

<b>Case Number:</b>	CM14-0211935		
<b>Date Assigned:</b>	02/04/2015	<b>Date of Injury:</b>	12/18/1997
<b>Decision Date:</b>	03/24/2015	<b>UR Denial Date:</b>	12/12/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	12/17/2014

### 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. 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: Ohio, West Virginia

Certification(s)/Specialty: Preventive Medicine, Occupational Medicine, Medical Toxicology

### 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 57 year old female, who sustained an industrial injury on 12/18/1987. The diagnoses have included chronic low back pain, lumbar radiculitis, lumbar disc pain and facet disease, right sacroiliac joint pain, myofascial pain syndrome, cervicalgia with cervical spondylosis, cervical radiculitis, right trochanteric bursitis, right ulnar nerve impingement, opioid dependency with efficacy and depression/anxiety due to chronic pain. Treatment to date has included medications and injections. Magnetic resonance imaging (MRI) of the lumbar spine dated 6/11/2011 showed hypertrophic facet arthropathy at L4-5 bilaterally. Currently, the IW complains of neck, low back and right leg pain with numbness and tingling. Current medications are working well. Average pain is rated as 7/10. Objective findings included referred pain to bilateral lower extremities, right leg pain to below right knee, and paraspinal muscle tenderness in the cervical and lumbar area. There is positive straight leg raise ion the right. On 12/12/2014, Utilization Review non-certified a request for a right transforaminal epidural steroid injection at L5-S1, Fentanyl patch 25mcg #15, Ambien 5mg #30, Vicodin 5/325mg #60, Amrix 30mg #30, Celebrex 200mg #60, Baclofen 10mg #60 and TN1 cream, noting that the clinical information submitted for review fails to meet the evidence based guidelines for the requested service. The MTUS and ODG were cited. On 12/17/2014, the injured worker submitted an application for IMR for review of transforaminal epidural steroid injection at L5-S1, Fentanyl patch, Ambien, Vicodin, Amrix, Celebrex, Baclofen and TN1 cream.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Right TFE at L4-5, L5-S1: Upheld**

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

**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 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." 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 research does not support a "series-of-three" injections in either the diagnostic or therapeutic phase. We recommend no more than 2 ESI injections. Radiculopathy does not appear to be documented with imaging studies. The patient is taking multiple medications, but the progress reports do not document unresponsiveness to the medications, in fact the available record states the medication regimen is reducing pain. Additionally, treatment notes do not indicate if other conservative treatments were tried and failed (exercises, physical therapy, etc). Additionally, no objective findings were documented to specify the dermatomal distribution of pain. As such, the request for L4-L5 AND L5-S1 TRANSFORAMINAL LUMBAR EPIDURAL STEROID INJECTION is deemed not medically necessary.

**Fentanyl patch 25mcg #15: Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Duragesic (fentanyl transdermal system); opioids Page(s): 44, 79. Decision based on Non-MTUS Citation Pain, Opioids, Specific drug list

**Decision rationale:** CA MTUS states and ODG agrees: "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 . . . 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." ODG does not recommend the use of opioids except for short use for severe cases, not to exceed 2 weeks. The patient has exceeded the 2 week recommended treatment length for opioid usage having used this medication for over a year. MTUS does not discourage use of opioids past 2 weeks, but does state that "ongoing review and documentation of pain relief, functional status, appropriate medication use, and side effects. 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. Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function, or improved quality of life." The treating physician does not include a complete pain assessment and the available records also do not detail failure of first line therapies prior to utilization of fentanyl. As such the request for fentanyl patches 25mcg x15 is deemed not medically necessary.

**Ambien 5mg #30:** 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) Stress & Mental Illness Chapter

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Pain, Zolpidem, insomnia treatment

**Decision rationale:** The CA MTUS silent regarding this topic. ODG states that zolpidem is a prescription short acting non-benzodiazepine hypnotic, which is approved for short-term treatment of insomnia. In this case, the patient has been taking this medication for at least a year. The available medical records note references to sleep hygiene but there is no discussion of the patient's personal sleep hygiene or the need for variance from the guidelines, such as: a) Wake at the same time everyday; (b) Maintain a consistent bedtime; (c) Exercise regularly (not within 2 to 4 hours of bedtime); (d) Perform relaxing activities before bedtime; (e) Keep your bedroom quiet and cool; (f) Do not watch the clock; (g) Avoid caffeine and nicotine for at least six hours before bed; (h) Only drink in moderation; & (i) Avoid napping. Medical documents also do not include results of these first line treatments, if they were used in treatment of the patient's insomnia. As such, the request for Ambien is deemed not medically necessary at this time.

