MAXIMUS Federal Services

Case Number:	CM14-0155951		
Date Assigned:	09/25/2014	Date of Injury:	03/10/2011
Decision Date:	10/27/2014	UR Denial Date:	08/20/2014
Priority:	Standard	Application Received:	09/23/2014

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. The expert reviewer is Board Certified in Occupational Medicine 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 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/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:

The claimant was injured on multiple dates. Ambien, Protonix, fentanyl patch, Lidoderm patch, a second opinion regarding medial branch blocks/RFA, and bilateral lumbar facet medial branch blocks are under review. The claimant was evaluated on 06/18/14 and he had multiple dates of cumulative trauma injuries with multiple body parts injured. He reportedly slipped on 03/10/11 and tweaked his back but did not fall. He is status post an MRI and lumbar epidural steroid injection. He was reinjured in 03/13/12 when he lifted a bottle of water. He attended physical therapy and had ongoing pain management with medications. He had cumulative trauma involving his right upper extremity from his wrist to his elbow and it was due to computer work. He reported an injury to his thoracic spine while pulling and lifting files. He reportedly was injured in 1995 when he fell back off a chair. He underwent imaging studies and epidural injections with temporary benefit. He eventually underwent fusion surgery in 1996 and hardware removal in 1997 and then lumbar fusion in 1998 and removal of hardware in 1999. He did not have any more treatment until March 2011 when he was reinjured. He had tripped and injured his hip. He had multiple pain complaints involving these body parts. He was taking medications including tramadol, fentanyl patch, Lidoderm patch, Protonix, a topical analgesic. He is status post surgery on his right elbow. He had tenderness with positive Tinel's. He had good range of motion of his shoulders. Sensation was decreased in the upper extremity on the right. He had decreased range of motion of the wrists. There was some tenderness but no neurologic deficits. He was diagnosed with right elbow medial and lateral epicondylitis and was status post an ORIF of the right forearm fracture. He had mild right wrist carpal tunnel syndrome and left wrist strain. He had moderate degenerative disc disease. He had reached MMI and was given an impairment rating. On 03/28/14, electrodiagnostic studies were normal in the lower extremities. On 05/14/14,his hip pain was improving and his low back pain

worsened at times with increased activity and physical therapy. He had been started on Elavil. He had difficulty with sleep. Lumbar facet medial branch blocks were recommended. He wanted to avoid medications and tramadol was discontinued. He was to continue physical therapy. He wanted a second opinion regarding the recommended medial branch blocks and radiofrequency ablation. He is also status post intramedullary nailing of a right femur fracture. On 06/19/14, additional therapy was recommended. He had made some progress with therapy. Topical analgesics were recommended. On 07/23/14, multiple medications were ordered. He had ongoing complaints of pain that was worse and he reported stress. His medications were helpful. He was using Xanax. He had difficulty with sleep and diarrhea. He was in no acute distress. Leg raise was positive and Patrick's test was positive for right hip pain. He also had a facet loading test was positive for axial pain bilaterally, left greater than right. Sensation was intact. There was tenderness over the lumbar paraspinals and right greater trochanteric bursa. He was diagnosed with lumbago, lumbar radiculopathy and facet dysfunction, anxiety, and right greater trochanteric bursitis. Physical therapy and a second opinion for medial branch block and radiofrequency ablation were requested. He was awaiting authorization for bilateral lumbar facet medial branch blocks from L3-L5. Radiofrequency ablation would be considered after the second opinion. He had failed nonsurgical treatment including therapy and oral medications. Lumbar myelography was also ordered.

IMR ISSUES, DECISIONS AND RATIONALES

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

Ambien 10mg #15, 1 daily at bedtime: 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 chapter; and the Non-MTUS Physician's Desk Reference

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines General Principles, various sections. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG): Formulary - Ambien

Decision rationale: The history and documentation do not objectively support the request for Ambien 10 mg tablets #15, one daily at bedtime. The MTUS indicate that good sleep patterns are likely to be beneficial in chronic pain situations. However, the use of sleep aids is not addressed. The ODG state "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. (Feinberg, 2008) See Insomnia treatment. 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, as outlined in Insomnia treatment. Ambien CR causes a greater frequency of dizziness,

