LOUISIANA BLUE

Select Muscle Relaxants

Policy # 00518
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Current Effective Date: 07/01/2026

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.

Investigational or experimental services are not covered. This includes any drug, device, procedure, or service provided under the investigational arm of a clinical trial or clinical study. These services are excluded from coverage under benefits.

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.*

Based on review of available data, the Company may consider select muscle relaxants, including, but not limited to the branded cyclobenzaprine products (Flexeril®, Amrix®, Fexmid®)‡, generic cyclobenzaprine extended release 15 mg and 30 mg capsules, generic cyclobenzaprine 7.5 mg tablets, brand/generic Norgesic Forte (orphenadrine citrate/aspirin/caffeine, orphengesic forte) tablets, brand/generic Fleqsuvy®‡ (baclofen oral suspension), Ozobax®‡ (baclofen oral solution), generic baclofen oral solution, Lyvispah™‡ (baclofen oral granules), Methocarbamol 1000 mg tablets (branded, generics, generic Tanlor®)‡, Baclofen 15 mg tablets (branded, generics), branded Metaxalone 640 mg tablet, Zanaflex®‡ 8 mg capsules, branded Tizanidine 8 mg capsules, and Ontralfy™‡ (tizanidine oral solution) to be **eligible for coverage**** when the below patient selection criteria are met for the requested drug.

Patient Selection Criteria

Coverage eligibility will be considered for select muscle relaxants, including, but not limited to the branded cyclobenzaprine products (Flexeril, Amrix, Fexmid), generic cyclobenzaprine extended release 15 mg and 30 mg capsules, generic cyclobenzaprine 7.5 mg tablets, brand/generic Norgesic Forte (orphenadrine citrate/aspirin/caffeine, orphengesic forte) tablets, brand/generic Fleqsuvy (baclofen oral suspension), Ozobax (baclofen oral solution), generic baclofen oral solution, Lyvispah (baclofen oral granules), Methocarbamol 1000 mg tablets (branded, generics, generic Tanlor), Baclofen 15 mg tablets (branded, generics), branded Metaxalone 640 mg tablet, Zanaflex 8 mg capsules, branded Tizanidine 8 mg capsules, and Ontralfy (tizanidine oral solution) when the following criteria are met for the requested drug:

- For branded cyclobenzaprine products (Flexeril, Amrix, Fexmid), generic cyclobenzaprine extended release 15 mg and 30 mg capsules, or generic 7.5 mg tablet requests:
    - There is clinical evidence or patient history that suggests the use of generically available oral cyclobenzaprine 5 mg or 10 mg tablets will be/was ineffective or will/did 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 brand/generic Norgesic Forte (orphenadrine citrate/aspirin/caffeine, orphengesic forte) tablet requests:
    - Patient has tried and failed (e.g., intolerance or inadequate response) at least TWO of the following GENERIC muscle relaxant products: orphenadrine citrate extended release tablets, carisoprodol/aspirin tablets, carisoprodol 350 mg tablets, cyclobenzaprine 5 mg or 10 mg tablets, metaxalone 400 mg or 800 mg tablets, methocarbamol 500 mg or 750 mg tablets, or tizanidine capsules/tablets unless there is clinical evidence or patient history that suggests the use of these alternative agents 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 Ozobax (baclofen oral solution), generic baclofen oral solution, brand/generic Fleqsuvy (baclofen oral suspension), or Lyvispah (baclofen oral granules) requests:
    - Patient is using the requested drug for one of the following:
        - Treatment of spasticity, muscle spasm, myoclonus, or muscle rigidity due to Multiple Sclerosis; OR
        - Treatment of spasticity, muscle spasm, myoclonus, or muscle rigidity due to spinal cord injury; OR
        - Treatment of spasticity, muscle spasm, myoclonus, or muscle rigidity due to spinal cord diseases; AND
    - Patient has a gastrostomy tube (G-tube) or is otherwise unable to swallow tablets and/or capsules; 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 is NOT currently taking other medications in tablet or capsule form.
      *(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 Methocarbamol 1000 mg tablet (branded, generics, generic Tanlor) requests:
    - There is clinical evidence or patient history that suggests the use of generically available methocarbamol 500 mg or 750 mg tablets will be/was ineffective or will/did 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 Baclofen 15 mg tablet (branded, generics) requests:
    - There is clinical evidence or patient history that suggests the use of generically available baclofen 5 mg, 10 mg or 20 mg tablets will be/was ineffective or will/did 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 branded Metaxalone 640 mg tablet requests:
    - There is clinical evidence or patient history that suggests the use of generically available metaxalone 400 mg or 800 mg tablets will be/was ineffective or will/did 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 Zanaflex 8 mg capsule or branded Tizanidine 8 mg capsule requests:
  - There is clinical evidence or patient history that suggests the use of generically available tizanidine 2 mg, 4 mg, or 6 mg capsules/tablets will be/was ineffective or will/did 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 Ontralfy (tizanidine oral solution) requests:
  - Patient has a gastrostomy tube (G tube) or is otherwise unable to swallow tablets or capsules AND patient is NOT currently taking any medication in tablet or capsule form.
    *(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 select cyclobenzaprine products, including, but not limited to the branded cyclobenzaprine products (Flexeril, Amrix, Fexmid), generic cyclobenzaprine extended release 15 mg and 30 mg capsules, or generic cyclobenzaprine 7.5 mg tablets WITHOUT clinical evidence or patient history that suggests the use of generically available oral cyclobenzaprine 5 mg or 10 mg tablets 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 brand/generic Norgesic Forte (orphenadrine citrate/aspirin/caffeine, orphengesic forte) tablets WITHOUT evidence that the patient has tried and failed (e.g., intolerance or inadequate response) at least TWO of the following GENERIC muscle relaxant products: orphenadrine citrate extended release tablets, carisoprodol/aspirin tablets, carisoprodol 350 mg tablets, cyclobenzaprine 5 mg or 10 mg tablets, metaxalone 400 mg or 800 mg tablets, methocarbamol 500 mg or 750 mg tablets, or tizanidine capsules/tablets to be **not medically necessary.****

