Effective Date **2/1/2024**
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Coverage Policy Number **IP0211**

Skeletal Muscle Relaxants

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Related Coverage Resources

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview

This policy supports medical necessity review for skeletal muscle relaxants:

- **Amrix®** (cyclobenzaprine extended-release oral capsule)
- **baclofen** oral solution
- **baclofen** oral suspension
- **chlorzoxazone** oral tablet
- **Fleqsuvy™** (baclofen oral suspension)
- **Lyvispah™** (baclofen oral granules)
- **Lorzone®** (chlorzoxazone oral tablet)
- **methocarbamol 1000 mg** oral tablet
- **Norgesic® 25 mg-385 mg-30 mg** (orphenadrine citrate, aspirin, caffeine oral tablet)
- **Norgesic® Forte 50 mg-770 mg-60 mg** (orphenadrine citrate, aspirin, caffeine oral tablet)
- **orphenadrine citrate, aspirin, caffeine 25 mg-385 mg-30 mg** oral tablet
- **Orphengesic® Forte 50 mg-770 mg-60 mg** (orphenadrine citrate, aspirin, caffeine oral tablet)
- **Ozobax®** (baclofen oral solution)
- **Ozobax® DS** (baclofen oral solution)

Receipt of sample product does not satisfy any criteria requirements for coverage.

Medical Necessity Criteria

Coverage varies across plans and requires the use of preferred products. Refer to the customer's benefit plan document for coverage details.

Employer Group Non-Preferred Products and Criteria:

Non-Preferred Product	Criteria
Amrix (cyclobenzaprine) 15 mg and 30 mg extended release capsule	There is documentation the individual has had an inadequate response, or is intolerant to the following (A): A. cyclobenzaprine 5 mg, 7.5 mg, or 10 mg tablet
baclofen 5 mg/5 mL solution	There is documentation the individual has had an inadequate response, or is intolerant to the following (A): A. baclofen tablet
baclofen 10 mg/ 5 mL oral solution	**Baclofen 10 mg/5 mL oral solution** is considered medically necessary when there is documentation of **ONE** of the following: A. Failure, contraindication or intolerance to baclofen tablets B. Inability to swallow baclofen tablets
baclofen 25mg/5 mL oral suspension	There is documentation the individual has an inability to use the following (A): A. baclofen tablet
chlorzoxazone 250 mg, 375 mg, and 750 mg tablet	There is documentation the individual has had an inadequate response, or is intolerant to the following (A): A. chlorzoxazone 500 mg tablet
Fleqsuvy™ baclofen oral suspension	There is documentation the individual has an inability to use the following (A): A. baclofen tablet
Lyvispah (baclofen) oral granules	**ONE** of the following (A or B): 1. Lyvispah will be administered via a feeding tube 2. Documented inability to use baclofen oral tablets
Lorzone (chlorzoxazone) 375 mg and 750 mg tablet	There is documentation the individual has had an inadequate response, or is intolerant to the following (A): A. chlorzoxazone 500 mg tablet
methocarbamol 1000 mg tablet	The individual is unable to achieve the desired dose with generic methocarbamol 500 mg AND 750 mg tablets.
Norgesic (orphenadrine, aspirin, and caffeine) 25-385-30 mg tablet	There is documentation the individual has had an inadequate response, contraindication, or is intolerant to **ALL** of the following (A, B, C, and D): A. chlorzoxazone 500 mg tablet B. metaxalone tablet C. methocarbamol tablet (500 mg or 750 mg) D. orphenadrine citrate ER tablet
Norgesic Forte (orphenadrine, aspirin, and caffeine) 50-770-60 mg tablet	There is documentation the individual has had an inadequate response, contraindication, or is intolerant to **ALL** of the following (A, B, C, and D): A. chlorzoxazone 500 mg tablet B. metaxalone tablet C. methocarbamol tablet (500 mg or 750 mg) D. orphenadrine citrate ER tablet
orphenadrine, aspirin, and	There is documentation the individual has had an inadequate response, contraindication, or is intolerant to **ALL** of the following (A, B, C, and D):

