi Respimat Serevent Diskus
Nebulized Long Acting COPD Products	Brovana arformoterol tartrate Perforomist formoterol fumarate Lonhala Magnair Yupelri	Generic fluticasone/salmeterol diskus^ Wixela Inhub^ Serevent Diskus Spiriva Respimat Spiriva HandiHaler Anoro Ellipta Stiolto Respimat Striverdi Respimat Incruse Ellipta Breyna (generic of Symbicort) Generic budesonide/formoterol fumarate
Inhaled Corticosteroids/Long Acting Beta Agonists (ICS/LABAs)	AirDuo Respiclick AirDuo Digihaler Advair Diskus Branded Generic Fluticasone/Vilanterol Branded Generic Fluticasone/Salmeterol HFA	Generic fluticasone/salmeterol diskus Wixela Inhub Advair HFA Breo Ellipta Breyna (generic of Symbicort) Generic budesonide/formoterol fumarate Fluticasone/Salmeterol-(branded generic of AirDuo Respiclick) Dulera
Inhaled Long Acting Antimuscarinic Agents (LAMAs)	Tudorza Pressair Seebri Neohaler	Spiriva Respimat Spiriva HandiHaler Incruse Ellipta

Inhaled Long Acting Antimuscarinic Agents/Long Acting Beta Agonists (LAMA/LABA)	Utibron Neohaler Bevespi Aerosphere Duaklir Pressair	Anoro Ellipta Stiolto Respimat
Inhaled Short Acting Beta Agonists (SABAs)	Proventil HFA Xopenex HFA Branded Generic Albuterol HFA ProAir Digihaler Branded Generic Levalbuterol HFA ProAir HFA	ProAir RespiClick Ventolin HFA Generic albuterol HFA
Inhaled Short Acting Beta Agonists/ Inhaled Corticosteroids (SABA/ICS)	Airsupra	ProAir RespiClick Ventolin HFA Generic albuterol HFA Arnuity Ellipta QVAR Pulimcort Flexhaler

^*Note that the use of more than one generic equivalent of Advair Diskus only counts as one product*

Background/Overview

The various products mentioned in this policy are approved for use in COPD and/or asthma patients, depending on the particular product.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

The patient selection criteria presented in this policy takes into consideration clinical evidence or patient history that suggests the preferred products listed in this policy will be ineffective or cause an adverse reaction to the patient. Based on a review of the available data and in the absence of any of the caveats mentioned, there is no advantage of using the non-preferred agents mentioned in this policy over the preferred agents mentioned in this policy.

References

1. Advair Diskus [package insert]. GlaxoSmithKline. Research Triangle Park, North Carolina. Updated April 2016.
2. Advair HFA [package insert]. GlaxoSmithKline. Research Triangle Park, North Carolina. Updated December 2014.
3. Aerospan [package insert]. Meda Pharmaceuticals. Somerset, New Jersey. Updated June 2015.
4. Alvesco [package insert]. Sunovion Pharmaceuticals, Inc. Marlborough, Massachusetts. January 2013.
5. Anoro Ellipta [package insert]. GlaxoSmithKline. Research Triangle Park, North Carolina. Updated February 2016.
6. Arcapta Neohaler [package insert]. Novartis. East Hanover, New Jersey. Updated September 2012.
7. Arnuity Ellipta [package insert]. GlaxoSmithKline. Research Triangle Park, North Carolina. Updated November 2014.
8. Asmanex HFA [package insert]. Merck and Company. Whitehouse Station, New Jersey. Updated July 2016.
9. Asmanex Twisthaler [package insert]. Merck and Company. Whitehouse Station, New Jersey. September 2014.
10. Breo Ellipta [package insert]. GlaxoSmithKline. Research Triangle Park, North Carolina. Updated July 2016.
11. Brovana [package insert]. Sunovion Pharmaceuticals. Marlborough, Massachusetts. Updated February 2014.
12. Dulera [package insert]. Merck. Whitehouse Station, New Jersey. Updated July 2016.
13. Flovent Diskus [package insert]. GlaxoSmithKline. Research Triangle Park, North Carolina. Updated May 2014.
14. Flovent HFA [package insert]. GlaxoSmithKline. Research Triangle Park, North Carolina. Updated July 2016.
15. Foradil Aerolizer [package insert]. Merck. Whitehouse Station, New Jersey. Updated September 2012.
16. Incruse Ellipta {package insert}. GlaxoSmithKline. Research Triangle Park, North Carolina. Updated February 2016.
17. Perforomist [package insert]. Mylan Specialty. Morgantown, West Virginia. Updated March 2013.
18. ProAir HFA [package insert]. Teva. Frazer, Pennsylvania. Updated June 2016.
19. ProAir Respiclick [package insert]. Frazer, Pennsylvania. Updated April 2016.
20. Proventil HFA [package insert]. Merck. Whitehouse Station, New Jersey. Updated December 2014.
21. Pulmicort Flexhaler [package insert[. AstraZeneca. Wilmington, Delaware. Updated July 2010.
22. Qvar [package insert]. Teva Respiratory, LLC. Horsham, Pennsylvania. Updated July 2014.
23. Seebri Neohaler. [package insert]. Novartis. East Hanover, New Jersey. Updated January 2016.

