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| Case Number: | CM13-0059700 | | |
| Date Assigned: | 12/30/2013 | Date of Injury: | 07/24/2013 |
| Decision Date: | 01/02/2015 | UR Denial Date: | 11/20/2013 |
| Priority: | Standard | Application Received: | 12/02/2013 |

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 & Environmental Medicine, has a subspecialty in Public Health and is licensed to practice in West Virginia & Ohio. 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:

This individual is a 35 year old male who sustained an industrially related injury on July 24th, 2013 involving his lower back. He has ongoing complaints of lumbar pain (7/10) worse when sitting with weakness and numbness to his right lower extremity. Physical examination (11/13) demonstrated; decreased spinal range of motion (not defined), decreased sensation in the right L5 dermatome and slightly reduced strength in the right lower extremity (4/5 to 5-/5). MRI of lumbar spine (8/7/13) showed mild/moderate facet arthropathy and a 3mm paracentral disc protrusion at L5-S1 without definite neural encroachment. An EMG study ((9/23/13) was within normal limits. This request is for transforaminal epidural steroid injections, Butrans transdermal patches for pain and Zanaflex for muscle spasm.

IMR ISSUES, DECISIONS AND RATIONALES

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

Transforaminal Epidural Steroid Injection on the right at L5 and S1: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Epidural steroid injections (ESIs).

MAXIMUS guideline: Decision based on MTUS ACOEM Chapter 12 Low Back Complaints Page(s): 287-315, Chronic Pain Treatment Guidelines Epidural steroid injections (ESIs) Page(s):

46. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Low Back - Lumbar & Thoracic (Acute & Chronic), Epidural steroid injections (ESIs), therapeutic

Decision rationale: MTUS Chronic pain medical treatment guidelines state that epidural steroid injections are "Recommended as an option for treatment of radicular pain (defined as pain in dermatomal distribution with corroborative findings of radiculopathy) . . . Epidural steroid injection can offer short term pain relief and use should be in conjunction with other rehab efforts, including continuing a home exercise program." There were no medical documents provided to conclude that other rehab efforts or home exercise program is ongoing. MTUS further defines the criteria for epidural steroid injections to include: 1) Radiculopathy must be documented by physical examination and corroborated by imaging studies and/or electrodiagnostic testing. 2) Initially unresponsive to conservative treatment (exercises, physical methods, NSAIDs and muscle relaxants). 3) Injections should be performed using fluoroscopy (live x-ray) for guidance. 4) If used for diagnostic purposes, a maximum of two injections should be performed. A second block is not recommended if there is inadequate response to the first block. Diagnostic blocks should be at an interval of at least one to two weeks between injections. 5) No more than two nerve root levels should be injected using transforaminal blocks. 6) No more than one interlaminar level should be injected at one session. 7) In the therapeutic phase, repeat blocks should be based on continued objective documented pain and functional improvement, including at least 50% pain relief with associated reduction of medication use for six to eight weeks, with a general recommendation of no more than 4 blocks per region per year. (Manchikanti, 2003) (CMS, 2004) (Boswell, 2007) 8) Current researches do not support "series-of-three" injections in either the diagnostic or therapeutic phase. We recommend no more than 2 ESI injections. Radiculopathy does appear to be documented with imaging studies or EMG. The patient is taking multiple medications, but the progress reports do not document how long the patient has been on these medications and the "unresponsiveness" to the medications. Additionally, treatment notes do not indicate if other conservative treatments were tried and failed (exercises, physical therapy, etc.). As such, the request for L5-S1 Transforaminal Lumbar Epidural Steroid Injection is deemed not medically necessary.

2 Prescriptions of Butrans 10mcg #4: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Buprenorphine Page(s): 26-27. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Chronic Pain, Butrans

Decision rationale: MTUS states that Suboxone (Butrans), which is a brand name of the drug known as buprenorphine, is "recommended for treatment of opiate addiction. Also recommended as an option for chronic pain, especially after detoxification in patients who have a history of opiate addiction." ODG states " Buprenorphine transdermal system (Butrans: FDA-approved for moderate to severe chronic pain. Available as transdermal patches at 5mcg/hr, 10mcg/hr and 20mcg/hr." The ODG states that Suboxone 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." The employee is using this medication for chronic pain. However, there is no medical documentation of any of the five conditions listed above which are the specific indications for using Suboxone instead of one of the first line agents. Therefore, the request for 2 Prescriptions of Butrans 10mcg #4 is deemed not medically necessary.

2 Prescriptions of Zanaflex 4mg #45: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Antispasticity/Antispasmodic Drugs.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Muscle Relaxants, Zanaflex Page(s): 63-67.

Decision rationale: Zanaflex is the brand name version of Tizanidine, which is a muscle relaxant. MTUS states concerning muscle relaxants "Recommend non-sedating muscle relaxants with caution as a second-line option for short-term treatment of acute exacerbations in patients with chronic LBP. Muscle relaxants may be effective in reducing pain and muscle tension, and increasing mobility. However, in most LBP cases, they show no benefit beyond NSAIDs in pain and overall improvement. Also there is no additional benefit shown in combination with NSAIDs. Efficacy appears to diminish over time, and prolonged use of some medications in this class may lead to dependence. Sedation is the most commonly reported adverse effect of muscle relaxant medications. These drugs should be used with caution in patients driving motor vehicles or operating heavy machinery. Drugs with the most limited published evidence in terms of clinical effectiveness include Chlorzoxazone, Methocarbamol, Dantrolene and baclofen. (Chou, 2004) According to a recent review in American Family Physician, skeletal muscle relaxants are the most widely prescribed drug class for musculoskeletal conditions (18.5% of prescriptions), and the most commonly prescribed antispasmodic agents are Carisoprodol, cyclobenzaprine, Metaxalone, and Methocarbamol, but despite their popularity, skeletal muscle relaxants should not be the primary drug class of choice for musculoskeletal conditions. "MTUS further states, "Tizanidine is a centrally acting alpha2-adrenergic agonist that is FDA approved for management of spasticity; unlabeled use for low back pain. Eight studies have demonstrated efficacy for low back pain. One study (conducted only in females) demonstrated a significant decrease in pain associated with chronic myofascial pain syndrome and the authors recommended its use as a first line option to treat myofascial pain. May also provide benefit as an adjunct treatment for fibromyalgia. "Refills or multiple prescriptions are not appropriate for Zanaflex due to the need for medical monitoring. In addition, it is not clear that the patient is getting relief from Zanaflex. As such the request for 2 prescriptions of Zanaflex 4mg #45 is deemed not medically necessary.