

Case Number:	CM15-0135479		
Date Assigned:	08/21/2015	Date of Injury:	06/19/2010
Decision Date:	09/22/2015	UR Denial Date:	06/23/2015
Priority:	Standard	Application Received:	07/13/2015

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: California

Certification(s)/Specialty: Internal 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:

The injured worker is a 78 year old male, who sustained an industrial injury on 6-19-2010. He reported pain in his head, face, neck, upper back and right shoulder after being assaulted. Diagnoses have included history of cervical spine discogenic disease with radiculitis exacerbation, cervical spine myofascial pain syndrome exacerbation, chronic neck pain syndrome, history of thoracic spine musculoligamentous sprain-strain exacerbation, history of lumbar spine musculoligamentous sprain-strain exacerbation, lumbar spine foraminal stenosis exacerbation, rule out lumbar spine spondylolisthesis, lumbar spine disc protrusion with radiculopathy and history of left shoulder sprain-strain. Treatment to date has included physical therapy, acupuncture and medication. According to the progress report dated 5-20-2015, the injured worker complained of pain in the neck, mid-upper back and left shoulder rated six out of ten and pain in the lower back rated eight out of ten. Objective findings revealed tenderness to palpation over the cervical, thoracic and lumbar paraspinal muscles and the left shoulder. Range of motion was restricted. Straight leg raise was positive on the right. There were no changes on neurocirculatory exam. Authorization was requested for Tramadol, Fexmid, Terocin patches and magnetic resonance imaging (MRI) of the cervical and lumbar spines.

IMR ISSUES, DECISIONS AND RATIONALES

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

Tramadol 50mg #60: Overturned

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Tramadol (Ultram), Opioids.

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

Decision rationale: Based on ODG guidelines, tramadol is recommended as an option. Tramadol is a centrally acting synthetic opioid analgesic and it provides inferior analgesia compared to a combination of Hydrocodone/ acetaminophen. (Turturro, 1998) As of November 2013, Tramadol has been designated a Schedule IV controlled substance. (DEA, 2013) Tramadol has unreliable analgesic activity and potential side effects such as serotonin syndrome. (Ray, 2013) Tramadol ER is an extended release opioid, but unlike other ER opioids, the FDA labeling limits dosing to a maximum clinical dose of 400 mg/day (equivalent to 80 MED, see Opioids, dosing). (FDA, 2014) The DEA announced that, effective August 18, 2014, Tramadol and Tramadol ER will be placed into Schedule 4 (low potential for abuse) of the federal Controlled Substances Act. Other ER opioids are Schedule 2 (high potential for abuse). (DEA, 2014) Tramadol is associated with an increased risk for hypoglycemia requiring hospitalization. Although rare, tramadol-induced hypoglycemia is a potentially fatal, adverse event. Hypoglycemia adds to mounting concerns about tramadol, a weak opioid, that counter the perception that it is a safer alternative to full opioids. The analysis associated tramadol use with a more than 3-fold increased risk of hospitalization for hypoglycemia during the first 30 days of use, and it remained statistically significant in patients with no history of treated diabetes. In this case the patient has been on tramadol 50 mg for several months and there is no good documentation of this medication improving his symptoms. Also, tramadol is an opioid and should be used for a short duration of time. Therefore, based on the ODG guidelines and the information in this case, the request for tramadol 50 mg #60 is medically necessary.

Fexmid 7.5mg #90: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Cyclobenzaprine (Flexeril).

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

Decision rationale: Based on ODG guidelines, Flexmid is recommended as an option, using a short course of therapy. Cyclobenzaprine (Flexeril) is more effective than placebo in the management of back pain; the effect is modest and comes at the price of greater adverse effects. The effect is greatest in the first 4 days of treatment, suggesting that shorter courses may be better. (Browning, 2001) Treatment should be brief; this medication is not recommended for longer than 2-3 weeks. There is also a post-op use. The addition of cyclobenzaprine to other agents is not recommended. (Clinical Pharmacology, 2008) Cyclobenzaprine-treated patients

with fibromyalgia were 3 times as likely to report overall improvement and to report moderate reductions in individual symptoms, particularly sleep. (Tofferi, 2004) Note: Cyclobenzaprine is closely related to the tricyclic antidepressants, e.g., amitriptyline. See Antidepressants. Cyclobenzaprine is associated with a number needed to treat of 3 at 2 weeks for symptom improvement in LBP and is associated with drowsiness and dizziness. In this case, the patient has been on flexmid since March 2015 which exceeds the recommended 2-3 weeks course for treatment. Therefore based on ODG guidelines and the information in this case, the request for Fexmid 7.5 mg #90 is not medically necessary.

