MAXIMUS Federal Services

Case Number:	CM15-0140881		
Date Assigned:	07/30/2015	Date of Injury:	12/14/1990
Decision Date:	10/07/2015	UR Denial Date:	07/12/2015
Priority:	Standard	Application Received:	07/20/2015

HOW THE IMR FINAL DETERMINATION WAS MADE

MAXIMUS Federal Services sent the complete case file to an expert reviewer. He/she has no affiliation with the employer, employee, providers or the claims administrator. 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 expert 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/Service. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

The Expert Reviewer has the following credentials:
State(s) of Licensure: Montana
Certification(s)/Specialty: Preventive Medicine, Occupational Medicine

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 injured worker is a 42 year old female who reported an industrial injury on 12-14-1990. Her diagnoses, and or impression, were noted to include: chronic pain syndrome; lumbosacral spondylosis without myelopathy; lumbago; thoracic or lumbosacral neuritis or radiculitis; other pain disorder related to psychological factors; sciatica; fasciitis; drug dependence - encounter for long-term use of other medications; and depression. No current imaging studies were noted. Her treatments were noted to include manual therapy and manipulation; TENS unit; Botox injections; thoracic trigger point injection therapy; diagnostic studies; multiple lumbosacral radio-frequency ablation procedures; medication management; and a return to work. The progress notes of 6-24-2015 reported ongoing low back and buttock pain status-post a good recovery following lumbar "RF"; and an episode of sciatica, with severe pain, that was emotionally triggered. Objective findings were noted to include a review of records and an unchanged examination from the previous visit; no specific objective findings were noted. The physician's requests for treatments were noted to include a detoxification program and Suboxone for pain.

IMR ISSUES, DECISIONS AND RATIONALES

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

5 day detox at facility: Overturned

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines, Pain Chronic.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Detoxification.

Decision rationale: The ODG guidelines state that detox programs are most commonly recommended when there is evidence of substance misuse or abuse, evidence that medication is not efficacious, or evidence of excessive complications related to use. Detoxification is defined as a medical intervention that manages a patient through withdrawal syndromes. While the main indication as related to substance-related disorders is evidence of aberrant drug behaviors, other indications for detoxification have been suggested. These include the following: (1) Intolerable side effects; (2) Lack of response to current pain medication treatment (particularly when there is evidence of increasingly escalating doses of substances known for dependence); (3) Evidence of hyperalgesia; (4) Lack of functional improvement; and/or (5) Refractory comorbid psychiatric illness. It can therefore be seen that a recommendation for detoxification does not necessarily imply a diagnosis of addiction, or of substance-related disorder. There are no specific guidelines that have been developed for detoxification for patients with chronic pain. This intervention does not constitute complete substance abuse treatment. The process of detoxification includes evaluation, stabilization, and preparation of the patient for further treatment that should be specifically tailored to each patient's diagnostic needs. Complete withdrawal of all medications is not always recommended, although evidence of abuse and/or dependence strengthens the rationale for such.(TIP 45, 2006) (Wright, 2009) (Benzon, 2005) For average hospital LOS if criteria are met, actual data shows, median 4 days; mean 4.1 days (0.2); discharges 78,219; charges (mean) $9,756. Best practice target (no complications), 4 days. In this case, The primary treating physician and patient have discussed her depression and other issues and concerns related to long-term use of opioids for her chronic pain condition. They have decided to pursue a 5 day detox program. The injured worker has continued to work and is motivated towards this goal. The request for 5 day detox at facility is reasonable for long-term management of her chronic pain and is medically necessary.

120 Subuxone 4/2: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Buprenorphine, Opioids for chronic pain, Opioids, specific drug list. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Buprenorphine for chronic pain and buprenorphine for opioid dependence.