**Vicodin 5-325mg #60:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines opioids Page(s): 74-96. Decision based on Non-MTUS Citation Low back, Opioids

**Decision rationale:** Vicodin is the brand name version of hydrocodone and acetaminophen, which is considered a short-acting opioid. ODG does not recommend the use of opioids for back pain except for short use for severe cases, not to exceed 2 weeks. The patient has exceeded the 2 week recommended treatment length for opioid usage. MTUS does not discourage use of opioids past 2 weeks, but does state that "ongoing review and documentation of pain relief, functional status, appropriate medication use, and side effects. 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. Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function, or improved quality of life." While the treating physician does indicate a range of pain scale for the patient, it does not meet several of the prescribing guidelines, such as documenting intensity of pain after taking opioid, pain relief, increased level of function, improved quality of life, or other objective and functional outcomes, which is necessary for continued ongoing use of opioids. As such the request for vicodin 5/325 x60 is deemed not medically necessary.

**Amrix 30mg #30:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Cyclobenzaprine, Medications for chronic pain, Antispasmodics Page(s): 41-42, 60-61, 64-66. Decision based on Non-MTUS Citation Pain, Cyclobenzaprine

**Decision rationale:** MTUS Chronic Pain Medical Treatment states for Cyclobenzaprine, "Recommended as an option, using a short course of therapy. . . The effect is greatest in the first 4 days of treatment, suggesting that shorter courses may be better. (Browning, 2001) Treatment should be brief." The medical documents indicate that patient is far in excess (over a year) of the initial treatment window and period. Additionally, MTUS outlines that "Relief of pain with the use of medications is generally temporary, and measures of the lasting benefit from this modality should include evaluating the effect of pain relief in relationship to improvements in function and increased activity. 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 should 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. Analgesic medications should show effects within 1 to 3 days, and the analgesic effect of antidepressants should occur within 1 week. A record of pain and function with the medication should be recorded. (Mens, 2005)." Medical documents do not fully detail the components outlined in the

guidelines above and do not establish the need for long term/chronic usage of cyclobenzaprine. ODG states regarding cyclobenzaprine, "Recommended as an option, using a short course of therapy . . . The addition of cyclobenzaprine to other agents is not recommended." Several other pain medications are being requested, along with cyclobenzaprine, which ODG recommends against. As such the request for cyclobenzaprine 30mg x30 is deemed not medically necessary.

**Celebrex 200mg #60: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, specific drug list & adverse effects.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Anti-inflammatory medications, Celebrex, NSAIDs Page(s): 22, 30, 70. Decision based on Non-MTUS Citation Pain, NSAIDs, GI symptoms & cardiovascular risk

**Decision rationale:** Anti-inflammatory medications are the traditional first line treatment for pain, but COX-2 inhibitors (Celebrex) should be considered if the patient has risk of GI complications, according to MTUS. The medical documentation provided does not indicate a reason for the patient to be considered high risk for GI complications. Risk factors for GI bleeding according to ODG include: (1) age > 65 years; (2) history of peptic ulcer, GI bleeding or perforation; (3) concurrent use of ASA, corticosteroids, and/or an anticoagulant; or (4) high dose or multiple NSAID (e.g., NSAID + low-dose ASA). Additionally, the medical records do not indicate that she is undergoing treatment for any of the FDA approved uses such as osteoarthritis, rheumatoid arthritis, juvenile rheumatoid arthritis in patients 2 years and older, ankylosing spondylitis, acute pain, and primary dysmenorrhea. As such, the request for CELEBREX 200mg x60 is deemed not medically necessary.

**Baclofen 10mg #60: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Muscle Relaxants (for pain).

**Decision rationale:** MTUS states "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." Additionally, MTUS states "Baclofen: The mechanism of action is blockade of the pre- and post-synaptic GABAB receptors. It is recommended orally for the treatment of spasticity and muscle spasm related to multiple sclerosis and spinal cord injuries. Baclofen has been noted to have benefits for treating lancinating, paroxysmal neuropathic pain (trigeminal neuralgia, non-FDA approved). (ICSI, 2007)." The treating physician has not provided documentation of muscle spasms related to multiple sclerosis or spinal cord injuries.

Additionally, the treating physician has not provided documentation of trials and failures of first line therapies and this individual has been taking the medication for over a year so it can not be considered to be a short term therapy at this point. As such the request for Baclofen 10mg, #60 is deemed not medically necessary.

**TN1 cream elbow:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-113. Decision based on Non-MTUS Citation Pain, Compound creams

**Decision rationale:** MTUS and ODG recommends usage of topical analgesics as an option, but also further details "primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed." The medical documents do not indicate failure of antidepressants or anticonvulsants. MTUS further states, "There is little to no research to support the use of many of these agents." As such the request for TN1 cream is deemed not medically necessary.