

<b>Case Number:</b>	CM15-0001300		
<b>Date Assigned:</b>	01/12/2015	<b>Date of Injury:</b>	05/29/1992
<b>Decision Date:</b>	03/11/2015	<b>UR Denial Date:</b>	12/19/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	01/05/2015

### 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: New York, Tennessee  
 Certification(s)/Specialty: Emergency 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 60 year old male, who sustained an industrial injury on 05/29/1992. He has reported ongoing severe neck pain and arm pain. The diagnoses have included failed neck surgery syndrome, degenerative disc disease of the cervical spine, cervical radiculopathy, cervical myofascial pain syndrome, obesity, depressive disorder, RCR, moderate occipital neuralgia, and chronic pain. Treatment to date has included placement of a intrathecal pump for pain control, conservative treatments, physical therapy, and cervical injections. Currently, the IW complains of ongoing and severe pain in the neck, upper back and arm. An evaluation and refill procedure for the IW's intrathecal (IT) pump was completed on 12/02/2014. During this procedure, the IT pump was noted to be in its end-life and required replacement. It was also noted that the pump was filled with morphine with a concentration of 13.5 mg/ml at 4.419 mg/ml per day. There was no recent imaging results provided or discussed. There was a documented long history of the current medications requested. On 12/18/2014 Utilization Review non-certified a prescription for OxyContin 80 mg #168, noting the lack of documented significant objective functional improvement with treatment, and the prescribed amount of combined morphine equivalent medications exceeding the recommended daily limit by 7 times. The MTUS was cited. On 12/18/2014 Utilization Review non-certified a prescription for Roxicodone 30 mg #112, noting the lack of documented significant objective functional improvement with treatment, and the prescribed amount of combined morphine equivalent medications exceeding the recommended daily limit by 7 times. The MTUS was cited. On 12/18/2014 Utilization Review non-certified a prescription for Senna laxative 8.6 mg #120 with 2 refills, noting the non-

certification of OxyContin and Roxicodone for which this prophylactic medication was prescribed. The MTUS was cited. On 12/18/2014 Utilization Review non-certified a prescription for Zanaflex 4 mg #120 with 2 refills, noting the lack of documented functional improvement in pain, spasms or function with the use of this medication. The MTUS, ACOEM Guidelines, (or ODG) was cited. On 12/18/2014 Utilization Review non-certified a request for toxicology screening, noting the non-certification of OxyContin and Roxicodone which this testing was requested to monitor. The MTUS and ODG were cited. On 12/18/2014 Utilization Review non-certified a prescription for compound creams (Ketoprofen 20%, Baclofen 2%, cyclobenzaprine 2%, lidocaine 5%, 120 grams) with 2 refills, noting the lack of support for treatment with topical agents which contain one or more of these medications. The MTUS was cited. On 12/18/2014 Utilization Review non-certified a request for a MRI of the lumbar spine, noting the approval of IT pump revision and recent request for a catheter dye study to determine the patency of the catheter to determine whether the catheter requires replacement. Without the need for replacement, a MRI is not supported. The ACOEM Guidelines and ODG were cited. On 12/18/2014 Utilization Review non-certified a request for a MRI of the thoracic spine, noting the approval of IT pump revision and recent request for a catheter dye study to determine the patency of the catheter to determine whether the catheter requires replacement. Without the need for replacement, a MRI is not supported. The ACOEM Guidelines and ODG were cited. On 01/05/2015, the injured worker submitted an application for IMR for review of OxyContin 80 mg #168, Roxicodone 30 mg #112, Senna laxative 8.6 mg #120 with 2 refills, Zanaflex 4 mg #120 with 2 refills, toxicology screening, compound creams (Ketoprofen 20%, Baclofen 2%, cyclobenzaprine 2%, lidocaine 5%, 120 grams) with 2 refills, MRI of the lumbar spine, and MRI of the thoracic spine.

### **IMR ISSUES, DECISIONS AND RATIONALES**

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

**Oxycontin 90mg #168:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Short-acting opioids.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Pain Interventions and Guidelines Page(s): 74-96.