24. Serevent Diskus [package insert]. GlaxoSmithKline. Research Triangle Park, North Carolina. Update unknown.
25. Spiriva Respimat [package insert]. Boehringer Ingelheim. Ridgefield, Connecticut. Updated June 2016.
26. Spiriva Handihaler [package insert]. Boehringer Ingelheim. Ridgefield, Connecticut. Updated January 2016.
27. Stiolto Respimat [package insert]. AstraZeneca. Wilmington, Delaware. Updated June 2016.
28. Striverdi Respimat [package insert]. Boehringer Ingelheim. Ridgefield, Connecticut. Updated June 2016.
29. Symbicort [package insert]. AstraZeneca. Wilmington, Delaware. Updated February 2016.
30. Tudorza Pressair [package insert]. AstraZeneca. Wilmington, Delaware. Updated March 2016.
31. Utibron Neohaler [package insert]. Novartis. East Hanover, New Jersey. Updated January 2016.
32. Ventolin HFA [package insert]. GlaxoSmithKline. Research Triangle Park, North Carolina. Updated December 2014.
33. Xopenex HFA [package insert]. Sunovion. Marlborough, Massachusetts. Updated March 2015.
34. Bevespi Aerosphere [package insert]. AstraZeneca. Wilmington, Delaware. Updated April 2016.
35. AirDuo Respiclick [package insert]. Teva. Frazer, Pennsylvania. Updated January 2017.
36. Armonair Respiclick [package insert]. Teva. Frazer, Pennsylvania. Updated January 2017.
37. Trelegy Ellipta [package insert]. GlaxoSmithKline. Research Triangle Park, North Carolina. Updated September 2017.
38. Lonhala Magnair [package insert]. Sunovion. Germany. January 2018.
39. Wixela Inhub [package insert]. Mylan Pharmaceuticals, Inc. Morgantown, West Virginia. Updated January 2019.
40. Fluticasone/salmeterol diskus. Prasco Laboratories. Mason, Ohio. Updated January 2019.
41. Albuterol Sulfate HFA. Ivax Pharmaceuticals. Waterford, Ireland. Updated January 2019.
42. Yupelri [package insert]. Mylan Specialty. Morgantown, West Virginia. Updated May 2019.
43. Budesonide/formoterol fumarate [package insert]. Astra Zenica. Wilmington, Delaware. Updated July 2019.
44. Duaklir Pressair [package insert]. AstraZeneca. Wilmington, Delaware. Updated February 2020.
45. ProAir Digihaler [package insert]. Teva Pharmaceuticals. Parsippany, New Jersey. Updated September 2019.
46. AirDuo Digihaler [package insert]. Teva Pharmaceuticals. Parsippany, New Jersey. Updated July 2019.
47. Armonair Digihaler [package insert]. Teva Pharmaceuticals. Parsippany, New Jersey. Updated February 2020.
48. Breztri Aerosphere [package insert]. AstraZeneca. Wilmington, Delaware. Updated July 2020.
49. Fluticasone propionate HFA [package insert]. Prasco Laboratories. Mason, Ohio. Updated May 2022.
50. Fluticasone furoate and vilanterol [package insert]. Prasco Laboratories. Mason, Ohio. Updated February 2022.

