

Drug Policy

Policy:	Carisoprodol Prior Approval Criteria	Annual Review Date: 12/21/2023 Last Revised Date: 12/21/2023
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OVERVIEW

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. When combined with opioids and/or benzodiazepines patients 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.

POLICY STATEMENT

This policy involves the use of carisoprodol. Prior authorization is recommended for pharmacy benefit coverage of carisoprodol. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

Prior authorization is recommended for prescription benefit coverage of carisoprodol. Approvals for carisoprodol are 30 days in duration. Only one additional approval will be given to a member in a 365-day time period. The following products are included:

- Soma
- Carisoprodol
- Carisoprodol/aspirin
- Carisoprodol/aspirin/codeine
- Carisoprodol/codeine
- Vanadom

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of carisoprodol containing medication is recommended in those who meet the following criteria:

Initial

1. Acute Musculoskeletal Condition. Approve in patients who meet the following criteria (a, b, c, and d):

- a) Patient is 16 years of age or older; AND

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- b) Requested medication will not be used in combination with an opiate and a benzodiazepine; AND
- c) The provider attests that they have reviewed the patient's controlled substance history by running an Ohio Automated Rx Reporting System (OARRS) Report (or respective prescription monitoring program in the provider's state of practice if available) and has no concerns; AND
- d) Patient has tried and failed at least TWO of the following: baclofen, cyclobenzaprine, metaxalone, tizanidine, orphenadrine, dantrolene, or methocarbamol; AND
- e) The patient does not have a history of acute intermittent porphyria; AND
- f) For brand Soma requests, the patient has tried generic carisoprodol AND cannot use the generic due to a formulation difference in inactive ingredients (e.g. dyes, fillers, preservatives, etc.) between the brand and generic

Extended

2. Acute Musculoskeletal Condition. Approve in patients who meet the following criteria (a, b, c, d, and e):

- a) Patient is 16 years of age or older; AND
- b) Requested medication will not be used in combination with an opiate and a benzodiazepine; AND
- c) The provider attests that they have reviewed the patient's controlled substance history by running an Ohio Automated Rx Reporting System (OARRS) Report (or respective prescription monitoring program in the provider's state of practice if available) and has no concerns; AND
- d) Patient has tried and failed at least TWO of the following: baclofen, cyclobenzaprine, metaxalone, tizanidine, orphenadrine, dantrolene, or methocarbamol; AND
- e) Second request for the medication is over 3 months from first request; AND
- f) The patient does not have a history of acute intermittent porphyria; AND
- g) For brand Soma request, the patient has tried generic carisoprodol AND cannot use the generic due to a formulation difference in inactive ingredients (e.g. dyes, fillers, preservatives, etc.) between the brand and generic

Initial Approval/ Extended Approval.

A) *Initial Approval:* 30 days

B) *Extended Approval:* 30 days (only 1 additional approval allowed in 365 days)

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Carisoprodol has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

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Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Soma [package insert]. Somerset, NJ; Meda Pharmaceutical Inc. March 2019.
2. Gonzalez LA, Gatch MB, Forster MJ et al. Abuse Potential of Soma®: the GABA Receptor as a Target. *Mol Cell Pharmacol*. 2009 Jan 1; 1(4): 180–186.
3. 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>
4. Carisoprodol. In: DRUGDEX [online database]. Truven Health Analytics; Greenwood Village, CO. Last updated 13 December 2023. Accessed on 19 December 2023.
5. Vanadom [package insert]. Birmingham, AL: Sallus Laboratories, LLC; March 2020.
6. Carisoprodol. In: Lexi-Drugs. Lexicomp. Wolters Kluwer Clinical Drug Information, Inc.; Riverwoods, IL. Available at: <http://www.online.lexi.com>. Last updated 18 December 2023. Accessed on 19 December 2023.