drowsiness, and headache compared to immediate release zolpidem. (Ambien & Ambien CR package insert) 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. (Morin, 2009) Due to adverse effects, FDA now requires lower doses for zolpidem. The dose of zolpidem for women should be lowered from 10 mg to 5 mg for IR products (Ambien, Edluar, Zolpimist, and generic) and from 12.5 mg to 6.25 mg for ER products (Ambien CR). The ER product is still more risky than IR. In laboratory studies, 15% of women and 3% of men who took a 10-milligram dose of Ambien had potentially dangerous concentrations of the drug in their blood eight hours later. Among those who took Ambien CR, the problem was more common: 33% of women and 25% of men had blood concentrations that would raise the risk of a motor vehicle accident eight hours later. 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. (FDA, 2013) 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 claimant's history of insomnia and potential reasons for it is unclear. Typically, sleep aids of this type are only recommended for short periods of time. There is no full history of insomnia or description of failed trials of basic sleep hygiene. The use of sleep aids/hypnotics for chronic conditions is discouraged by the ODG. The medical necessity of the use of this medication has not been clearly demonstrated. Therefore this request is not medically necessary.

Protonix 40mg #30, 1 tablet daily: 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 chapter

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Proton pump inhibitors, Page(s): 102.

Decision rationale: The history and documentation do not objectively support the request for Protonix 40 mg #30 with unknown frequency and duration. The MTUS state proton pump inhibitors are "recommended for patients at intermediate risk for gastrointestinal events and no cardiovascular disease:(1) A non-selective NSAID with either a PPI (Proton Pump Inhibitor, for example, 20 mg omeprazole daily) or misoprostol (200 g four times daily) or (2) a Cox-2 selective agent. In this case, there is no documentation of GI conditions or increased risk to support the use of this medication. The medical necessity of this request for Protonix 40 mg, #30 has not been clearly demonstrated.

Fentanyl patch 12mg #30, apply every 72 hours: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 44. Decision based on Non-MTUS Citation FDA Guidelines

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Fentanyl, Page(s): 78.

Decision rationale: The history and documentation do not objectively support the request for the opioid, fentanyl patch 12 mg [sic] #30, applied every 72 hours. The MTUS states "Duragesic (fentanyl transdermal system) is not recommended as a first-line therapy. Duragesic is the trade name of a fentanyl transdermal therapeutic system, which releases fentanyl, a potent opioid, slowly through the skin. It is manufactured by ALZA Corporation and marketed by [redacted] (both subsidiaries of Johnson & Johnson). The FDA-approved product labeling states that Duragesic is indicated in the management of chronic pain in patients who require continuous opioid analgesia for pain that cannot be managed by other means. MTUS also outlines several components of initiating and continuing opioid treatment and states "a therapeutic trial of opioids should not be employed until the patient has failed a trial of non-opioid analgesics. Before initiating therapy, the patient should set goals, and the continued use of opioids should be contingent on meeting these goals." In these records, there is no documentation of trials and subsequent failure of or intolerance to first-line drugs such as acetaminophen or nonsteroidal anti-inflammatory drugs. MTUS further explains, "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." There is also no indication that periodic monitoring of the claimant's pattern of use and response to this medication, including assessment of pain relief and functional benefit, has been or will be done. There is no evidence that he has been involved in an ongoing rehab program to help maintain any benefits he receives from treatment measures. Additionally, the 4A's "analgesia, activities of daily living, adverse side effects, and aberrant drug-taking behaviors" should be followed and documented per the guidelines. The claimant's pattern of use of Norco is unclear other than she takes it. There is no evidence that a signed pain agreement is on file at the provider's office and no evidence that a pain diary has been recommended and is being kept by the claimant and reviewed by the prescriber. As such, the medical necessity of the ongoing use of fentanyl patch 12 mg [sic] #30, applied every 72 hours has not been clearly demonstrated.

Lidoderm patch 5% #30, apply once daily: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 56-57. Decision based on Non-MTUS Citation Official Disability Guidelines

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical analgesics, Page(s): 143.

Decision rationale: The history and documentation do not objectively support the request for Lidoderm patches 5% #30 applied once daily. The MTUS state "topical agents may be recommended as an option [but are] 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)." There is no evidence of failure of all other first line drugs. The claimant received refills of other medications, also and there is no documentation of failures of trials of first line drugs such as acetaminophen and also local modalities. The MTUS also state "before prescribing any medication for pain, the following should occur: (1) determine the aim of use of the medication; (2) determine the potential benefits and adverse effects; (3) determine the patient's preference. Only one

medication to be given at a time, and interventions that are active and passive should remain unchanged at the time of the medication change. A trial should be given for each individual medication." There is no evidence that these criteria have been met for Lidoderm patches. The medical necessity of this request for Lidoderm 5% #30 has not been clearly demonstrated.

