Select Muscle Relaxants

Policy # 00518
Original Effective Date: 01/01/2017
Current Effective Date: 07/13/2020

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.*

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, and Ozobax®‡ (baclofen 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, or Ozobax (baclofen 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 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 tablets, methocarbamol 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 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) 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 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 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.****

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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 tablets, methocarbamol 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) 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.****

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) for any indications other than its 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 tablets, methocarbamol tablets, and tizanidine capsules/tablets.

Ozobax is 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. Criteria in this policy address the qualifications for an oral solution dosage form. This policy ensures the usage is appropriate for the oral solution dosage form as it is most economical to use the tablet form of baclofen. It should also be noted that the clinical trials portion of the package insert only refers to studies done with baclofen tablets.

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 is indicated for the treatment of spasticity, muscle spasm, myoclonus, or muscle rigidity due to multiple sclerosis, spinal cord injury, or spinal cord diseases.

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Rationale/Source

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 tablets, methocarbamol tablets, or tizanidine capsules/tablets).

Additionally, this policy targets the use of Ozobax (baclofen oral solution). The oral solution of baclofen should only be reserved for those that are unable to take tablets and/or capsules, as well as those who are using the medication per the Food and Drug Administration's labeled indications. Based on a review of the available data, there is no advantage of using Ozobax other than the reasons listed in this medical policy.

References

1. Flexeril [package insert]. Ortho-McNeil-Janssen Pharamceuticals. 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.

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Policy History

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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.

Next Scheduled Review Date: 06/2021

*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:

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1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated 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.