**Decision rationale:** Oxycontin is an extended release preparation of the opioid medication, oxycodone. Chronic Pain Medical Treatment Guidelines state that opioids are not recommended as a first line therapy. Opioid should be part of a treatment plan specific for the patient and should follow criteria for use. Criteria for use include establishment of a treatment plan, determination if pain is nociceptive or neuropathic, failure of pain relief with non-opioid analgesics, setting of specific functional goals, and opioid contract with agreement for random drug testing. If analgesia is not obtained, opioids should be discontinued. The patient should be screened for likelihood that he or she could be weaned from the opioids if there is no improvement in pain or function. It is recommended for short-term use if first-line options, such as acetaminophen or NSAIDs have failed. In this case the oxycontin 80 mg 1-2 tabs q8h is as needed with a potential maximum daily dose of 480 mg. This equals 720 mg morphine

equivalents. This, in addition to the 120 mg roxicodone daily (180 mg morphine equivalents) exceeds the recommended daily maximum of 120 morphine equivalents. In addition the patient has been using Oxycontin since at least May 2014 and has not obtained analgesia. Criteria for opioid use have not been met. The request should not be authorized.

**Roxicodone 30mg #112: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Short-acting Opioids.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Pain Interventions and Guidelines Page(s): 74-96.

**Decision rationale:** Roxicodone is an immediate release preparation of oxycodone. Chronic Pain Medical Treatment Guidelines state that opioids are not recommended as a first line therapy. Opioid should be part of a treatment plan specific for the patient and should follow criteria for use. Criteria for use include establishment of a treatment plan, determination if pain is nociceptive or neuropathic, failure of pain relief with non-opioid analgesics, setting of specific functional goals, and opioid contract with agreement for random drug testing. If analgesia is not obtained, opioids should be discontinued. The patient should be screened for likelihood that he or she could be weaned from the opioids if there is no improvement in pain or function. It is recommended for short-term use if first-line options, such as acetaminophen or NSAIDs have failed. In this case the roxicodone 30 mg every six hours daily is a daily dose of 120 mg. This equals 180 mg morphine equivalents. This, in addition to the maximum prescribed 480 mg oxycontin (720 mg morphine equivalents) exceeds the recommended daily maximum of 120 morphine equivalents. In addition the patient has been using Roxicodone since at least May 2014 and has not obtained analgesia. Criteria for opioid use have not been met. The request should not be authorized.

**Senna Laxative 8.6mg #120 with 2 refills: Upheld**

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

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Pain Opioid-induced constipation treatment Drugs for Irritable Bowel Syndrome Treatment Guidelines from The Medical Letter, July 1, 2011

**Decision rationale:** Senna is a laxative that acts as a colonic stimulant. Opioid-induced constipation is a common adverse effect of long-term opioid use because the binding of opioids to peripheral opioid receptors in the gastrointestinal (GI) tract results in absorption of electrolytes, such as chloride, with a subsequent reduction in small intestinal fluid. Activation of enteric opioid receptors also results in abnormal GI motility. Constipation occurs commonly in patients receiving opioids and can be severe enough to cause discontinuation of therapy. If prescribing opioids has been determined to be appropriate, then ODG recommend that prophylactic treatment of constipation should be initiated. First-line: When prescribing an opioid,

and especially if it will be needed for more than a few days, there should be an open discussion with the patient that this medication may be constipating, and the first steps should be identified to correct this. Simple treatments include increasing physical activity, maintaining appropriate hydration by drinking enough water, and advising the patient to follow a proper diet, rich in fiber. These can reduce the chance and severity of opioid-induced constipation and constipation in general. In addition, some laxatives may help to stimulate gastric motility. Other over-the-counter medications can help loosen otherwise hard stools, add bulk, and increase water content of the stool. Second-line: If the first-line treatments do not work, there are other second-line options. About 20% of patients on opioids develop constipation, and some of the traditional constipation medications don't work as well with these patients, because the problem is not from the gastrointestinal tract but from the central nervous system, so treating these patients is different from treating a traditional patient with constipation. Second line options include methylnaltrexone and lubiprostone. In this case there is no documentation in the medical record that the patient is suffering from constipation. Review of systems in the history reports no constipation. There is no medical indication for the Senna. The request should not be authorized.

**Zanaflex 4mg #120 with 2 refills:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Tizanidine (Zanaflex); Muscle relaxants (for pain).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Pain Interventions and Guidelines Page(s): 63, 65.

**Decision rationale:** Zanaflex is the muscle relaxant tizanidine. Tizanidine is a muscle relaxant that acts centrally as an alpha2-adrenergic agonist that is FDA approved for management of spasticity. Side effects include somnolence, dizziness, dry mouth, hypotension, weakness, and hepatotoxicity. Non-sedating muscle relaxants are recommended with caution as a second-line option for short-term treatment (less than two weeks) 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. In this case the patient had been taking the Zanaflex since at least May 2014. The duration of treatment surpasses the recommended short-term duration of two weeks. The request should not be authorized.

