LOUISIANA BLUE

Nasal Allergy Medications

Policy # 00301
Original Effective Date: 05/22/2013
Current Effective Date: 12/09/2024

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.*

For Patients With "Step Therapy" (generic before brand) ONLY:

Based on review of available data, the Company may consider brand name nasal allergy medications including, but not limited to Omnaris®‡ (ciclesonide), Astepro®‡ (azelastine), Xhance®‡ (fluticasone propionate), Dymista®‡ (azelastine/fluticasone propionate), and Ryaltris®‡ (olopatadine/mometasone) to be **eligible for coverage**** when one of the below patient selection criteria is met:

Patient Selection Criteria

Coverage eligibility will be considered for brand name nasal allergy medications when one of the following criteria is met:

- For all brand name nasal allergy medications: the patient has tried and failed one prescription generic nasal allergy medication (e.g., budesonide, flunisolide, fluticasone, triamcinolone, mometasone, or azelastine nasal sprays); OR
- There is clinical evidence or patient history that suggests the generically available products will be ineffective or 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 brand name nasal allergy medications when patient selection criteria are not met or for usage not included in the above patient selection criteria 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.*

For Patients With "Prior Authorization" ONLY:

Based on review of available data, the Company may consider Xhance (fluticasone propionate) and Ryaltris (olopatadine/mometasone) to be **eligible for coverage**** when the patient selection criteria are met:

Patient Selection Criteria

Coverage eligibility will be considered for Xhance (fluticasone propionate) and Ryaltris (olopatadine/mometasone) when the following criteria are met:

- For Xhance requests ONLY:
  - Patient has a diagnosis of chronic rhinosinusitis, with or without nasal polyps; AND
  - Patient is 18 years of age or older; AND
  - Patient has tried and failed (e.g., intolerance or inadequate response) BOTH generic prescription mometasone nasal spray AND generic prescription or over the counter (OTC) fluticasone nasal spray for at least 1 month EACH of therapy unless there is clinical evidence or patient history that suggests the use of the alternatives will be ineffective or cause an adverse reaction to the patient.
    *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met)*
- For Ryaltris requests ONLY:
  - Patient has a diagnosis of seasonal allergic rhinitis; AND
  - Patient is experiencing symptoms of seasonal allergic rhinitis (e.g., rhinorrhea, nasal congestion, sneezing, or nasal itching); AND
  - Patient is 12 years of age or older; AND
  - Patient has tried and failed (e.g., intolerance or inadequate response) one generic prescription or OTC corticosteroid nasal allergy medication (e.g., fluticasone, mometasone, budesonide) unless there is clinical evidence or patient history that suggests the use of these alternatives will be ineffective or cause an adverse reaction to the patient; AND
    *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met)*

- Patient has tried and failed (e.g., intolerance or inadequate response) one prescription antihistamine nasal allergy medication (e.g., azelastine, olopatadine) unless there is clinical evidence or patient history that suggests the use of antihistamine nasal allergy medications will be ineffective or cause an adverse reaction to the patient.
  *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met)*

When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of Xhance (fluticasone propionate) when the patient has NOT tried and failed (e.g., intolerance or inadequate response) BOTH generic prescription mometasone nasal spray AND generic prescription or OTC fluticasone nasal spray for at least 1 month EACH of therapy to be **not medically necessary.****

Based on review of available data, the Company considers the use of Ryaltris (olopatadine/mometasone) when the patient has NOT tried and failed (e.g., intolerance or inadequate response) BOTH one generic prescription or OTC corticosteroid nasal allergy medication AND one generic prescription antihistamine nasal allergy medication to be **not medically necessary.****

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers the use of Xhance (fluticasone propionate) in patients under 18 years of age OR for any indication other than for the treatment of chronic rhinosinusitis, with or without nasal polyps to be **investigational.***

Based on review of available data, the Company considers the use of Ryaltris (olopatadine/mometasone) in patients under 12 years of age OR for any indication other than for the treatment of seasonal allergic rhinitis to be **investigational.***

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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.*

For Patients With BOTH "Prior Authorization" AND "Step Therapy":