Referral for second opinion regarding medial branch block/radiofrequency ablation (Pain Management Referral): Upheld

Claims Administrator guideline: Decision based on MTUS ACOEM Chapter 12 Low Back Complaints Page(s): 300-301. Decision based on Non-MTUS Citation Official Disability Guidelines, Low Back chapter

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation American College of Occupational and Environmental Medicine (ACOEM), 2nd Edition, (2004): Chapter 7, Independent Medical Examinations and Consultations, page 127

Decision rationale: The history and documentation do not objectively support the request for a second opinion regarding medial branch block/radiofrequency ablation (Pain Management Referral). The claimant has chronic low back pain and has been advised to undergo medial branch blocks and radiofrequency ablation, which typically would depend on the results of the MBB. He has been diagnosed with lumbar radiculopathy and it is not clear how facet dysfunction has been diagnosed. Lumbar myelography was also recommended at about the same time and it would appear that radiculopathy was still suspected. The medical necessity of considering medial branch blocks and radiofrequency ablation is unclear and therefore a second opinion regarding medial branch blocks has not been demonstrated.

Bilateral L3, L4, and L5 lumbar facet medial branch block with fluoroscopy: Upheld

Claims Administrator guideline: Decision based on MTUS ACOEM Chapter 12 Low Back Complaints Page(s): 300. Decision based on Non-MTUS Citation Official Disability Guidelines, Low Back chapter

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG): Low Back, medial branch nerve blocks

Decision rationale: The history and documentation do not objectively support the request for bilateral L3, L4, and L5 lumbar facet medial branch block with fluoroscopy. The MTUS do not address these types of injections. The ODG state "recommend no more than one set of medial branch diagnostic blocks prior to facet neurotomy, if neurotomy is chosen as an option for treatment (a procedure that is still considered "under study"). Diagnostic blocks may be performed with the anticipation that if successful, treatment may proceed to facet neurotomy at the diagnosed levels. Current research indicates that a minimum of one diagnostic block be performed prior to a neurotomy, and that this be a medial branch block (MBB). Although it is suggested that MBBs and intra-articular blocks appear to provide comparable diagnostic

information, the results of placebo-controlled trials of neurotomy found better predictive effect with diagnostic MBBs. In addition, the same nerves are tested with the MBB as are treated with the neurotomy. The use of a confirmatory block has been strongly suggested due to the high rate of false positives with single blocks (range of 25% to 40%) but this does not appear to be cost effective or to prevent the incidence of false positive response to the neurotomy procedure itself. (Cohen, 2007) (Bogduk, 2000) (Cohen2, 2007) (Mancchukonda, 2007) (Dreyfuss, 2000) (Manchikanti2, 2003) (Datta, 2009).... Criteria for the use of diagnostic blocks for facet "mediated" pain: Clinical presentation should be consistent with facet joint pain, signs & symptoms.1. One set of diagnostic medial branch blocks is required with a response of 70%. The pain response should last at least 2 hours for Lidocaine.2. Limited to patients with low-back pain that is non-radicular and at no more than two levels bilaterally.3. There is documentation of failure of conservative treatment (including home exercise, PT and NSAIDs) prior to the procedure for at least 4-6 weeks.4. No more than 2 facet joint levels are injected in one session (see above for medial branch block levels).5. Recommended volume of no more than 0.5 cc of injectate is given to each joint.6. No pain medication from home should be taken for at least 4 hours prior to the diagnostic block and for 4 to 6 hours afterward.7. Opioids should not be given as a "sedative" during the procedure.8. The use of IV sedation (including other agents such as midazolam) may be grounds to negate the results of a diagnostic block, and should only be given in cases of extreme anxiety.9. The patient should document pain relief with an instrument such as a VAS scale, emphasizing the importance of recording the maximum pain relief and maximum duration of pain. The patient should also keep medication use and activity logs to support subjective reports of better pain control.10. Diagnostic facet blocks should not be performed in patients in whom a surgical procedure is anticipated. (Resnick, 2005)11. Diagnostic facet blocks should not be performed in patients in whom a surgical procedure is anticipated. (Resnick, 2005) 11. Diagnostic facet blocks should not be performed in patients who have had a previous fusion procedure at the planned injection level. [Exclusion Criteria that would require UR physician review: Previous fusion at the targeted level. (Franklin, 2008)" The notes indicate that radiofrequency is under consideration based on the results of these injections. However, in this case, the claimant has a diagnosis of radiculopathy and a myelogram was also ordered so it appears that radiculopathy was still present and still was being evaluated. The medical necessity of considering medial branch blocks and radiofrequency ablation is unclear and therefore a second opinion regarding medial branch blocks has not been demonstrated. Therefore this request is not medically necessary.