MAXIMUS Federal Services

Case Number:	CM14-0195381		
Date Assigned:	12/03/2014	Date of Injury:	12/11/2009
Decision Date:	01/21/2015	UR Denial Date:	11/06/2014
Priority:	Standard	Application Received:	11/21/2014

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 Family Practice, 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:

This 50-year-old toll collector reported injuries with a date of 12/11/09 resulting from reaching out to collect tolls. Initially the injuries involved her neck, left shoulder and arm. Initial treatment included medications, physical therapy and chiropractic manipulation. She underwent left shoulder surgery in 10/12. Since her injury she has had several long periods when she did not work. She returned to full time work as a customer service representative in 8/13, and has continued to work full time with occasional missed days due to pain. Missed days have increased lately. The records contain a 5/28/14 AME evaluation from a neurologist. He noted that many of the patient's symptoms had improved since her return to work, and that she was taking about 75 Norco over about 90 days. She had no radicular symptoms, and her neurological exam was completely normal. He reviewed her cervical MRI from 7/14/12, and stated that it showed minimal paracentral disc protrusions measuring up to 2mm at multiple levels, without spinal canal or nerve root impingement. He concluded that the patient had no ratable neurological impairment. Her primary treater, an orthopedist, sees the patient about once per month. His diagnoses include cervical sprain with radiculitis; impingement syndrome left shoulder/status post decompression with some loss of motion; element of depression, sleep issues, headaches, weight gain, hypertension, sexual dysfunction and GERD. There are records of visits to the primary treater's office ranging from 12/31/13 to 11/18/14. Every visit notes that the patient has pain in her neck and left shoulder. All have minimal documentation of physical findings, which usually include shoulder tenderness, full range of motion and mild weakness of the left shoulder. Norco was prescribed at virtually every visit, usually Norco 10 #60 or #90. On 7/21/14 there is a notation that the patient had recently been to the ER because of increased pain. Exam findings included only tenderness of the left shoulder and back. Norco 10#90 was prescribed and tramadol 50 mg #60 dispensed. Authorization for chiropractic treatment was

requested. On 7/21/14 the patient was noted to have decreased cervical range of motion and tenderness of neck and left shoulder. A cervical traction device was requested, trigger point injections were recommended. #90 Norco 10 were prescribed. The 9/22/14 visit had essentially the same findings, and Norco 10 #90 was again prescribed. On 10/17 the patient is described as having new pain that radiates to the left second and third fingers, with an exam notable for decreased sensation in a left C6-7 distribution. Plan included cervical MRI, bilateral upper extremity neurodiagnostic testing, Norco 10 #120, Flexeril 7.5 #60, Nalfon 400 #60, LidoPro lotion 4 oz., and Terocin patches #20 for topical relief. On 11/18/14, the patient's symptoms are described as being identical, but decreased sensation is no longer documented in the left upper extremity. Requests for medications are unchanged and again include Norco 10 # 120. The request for cervical MRI was denied in UR on 11/6/14 on the basis that there was no objective documentation of radicular pain with citation of ACOEM guidelines. The upper extremity neurodiagnostic testing was denied in the same report on the basis that there were no documented radicular pain or exam findings consistent with nerve compromise except for left- sided C7 sensation deficit, again citing ACOEM. LidoPro lotion and Terocin patches were de nied on the basis that topical analgesic creams are largely experimental and are only recommended for neuropathic pain after failed first-line therapy. MTUS Chronic Pain Treatment Guidelines were cited.

IMR ISSUES, DECISIONS AND RATIONALES

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

MRI cervical spine without contrast: Overturned

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation ODG, MRI

MAXIMUS guideline: Decision based on MTUS ACOEM Chapter 8 Neck and Upper Back Complaints Page(s): 178. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Neck and Upper Back chapter, Magnetic Resonance Imaging

Decision rationale: According to the ACOEM citations above, unequivocal finding that identify specific nerve compromise on the neurologic examination are sufficient evidence to warrant imaging studies if symptoms persist. The ODG reference states that indications for MRI (magnetic resonance imaging) include chronic neck pain, radiographs normal, neurologic signs or symptoms present. The clinical documentation in this case supports the performance of a cervical MRI. This patient, after returning to full time work and being relatively stable for months, has developed increasing pain requiring ER visits and escalating doses of opioids. The pain is described as newly radiating down her left arm to her second and third fingers, and has not resolved over a period of at least four weeks. Although documentation of physical findings is suboptimal and does not usually contain a neurological exam, the 10/17/14 notes documents that the patient has decreased sensation in a left C6-7 distribution, which includes the second and third fingers. This is reasonably clear documentation of C7 nerve root compromise. Given the patient's obviously deteriorating condition, I feel it is important to proceed to a definitive diagnostic procedure rather than to insist that the provider provide perfect documentation that

exactly meets guideline requirements. Based on the citations mentioned above and on the clinical information provided for my review, an MRI of the cervical spine is medically necessary.