Decision rationale: The MTUS notes that on-going pain opioid management actions should include: (a) Prescriptions from a single practitioner taken as directed, and all prescriptions from a single pharmacy. (b) The lowest possible dose should be prescribed to improve pain and

function. (c) Office: Ongoing review and documentation of pain relief, functional status, appropriate medication use, and side effects. Pain assessment should include: current pain; the least reported pain over the period since last assessment; average pain; intensity of pain after taking the opioid; how long it takes for pain relief; and how long pain relief lasts. Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function, or improved quality of life. Information from family members or other caregivers should be considered in determining the patient's response to treatment. The 4 A's for Ongoing Monitoring: Four domains have been proposed as most relevant for ongoing monitoring of chronic pain patients on opioids: pain relief, side effects, physical and psychosocial functioning, and the occurrence of any potentially aberrant (or nonadherent) drug-related behaviors. These domains have been summarized as the "4 A's" (analgesia, activities of daily living, adverse side effects, and aberrant drug taking behaviors). The monitoring of these outcomes over time should affect therapeutic decisions and provide a framework for documentation of the clinical use of these controlled drugs. (Passik, 2000) (d) Home: To aid in pain and functioning assessment, the patient should be requested to keep a pain dairy that includes entries such as pain triggers, and incidence of end-of-dose pain. It should be emphasized that using this diary will help in tailoring the opioid dose. This should not be a requirement for pain management. (e) Use of drug screening or inpatient treatment with issues of abuse, addiction, or poor pain control. (f) Documentation of misuse of medications (doctor-shopping, uncontrolled drug escalation, drug diversion). (g) Continuing review of overall situation with regard to nonopioid means of pain control. (h) Consideration of a consultation with a multidisciplinary pain clinic if doses of opioids are required beyond what is usually required for the condition or pain does not improve on opioids in 3 months. Consider a psych consult if there is evidence of depression, anxiety or irritability. Consider an addiction medicine consult if there is evidence of substance misuse. The ODG guidelines note that Suboxone (Buprenorphine hydrochloride and naloxone hydrochloride sublingual film) is recommended as an option for treatment of chronic pain (consensus based) in selected patients (not first-line for all patients). Suggested populations: (1) Patients with a hyperalgesic component to pain; (2) Patients with centrally mediated pain; (3) Patients with neuropathic pain; (4) Patients at high-risk of non-adherence with standard opioid maintenance; (5) For analgesia in patients who have previously been detoxified from other high-dose opioids. Use for pain with formulations other than Butrans is off-label. Due to complexity of induction and treatment the drug should be reserved for use by clinicians with experience. Drug description: Buprenorphine is a schedule-III controlled substance. Its mechanism of action is complex, involving four different opioid receptors at central and peripheral sites. It is primarily classified as a partial mu-agonist and kappa antagonist. It blocks effects of subsequently administered opioid agonists. Buprenorphine hydrochloride and naloxone hydrochloride sublingual film (Suboxone; no generics): Available as a film in doses of buprenorphine/ naloxone of 2mg/0.5mg, 4mg/1 mg, 8mg/2 mg and 12mg/3 mg. Tablet formulations are available as 2mg/0.5mg and 8mg/2mgs. Discontinuation of branded Suboxone sublingual tablets is to occur on 3/18/13, being replaced by the sublingual film described above.In this case, the medical records document that the treating physician, who is a pain specialist, has recommended a 5 day detox program. That request has been determined to be medically necessary. As such, it is likely that Suboxone would be used as part of that program and possibly used as a long-term treatment. Current use should be deferred to the detox program. The request for 120 Subuxone 4/2 is not considered to be medically necessary.

30 Ambien CR 12.5mg with 2 refills: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines, Pain Chronic.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Drug formulary, Zolpidem (Ambien).

Decision rationale: The ODG guidelines note that zolpidem (Ambien) 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. Ambien CR offers no significant clinical advantage over regular release zolpidem. Ambien CR is approved for chronic use, but chronic use of hypnotics in general is discouraged. Ambien CR causes a greater frequency of dizziness, drowsiness, and headache compared to immediate release zolpidem. Cognitive behavioral therapy (CBT) should be an important part of an insomnia treatment plan. A study of patients with persistent insomnia found that the addition of zolpidem immediate release to CBT was modestly beneficial during acute (first 6 weeks) therapy, but better long-term outcomes were achieved when zolpidem IR was discontinued and maintenance CBT continued. Due to adverse effects the FDA now requires lower doses for zolpidem. Even at the lower dose of Ambien CR now recommended by the FDA, 15% of women and 5% of men still had high levels of the drug in their system in the morning. According to SAMHSA, zolpidem is linked to a sharp increase in ED visits, so it should be used safely for only a short period of time.In this case, the medical records document use of Ambien well beyond the two to six weeks (short- term) recommendation for treatment and the current request is for an additional 3 month supply. The request for AmbienCR 12.5mg #30 with 2 refills is not consistent with ODG recommendations and is not medically necessary.

