Clinical Policy: Skeletal Muscle Relaxants, Non-Benzodiazepine Agents

Reference Number: OH.PHAR.PPA.46
Effective Date: 01.01.2020
Last Review Date:
Line of Business: Medicaid

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

CNS AGENTS: SKELETAL MUSCLE RELAXANTS - ORAL

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
BACLOFEN (generic of Lioresal®) CHLORZOXAZONE (generic of Parafon Forte®) CYCLOBENZAPRINE (generic of Flexeril®) DANTROLENE (generic of Dantrium®) METHOCARBAMOL (generic of Robaxin®) TIZANIDINE tablets (generic of Zanaflex®)	CARISOPRODOL (generic of Soma®) * CARISOPRODOL COMPOUND (generic of Soma Compound®) * CARISOPRODOL COMPOUND W/CODEINE (generic of Soma Compound w/Codeine®) * CYCLOBENZAPRINE ER (generic of Amrix®) FEXMID® (cyclobenzaprine) LORZONE® (chlorzoxazone) METAXALONE (generic of Skelaxin®) ORPHENADRINE (generic of Norflex®) ORPHENADRINE COMPOUND (generic of Norgesic®) ORPHENADRINE COMPOUND FORTE (generic of Norgesic Forte®) TIZANIDINE capsules (generic of Zanaflex®)

* Note: Clinical criteria must be met for Soma®/Carisoprodol products– approvable only if no other muscle relaxant or agent to treat fibromyalgia, or any musculoskeletal condition, would serve the clinical needs of the patient.

FDA Approved Indication(s)

- Refer to Clinical Pharmacology or other appropriate clinical resource for FDA approved indications

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that carisoprodol, carisoprodol compound, carisoprodol compound w/codeine, cyclobenzaprine er, Fexmid®, Lorzone®, metaxalone, orphenadrine, orphenadrine compound, orphenadrine compound forte and tizanidine caspules are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Prescribed indication is FDA-approved or supported by standard pharmacopeias

1. Member has had therapeutic failure to a 30 day trial of a medication not requiring prior approval unless one of the following:
   a. Allergy to medications not requiring prior approval
   b. Contraindication to or drug interaction with medications not requiring prior approval
   c. History of unacceptable/toxic side effects to medications not requiring prior approval
2. If the requested medication is soma/carisoprodol product it is approvable only if no other muscle relaxant or agent to treat fibromyalgia, or any musculoskeletal condition, would serve the clinical needs of the patient.

Approval duration: 12 months

II. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – CP.PMN.53 for Medicaid or evidence of coverage documents.

III. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
baclofen oral tablets	5 mg PO TID; increase slowly every 3 days by 5 mg PO TID up to 40 to 80 mg/day given in 3 to 4 divided doses	150 mg/day
Chlorzoxazone (Parafon Forte®)	250 to 500 mg PO given 3 to 4 times per day. May increase to 750 mg PO 3 or 4 times daily	3,000 mg/day

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Cyclobenzaprine (Flexeril®)	5 mg PO 3 TID; If needed, may increase to 7.5 mg or 10 mg PO TID	30 mg/day
dantrolene (Dantrium®)	25 mg PO QD; a gradual dose titration of 25 mg PO QD for 7 days, 25 mg PO TID for 7 days, 50 mg PO TID for 7 days, and 100 mg PO TID QD is recommended.	400 mg/day
Methocarbamol (Robaxin®)	Refer to prescribing information or Micromedex	Refer to prescribing information or Micromedex
Tizanidine (Zanaflex®)	2 mg PO QD; dose can be repeated at 6 to 8 hour intervals as needed to a maximum of 3 doses/24 hrs. Gradually increase the dose by 2 to 4 mg at each dose, with 1-4 days in between dose increases until satisfactory reduction in muscle tone is achieved.	36 mg/day

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic

Appendix C: Contraindications/Boxed Warnings

- Refer to Clinical Pharmacology or other appropriate clinical resource for contraindications or black box warnings

IV. Dosage and Administration

A. Varies by drug product. See FDA approved dosing and administration.

V. Product Availability

A. Varies by drug product. Refer to Clinical Pharmacology or other appropriate clinical resource for product availability.

VI. References

Refer to package insert

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	11.2019	

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.