Based on review of available data, the Company considers the use of Ozobax (baclofen oral solution), generic baclofen oral solution, brand/generic Fleqsuvy (baclofen oral suspension), Lyvispah (baclofen oral granules), or Ontralfy (tizanidine oral solution) WITHOUT documentation that the patient has a gastrostomy tube (G-tube) or is otherwise unable to swallow tablets and/or capsules AND WITHOUT documentation that the patient is NOT currently taking other medications in tablet or capsule form to be **not medically necessary.****

Based on review of available data, the Company considers the use of Methocarbamol 1000 mg tablets (branded, generics, generic Tanlor) WITHOUT clinical evidence or patient history that suggests the use of generically available methocarbamol 500 mg or 750 mg tablets 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 Baclofen 15 mg tablets (branded, generics) WITHOUT clinical evidence or patient history that suggests the use of generically available baclofen 5 mg, 10mg, or 20 mg tablets 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 branded Metaxalone 640 mg tablets WITHOUT clinical evidence or patient history that suggests the use of generically available metaxalone 400 mg or 800 mg tablets 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 Zanaflex 8 mg capsules or branded Tizanidine 8 mg capsules WITHOUT clinical evidence or patient history that suggests the use of generically available tizanidine 2 mg, 4 mg, or 6 mg capsules/tablets will be/was ineffective or will/did cause an adverse reaction to the patient 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 Ozobax (baclofen oral solution), generic baclofen oral solution, brand/generic Fleqsuvy (baclofen oral suspension), or Lyvispah (baclofen oral granules) for any indications other than their Food and Drug Administration approved indications to be **investigational.***

Background/Overview

Flexeril, Amrix, and Fexmid are ALL indicated as an adjunct to rest and physical therapy for relief of muscle spasm associated with acute, painful musculoskeletal conditions. Flexeril is commonly found in generic form at a very inexpensive cost. The generic version of Flexeril, cyclobenzaprine, is available in 5 mg and 10 mg tablets. Amrix is supplied as 15 mg and 30 mg extended release capsules, and is now available in generic form (although still substantially more expensive than the 5 mg and 10 mg generic cyclobenzaprine tablets). Clinical trials for Amrix did use the strengths of 15 mg and 30 mg and compared it to placebo as well as generic cyclobenzaprine. Amrix performed better than placebo, but there was no difference between using Amrix and using generic cyclobenzaprine in the clinical trials. Fexmid is supplied as 7.5 mg tablets. There was limited information online for this product, but the clinical trials portion of the package insert only refers to studies that have been done with the 5 mg and 10 mg versions of cyclobenzaprine. Fexmid does, however, have a generic equivalent 7.5 mg product, but the price of the generic 7.5 mg product is substantially higher than the 5 mg and 10 mg cyclobenzaprine generics.

