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| Case Number: | CM13-0025938 | | |
| Date Assigned: | 11/22/2013 | Date of Injury: | 08/21/1998 |
| Decision Date: | 02/11/2014 | UR Denial Date: | 08/21/2013 |
| Priority: | Standard | Application Received: | 09/17/2013 |

HOW THE IMR FINAL DETERMINATION WAS MADE

MAXIMUS Federal Services sent the complete case file to a physician reviewer. He/she has no affiliation with the employer, employee, providers or the claims administrator. The physician reviewer is Board Certified in Pain Management, has a subspecialty in Disability Evaluation and is licensed to practice in California. He/she has been in active clinical practice for more than five years and is currently working at least 24 hours a week in active practice. The physician reviewer was selected based on his/her clinical experience, education, background, and expertise in the same or similar specialties that evaluate and/or treat the medical condition and disputed items/services. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

CLINICAL CASE SUMMARY

The expert reviewer developed the following clinical case summary based on a review of the case file, including all medical records:

This is a 40 years old female who was injured in an industrial related accident in 8/9/1998. The accident occurred when patient fell face first off a set of stairs and after the fall experienced pain in the neck, back and right upper extremity. Pt has been treated both conservatively and with surgery. However, patient continue to have chronic neck, shoulder, and head pain(migraines) Review of the records show that the patient has been seen and treated by multiple neurologists and tried different medications without any relief from the pain of her migraines. . She has been diagnosed with complex regional pain syndrome to her right upper extremity. She has been treated for a long time at a pain management clinic. She reports having nausea and vomiting and feeling extremely tired. She has also been treated with different narcotic medications and different does over time. In addition to the diagnosis of complex pain syndrome of the right upper extremity noted above, patient also has the following diagnoses: chronic back pain, cervical disc disease, cervicogenic migraines, chronic anxiety, chronic left lower extremity pain and chronic constipation. At issue is the prescriptions for compounded topical (Ketamine 5%, Gabapentin 10%, Clonidine 0.2% and Baclofen 240 gm; Oxycontin 40 mg #105; Oxycodone 15 mg #75; Oxycodone 15 mg #75 and Soma 350 mg # 90.

IMR ISSUES, DECISIONS AND RATIONALES

The Final Determination was based on decisions for the disputed items/services set forth below:

Compounded topical cream (Katamine 5%, Gabapentin 10 %, Clonidine 0.2% and Baclofen 240 mg): Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-113.

Decision rationale: According to Chronic Pain Medical Treatment Guidelines (MTUS (Effective July 18, 2009) page 56 of 127, Ketamine is not recommended for treatment of chronic pain since there is insufficient evidence supporting its use. There are no quality studies that support the use of ketamine for chronic pain, but it is under study for CRPS. (Goldberg², 2005) (Grant, 1981) (Rabben, 1999) Ketamine is an anesthetic in animals and humans, and also a drug of abuse in humans, but ketamine may offer a promising therapeutic option in the treatment of appropriately selected patients with intractable CRPS. More study is needed to further establish the safety and efficacy of this drug. (Correll, 2004) One very small study concluded that ketamine showed a significant analgesic effect on peripheral neuropathic pain, but the clinical usefulness is limited by disturbing side effects. Another study by the same author with a sample size too small for ODG (10) concluded that ketamine showed a significant analgesic effect in patients with neuropathic pain after spinal cord injury, but ketamine was associated with frequent side effects. (Kvarnström, 2003-4). Therefore the prescription of Ketamine 5% cream is not medically necessary. Also in page 111 to 113, of the MTUS Guidelines, states "Topical Ketamine: Under study: Only recommended for treatment of neuropathic pain in refractory cases in which all primary and secondary treatment has been exhausted. Topical ketamine has only been studied for use in non-controlled studies for CRPS I and post-herpetic neuralgia and both have shown encouraging results. The exact mechanism of action remains undetermined. (Gammaitoni, 2000) (Lynch, 2005) See also Glucosamine (and Chondroitin Sulfate)". Largely experimental in use with few randomized controlled trials to determine efficacy or safety. Primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. (Namaka, 2004) These agents are applied locally to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. (Colombo, 2006) Many agents are compounded as monotherapy or in combination for pain control (including NSAIDs, opioids, capsaicin, local anesthetics, antidepressants, glutamate receptor antagonists, α -adrenergic receptor agonist, adenosine, cannabinoids, cholinergic receptor agonists, β agonists, prostanoids, bradykinin, adenosine triphosphate, biogenic amines, and nerve growth factor). (Argoff, 2006) There is little to no research to support the use of many of these agents. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Baclofen: Not recommended. There is currently one Phase III study of Baclofen-Amitriptyline- Ketamine gel in cancer patients for treatment of chemotherapy-induced peripheral neuropathy. There is no peer-reviewed literature to support the use of topical Baclofen. Therefore the request

Oxycontin 40 mg #105: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids
Page(s): 81-89.