51. Fluticasone propionate and salmeterol [package insert]. Prasco Laboratories. Mason, Ohio. Updated August 2022.
52. Airsupra [package insert]. AstraZeneca. Wilmington, Delaware. Updated January 2023.

Policy History

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09/08/2016	Medical Policy Committee review
09/21/2016	Medical Policy Implementation Committee approval. New policy.
08/03/2017	Medical Policy Committee review
08/23/2017	Medical Policy Implementation Committee approval. Moved Stiolto Respimat to a preferred agent. New drug (AirDuo) placed in the non-preferred position. Branded generic of AirDuo (fluticasone/salmeterol) place in preferred position. Adjust existing criteria based on these changes.
01/04/2018	Medical Policy Committee review
01/17/2018	Medical Policy Implementation Committee approval. Placed new drug, Armonair Respiclick, in the non-preferred column for ICS products. Added a new section for new drug class (LAMA/ICS/LABA) and placed Trelegy Ellipta in the preferred column.
06/07/2018	Medical Policy Committee review
06/20/2018	Medical Policy Implementation Committee approval. Switched Dulera to a preferred product. Added Lonhala Magnair to the policy. Changed nebulized long acting beta agonists to nebulized long acting COPD products. Added Advair Diskus and Symbicort as preferred options prior to Brovana, Perforomist, and Lonhala Magnair.
06/06/2019	Medical Policy Committee review
06/19/2019	Medical Policy Implementation Committee approval. Added the branded generic Albuterol HFA as a non-preferred option. Added the generics for Advair Diskus (generic, Wixela Inhub) as preferred options for therapy. Added a new product, Yupelri, to the policy in a non-preferred position.
06/04/2020	Medical Policy Committee review
06/10/2020	Medical Policy Implementation Committee approval. Removed Advair Diskus from the preferred products as it now has generic equivalents. Added Budesonide/Formoterol Fumarate branded generic to the policy (Authorized Generic of Symbicort) as a non-preferred option in the ICS/LABA class. Added generic albuterol HFA as a preferred option in the SABA class. Added ProAir Digihaler as a non-preferred option in the SABAs. Added Duaklir Pressair as a non-preferred option in LAMA/LABA class

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09/03/2020	Medical Policy Committee review
09/09/2020	Medical Policy Implementation Committee approval. Added Advair Diskus brand as a non-preferred product. Changed ProAir HFA to non-preferred.
01/07/2021	Medical Policy Committee review
01/13/2021	Medical Policy Implementation Committee approval. Added three new FDA approved products to the non-preferred category: AirDuo Digihaler, Armonair Digihaler, and Breztri Aerosphere.
08/05/2021	Medical Policy Committee review
08/11/2021	Medical Policy Implementation Committee approval. Changed Pulmicort Flexhaler from non-preferred to preferred. Added two new generic products, arformoterol and formoterol nebulized products, to the policy.
08/04/2022	Medical Policy Committee review
08/10/2022	Medical Policy Implementation Committee approval. Added branded generic Fluticasone Propionate HFA and branded generic Fluticasone-Vilanterol to the policy as non-preferred agents.
07/06/2023	Medical Policy Committee review
07/12/2023	Medical Policy Implementation Committee approval. Added branded generic Fluticasone propionate/Salmeterol HFA to policy as a non-preferred agent.
08/03/2023	Medical Policy Committee review
08/09/2023	Medical Policy Implementation Committee approval. Removed Breztri as a targeted agent.
12/07/2023	Medical Policy Committee review
12/13/2023	Medical Policy Implementation Committee approval. Added new product, Airsupra as a non-preferred agent to policy with criteria. Added Breyna, generic of Symbicort, and generic budesonide/formoterol fumarate as preferred agents to the policy. Removed branded generic Budesonide/Formoterol Fumarate from policy.
03/07/2024	Medical Policy Committee review
03/13/2024	Medical Policy Implementation Committee approval. Removed brand Flovent due to its discontinuation. Added statement regarding availability of authorized generic fluticasone for patients <6 years of age. Moved brand Symbicort to non-preferred status due to availability of generic.
03/06/2025	Medical Policy Committee review
03/12/2025	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 03/2026

**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;
B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.