90 Baclofen 10mg, plus 2 refills: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Muscle relaxants (for pain).

Decision rationale: The MTUS notes that muscle relaxants are recommended with caution as a second line option for short term treatment of acute exacerbations in patients with chronic low back pain. Muscle relaxants may be effective in reducing pain and muscle tension and increasing mobility. However, in most low back pain cases they show no benefit beyond nonsteroidal anti-inflammatory drugs in pain and overall improvement. Efficacy does appear to diminish over

time. Sedation as the most commonly reported adverse effect of muscle relaxant medications. Muscle relaxants are a broad range of medications that are generally divided into antispasmodics, antispasticity drugs, and drugs with both actions. Baclofen is an antispasticity drug used to decrease spasticity in conditions such as cerebral palsy, MS, and spinal cord injuries (upper motor neuron syndromes). The mechanism of action is blockade of the pre- and post-synaptic GABAB receptors. It is recommended orally for the treatment of spasticity and muscle spasm related to multiple sclerosis and spinal cord injuries. Baclofen has been noted to have benefits for treating lancinating, paroxysmal neuropathic pain (trigeminal neuralgia, nonFDA approved). (ICSI, 2007) Side Effects: Sedation, dizziness, weakness, hypotension, nausea, respiratory depression and constipation. This drug should not be discontinued abruptly (withdrawal includes the risk of hallucinations and seizures). Use with caution in patients with renal and liver impairment. Dosing: Oral: 5 mg three times a day. Upward titration can be made every 3 days up to a maximum dose of 80 mg a day. (See, 2008) In this case the records show that baclofen has been used on a long-term basis with the current request. This clearly exceeds the MTUS recommendation for short-term use. The request for baclofen 10 mg #60 is not medically necessary.

120 Oxycodone HCL 15mg: Overturned

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Opioids (Classification), Opioids, criteria for use, Opioids for chronic pain, Opioids for neuropathic pain, Opioids, long-term assessment, Opioids, specific drug list, Opioids, steps to avoid misuse/addiction.

Decision rationale: The MTUS states that reasonable alternatives to opioid use should be attempted. There should be a trial of non-opioid analgesics. When subjective complaints do not correlate with clinical studies a second opinion with a pain specialist and a psychological assessment should be obtained. The lowest possible dose should be prescribed to improve pain and function. Ongoing use of oxycodone/acetaminophen requires review and documentation of pain relief, functional status, appropriate medication use, and side effects. Pain assessment should include: the least reported pain over the period since the last assessment; average pain; intensity of pain after taking the opioid; how long it takes for pain relief; and how long pain relief lasts. In this case the medical records do document long-term use of oxycodone with no side effects or aberrant pain behaviors. The records do documentation functional improvement, allowing her to work and maintain ADLs. There has not been any documented attempt to decrease or wean medication over time but the dose required has been modified with temporary improvement related to other treatments such as RF ablation. The treating physician, who does specialize in pain management, has discussed the issues related to long-term use of opioids and together they have decided to pursue a detox program. Appropriate documentation for continued use of oxycodone should be provided as noted in the MTUS guidelines above. With that said, the ongoing requirement for oxycodone 15mg #120 is justified and is considered to be medically necessary.

6 guided meditation sessions: Overturned

Claims Administrator guideline: Decision based on MTUS Stress-Related Conditions 2004.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Yoga, Mindfulness meditation.