Based on review of available data, the Company may consider brand name nasal allergy medications including, but not limited to Omnaris (ciclesonide), Astepro (azelastine), Xhance (fluticasone propionate), Dymista (azelastine/fluticasone propionate), and Ryaltris (olopatadine/mometasone) to be **eligible for coverage**** when the below patient selection criteria are met:

Patient Selection Criteria

Coverage eligibility will be considered for brand name nasal allergy medications when the following criteria are met for the requested drug:

- For requests OTHER than Xhance:
  - Patient has tried and failed one prescription generic nasal allergy medication (e.g., budesonide, flunisolide, fluticasone, triamcinolone, mometasone, or azelastine nasal sprays); OR
    *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met)*
  - There is clinical evidence or patient history that suggests the generically available products will be ineffective or cause an adverse reaction to the patient.
    *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met)*
- For Xhance requests ONLY:
  - Patient has a diagnosis of chronic rhinosinusitis, with or without nasal polyps; AND
  - Patient is 18 years of age or older; AND
  - Patient has tried and failed (e.g., intolerance or inadequate response) BOTH generic prescription mometasone nasal spray AND generic prescription or OTC fluticasone nasal spray for at least 1 month EACH of therapy unless there is clinical evidence or patient history that suggests the use of the alternatives will be ineffective or cause an adverse reaction to the patient.
    *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met)*
- For Ryaltris requests ONLY:
  - Patient has a diagnosis of seasonal allergic rhinitis; AND
  - Patient is experiencing symptoms of seasonal allergic rhinitis (e.g., rhinorrhea, nasal congestion, sneezing, or nasal itching); AND
  - Patient is 12 years of age or older; AND

- Patient has tried and failed (e.g., intolerance or inadequate response) one generic prescription or OTC corticosteroid nasal allergy medication (e.g., fluticasone, mometasone, budesonide) unless there is clinical evidence or patient history that suggests the use of these alternatives will be ineffective or cause an adverse reaction to the patient; AND
  *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met)*
- Patient has tried and failed (e.g., intolerance or inadequate response) one prescription antihistamine nasal allergy medication (e.g., azelastine, olopatadine) unless there is clinical evidence or patient history that suggests the use of antihistamine nasal allergy medications will be ineffective or cause an adverse reaction to the patient.
  *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met)*

When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of brand name nasal allergy medications (other than Xhance and Ryaltris) when the patient has NOT tried and failed one prescription generic nasal allergy medication (e.g., budesonide, flunisolide, fluticasone, triamcinolone, mometasone, or azelastine nasal sprays) OR when there is NO documentation of clinical evidence or patient history that suggests the generically available products will be ineffective or cause an adverse reaction to the patient to be **not medically necessary.****

Based on review of available data, the Company considers the use of Xhance (fluticasone propionate) when the patient has NOT tried and failed (e.g., intolerance or inadequate response) BOTH generic prescription mometasone nasal spray AND generic prescription or OTC fluticasone nasal spray for at least 1 month EACH of therapy to be **not medically necessary.****

Based on review of available data, the Company considers the use of Ryaltris (olopatadine/mometasone) when the patient has NOT tried and failed (e.g., intolerance or inadequate response) BOTH one generic prescription or OTC corticosteroid nasal allergy medication AND one generic prescription antihistamine nasal allergy medication to be **not medically necessary.****

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers the use of Xhance (fluticasone propionate) in patients under 18 years of age OR for any indication other than chronic rhinosinusitis, with or without nasal polyps to be **investigational.***

Based on review of available data, the Company considers the use of Ryaltris (olopatadine/mometasone) in patients under 12 years of age OR for any indication other than for the treatment of seasonal allergic rhinitis to be **investigational.***

Background/Overview

Nasal allergy medications include those that are steroid based and those that are relatively selective histamine (H)-1 receptor antagonists. These drugs are approved for various indications such as seasonal allergic rhinitis and perennial allergic rhinitis.

Xhance (approved in September of 2017) is a nasal corticosteroid indicated for the treatment of nasal polyps in patients 18 years of age or older. In 2023, the labeled indication for Xhance was revised to chronic rhinosinusitis with nasal polyps and in March 2024, the FDA approved the expanded indication of Xhance to include chronic rhinosinusitis with or without nasal polyps. It contains fluticasone propionate (similar to generic fluticasone propionate) but at a different dose. Mometasone is also approved by the Food and Drug Administration (FDA) for the treatment of nasal polyps. Guidelines do not prefer one product over the other for nasal polyps. Both fluticasone propionate and mometasone offer generic formulations that provide both an efficacious and economical option over the branded Xhance product.

