Original Effective Date: 08/01/2017
Current Effective Date: 12/21/2023
Last P&T Approval/Version: 10/25/2023
Next Review Due By: 10/2024
Policy Number: C11268-A

Carisoprodol Products

PRODUCTS AFFECTED

carisoprodol, carisoprodol w/ aspirin, carisoprodol w/ aspirin & codeine, Soma (carisoprodol), Vanadom (carisoprodol)

COVERAGE POLICY

Coverage for services, procedures, medical devices, and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any. This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:
Acute, painful musculoskeletal conditions

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory generic and that generic drugs will be dispensed whenever available.

A. ACUTE PAINFUL, MUSCULOSKELETAL CONDITIONS:
1. Member has a diagnosis of a painful musculoskeletal condition AND the same source of pain is

acute (<3 months)
AND

2. Prescriber attests (or the clinical reviewer has found that) the member does NOT have ANY of the following:
   (a) History of acute intermittent porphyria
   (b) Dual therapy with more than ONE extended-release opioid analgesic or ONE immediate release opioid analgesic
   (c) Dual therapy with an anti-anxiety benzodiazepine(s) [Alprazolam (Xanax), Clonazepam (Klonopin), Diazepam (Valium), Lorazepam (Ativan), Oxazepam (Serax), Chlordiazepoxide (Librium), Clorazepate dipotassium (Tranxene)]
   (d) Dual therapy with an opioid analgesic AND an anti- anxiety benzodiazepine
   AND
3. Member has a documented trial and failure, serious side effects or clinical contraindication to THREE preferred non- narcotic muscle relaxants (i.e., cyclobenzaprine, baclofen, methocarbamol, etc.)
   AND
4. Member has a documented trial and failure, serious side effects or clinical contraindication to TWO formulary non-steroid anti- inflammatory drugs (NSAIDs)

CONTINUATION OF THERAPY:
N/A

DURATION OF APPROVAL:
Initial Authorization: 21 days, Continuation of Therapy: NA

PRESCRIBER REQUIREMENTS:
No requirement

AGE RESTRICTIONS:
16 years of age and older

QUANTITY:
Soma (carisoprodol): 4 tablets per day, Maximum of 168 tabs per 12 months
Carisoprodol w/ Aspirin: 8 tablets per day
Carisoprodol w/ Aspirin & Codeine: 8 tablets per day

PLACE OF ADMINISTRATION:
The recommendation is that oral medications in this policy will be for pharmacy benefit coverage and patient self-administered.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Oral

DRUG CLASS:
Central Muscle Relaxants

FDA-APPROVED USES:
Treatment of musculoskeletal pain associated with acute, painful musculoskeletal conditions

COMPENDIAL APPROVED OFF-LABELED USES:

None

APPENDIX

APPENDIX:
None

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:
Carisoprodol is indicated for acute musculoskeletal conditions. Exact mechanism of action is not clear, but its sedative effects are likely due to its metabolite, meprobamate. Meprobamate has activity at GABA receptors and is a controlled substance indicated for anxiety. 2 When combined with opioids and/or benzodiazepines member s are at an increased risk for respiratory depression, confusion, seizures, and possibly death. Carisoprodol alone or with opioids and benzodiazepines reportedly caused more than 30,000 emergency department visits in 2009.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
To reduce abuse potential, the duration of therapy should not exceed 2 to 3 weeks; data supporting efficacy for prolonged periods are not available. Contraindications to carisoprodol include: history of acute intermittent porphyria or a hypersensitivity reaction to a carbamate such as meprobamate.

OTHER SPECIAL CONSIDERATIONS:
Carisoprodol with aspirin and codeine is a schedule III-controlled substance. Other carisoprodol products are schedule IV-controlled substances.

CODING/BILLING INFORMATION

Note: 1) This list of codes may not be all-inclusive. 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

HCPCS CODE	DESCRIPTION
NA	

AVAILABLE DOSAGE FORMS:
Carisoprodol TABS 250MG
Carisoprodol TABS 350MG
Carisoprodol-Aspirin TABS 200-325MG
Carisoprodol-Aspirin-Codeine TABS 200-325-16MG
Soma TABS 250MG
Soma TABS 350MG
Vanadom TABS 350MG

REFERENCES

1. Soma [package insert]. Somerset, NJ; Meda Pharmaceutical Inc. May 2023.
2. Carisoprodol tablet [package insert]. Kansas City, MO; Nostrum Laboratories Inc. February 2020.
3. Vanadom (carisoprodol) [prescribing information]. Birmingham, AL: Sallus Laboratories LLC; March 2020.
4. Gonzalez LA, Gatch MB, Forster MJ et al. Abuse Potential of Soma®: the GABAA Receptor as a

Target. Mol Cell Pharmacol. 2009 Jan 1; 1(4): 180–186.
5. Fundin, J. The perfect storm: Opioid risks and 'the holy trinity'. Pharmacy Times. September 24,2014. Available at: http://www.pharmacytimes.com/contributor/jeffrey- fudin/2014/09/the- perfect-storm-opioid-risks-and-the-holy-trinity
6. Qaseem, A., Wilt, T. J., McLean, R. M., & Forciea, M. A. (2017). Noninvasive Treatments for Acute, Subacute, and Chronic Low Back Pain: A Clinical Practice Guideline From the American College of Physicians. Annals of Internal Medicine, 166(7), 514. https://doi.org/10.7326/m16-2367

SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Required Medical Information Contraindications/Exclusions/Di scontinuation Available Dosage Forms References	Q4 2023
REVISION- Notable revisions: Quantity Other Special Considerations Available Dosage Forms References	Q4 2022
Q2 2022 Established tracking in new format	Historical changes on file