Decision rationale: The California MTUS section on Oxycodone immediate release (OxyIR® capsule; Roxicodone® tablets; generic available), Oxycodone controlled release (OxyContin®): [Boxed Warning]: Oxycontin® Tablets are a controlled release formulation of Oxycodone hydrochloride indicated for the management of moderate to severe pain when a continuous, around-the-clock analgesic is needed for an extended period of time. OxyContin tablets are NOT intended for use as a prn analgesic. Side Effects: See opioid adverse effects. Analgesic dose: (Immediate release tablets) 5mg every 6 hours as needed. Controlled release: In opioid naive patients the starting dose is 10mg every 12 hours. Doses should be tailored for each individual patient, factoring in medical condition, the patient's prior opioid exposure, and other analgesics the patient may be taking. See full prescribing information to calculate conversions from other opioids. Note: See manufacturer's special instructions for prescribing doses of over 80mg and 160mg. Dietary caution: patients taking 160mg tablets should be advised to avoid high fat meals due to an increase in peak plasma concentration. Based on records provided, there is no documentation that the patient has been screened for aberrant behavior, there is no documentation that opioids have had any functional or vocational benefit or that they have resulted in a reduction in the patient's pain. Therefore the request for Oxycontin is not certified.

Oxycodone 15 mg #75: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids
Page(s): 81-89.

Decision rationale: The California MTUS section on Hydrocodone/Acetaminophen (Anexsia®; Co-Gesic®; Hycetâ; Lorcet®, Lortab®; Margesic-H®, Maxidoneâ; Norco®, Stagesic®, Vicodin®, Xodol®, Zydone®; generics available): Indicated for moderate to moderately severe pain. Note: there are no FDA-approved Hydrocodone products for pain unless formulated as a combination. Side Effects: See opioid adverse effects. Analgesic dose: The usual dose of 5/500mg is 1 or 2 tablets PO every four to six hours as needed for pain (Max 8 tablets/day). For higher doses of Hydrocodone (>5mg/tab) and acetaminophen (>500mg/tab) the recommended dose is usually 1 tablet every four to six hours as needed for pain. Hydrocodone has a recommended maximum dose of 60mg/24 hours. The dose is limited by the dosage of acetaminophen, which should not exceed 4g/24 hours. Based on records provided, there is no documentation that the patient has been screened for aberrant behavior, there is no documentation that opioids have had any functional or vocational benefit or that they have resulted in a reduction in the patient's pain. Therefore the request for Oxycodone 15 mg #75 is not medically necessary.

Compazine 5 mg #90: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation FDA information on Compazine for medical professionals.

Decision rationale: Recommended for control of severe nausea and vomiting and treatment of schizophrenia, Compazine (prochlorperazine) is effective for the short-term treatment of generalized non-psychotic anxiety. However, Compazine is not the first drug to be used in therapy for most patients with non-psychotic anxiety, because certain risks associated with its use are not shared by common alternative treatments (e.g., benzodiazepines). When used in the treatment of non-psychotic anxiety, Compazine should not be administered at doses of more than 20 mg per day or for longer than 12 weeks, because the use of Compazine higher doses or for longer intervals may cause persistent tardive dyskinesia that may prove irreversible (see WARNINGS). The effectiveness of Compazine as treatment for non-psychotic anxiety was established in 4-week clinical studies of outpatients with generalized anxiety disorder. This evidence does not predict that Compazine will be useful in patients with other non-psychotic conditions in which anxiety, or signs that mimic anxiety, are found (e.g., physical illness, organic mental conditions, agitated depression, character pathologies, etc.). Compazine has not been shown effective in the management of behavioral complications in patients with mental retardation. In this patient, the nausea is said to be due to opioids. At this time the patient is not authorized for any opioids and there is no other indication for Compazine. Therefore the request for Compazine 5 mg #90 is not medically necessary.

Xanax 1 mg #15: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Benzodiazepines Page(s): 24.

Decision rationale: According to Chronic Pain Medical Treatment guideline (MTUS 2009), page 24 of 127, Benzodiazepines (XANAX): Not recommended for long-term use because long-term efficacy is unproven and there is a risk of dependence. Most guidelines limit use to 4 weeks. Their range of action includes sedative/hypnotic, anxiolytic, anticonvulsant, and muscle relaxant. Chronic benzodiazepines are the treatment of choice in very few conditions. Tolerance to hypnotic effects develops rapidly. Tolerance to anxiolytic effects occurs within months and long-term use may actually increase anxiety. A more appropriate treatment for anxiety disorder is an antidepressant. Tolerance to anticonvulsant and muscle relaxant effects occurs within weeks. (Baillargeon, 2003) (Ashton, 2005) Benzodiazepines are not supported for long-term use due to unproven efficacy and risk of dependence. Therefore the request for Xanax 1 mg #15 is not medically necessary.

Soma 350 mg #90: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Carisoprodol Page(s): 29.

Decision rationale: The California MTUS section on Muscle relaxant Carisoprodol (Soma®): Not recommended. 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) 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, 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). Therefore the request for Soma 350 mg #90 is not medically necessary.