



**MEDICAL EVALUATORS
OF TEXAS** ASO, L.L.C.

1225 North Loop West • Suite 1055 • Houston, TX 77008
800-845-8982 FAX: 713-583-5943

Notice of Independent Review Decision

DATE OF REVIEW: February 20, 2014

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE

Soma 350 mg one p.o. t.i.d., #90

**A DESCRIPTION OF THE QUALIFICATIONS FOR EACH PHYSICIAN OR OTHER
HEALTH CARE PROVIDER WHO REVIEWED THE DECISION**

This case was reviewed by a board certified Orthopaedic surgeon currently licensed and practicing in the State of Texas.

REVIEW OUTCOME

Upon independent review the reviewer finds that the previous adverse determination/adverse determinations should be:

- Upheld (Agree)
- Overturned (Disagree)
- Partially Overturned (Agree in part/Disagree in part)

INFORMATION PROVIDED TO THE IRO FOR REVIEW

Type of Document Received	Date(s) of Record
Office visit	11/12/2013
Notice of utilization review findings	11/26/2013
Medical Interlocutory Order request	01/10/2014
A request for an IRO	02/06/2014



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EMPLOYEE CLINICAL HISTORY [SUMMARY]:

is a male who injured his lower back on xx/xx/xx, for which he had multiple surgeries. A follow up note dated 11/12/2013 indicates he continues to experience stabbing pain in his lower back and burning in thighs associated with pins/needles in the feet. On physical exam, he was having difficulty rising from a seated to standing position. Forward bending was restricted. He was standing forward flexed at least 10°. He was diagnosed with post laminectomy syndrome, L1 HNP with L1 stenosis, chronic mechanical lower back pain and neuropathic leg pain. noted that he tried multiple opiate analgesics for several years with satisfactory pain control. He prescribed Talwin NX one every 3-4 hours p.r.n. for pain, #150 for 1 month supply; Duragesic 50 mcg patches, using one every three days, #10 for 1 month supply; and Soma 350 mg one p.o. t.i.d. p.r.n. for muscle spasm, typically brand name, #90 for 1 month supply. There is a previous adverse determination who stated “these medications are not supported by the ODG and are not on the approved Texas workers’ compensation formulary. The clinical provided does not establish medical necessity for why a deviation should be allowed. Therefore, the request is not authorized.” The current request is whether or not Soma 350 mg p.o. t.i.d. p.r.n., #90 is medically necessary and reasonable medication.

ANALYSIS AND EXPLANATION OF THE DECISION INCLUDE CLINICAL BASIS, FINDINGS AND CONCLUSIONS USED TO SUPPORT THE DECISION.

As per ODG, Soma is FDA approved for symptomatic relief of discomfort associated with acute pain in musculoskeletal conditions as an adjunct to rest and physical therapy. The primary metabolite is meprobamate and is a schedule IV controlled substance. This patient continues to experience stabbing pain in his lower back. He had several surgeries and has chronic mechanical lower back and neuropathic pain. He requires long-term pain relief for chronic lower back pain and Soma is not indicated for long-term use as per ODG. Other methods of pain relief should be utilized.

ODG Criteria for Carisoprodol (Soma®) – Pain (Chronic)

Not recommended. This medication is FDA-approved for symptomatic relief of discomfort associated with acute pain in musculoskeletal conditions as an adjunct to rest and physical therapy. (AHFS, 2008) This medication is not indicated for long-term use. Carisoprodol is a commonly prescribed, centrally acting skeletal muscle relaxant whose primary active metabolite is meprobamate (a Schedule-IV controlled substance). As of January 2012, carisoprodol is scheduled by the DEA as a Schedule IV medication. (DEA, 2012) It has been suggested that the main effect is due to generalized sedation and treatment of anxiety.

Beers criteria: The AGS updated Beers criteria for inappropriate medication use includes carisoprodol. This is a list of potentially inappropriate medications for older adults. (AGS, 2012)



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Abuse: Abuse has been noted for sedative and relaxant effects. In regular abusers the main concern is the accumulation of meprobamate. Carisoprodol abuse has also been noted in order to augment or alter effects of other drugs. This includes the following: (1) increasing sedation of benzodiazepines or alcohol; (2) use to prevent side effects of cocaine; (3) use with tramadol to produce relaxation and euphoria; (4) as a combination with hydrocodone, an effect that some abusers claim is similar to heroin (referred to as a "Las Vegas Cocktail"); & (5) as a combination with codeine (referred to as "Soma Coma"). (Reeves, 1999) (Reeves, 2001) (Reeves, 2008) (Schears, 2004) (Owens, 2007) (Reeves, 2012) There was a 300% increase in numbers of emergency room episodes related to carisoprodol from 1994 to 2005. (DHSS, 2005) Hospital emergency department visits involving the misuse of carisoprodol have doubled over five years, study shows. (SAMHSA, 2011)

Intoxication signs: Intoxication appears to include subdued consciousness, decreased cognitive function, and abnormalities of the eyes, vestibular function, appearance, gait and motor function. Intoxication includes the effects of both carisoprodol and meprobamate, both of which act on different neurotransmitters. (Bramness, 2007) (Bramness, 2004)

Withdrawal: A withdrawal syndrome has been documented that consists of insomnia, vomiting, tremors, muscle twitching, anxiety, and ataxia when abrupt discontinuation of large doses occurs. This is similar to withdrawal from meprobamate. (Reeves, 2010) (Reeves, 2007) (Reeves, 2004)

Weaning: There is little research in terms of weaning of high dose carisoprodol and there is no standard treatment regimen for patients with known dependence. Most treatment includes treatment for symptomatic complaints of withdrawal. Another option is to switch to phenobarbital to prevent withdrawal with subsequent tapering. A maximum dose of phenobarbital is 500 mg/day and the taper is 30 mg/day with a slower taper in an outpatient setting. Tapering should be individualized for each patient. (Boothby, 2003) For more information and references, see Muscle relaxants. See also Weaning, carisoprodol (Soma®).



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**A DESCRIPTION AND THE SOURCE OF THE SCREENING CRITERIA OR OTHER
CLINICAL BASIS USED TO MAKE THE DECISION:**

- ACOEM- AMERICAN COLLEGE OF OCCUPATIONAL & ENVIRONMENTAL MEDICINE UM KNOWLEDGEBASE
- AHCPR- AGENCY FOR HEALTHCARE RESEARCH & QUALITY GUIDELINES
- DWC- DIVISION OF WORKERS COMPENSATION POLICIES OR GUIDELINES
- EUROPEAN GUIDELINES FOR MANAGEMENT OF CHRONIC LOW BACK PAIN
- INTERQUAL CRITERIA
- MEDICAL JUDGEMENT, CLINICAL EXPERIENCE AND EXPERTISE IN ACCORDANCE WITH ACCEPTED MEDICAL STANDARDS
- MERCY CENTER CONSENSUS CONFERENCE GUIDELINES
- MILLIMAN CARE GUIDELINES
- ODG- OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES**
- PRESSLEY REED, THE MEDICAL DISABILITY ADVISOR
- TEXAS GUIDELINES FOR CHIROPRACTIC QUALITY ASSURANCE & PRACTICE PARAMETERS
- TEXAS TACADA GUIDELINES
- TMF SCREENING CRITERIA MANUAL
- PEER REVIEWED NATIONALLY ACCEPTED MEDICAL LITERATURE (PROVIDE A DESCRIPTION)
- OTHER EVIDENCE BASED, SCIENTIFICALLY VALID, OUTCOME FOCUSED GUIDELINES (PROVIDE A DESCRIPTION)