Norgesic Forte is indicated for the symptomatic relief of mild to moderate pain of acute musculoskeletal disorders. This drug is available in generic form, however even the generic form of the drug is more expensive than other alternatives. This product continually enters and exits the marketplace but was originally approved in 1964. There are a wide array of generic musculoskeletal agents in generic form that would be fitting alternatives to Norgesic Forte and its generic, including: orphenadrine citrate extended release tablets, carisoprodol/aspirin tablets, carisoprodol 350 mg tablets, cyclobenzaprine 5 mg or 10 mg tablets, metaxalone 400 mg or 800 mg tablets, methocarbamol 500 mg or 750 mg tablets, and tizanidine capsules/tablets.

Oral baclofen products are available in a variety of dosage forms including solutions, suspensions, oral tablets of various strengths, generic products, brand products, and authorized (or branded) generic products. Ozobax, Fleqsuvy, and Lyvispah are all indicated for the treatment of spasticity, muscle spasm, myoclonus, or muscle rigidity due to multiple sclerosis, spinal cord injury, or spinal cord diseases. Ozobax is an oral solution containing baclofen 5 mg per 5 mL, while Fleqsuvy is an oral suspension with the same concentration. Lyvispah is an oral granule formulation available in 5 mg, 10 mg, and 20 mg strength packets. Criteria in this policy address the qualifications for an oral solution, oral suspension, or oral granule dosage form. This policy ensures the usage is appropriate for these three dosage forms as it is most economical to use the tablet form of baclofen. It should also be noted that the clinical trials portion of both package inserts for Ozobax and Fleqsuvy only refers to studies done with baclofen tablets, while the Lyvispah package insert only mentions completing bioavailability studies compared to baclofen oral tablets. Generic baclofen tablets are available in 5 mg, 10 mg, and 20 mg strengths. Baclofen is also available in a branded and generic 15 mg tablet, which is significantly more expensive than the other generically available strengths and shows no clinical benefit over these products.

Methocarbamol 1000 mg tablets are indicated as an adjunct to rest, physical therapy, and other measures for the relief of discomfort associated with acute, painful musculoskeletal conditions. Methocarbamol was first approved by the Food and Drug Administration (FDA) in 1957 under brand names Robaxin®‡ and Robaxin®-750‡. It was originally available as 500 mg and 750 mg tablets. The brands of both tablets have since been discontinued, and now they are only available generically. Because Methocarbamol was first approved in 1957, there is no evidence of clinical efficacy as this drug was approved before manufacturers were mandated by the FDA to prove effectiveness.

Metaxalone first entered the market in 1962 under the brand name Skelaxin®‡. It's a skeletal muscle relaxant indicated as an adjunct to rest, physical therapy, and other measures for the relief of discomforts associated with acute, painful musculoskeletal conditions. The brand name product, available as an 800 mg tablet, has since been discontinued. Generic forms containing the active ingredient, metaxalone, are available as 400 mg and 800 mg tablets. A much more costly branded formulation of metaxalone launched as a 640 mg tablet. This newly available strength does not show a clinical advantage over the generically available and more cost-effective 400 mg and 800 mg strengths.

Zanaflex, first approved in 1996, is indicated for the treatment of spasticity. It's often used off label for the treatment of skeletal muscle spasm and/or musculoskeletal pain. Its active ingredient, tizanidine, is available in multiple oral formulations, including capsules, tablets, and now an oral solution (Ontralfy). Generic tizanidine is widely available and cost-effective in strengths of 2 mg, 4 mg, and 6 mg tablets and capsules. While Ontralfy provides a liquid formulation that may offer an alternative for patients who have difficulty swallowing solid dosage forms, it does not offer additional clinical benefit over existing tizanidine products. Similarly, Zanaflex 8 mg capsules and branded Tizanidine 8 mg capsules are significantly more expensive than generically available tizanidine formulations and do not offer any meaningful clinical advantage over these lower-cost options.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

Flexeril, Amrix, and Fexmid are all indicated as an adjunct to rest and physical therapy for relief of muscle spasm associated with acute, painful musculoskeletal conditions. Flexeril was approved in 1977, and Amrix was approved in February of 2007. An approval date could not be located for Fexmid. There are generic equivalents available for the 5 mg, 7.5 mg, 10 mg, 15 mg, and 30 mg doses.

Norgesic Forte is indicated for the symptomatic relief of mild to moderate pain of acute musculoskeletal disorders. This drug is available in generic form.

Ozobax and Fleqsuvy are both indicated for the treatment of spasticity, muscle spasm, myoclonus, or muscle rigidity due to multiple sclerosis, spinal cord injury, or spinal cord diseases. Lyvispah was most recently approved for the same indications in 2021. Lioresal tablets were first approved in 1977 but have since been discontinued. Baclofen tablets are generically available in 5 mg, 10 mg, and 20 mg strengths. Branded Baclofen 15 mg tablets became available in March of 2024, and generic versions of the 15 mg tablets launched in mid 2024.

