

Carisoprodol products Policy Number: C11268-A

CRITERIA EFFECTIVE DATES:

ORIGINAL EFFECTIVE DATE	LAST REVIEWED DATE	NEXT REVIEW DATE
8/1/2017	9/25/2019	9/25/2019
J CODE	TYPE OF CRITERIA	LAST P&T APPROVAL/VERSION
NA	RxPA	Q4 2019 20191030C11268-A

PRODUCTS AFFECTED:

Soma (carisoprodol), Carisoprodol w/ Aspirin, Carisoprodol w/ Aspirin & Codeine

DRUG CLASS:

Central Muscle Relaxants

ROUTE OF ADMINISTRATION:

Oral

PLACE OF SERVICE:

Retail Pharmacy

AVAILABLE DOSAGE FORMS:

Carisoprodol Tab 250MG, Carisoprodol Tab 350MG, Carisoprodol Powder, Soma Tabs 250MG, Soma Tabs 350MG, Carisoprodol w/ Aspirin Tab 200-325 MG, Carisoprodol w/ Aspirin & Codeine Tab 200-325-16 MG

FDA-APPROVED USES:

treatment of musculoskeletal pain associated with acute, painful musculoskeletal conditions

COMPENDIAL APPROVED OFF-LABELED USES: None

COVERAGE CRITERIA: INITIAL AUTHORIZATION

DIAGNOSIS: acute, painful musculoskeletal conditions

REQUIRED MEDICAL INFORMATION:

- A. ACUTE PAINFUL, MUSCULOSKELETAL CONDITIONS:
 - 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) OR (d) Dual therapy with an opioid analgesic AND an anti- anxiety benzodiazepine AND
 - 2. Member has a documented trial and failure or contraindication of THREE preferred nonnarcotic muscle relaxants (ie. cyclobenzaprine, baclofen, methocarbamol, etc) AND

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3. Member has a documented trial and failure or contraindication of TWO formulary non- steroid anti-inflammatory drugs(NSAIDs)

DURATION OF APPROVAL:

Initial Authorization: 21 days, Continuation of Therapy: NA

QUANTITY:

Maximum of 168 tabs per 12 months

PRESCRIBER REQUIREMENTS:

No requirement

AGE RESTRICTIONS:

16 years of age and older

GENDER:

Male and female

CONTINUATION OF THERAPY: NA

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

OTHER SPECIAL 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 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

APPENDIX:

None

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.

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REFERENCES:

- 1. Soma [package insert]. Somerset, NJ; Meda Pharmaceutical Inc. January 2013.
- 2. 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.
- 3. Fundin, J. The perfect storm: Opioid risks and 'the holy trinity'. Pharmacy Times. September 24,2014. Available at: <u>http://www.pharmacytimes.com/contributor/jeffrey-fudin/2014/09/the-</u>perfect- storm-opioid-risks-and-the-holy-trinity