EMG left upper extremity: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation ODG, EMGs

MAXIMUS guideline: Decision based on MTUS ACOEM Chapter 8 Neck and Upper Back Complaints Page(s): 178 and 182.

Decision rationale: According to the ACOEM citations above, unequivocal findings that identify specific nerve compromise on the neurologic examination are sufficient evidence to warrant imaging studies if symptoms persist. EMG (electromyography) is recommended "to clarify nerve root dysfunction in cases of suspected disk herniation pre-operatively or before epidural injection." It is not recommended for diagnosis of nerve root involvement if findings of history, physical exam and imaging sturdy are consistent. The clinical documentation in this case does not support the performance of EMG. No epidural injection or surgery is contemplated. Findings of history and physical exam are consistent and sufficient to warrant an imaging study rather than the performance of an EMG. Based on the citations above and on the clinical findings in this case, a left upper extremity EMG is not medically necessary.

EMG right upper extremity: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation ODG, EMGs

MAXIMUS guideline: Decision based on MTUS ACOEM Chapter 8 Neck and Upper Back Complaints Page(s): 178 and 182.

Decision rationale: According to the ACOEM citations above, unequivocal finding that identify specific nerve compromise on the neurologic examination are sufficient evidence to warrant imaging studies if symptoms persist. EMG (electromyography) is recommended "to clarify nerve root dysfunction in cases of suspected disk herniation pre-operatively or before epidural injection." It is not recommended for diagnosis of nerve root involvement if findings of history, physical exam and imaging sturdy are consistent. The clinical documentation in this case does not support the performance of EMG. No epidural injection or surgery is contemplated. Findings of history and physical exam are consistent and sufficient to warrant an imaging study rather than the performance of an EMG. Based on the citations above and on the clinical findings in this case, a right upper extremity EMG is not medically necessary.

NCV left upper extremity: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation ODG, NCVs

MAXIMUS guideline: Decision based on MTUS ACOEM Chapter 8 Neck and Upper Back Complaints Page(s): 178. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), neck and upper back chapter, nerve conduction studies

Decision rationale: According to the ACOEM Guideline cited above, unequivocal finding that identify specific nerve compromise on the neurologic examination are sufficient evidence to warrant imaging studies if symptoms persist. When the neurologic examination is less clear, however, further physiologic evidence of nerve dysfunction can be obtained before ordering an imaging study. Electromyography (EMG), and nerve conduction velocities (NCV), including H-reflex tests, may help identify subtle focal neurologic dysfunction in patients with neck or arm symptoms, or both, lasting more than three or four weeks. The ODG citations states that there is minimal justification for performing nerve conduction studies when a patient is already presumed to have symptoms on the basis of radiculopathy. While cervical electrodiagnostic studies are not necessary to demonstrate a cervical radiculopathy, they have been suggested to confirm a brachial plexus abnormality, diabetic neuropathy, or some problem other than a cervical radiculopathy, with caution that these studies can result in unnecessary over treatment. The clinical documentation in this case does not support the performance of nerve conduction studies in this patient. Her symptoms are clearly presumed to be, and probably are radicular. Although the documentation is somewhat poor, it appears likely that she has symptoms and findings compatible with a left C7 radiculopathy. The test of choice in this case would not be nerve conduction studies, which are ordered when there is concern for more peripherally located neuropathy. According to the evidence-based citations above and to the clinical documentation provided for my review, a left upper extremity nerve conduction velocity study is not medically necessary.

NCV right upper extremity: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation ODG, NCVs

MAXIMUS guideline: Decision based on MTUS ACOEM Chapter 8 Neck and Upper Back Complaints Page(s): 178. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), neck and upper back chapter, nerve conduction studies

Decision rationale: According to the ACOEM Guideline cited above, unequivocal findings that identify specific nerve compromise on the neurologic examination are sufficient evidence to warrant imaging studies if symptoms persist. When the neurologic examination is less clear, however, further physiologic evidence of nerve dysfunction can be obtained before ordering an imaging study. Electromyography (EMG), and nerve conduction velocities (NCV), including H-reflex tests, may help identify subtle focal neurologic dysfunction in patients with neck or arm symptoms, or both, lasting more than three or four weeks. The ODG citations states that there is minimal justification for performing nerve conduction studies when a patient is already presumed to have symptoms on the basis of radiculopathy. While cervical electrodiagnostic studies are not necessary to demonstrate a cervical radiculopathy, they have been suggested to confirm a brachial plexus abnormality, diabetic neuropathy, or some problem other than a cervical radiculopathy, with caution that these studies can result in unnecessary over treatment.

