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Section:	Prescription Drugs	**Effective Date:**	October 1, 2025
Subsection:	Neuromuscular Agents	**Original Policy Date:**	June 24, 2016
Subject:	Soma	**Page:**	1 of 5

Last Review Date: September 19, 2025

Soma

Description

Soma (carisoprodol), Soma Compound (carisoprodol and aspirin), Soma Compound w/ Codeine (carisoprodol and aspirin and codeine)

Background
Soma, Soma Compound, and Soma Compound with Codeine are centrally acting skeletal muscle relaxants used to relieve discomfort associated with acute, painful musculoskeletal conditions in people 16 years of age or older. Soma, Soma Compound, and Soma Compound with Codeine should only be used for acute treatment periods up to two or three weeks and are not recommended in pediatric patients less than 16 years of age. Soma, Soma Compound and Soma Compound with Codeine have sedative properties and all patients require monitoring for signs of drug dependence, withdrawal, and abuse because of risk for seizures associated with multiple drug overdoses (1-3).

Regulatory Status
FDA-approved indications: Soma, Soma Compound, and Soma Compound with Codeine are indicated for the relief of discomfort associated with acute, painful musculoskeletal conditions in adults (1-3).

Limitations of Use:
Soma should only be used for short periods (up to two or three weeks) (1-3).

Soma is contraindicated in acute intermittent porphyria or hypersensitivity to carbamate such as meprobamate (1-3).

Soma Compound and Soma Compound with Codeine are contraindicated in patients with serious GI complication (i.e., bleeding, perforations, obstruction) due to aspirin use and patients with aspirin induced asthma (a symptom complex which occurs in patients who have asthma, rhino sinusitis, and nasal polyps who develop a severe, potentially fatal bronchospasm shortly after taking aspirin or other NSAIDs) (2-3).

Codeine sulfate has a boxed warning and is contraindicated for postoperative pain management in children who have undergone tonsillectomy and/or adenoidectomy due to respiratory depression in those children who are ultra rapid metabolizers (3).

Soma agents has been subject to abuse, dependence, withdrawal, misuse, and criminal diversion. Abuse of Soma agents poses a risk of over dosage which may lead to death, CNS and respiratory depression, hypotension, seizures, and other disorders. Withdrawal symptoms have been reported following abrupt cessation of Soma after prolonged use. Reported withdrawal symptoms included insomnia, vomiting, abdominal cramps, headache, tremors, muscle twitching, ataxia, hallucinations, and psychosis. One of Soma's metabolites, meprobamate (a controlled substance), may also cause dependence (1-3).

Soma agents should be used with caution in patients with respiratory depression, seizures, and when used in conjunction with alcohol or other drugs that cause central nervous system depression (1).

Limit the length of treatment to three weeks for the relief of acute musculoskeletal discomfort, keep careful prescription records, monitor for signs of abuse and overdose, and educate patients and their families about abuse and on proper storage and disposal (1-3).

The safety and efficacy of Soma, Soma Compound, and Soma Compound with Codeine in patients under 16 years of age have not been established (1-3).

Related policies

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Soma may be considered **medically necessary** if the conditions indicated below are met.

Soma may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 16 years of age or older

Diagnosis

Patient must have the following:

Acute, painful musculoskeletal conditions

AND NONE of the following:

1. History of acute intermittent porphyria
2. Dual therapy with more than **ONE** extended release opioid analgesic and **ONE** immediate release opioid analgesic
3. Dual therapy with an anti-anxiety benzodiazepine(s)
    a. Alprazolam (Xanax)
    b. Clonazepam (Klonopin)
    c. Diazepam (Valium)
    d. Lorazepam (Ativan)
    e. Oxazepam (Serax)
    f. Chlordiazepoxide (Librium)
    g. Clorazepate dipotassium (Tranxene)

Prior – Approval *Renewal* Requirements

Same as above

Policy Guidelines

Pre - PA Allowance

Age 16 years of age or older

Quantity

Strength	Quantity Limit
Soma 250mg **OR** 350mg	360 tablets per 90 days
Soma Compound 200mg-325mg	
Soma Compound with Codeine 200mg-325mg-16mg	

Maximum daily limit of any combination: 1400mg

Prior - Approval Limits

Age 16 years of age or older

Quantity

Strength	Quantity Limit
Soma 250mg **OR** 350mg	Pre-PA allows for the FDA recommended maximum dosage
Soma Compound 200mg-325mg	
Soma Compound with Codeine 200mg-325mg-16mg	

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Soma, Soma Compound and Soma Compound with Codeine are centrally acting skeletal muscle relaxants used to relieve discomfort associated with acute, painful musculoskeletal conditions in people 16 years of age or older. Concomitant use of CNS depressants such as benzodiazepines, opioids, and tricyclic antidepressants may increase the risk of misuse, drug dependence, withdrawal, and abuse. All patients require monitoring for signs of drug dependence, withdrawal, and abuse because of risk for seizures associated with multiple drug

overdoses. The safety and efficacy of Soma in patients under 16 years of age has not been established (1-3).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Soma while maintaining optimal therapeutic outcomes.

References

1. Soma [package insert]. Somerset, NJ: Meda Pharmaceuticals, Inc.; May 2023.
2. Soma Compound [package insert]. Somerset, NJ: Meda Pharmaceuticals, Inc.; January 2013.
3. Soma Compound w/ Codeine [package insert]. Somerset, NJ: Meda Pharmaceuticals, Inc.; May 2013.

Policy History

Date	Action
June 2016	Addition to Soma PA
December 2016	Annual editorial review and reference update
September 2017	Annual editorial review and reference update
September 2018	Annual editorial review Removal of tapers from criteria
September 2019	Annual review and reference update
September 2020	Annual review
September 2021	Annual review
September 2022	Annual review
September 2023	Annual review and reference update
December 2023	Annual review
September 2024	Annual review
December 2024	Annual review
September 2025	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on September 19, 2025 and is effective on October 1, 2025.