Robaxin, the first branded methocarbamol product, was first approved in 1957 as adjunct to rest, physical therapy, and other measures for the relief of discomfort associated with acute, painful, musculoskeletal conditions. Branded Methocarbamol 1000 mg tablets became available in September of 2022. Generic methocarbamol 1000 mg tablets, including generic Tanlor, became available in 2024.

Skelaxin was FDA approved in 1962 as an adjunct to rest, physical therapy, and other measures for the relief of discomforts associated with acute, painful musculoskeletal conditions. This drug is available as generic metaxalone tablets in strengths of 400 mg and 800 mg. A branded Metaxalone 640 mg tablet product launched in early 2025.

Zanaflex is indicated for the treatment of spasticity but is often used off-label for the treatment of skeletal muscle spasm and/or musculoskeletal pain. Generic formulations of tizanidine exist in strengths of 2 mg, 4 mg and 6 mg. Zanaflex launched as an 8 mg capsule in October 2025. Additional tizanidine formulations, branded Tizanidine 8 mg capsule and Ontralfy (tizanidine oral solution), became available in early 2026.

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 regulations, other plan medical policies, and accredited national guidelines.

For the branded cyclobenzaprine products (Flexeril, Amrix, Fexmid), the patient selection criteria presented in this policy takes into consideration clinical evidence or patient history that suggests the use of generically available oral cyclobenzaprine 5 mg or 10 mg tablets 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 select cyclobenzaprine products, including, but not limited to the branded cyclobenzaprine products (Flexeril, Amrix, Fexmid), generic cyclobenzaprine extended release 15 mg and 30 mg capsules, or generic cyclobenzaprine 7.5 mg tablets over the generically available oral cyclobenzaprine 5 mg or 10 mg tablets.

This policy also targets use of brand/generic Norgesic Forte to ensure that other efficacious and economical products are used. Based on review of available data, there is no advantage of using brand/generic Norgesic Forte over the available generic alternative products mentioned in this policy (orphenadrine citrate extended release tablets, carisoprodol/aspirin tablets, carisoprodol 350 mg tablets, cyclobenzaprine 5 mg or 10 mg tablets, metaxalone 400 mg or 800 mg tablets, methocarbamol 500 mg or 750 mg tablets, or tizanidine capsules/tablets).

Additionally, this policy targets the use of Ozobax (baclofen oral solution), generic baclofen oral solution, Fleqsuvy (baclofen oral suspension), and Lyvispah (baclofen oral granules). The oral solution, oral suspension, and oral granule forms of baclofen should only be used for those that are unable to take tablets and/or capsules, as well as those who are using the medication per the FDA's labeled indications. Based on a review of the available data, there is no advantage of using Ozobax, Fleqsuvy, or Lyvispah other than the reasons listed in this medical policy. Branded and generic Baclofen 15mg tablets are also targeted by this policy. The patient selection criteria for this product takes into consideration clinical evidence or patient history that suggests the generically available, and more cost-effective alternatives of baclofen 5 mg, 10 mg or 20 mg will be ineffective or cause an adverse reaction to the patient.

Branded and generic Methocarbamol 1000 mg tablets are targeted by this policy to ensure that other products that are equally efficacious, yet economical, are being used. There is no clinical advantage of using branded Methocarbamol 1000 mg tablets over generically available methocarbamol 500 mg or 750 mg tablets unless there is clinical evidence or patient history that suggests otherwise.

Branded Metaxalone 640 mg tablets are targeted by this policy to ensure that other products that are equally efficacious, yet economical, are being used. There is no clinical advantage of using branded Metaxalone 640 mg tablets over generically available methocarbamol 400 mg or 800 mg tablets unless there is clinical evidence or patient history that suggests otherwise.

Zanaflex 8 mg capsules and branded Tizanidine 8 mg capsules are targeted by this policy to ensure that other products that are equally efficacious, yet economical, are being used. There is no clinical advantage of using branded Zanaflex 8 mg capsules or branded Tizanidine 8 mg capsules over generically available tizanidine capsules/tablets unless there is clinical evidence or patient history that suggests otherwise. Additionally, the oral solution formulation of tizanidine should only be used for those that are unable to take tablets and/or capsules.

