



Medical Review Institute of America, Inc.
America's External Review Network

DATE OF REVIEW: May 28, 2010

IRO Case #:

Description of the services in dispute:

Medical necessity of Ambien CR 12.5 mg, Soma 350 mg, and clonazepam 0.5 mg.

A description of the qualifications for each physician or other health care provider who reviewed the decision

This physician reviewer is board certified by the American Board of Anesthesiology in General Anesthesiology and Pain Medicine. This reviewer is a member of American Society of Anesthesiology, American Society of Interventional Pain Physicians, and American Society of Regional Anesthesia.

Review Outcome

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

Upheld

The medical necessity for Ambien CR 12.5 mg, Soma 350 mg, and clonazepam 0.5 mg is not established.

Information provided to the IRO for review

Medical Records from the state:

Request for Review by and Independent Review Organization, 5/10/10, 9 pages.

Notice of Utilization Review Findings, 3/31/10, 4 pages.

Notice of Utilization Review Findings, 4/30/10, 3 pages.

Letter, 4/30/10, 1 page.

Record from Forte':

Texas Dept. of Insurance, Notice of Utilization Review, 5/11/10, 1 page.

MD, Letter of Medical Necessity, 3/22/10, 1 page.

MD, Progress Note, 4/19/10, 1 page.

MD, Progress Note, 3/22/10, 1 page.

MD, Progress Note, 2/22/10, 1 page.

MD, Progress Note, 1/25/10, 1 page.

MD, Progress Note, 12/28/09, 1 page.

Notice of Independent Review, 5/11/10, 1 page.
MD, Progress Note, 11/30/09, 1 page.
MD, Progress Note, 11/02/09, 1 page.
Occupational Health Systems, Independent Medical Exam, 13 pages.
MD, Progress Note, 10/05/09, 1 page.

Texas DOI:

Notice of Independent Review, 5/11/10, 1 page.
MD, Progress Note, 9/8/09, 1 page.
MD, Progress Note, 8/11/09, 1 page.
MD, Progress Note, 7/14/09, 1 page.
MD, Progress Note, 6/17/09, 1 page.
MD, Progress Note, 5/18/09, 1 page.
MD, Progress Note, 4/20/09, 1 page.
MD, Progress Note, 3/27/09, 1 page.
MD, Progress Note, 2/26/09, 1 page.
MD, Progress Note, 1/30/09, 1 page.
MD, Progress Note, 1/2/09, 1 page.
MD, Progress Note, 12/2/08, 1 page.
MD, Progress Note, 11/4/08, 1 page.
MD, Progress Note, 10/7/08, 1 page.
MD, Progress Note, 10/19/08, 1 page.
MD, Progress Note, 8/1/08, 1 page.
MD, Progress Note, 7/2/08, 1 page.
MD, Progress Note, 6/4/08, 1 page.
MD, Progress Note, 5/5/08, 1 page.
MD, Progress Note, 4/7/08, 1 page.
MD, Progress Note, 3/7/08, 1 page.
MD, Progress Note, 2/12/08, 1 page.
MD, Progress Note, 1/15/08, 1 page.
MD, Progress Note, 2/19/07, 1 page.
MD, Progress Note, 12/14/07, 1 page.
MD, Progress Note, 11/19/07, 1 page.
MD, Progress Note, 10/25/07, 1 page.
MD, Progress Note, 9/25/07, 1 page.
MD, Progress Note, 8/23/07, 1 page.
MD, Progress Note, 8/1/07, 1 page.
MD, Progress Note, 7/25/07, 1 page.
MD, Progress Note, 6/25/07, 1 page.
MD, Progress Note, 5/25/07, 1 page.
MD, Progress Note, 4/25/07, 1 page.
MD, Progress Note, 3/30/07, 1 page.
MD, Progress Note, 3/2/07, 4 pages.

Patient clinical history [summary]

The patient is a male who sustained injury 10 years ago while lifting a manhole cover; date of injury was xx/xx/xx. The patient has undergone two back surgeries and has been diagnosed with post lumbar laminectomy syndrome, lumbar facet syndrome, depression and anxiety, chronic pain syndrome, and lumbar radiculopathy. Current medications include Vicoprofen, Klonopin, Cymbalta, Lidoderm patches, Soma, and Ambien CR.

Analysis and explanation of the decision include clinical basis, findings and conclusions used to support the decision.

Ambien CR is a short-acting nonbenzodiazepine hypnotic used for the treatment of insomnia. The Official Disability Guidelines support its use for two to six weeks with the treatment of insomnia. There is concern in the literature that they may increase pain and depression over long-term use, therefore, the medical necessity in this gentleman's case with history of depression and chronic pain is not supported.

Soma 350 mg is the brand name of carisoprodol. It is suggested as an adjunct in painful skeletal conditions for acute "no longer than two to three-period" back ache. Withdrawal symptoms may occur with abrupt discontinuation and would require weaning. The use of Soma in this patient's case is not supported over the long term.

Clonazepam is the generic name of Klonopin, which is a benzodiazepine anxiety medication. Clonazepam is primarily used as an adjunct during the initiation of a selective serotonin reuptake inhibitor (SSRI). Its long-term use is problematic and physiologic dependence can occur with long-term use. These drugs have no antidepressant effect. The Official Disability Guidelines would not support the use of this medication for in the long term as it has been utilized in this patient's case.

A description and the source of the screening criteria or other clinical basis used to make the decision:

Official Disability Guidelines, Pain Chapter.

Clonazepam

Benzodiazepines: Effective for acute treatment. Long-term use is problematic as few patients achieve and sustain remission with monotherapy. These agents are used primarily as an adjunct for stabilization during initiation of an SSRI or SNRI. The disadvantage of use is the risk of abuse and physiological dependence with long-term use. These drugs also have no anti-depressant effect.

Diazepam (Valium®, generic available): Dosing information: 5–15 mg daily. Clonazepam

(Klonopin®, generic available): Dosing information: 1–2 mg up to TID.

Soma

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). Carisoprodol is now scheduled in several states but not on a federal level. It has been suggested that the main effect is due to generalized sedation and treatment of anxiety. 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) There was a 300% increase in numbers of emergency room episodes related to carisoprodol from 1994 to 2005. (DHSS, 2005) 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) 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) 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 of medications.

Ambien

Zolpidem is a prescription short-acting nonbenzodiazepine hypnotic, which is approved for the short-term (usually two to six weeks) treatment of insomnia. Proper sleep hygiene is critical to the individual with chronic pain and often is hard to obtain. Various medications may provide short-term benefit. While sleeping pills, so-called minor tranquilizers, and anti-anxiety agents are commonly prescribed in chronic pain, pain specialists rarely, if ever, recommend them for long-term use. They can be habit-forming, and they may impair function and memory more than opioid pain relievers. There is also concern that they may increase pain and depression over the long-term. (Feinberg, 2008)