Select Cyclobenzaprine Products

Policy # 00518
Original Effective Date: 01/01/2017
Current Effective Date: 08/15/2018

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 cyclobenzaprine products, including, but not limited to Flexeril®‡, Amrix®‡, Fexmid®‡, and generic cyclobenzaprine 7.5 mg tablets to be **eligible for coverage** when the below patient selection criterion is met:

Patient Selection Criteria
Coverage eligibility will be considered for select cyclobenzaprine products, including, but not limited to Flexeril, Amrix, Fexmid, or generic cyclobenzaprine 7.5 mg tablets when the following criterion is met:

- 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.

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 Flexeril, Amrix, Fexmid, 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.****

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. 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.

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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 Feburary of 2007. An approval date could not be located for Fexmid. There are generic equivalents available for the 5 mg, 7.5 mg, and 10 mg doses.

Rationale/Source

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 Flexeril, Amrix, Fexmid, or generic cyclobenzaprine 7.5 mg tablets over the generically available oral cyclobenzaprine 5 mg or 10 mg tablets.

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.

Policy History

Original Effective Date:	01/01/2017
Current Effective Date:	08/15/2018
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.
Next Scheduled Review Date:	08/2019

**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.

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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.