Decision rationale: The ODG guidelines note that mind-body medicine (MBM) therapies broadly include meditation, hypnosis, guided imagery, relaxation therapies, biofeedback, spiritual healing, yoga, tai chi, qigong, art therapy, light therapy, and others. Mindfulness is defined as a nonjudgmental moment-to-moment awareness, including mindful movement (body awareness during yoga postures). The medical literature on mindfulness-based stress reduction (MBSR) is favorable, especially for chronic pain, anxiety, and general psychologic health; however, many of the studies are self-controlled, comparing a patient's pretreatment symptoms with post treatment. In a study examining chronic pain patients, with mean duration of pain of 8.1 years, including of low back pain, headache, and neck/shoulder pain, patients were evaluated before and after the 8-week intervention, then for 48 months in follow-up. Of patients, 60% to 72% reported moderately or greatly decreased pain, decreased psychologic symptoms, and decreased general medical complaints. 86% responded affirmatively the program. Gains in medical and psychologic symptoms were maintained at 4-year follow-up. (Barrows, 2002) Treatment is up to 13-20 visits over 7-20 weeks (individual sessions), if progress is being made. (The provider should evaluate symptom improvement during the process, so treatment failures can be identified early and alternative treatment strategies can be pursued if appropriate.) In this case, the injured worker has a chronic pain condition with related psychological factors. She has approval recommended for a 5 day detox program. The 6 guided meditation sessions could be very beneficial moving forward in conjunction with the detox program. The request for 6 guided meditation sessions is medically necessary.

12 physical therapy sessions: Upheld

Claims Administrator guideline: Decision based on MTUS Low Back Complaints 2004.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Manual therapy & manipulation.

Decision rationale: The MTUS notes that physical medicine is recommended as indicated below. Passive therapy (those treatment modalities that do not require energy expenditure on the part of the patient) can provide short term relief during the early phases of pain treatment and are directed at controlling symptoms such as pain, inflammation and swelling and to improve the rate of healing soft tissue injuries. They can be used sparingly with active therapies to help control swelling, pain and inflammation during the rehabilitation process. Active therapy is based on the philosophy that therapeutic exercise and/or activity are beneficial for restoring flexibility, strength, endurance, function, range of motion, and can alleviate discomfort. Active therapy requires an internal effort by the individual to complete a specific exercise or task. This form of therapy may require supervision from a therapist or medical provider such as verbal,

visual and/or tactile instruction(s). Patients are instructed and expected to continue active therapies at home as an extension of the treatment process in order to maintain improvement levels. Home exercise can include exercise with or without mechanical assistance or resistance and functional activities with assistive devices Physical Medicine Guidelines - Allow for fading of treatment frequency (from up to 3 visits per week to 1 or less), plus active self-directed home Physical Medicine. Myalgia and myositis, unspecified (ICD9 729.1): 9-10 visits over 8 weeks Neuralgia, neuritis, and radiculitis, unspecified (ICD9 729.2) 8-10 visits over 4 weeks. The ODG Physical Therapy Guidelines allow for fading of treatment frequency (from up to 3 or more visits per week to 1 or less), plus active self-directed home PT. Lumbar sprains and strains (ICD9 847.2): 10 visits over 8 weeks. Sprains and strains of unspecified parts of back (ICD9 847):10 visits over 5 weeks. Sprains and strains of sacroiliac region (ICD9 846): 10 visits over 8 weeks. Lumbago; Backache, unspecified (ICD9 724.2; 724.5): 9 visits over 8 weeks. Intervertebral disc disorders without myelopathy (ICD9 722.1; 722.2; 722.5; 722.6; 722.8): 10 visits over 8 weeks. Post-injection treatment: 1-2 visits over 1 week. Post-surgical treatment (discectomy/laminectomy): 16 visits over 8 weeks. Post-surgical treatment (arthroplasty): 26 visits over 16 weeks. Post-surgical treatment (fusion, after graft maturity): 34 visits over 16 weeks. Intervertebral disc disorder with myelopathy (ICD9 722.7): 10 visits over 8 weeks. Spinal stenosis (ICD9 724.0): 10 visits over 8 weeks. Sciatica; Thoracic/lumbosacral neuritis/ radiculitis, unspecified (ICD9 724.3; 724.4): 10-12 visits over 8 weeks. In this case, the request for 12 visits for chronic low back pain exceeds the number of visits recommended in the MTUS and ODG guidelines. There is no rationale provided for necessity of additional supervised physical therapy as opposed to a continuing home exercise program. The request for 12 physical therapy sessions is not medically necessary.