**Toxicology screen:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Criteria for Use of Urine Drug Testing

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Pain Interventions and Guidelines Page(s): 78. Decision based on Non-MTUS Citation Pain, urine drug testing

**Decision rationale:** Chronic Pain Medical Treatment Guidelines state that urinary drug testing should be used if there are issues of abuse, addiction, or pain control in patients being treated with opioids. ODG criteria for Urinary Drug testing are recommended for patients with chronic opioid use. Patients at low risk for addiction/aberrant behavior should be tested within 6 months of initiation of therapy and yearly thereafter. Those patients with moderate risk for addiction/aberrant behavior should undergo testing 2-3 times/year. Patients with high risk of addiction/aberrant behavior should be tested as often as once per month. In this case the patient had a urine drug screen in July 2014. There is no documentation that the patient has exhibited addiction/aberrant behavior. Urine drug testing is indicated annually in July 2015. Medical necessity has not been established. The request should not be authorized.

**Compound Creams (Ketoprofen 20%, Baclofen 2%, Cyclobenzaprine 2%, Lidocaine 5%, 120gm) with 2 refills:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Pain Interventions and Guidelines Page(s): 63, 65, 111-112.

**Decision rationale:** This medication is a topical analgesic containing ketoprofen, baclofen, cyclobenzaprine, and lidocaine. Topical analgesics are recommended for neuropathic pain when anticonvulsants and antidepressants have failed. Compounded topical analgesics are commonly prescribed and there is little to no research to support the use of these compounds. Furthermore, the guidelines state that "Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." Ketoprofen is not currently FDA approved for a topical application. It has an extremely high incidence of photocontact dermatitis. Absorption of the drug depends on the base it is delivered in. Topical treatment can result in blood concentrations and systemic effect comparable to those from oral forms, and caution should be used for patients at risk, including those with renal failure. It is not recommended. Baclofen is a muscle relaxant, recommended orally for the treatment of spasticity and muscle spasm related to multiple sclerosis and spinal cord injuries. There is no peer-reviewed literature to support the use of topical baclofen. It is not recommended. Cyclobenzaprine is a muscle relaxant. There is no evidence for use of any muscle relaxant as a topical product. It is not recommended. Lidocaine is recommended for localized peripheral pain after the evidence of a trial for first-line therapy, such as an antidepressant or antiepileptic drug. It is only FDA approved for the treatment of post-herpetic neuralgia. The guidelines state that further research is needed to recommend this treatment for chronic neuropathic pain. The patient was given a sample of this medication in November 2014. There is no documentation that this medication has been effective. In addition this medication contains drugs that are not recommended. Therefore the medication cannot be recommended. The request should not be authorized.

## **MRI (magnetic resonance imaging) for the lumbar spine: Upheld**

**Claims Administrator guideline:** Decision based on MTUS ACOEM Chapter 8 Neck and Upper Back Complaints, Chapter 12 Low Back Complaints Page(s): 303-304. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), MRI (magnetic resonance imaging)

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Low Back, Lumbar and Thoracic MRI's

**Decision rationale:** MRI of the spine is recommended for indications below. MRI's are test of choice for patients with prior back surgery. MRI of the lumbar spine for uncomplicated low back pain, with radiculopathy, is 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). 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 In this case the request for MRI of the lumbar spine is to evaluate for possible granuloma at the catheter tip of the intrathecal pump prior to removal. This is not an indication for MRI of the lumbar spine. The patient has no new neurologic findings or significant change in symptoms. MRI of the lumbar spine is not medically necessary. The request should not be authorized.

## **MRI (magnetic resonance imaging) of the thoracic spine: Upheld**

**Claims Administrator guideline:** Decision based on MTUS ACOEM Chapter 8 Neck and Upper Back Complaints, Chapter 12 Low Back Complaints Page(s): 303-304.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Low Back, Lumbar and Thoracic MRI's

**Decision rationale:** MRI of the spine is recommended for indications below. MRI's are test of choice for patients with prior back surgery. MRI of the lumbar spine for uncomplicated low back pain, with radiculopathy, is 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). 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. In this case the request for MRI of the thoracic spine is to evaluate for possible granuloma at the catheter tip of the intrathecal pump prior to removal. This is not an indication for MRI of the thoracic spine. The patient has no new neurologic findings or significant change in symptoms. MRI of the thoracic spine is not medically necessary. The request should not be authorized.