Terocin patches #30: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Capsaicin, Topical, Lidocaine, Topical, Salicylate Topicals.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic) Chapter: Lidoderm (Lidocaine patch).

Decision rationale: Based on ODG guidelines, lidocaine patches are not recommended until after a trial of a first-line therapy, according to the criteria below. Lidoderm is the brand name for a lidocaine patch produced by Endo Pharmaceuticals. Topical lidocaine may be recommended for localized neuropathic pain after there has been evidence of a trial of first-line therapy (tri-cyclic or SNRI anti-depressants or an AED such as gabapentin or Lyrica). This is not a first-line treatment and is only FDA approved for post-herpetic neuralgia. Formulations that do not involve a dermal-patch system are generally indicated as local anesthetics and anti-pruritics. For more information and references, see Topical analgesics. [Lidoderm ranked #2 in amount billed for WC in 2011. (Coventry, 2012)] Criteria for use of Lidoderm patches: (a) Recommended for a trial if there is evidence of localized pain that is consistent with a neuropathic etiology. (b) There should be evidence of a trial of first-line neuropathy medications (tri-cyclic or SNRI anti-depressants or an AED such as gabapentin or Lyrica). (c) This medication is not generally recommended for treatment of osteoarthritis or treatment of myofascial pain/trigger points. (d) An attempt to determine a neuropathic component of pain should be made if the plan is to apply this medication to areas of pain that are generally secondary to non-neuropathic mechanisms (such as the knee or isolated axial low back pain). One recognized method of testing is the use of the Neuropathic Pain Scale. (e) The area for treatment should be designated as well as number of planned patches and duration for use (number of hours per day). (f) A Trial of patch treatment is recommended for a short-term period (no more than four weeks). (g) It is generally recommended that no other medication changes be made during the trial period. (h) Outcomes should be reported at the end of the trial including improvements in pain and function, and decrease in the use of other medications. If improvements cannot be determined, the medication should be discontinued. (i) Continued outcomes should be intermittently measured and if improvement does not continue, lidocaine patches should be discontinued. There are no guidelines for indications for use of menthol or capsaicin creams, they are thought to be experimental. Therefore a combination topical analgesic which has components which are not recommended, then the entire compound cannot be recommended. Terocin is composed of lidocaine, menthol, methyl salicylate and capsaicin.

Therefore, based on ODG guidelines, the request for Terocin patches #30 is not medically necessary.

MRI (Magnetic Resonance Imaging) of the cervical spine, quantity: 1: Upheld

Claims Administrator guideline: Decision based on MTUS ACOEM Chapter 8 Neck and Upper Back Complaints Page(s): 177-178.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Neck and Upper Back Chapter: Magnetic Resonance imaging (MRI).

Decision rationale: Based on ODG guidelines, cervical spine MRI is not recommended except for indications list below. Patients who are alert, have never lost consciousness, are not under the influence of alcohol and/or drugs, have no distracting injuries, have no cervical tenderness, and have no neurologic findings, do not need imaging. Patients who do not fall into this category should have a three-view cervical radiographic series followed by computed tomography (CT). In determining whether or not the patient has ligamentous instability, magnetic resonance imaging (MRI) is the procedure of choice, but MRI should be reserved for patients who have clear-cut neurologic findings and those suspected of ligamentous instability. Repeat MRI is not routinely recommended, and should be reserved for a significant change in symptoms and/or findings suggestive of significant pathology (eg, tumor, infection, fracture, neurocompression, recurrent disc herniation). (Anderson, 2000) (ACR, 2002) See also ACR Appropriateness Criteria. MRI imaging studies are valuable when physiologic evidence indicates tissue insult or nerve impairment or potentially serious conditions are suspected like tumor, infection, and fracture, or for clarification of anatomy prior to surgery. MRI is the test of choice for patients who have had prior back surgery. (Bigos, 1999) (Bey, 1998) (Volle, 2001) (Singh, 2001) (Colorado, 2001) For the evaluation of the patient with chronic neck pain, plain radiographs (3-view: anteroposterior, lateral, open mouth) should be the initial study performed. Patients with normal radiographs and neurologic signs or symptoms should undergo magnetic resonance imaging. If there is a contraindication to the magnetic resonance examination such as a cardiac pacemaker or severe claustrophobia, computed tomography myelography, preferably using spiral technology and multiplanar reconstruction is recommended. (Daffner, 2000) (Bono, 2007) Indications for imaging: MRI (magnetic resonance imaging): Chronic neck pain (after 3 months conservative treatment), radiographs normal, neurologic signs or symptoms present- Neck pain with radiculopathy if severe or progressive neurologic deficit; Chronic neck pain, radiographs show spondylosis, neurologic signs or symptoms present; Chronic neck pain, radiographs show old trauma, neurologic signs or symptoms present; Chronic neck pain, radiographs show bone or disc margin destruction; Suspected cervical spine trauma, neck pain, clinical findings suggest ligamentous injury (sprain), radiographs and/or CT 'normal'; Known cervical spine trauma: equivocal or positive plain films with neurological deficit; Upper back/thoracic spine trauma with neurological deficit. In this case, the patient does suffer from chronic neck pain of greater than 3 months duration, but no recent cervical spine films were performed. There does not appear to be a significant change in his symptoms or examination. Therefore, based on ODG guidelines, the request for cervical spine MRI is not medically necessary.