The clinical documentation in this case does not support the performance of nerve conduction studies in this patient. Her symptoms are clearly presumed to be, and probably are radicular. Although the documentation is somewhat poor, it appears likely that she has symptoms and findings compatible with a left C7 radiculopathy. The test of choice in this case would not be nerve conduction studies, which are ordered when there is concern for more peripherally located neuropathy. According to the evidence-based citations above and to the clinical documentation provided for my review, a right upper extremity nerve conduction velocity study is not medically necessary.

LidoPro lotion 4oz: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Medications for Chronic Pain; Topical analgesics Page(s): 60; 111-113.

Decision rationale: LidoPro ointment is a compounded preparation that contains capsaicin, lidocaine, menthol, and methyl salicylate. The first reference cited above states that medications should be started individually while other treatments are held constant, with careful assessment of function. There should be functional improvement with each medication in order to continue it. The Topical analgesics guideline states that topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. They are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Capsaicin is recommended as an option in patients who have not responded to or are intolerant to other treatments. There is no evidence supporting formulations which contain over 0.025% capsaicin. It has been shown to have some efficacy in patients with osteoarthritis, fibromyalgia, and chronic non-specific back pain. Lidocaine is indicated for localized neuropathic pain if there is evidence of a trial of first-line therapy (tri-cyclic or SNRI anti-depressants or an AED such as gabapentin or Lyrica). Only FDA-approved product are indicated, and no other commercially approved topical formulations of lidocaine (whether creams, lotions or gels) are indicated for neuropathic pain. Topical lidocaine is not indicated for non-neuropathic pain. The clinical findings in this case do not support the use of LidoPro ointment. Use of this ointment means that four medications are being started simultaneously. The medications cannot be monitored individually and it would be impossible to tell which medication caused any side effect or any functional improvement that might result. For this reason alone, this ointment is not medically indicated. This ointment contains 0.0325% capsaicin, which is higher that the percentage supported by evidence. Although it is possible that this patient has neuropathic pain, no trial of an appropriate antidepressant or AED has been documented, so topical lidocaine is not indicated for this patient. In addition, the only FDA-approved form of topical lidocaine is the Lidoderm patch. This ointment is therefore not FDA approved, and automatically not medically necessary. Based on the evidence-based citations above and the medical information provided for my review, LidoPro ointment 4 oz. is not medically necessary.

Terocin patches: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Medications for Chronic Pain; Topical analgesics Page(s): 60; 111-113. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence, FDA warning concerning topical anesthetic creams, December 5, 2006

Decision rationale: Terocin patches contain 4% menthol and 4% lidocaine. The first reference cited above states that medications should be started individually while other treatments are held constant, with careful assessment of function. There should be functional improvement with each medication in order to continue it. The Topical analgesics guideline states that topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. They are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Lidocaine is indicated for localized neuropathic pain if there is evidence of a trial of first-line therapy (tri-cyclic or SNRI anti-depressants or an AED such as gabapentin or Lyrica). Only FDA-approved product are indicated, and no other commercially approved topical formulations of lidocaine (whether creams, lotions or gels) are indicated for neuropathic pain. Topical lidocaine is not indicated for non-neuropathic pain. The FDA reference states that the FDA is concerned about serious public health risks related to compounded topical anesthetic creams. Exposure to high concentrations of local anesthetics, like those in compounded topical anesthetic creams, can cause grave reactions including seizures and irregular heartbeats. Two deaths have been connected to compounded topical anesthetic creams made by [redacted] and [redacted], two of the five pharmacies receiving warning letters. Similar topical anesthetic creams are compounded by the other firms, and today's action serves as a general warning to firms that produce standardized versions of these creams. These creams contain high doses of local anesthetics including lidocaine, tetracaine, benzocaine, and prilocaine. When different anesthetics are combined into one product, each anesthetic's potential for harm is increased. This potential harm may also increase if the product is left on the body for long periods of time or applied to broad areas of the body, particularly if an area is then covered by a bandage, plastic, or other dressing. The clinical findings in this case do not support the use of Terocin patches. Use of this patch means that two medications are being started simultaneously. It is also is being started at the same time as another topical medication which contains lidocaine. The medications cannot be monitored individually and it would be impossible to tell which medication caused any side effect or any functional improvement that might result. For this reason alone, this patch is not medically indicated. Although it is possible that this patient has neuropathic pain, no trial of an appropriate antidepressant or AED has been documented, so topical lidocaine is not indicated for this patient. In addition, the only FDA-approved form of topical lidocaine is the Lidoderm patch. This patch is therefore not FDA approved, and automatically not medically necessary. The combination of two non-FDA-approved topical lidocaine products puts the patient at increased risk of side effects from lidocaine such as irregular heartbeat, seizure or even death. Based on the

evidence-based citations above and the medical information provided for my review, Terocin Patch is not medically necessary.