References

1. Flexeril [package insert]. Ortho-McNeil-Janssen Pharmaceuticals. Titusville, New Jersey. Updated April of 2013.
2. Amrix [package insert]. Adare Pharmaceuticals. Vandalia, Ohio Updated May of 2016.
3. Fexmid [package insert]. Shionogi, Inc. Florham Park, New Jersey. Updated October 2014.
4. Norgesic Forte [package insert]. Poly Pharmaceuticals, Inc. Owens Cross Roads, Alabama. Updated September 2018.
5. Ozobax [package insert]. Metacel Pharmaceuticals, LLC. Athens, Georgia. Updated September 2019.
6. Fleqsuvy [package insert]. Azurity Pharmaceuticals, LLC. Wilmington, Massachusetts. Updated February 2022.
7. Lyvispah [package insert]. Saol Therapeutics, Inc. Roswell, Georgia. Updated November 2021.
8. Methocarbamol Tablets [package insert]. Misemer Pharmaceutical, Inc. Updated March 2022.
9. Baclofen Tablets [package insert]. Rubicon Research Private Limited. Thane, India. March 2024.
10. Tanlor [package insert]. Forte Bio-Pharma, LLC. Las Vegas, NV. Updated July 2024.
11. Metaxalone 640 mg Tablets [package insert]. Primus Pharmaceuticals. Scottsdale, AZ. Updated February 2025.
12. Zanaflex 8 mg Capsules [package insert]. Trifluent Pharma, LLC. San Antonio, TX. Updated September 2025.
13. Ontralfy [package insert]. Rosemont Pharmaceuticals, LLC. Greenville, SC. Updated October 2025.

Policy History

Original Effective Date: 01/01/2017
Current Effective Date: 07/01/2026

08/04/2016	Medical Policy Committee review
08/17/2016	Medical Policy Implementation Committee approval. New policy.
08/03/2017	Medical Policy Committee review
08/23/2017	Medical Policy Implementation Committee approval. No change to coverage.
08/09/2018	Medical Policy Committee review
08/15/2018	Medical Policy Implementation Committee approval. No change to coverage.
08/01/2019	Medical Policy Committee review
08/14/2019	Medical Policy Implementation Committee approval. Added generic Amrix (cyclobenzaprine 15 mg and 30 mg extended release capsules) to the policy. Added a recent entrant to the market, Norgesic Forte and its generic, to the policy.
06/04/2020	Medical Policy Committee review
06/10/2020	Medical Policy Implementation Committee approval. Added a new product, Ozobax, to the policy along with criteria for use. Updated Background and rationale sections. Added an investigational section to address Ozobax.
06/03/2021	Medical Policy Committee review
06/09/2021	Medical Policy Implementation Committee approval. No change to coverage.
04/07/2022	Medical Policy Committee review
04/13/2022	Medical Policy Implementation Committee approval. Added a new product, Fleqsuvy, to the policy.

08/04/2022	Medical Policy Committee review
08/10/2022	Medical Policy Implementation Committee approval. Added a new product, Lyvispah, to the policy.
04/06/2023	Medical Policy Committee review
04/12/2023	Medical Policy Implementation Committee approval. Added a new product, branded Methocarbamol 1000 mg, to the policy.
09/07/2023	Medical Policy Committee review
09/13/2023	Medical Policy Implementation Committee approval. Added a new product, generic Fleqsuvy, to the policy.
06/06/2024	Medical Policy Committee review
06/12/2024	Medical Policy Implementation Committee approval. Added a new product, branded Baclofen 15mg tablets, to the policy with relevant criteria and background information.
12/05/2024	Medical Policy Committee review
12/11/2024	Medical Policy Implementation Committee approval. Added new products, generic baclofen 15 mg tablets, generic methocarbamol 1000 mg tablets, and generic Tanlor tablets, to the policy with relevant criteria and background information.
12/04/2025	Medical Policy Committee review
12/10/2025	Medical Policy Implementation Committee approval. Added new products, Metaxalone 640 mg, generic baclofen 10mg/5mL solution, and Zanaflex 8 mg capsule, to the policy with relevant criteria and background information.
06/04/2026	Medical Policy Committee review
06/10/2026	Medical Policy Implementation Committee approval. Added new products, Ontralfy (tizanidine oral solution) and branded Tizanidine 8 mg capsule, to the policy with relevant criteria and background information.

*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.

NOTICE: If an authorization for an ongoing course of treatment has been provided to a member and the member changes from one health plan to another health plan (e.g., a member moves from carrier A to Louisiana Blue), Louisiana Blue may honor the previous health plan's authorization for the same service under the same type of in-network benefit for a 90-day transition period. Documentation of the authorization for the ongoing course of treatment from the previous health plan must be provided to us by the member or their provider and the services provided for the course of treatment must otherwise be a covered service under the Louisiana Blue health plan. This provision does not apply to medications covered under the plan's pharmacy benefit.