MRI (Magnetic Resonance Imaging) of the lumbar spine, quantity: 1: Upheld

Claims Administrator guideline: Decision based on MTUS ACOEM Chapter 12 Low Back Complaints Page(s): 303.

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: Lumbar & Thoracic Chapter: MRIs.

Decision rationale: Based on ODG guidelines, lumbar spine MRIs are recommended for indications below. MRI's are test of choice for patients with prior back surgery, but for uncomplicated low back pain, with radiculopathy, not recommended until after at least one month conservative therapy, sooner if severe or progressive neurologic deficit. Repeat MRI is not routinely recommended, and should be reserved for a significant change in symptoms and/or findings suggestive of significant pathology (eg, tumor, infection, fracture, neurocompression, recurrent disc herniation). MRI, although excellent at defining tumor, infection, and nerve compression, can be too sensitive with regard to degenerative disease findings and commonly displays pathology that is not responsible for the patient's symptoms. With low back pain, clinical judgment begins and ends with an understanding of a patient's life and circumstances as much as with their specific spinal pathology. (Carragee, 2004) Diagnostic imaging of the spine is associated with a high rate of abnormal findings in asymptomatic individuals. Herniated disk is found on magnetic resonance imaging in 9% to 76% of asymptomatic patients; bulging disks, in 20% to 81%; and degenerative disks, in 46% to 93%. (Kinkade, 2007) Baseline MRI findings do not predict future low back pain. (Borenstein, 2001) MRI findings may be preexisting. Many MRI findings (loss of disc signal, facet arthrosis, and end plate signal changes) may represent progressive age changes not associated with acute events. As an alternative to MRI, a pain assessment tool named Standardized Evaluation of Pain (StEP), with six interview questions and ten physical tests, identified patients with radicular pain with high sensitivity (92%) and specificity (97%). The diagnostic accuracy of StEP exceeded that of a dedicated screening tool for neuropathic pain and spinal magnetic resonance imaging. Imaging after a trial of treatment is recommended for patients who have minor risk factors for cancer, inflammatory back disease, vertebral compression fracture, radiculopathy, or symptomatic spinal stenosis. Subsequent imaging should be based on new symptoms or changes in current symptom. Among workers with LBP, early MRI is not associated with better health outcomes and is associated with increased likelihood of disability and its duration. (Graves, 2012) There is support for MRI, depending on symptoms and signs, to rule out serious pathology such as tumor, infection, fracture, and cauda equina syndrome. Patients with severe or progressive neurologic deficits from lumbar disc herniation, or subjects with lumbar radiculopathy who do not respond to initial appropriate conservative care, are also candidates for lumbar MRI to evaluate potential for spinal interventions including injections or surgery. For unequivocal evidence of radiculopathy, MRI with and without contrast is best test for prior back surgery. Indications for imaging -- Magnetic resonance imaging:- Thoracic spine trauma: with neurological deficit - Lumbar spine trauma: trauma, neurological deficit - Lumbar spine trauma: seat belt (chance) fracture (If focal, radicular findings or other neurologic deficit) - Uncomplicated low back pain, suspicion of cancer, infection, other "red flags" - Uncomplicated low back pain, with radiculopathy, after at least 1

month conservative therapy, sooner if severe or progressive neurologic deficit. - Uncomplicated low back pain, prior lumbar surgery - Uncomplicated low back pain, cauda equina syndrome - Myelopathy (neurological deficit related to the spinal cord), traumatic- Myelopathy, painful - Myelopathy, sudden onset - Myelopathy, stepwise progressive - Myelopathy, slowly progressive -Myelopathy, infectious disease patient - Myelopathy, oncology patient - Repeat MRI: When there is significant change in symptoms and/or findings suggestive of significant pathology (eg, tumor, infection, fracture, neurocompression, recurrent disc herniation). In this case, the patient has been complaining of low back pain and noted to have right sided radiculopathy on exam. However, there is no significant change in his symptoms or exam that would warrant an MRI. No red flag symptoms are identified. Therefore, based on ODG guidelines and the information in this case, the request for lumbar spine MRI is not medically necessary.