Non-Preferred Product	Criteria
caffeine 25-385-30 mg tablet	A. chlorzoxazone 500 mg tablet B. metaxalone tablet C. methocarbamol tablet (500 mg or 750 mg) D. orphenadrine citrate ER tablet
orphenadrine, aspirin, and caffeine 50-770-60 mg tablet	There is documentation the individual has had an inadequate response, contraindication, or is intolerant to **ALL** of the following (A, B, C, and D): A. chlorzoxazone 500 mg tablet B. metaxalone tablet C. methocarbamol tablet (500 mg or 750 mg) D. orphenadrine citrate ER tablet
Orphengesic Forte (orphenadrine, aspirin, and caffeine) 50-770-60 mg tablet	There is documentation the individual has had an inadequate response, contraindication, or is intolerant to **ALL** of the following (A, B, C, and D): A. chlorzoxazone 500 mg tablet B. metaxalone tablet C. methocarbamol tablet (500 mg or 750 mg) D. orphenadrine citrate ER tablet
Ozobax (baclofen) 5 mg/5 mL solution	There is documentation the individual has had an inadequate response, or is intolerant to the following (A): A. baclofen tablet
Ozobax (baclofen) 10 mg/5 mL solution	**Ozobax 10 mg/5 mL oral solution** is considered medically necessary when there is documentation of **ONE** of the following: A. Failure, contraindication or intolerance to baclofen tablets B. Inability to swallow baclofen tablets

Individual and Family Plan Non-Preferred Products and Criteria:

Non-Preffered Product	Criteria
baclofen 10 mg/ 5 mL oral solution	**Baclofen 10 mg/5 mL oral solution** is considered medically necessary when there is documentation of **ONE** of the following: A. Failure, contraindication or intolerance to baclofen tablets B. Inability to swallow baclofen tablets
Ozobax (baclofen) 10 mg/5 mL solution	**Ozobax 10 mg/5 mL oral solution** is considered medically necessary when there is documentation of **ONE** of the following: A. Failure, contraindication or intolerance to baclofen tablets B. Inability to swallow baclofen tablets

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When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Reauthorization Criteria

Skeletal muscle relaxants are considered medically necessary for continued use when initial criteria are met AND there is documentation of beneficial response.

Authorization Duration

Initial and reauthorization approval duration is up to 3 months.

Conditions Not Covered

Any other use is considered not medically necessary.

Background

OVERVIEW
Skeletal muscle relaxants have a variety of uses and indications. Table 1 below details the Food and Drug Administration (FDA)-approved labeled uses for these skeletal muscle relaxant products.

Table 1. FDA-Approved Labeled Uses for Skeletal Muscle Relaxants.[4-12]

Drug	FDA-Approved Labeled Use(s)
baclofen solution (Ozobax, generics)	• Indicated for the treatment of spasticity resulting from multiple sclerosis, particularly for the relief of flexor spasms and concomitant pain, clonus, and muscular rigidity. • May also be of some value in patients with spinal cord injuries and other spinal cord diseases. <u>Limitations of Use</u> Not indicated in the treatment of skeletal muscle spasm resulting from rheumatic disorders.
chlorzoxazone tablets (Lorzone, generics) metaxalone tablets (Skelaxin, generics) methocarbamol tablets (Robaxin, generics) orphenadrine citrate extended-release tablets (Norflex, generics)	• As an adjunct to rest, physical therapy, and other measures for the relief of discomfort(s) associated with acute, painful musculoskeletal conditions.
cyclobenzaprine tablets (Fexmid, Flexeril, generics)	• As an adjunct to rest and physical therapy for relief of muscle spasm associated with acute, painful musculoskeletal conditions. Improvement is manifested by relief of muscle spasm and its associated signs and symptoms, namely, pain, tenderness, limitation of motion, and restriction in activities of daily living. Cyclobenzaprine HCl/Fexmid/Flexeril should be used only for short periods (up to 2 or 3 weeks) because adequate evidence of effectiveness for more prolonged use is not available and because muscle spasm associated with acute, painful musculoskeletal conditions is generally of short duration and specific therapy for longer periods is seldom warranted. Cyclobenzaprine HCl/Fexmid/Flexeril has not been found effective in the treatment of spasticity associated with cerebral or spinal cord disease, or in children with cerebral palsy.
cyclobenzaprine extended-release capsules (Amrix, generics)	• As an adjunct to rest and physical therapy for relief of muscle spasm associated with acute, painful musculoskeletal conditions. Improvement is manifested by relief of muscle spasm and its associated signs and symptoms, namely, pain, tenderness, and limitation of motion. Amrix should be used only for short periods (up to two or three weeks) because adequate evidence of effectiveness for more prolonged use is not available and because muscle spasm associated with acute, painful musculoskeletal conditions is generally of short duration and specific therapy for longer periods is seldom warranted. Amrix has not been found effective in the treatment of spasticity associated with cerebral or spinal cord disease or in children with cerebral palsy.

methocarbamol (Robaxin, generics)	• Adjunctive treatment of muscle spasm associated with acute painful musculoskeletal conditions.
orphenadrine citrate/aspirin/caffeine tablets (Norgesic Forte, generics)	• Symptomatic relief of mild to moderate pain of acute musculoskeletal disorders. • The orphenadrine component is indicated as an adjunct to rest, physical therapy, and other measures for the relief of discomfort associated with acute painful musculoskeletal conditions.

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