Ryaltris was approved in January of 2022. It is a combination of olopatadine, an antihistamine, and mometasone, a nasal corticosteroid, that is indicated for the treatment of symptoms of seasonal allergic rhinitis in adult and pediatric patients 12 years of age and older. The recommended dose of Ryaltris is two sprays in each nostril twice daily. Both medications included in Ryaltris are available in generic formulations. Choosing the generically available agents is a more cost-effective option that provides equally efficacious treatment outcomes.

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.

In regards to step therapy: the patient selection criteria presented in this policy takes into consideration clinical evidence or patient history that suggests the available generic nasal allergy medications will be ineffective or cause an adverse reaction to the patient. Based on a review of the data, in the absence of the above mentioned caveats, there is no advantage of using a brand name nasal allergy medication over the available generic nasal allergy medications. Generic drugs are considered to have equal bioavailability and efficacy in comparison to brand name drugs.

In regards to prior authorization: The efficacy of Xhance was shown in two randomized trials that demonstrated a reduction in nasal congestion/obstruction. Generic mometasone also carries this indication (treatment of nasal polyps) and other studies have proven the efficacy of generic fluticasone propionate (now available OTC) in the treatment of nasal polyps. Xhance was not studied head to head with these generic agents and no claims to superiority can be made. Generic mometasone and fluticasone formulations have been a mainstay of therapy prior to the approval of Xhance. Ryaltris was studied in two randomized controlled trials in patient who had a history of seasonal allergic rhinitis. Its comparators were placebo, mometasone furoate, and olopatadine hydrochloride. Although Ryaltris proved successful in reducing nasal symptoms, it was not directly compared to mometasone and olopatadine combination therapy. Claims of Ryaltris being superior to these generically available options cannot be made.

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Policy History

Original Effective Date: 05/22/2013
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05/02/2013	Medical Policy Committee review
05/22/2013	Medical Policy Implementation Committee approval. New policy.
06/05/2014	Medical Policy Committee review
06/18/2014	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
06/04/2015	Medical Policy Committee review
06/17/2015	Medical Policy Implementation Committee approval. Coverage eligibility unchanged. Added budesonide to criteria.
06/02/2016	Medical Policy Committee review
06/20/2016	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
06/01/2017	Medical Policy Committee review
06/21/2017	Medical Policy Implementation Committee approval. Added mometasone to step 1.
03/01/2018	Medical Policy Committee review
03/21/2018	Medical Policy Implementation Committee approval. Added Xhance to step therapy. Also separated out into step, step/pa, and PA only to address the PA added to Xhance. Updated background to reflect the addition of Xhance.
03/07/2019	Medical Policy Committee review
03/20/2019	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
05/02/2019	Medical Policy Committee review
05/15/2019	Medical Policy Implementation Committee approval. Inserted language to allow OTC use as an option for the fluticasone requirement.
05/07/2020	Medical Policy Committee review
05/13/2020	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
05/06/2021	Medical Policy Committee review
05/12/2021	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

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05/05/2022	Medical Policy Committee review
05/11/2022	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
11/03/2022	Medical Policy Committee review
11/09/2022	Medical Policy Implementation Committee approval. Added Ryaltris to the policy with criteria. Updated relevant sections.
11/02/2023	Medical Policy Committee review
11/08/2023	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
11/07/2024	Medical Policy Committee review
11/13/2024	Medical Policy Implementation Committee approval. Updated criteria and background information to reflect Xhance's expanded indication for the treatment of chronic rhinosinusitis with OR without nasal polyps. Also, removed obsolete brand products Nasonex, Veramyst, Rhinocort Aqua, Flonase, Beconase AQ, Astelin, and Patanase from the policy.

Next Scheduled Review Date: 11/2025

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
    1. Consultation with technology evaluation center(s);
    2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
    3. Reference to federal regulations.

**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.

‡ Indicated trademarks are the registered trademarks of their respective owners.

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.