



Louisiana

Select Inhaled Respiratory Agents

Policy # 00526

Original Effective Date: 01/01/2017

Current Effective Date: 09/13/2021

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), and Armonair Digihaler^{™‡} (fluticasone propionate) 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), or Armonair Digihaler (fluticasone propionate) when the following criterion is met:

- There is clinical evidence or patient history that suggests the use of Arnuity^{™‡} Ellipta^{®‡} (fluticasone furoate), Flovent^{®‡} Diskus^{®‡} (fluticasone propionate), Flovent^{®‡} HFA (fluticasone propionate), 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 Aerospan (flunisolide), Alvesco (ciclesonide), Asmanex Twisthaler (mometasone furoate), Asmanex HFA (mometasone furoate), Armonair Respiclick (fluticasone propionate), or Armonair Digihaler (fluticasone propionate) WITHOUT clinical evidence or patient history that suggests the use of Arnuity Ellipta (fluticasone

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furoate), Flovent Diskus (fluticasone propionate), Flovent HFA (fluticasone propionate), 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**.**

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 Beta Agonists (LABAs)

Based on review of available data, the Company may consider the inhaled long acting beta agonists Arcapta^{TM†} Neohaler^{TM†} (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:

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- *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:

Patient Selection Criteria

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), or Symbicort^{®‡} (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

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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), or Symbicort (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**.**

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/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 AirDuoTM‡ Respiclick (fluticasone propionate/salmeterol), AirDuo Digihaler (fluticasone propionate/salmeterol), branded generic Budesonide/Formoterol Fumarate, and Advair Diskus (fluticasone propionate/salmeterol) 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), branded generic Budesonide/Formoterol Fumarate, or Advair Diskus (fluticasone propionate/salmeterol) 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

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HFA (fluticasone propionate/salmeterol), Breo[®] Ellipta (fluticasone furoate/vilanterol), Symbicort (budesonide/formoterol fumarate dihydrate), the branded generic Fluticasone Propionate/Salmeterol (branded generic of AirDuo Respiclick), or Dulera[®] (mometasone furoate/formoterol furoate) 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), branded generic Budesonide/Formoterol Fumarate, or Advair Diskus (fluticasone propionate/salmeterol) 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), Symbicort (budesonide/formoterol fumarate dihydrate), the branded generic Fluticasone Propionate/Salmeterol (branded generic of AirDuo Respiclick), or Dulera (mometasone furoate/formoterol furoate) 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 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:

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- 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^{TM, ‡} (glycopyrrolate/formoterol fumarate), Utibron^{TM, ‡} Neohaler (indacaterol/glycopyrrolate), and Duaklir^{® †} Pressair (aclidinium/formoterol fumarate) to be **eligible for coverage**** when the below patient selection criterion is met:

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.

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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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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 Long Acting Antimuscarinic Agents/Corticosteroids/Long Acting Beta Agonists (LAMA/ICS/LABAs)

Based on review of available data, the Company may consider the inhaled long acting antimuscarinic agents/corticosteroids/long acting beta agonist Breztri Aerosphere^{TM‡} (budesonide/glycopyrrolate/formoterol fumarate) to be **eligible for coverage**** when the below patient selection criterion is met:

Patient Selection Criteria

Coverage eligibility will be considered for Breztri Aerosphere (budesonide/glycopyrrolate/formoterol fumarate) when the following criterion is met:

- There is clinical evidence or patient history that suggests the use of Trelegy^{TM‡} Ellipta (fluticasone furoate/umeclidinium/vilanterol) 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 Breztri Aerosphere (budesonide/glycopyrrolate/formoterol fumarate) WITHOUT clinical evidence or patient history

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that suggests the use of Trelegy Ellipta (fluticasone furoate/umeclidinium/vilanterol) will be/was ineffective or will/did cause an adverse reaction to the patient to be **not medically necessary**.**

Schematic

Class	Non-Preferred Products	Preferred Products
Inhaled Corticosteroids (ICS)	Aerospan Alvesco Asmanex Twisthaler Asmanex HFA Armonair Respiclick Armonair Digihaler	Arnuity Ellipta Flovent Diskus Flovent HFA 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 Symbicort
Inhaled Corticosteroids/Long Acting Beta Agonists (ICS/LABAs)	AirDuo Respiclick AirDuo Digihaler Branded Generic Budesonide/Formoterol Fumarate Advair Diskus	Generic fluticasone/salmeterol diskus Wixela Inhub Advair HFA Breo Ellipta Symbicort Fluticasone/Salmeterol-(branded generic of AirDuo Respiclick) Dulera

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Inhaled Long Acting Antimuscarinic (LAMAs)	Acting Agents	Tudorza Pressair Seebri Neohaler	Spiriva Respimat Spiriva HandiHaler Incruse Ellipta
Inhaled Long Acting Antimuscarinic (LAMA/LABA)	Acting Agents/Long Acting Beta Agonists	Utibron Neohaler Bevespi Aerosphere Duaklir Pressair	Anoro Ellipta Stiolto Respimat
Inhaled Short Acting Agonists (SABAs)	Acting Beta Agonists	Proventil HFA Xopenex HFA Branded Generic Albuterol HFA ProAir Digihaler Branded Generic Levalbuterol HFA ProAir HFA	ProAir RespiClick Ventolin HFA Generic albuterol HFA
Inhaled Long Acting Antimuscarinic Agents/Corticosteroids/Long Acting Beta Agonists (LAMA/ICS/LABAs)	Acting Beta Agonists	Breztri Aerosphere	Trelegy Ellipta

^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

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.

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41. Albuterol Sulfate HFA. Ivax Pharmaceuticals. Waterford, Ireland. Updated January 2019.
42. Yupelri [package insert]. Mylan Specialty. Morgantown, West Virginia. Updated May 2019.

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Louisiana

Select Inhaled Respiratory Agents

Policy # 00526

Original Effective Date: 01/01/2017

Current Effective Date: 09/13/2021

- 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.

Policy History

Original Effective Date: 01/01/2017

Current Effective Date: 09/13/2021

- 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) placed 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 Resplick, 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

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- 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
- 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.

Next Scheduled Review Date: 08/2022

****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

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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.

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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.

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