

<b>Case Number:</b>	CM13-0005575		
<b>Date Assigned:</b>	07/07/2014	<b>Date of Injury:</b>	02/28/2000
<b>Decision Date:</b>	09/08/2014	<b>UR Denial Date:</b>	07/19/2013
<b>Priority:</b>	Standard	<b>Application Received:</b>	08/01/2013

### 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 Physical Medicine & Rehabilitation, has a subspecialty in Interventional Spine 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:

The patient is a 52-year-old female with a date of injury of 02/28/2000. The listed diagnoses per [REDACTED] are: 1. Cervical radiculopathy. 2. Facet arthropathy, cervical. 3. Sacroiliac joint dysfunction, left. 4. Lumbar radiculopathy, left. 5. Facet arthropathy, lumbar spine. 6. Lumbar discogenic spine pain. 7. Degenerative disk disease, lumbar. 8. Thoracic outlet syndrome, left. 9. Rule out lumbar radiculopathy, right. According to progress report 06/14/2013, the patient presents with cervical area, bilateral upper extremity, low back, and bilateral lower extremity pain. The pain is throbbing and radiates down left lower extremities and left buttock area. The patient reports worsening of her low back pain and has had little improvement after her caudal epidural injection. The provider notes facet joints injections in the past have helped her with her pain. Previous pain is rated as 3, current pain is 9 and duration of pain is constant. The patient's medication regimen includes Ibuprofen 800 mg, Lidoderm 5% patch, Voltaren gel, and Synthroid tablets. Examination of the cervical spine revealed diffuse tenderness over the cervical area with limited range of motion. Examination of the thoracic spine revealed left parathoracic tenderness. Examination of the lumbar spine revealed decreased lower doses and severe tenderness over the lumbar facet joints. Straight leg raise is negative bilaterally. There is moderate tenderness over the left sacroiliac joint. Flexion, Abduction, External Rotation, and Extension (FABERE) and Patrick's tests are positive for the left sacroiliac (SI) joint. The provider states he will start the patient on Diclofenac Sodium 50 mg 1 tablet by mouth, two times a day (p.o. b.i.d.) He is also requesting a refill of Ibuprofen 800 mg, Lidoderm 5% patch, Voltaren 1% gel and a facet joint injection. Utilization Review denied the request on 07/19/2013.

## IMR ISSUES, DECISIONS AND RATIONALES

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

### **FACET JOINT INJECTION:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS ACOEM Chapter 12 Low Back Complaints Page(s): 300-301. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) ODG guidelines on Lumbar Facet joint signs & symptoms: Recommend diagnostic criteria below. Diagnostic blocks are required as there are no findings on history, physical or imaging studies that consistently aid in making this diagnosis. Controlled comparative blocks have been suggested due to the high false-positive rates (17% to 47% in the lumbar spine), but the use of this technique has not been shown to be cost-effective or to prevent a false-positive response to a facet neurotomy. (Bogduk, 2005) (Cohen 2007) (Bogduk, 2000) (Cohen2, 2007) (Manchukonda 2007) (Dreyfuss 2000) (Manchikanti 2003) The most commonly involved lumbar joints are L4-5 and L5-S1. (Dreyfus, 2003) In the lumbar region, the majority of patients have involvement in no more than two levels. (Manchikanti, 2004) Mechanism of injury: The cause of this condition is largely unknown, but suggested etiologies have included microtrauma, degenerative changes, and inflammation of the synovial capsule. The overwhelming majority of cases are thought to be the result of repetitive strain and/or low-grade trauma accumulated over the course of a lifetime. Less frequently, acute trauma is thought to be the mechanism, resulting in tearing of the joint capsule or stretching beyond physiologic limits. Osteoarthritis of the facet joints is commonly found in association with degenerative joint disease. (Cohen 2007) Symptoms: There is no reliable pain referral pattern, but it is suggested that pain from upper facet joints tends to extend to the flank, hip and upper lateral thighs, while the lower joint mediated pain tends to penetrate deeper into the thigh (generally lateral and posterior). Infrequently, pain may radiate into the lateral leg or even more rarely into the foot. In the presence of osteophytes, synovial cysts or facet hypertrophy, radiculopathy may also be present. (Cohen 2007) In 1998, Revel et al. suggested that the presence of the following were helpful in identifying patients with this condition: (1) age > 65; (2) pain relieved when supine; (3) no increase in pain with coughing, hyperextension, forward flexion, rising from flexion or extension/rotation. (Revel, 1998) Recent research has corroborated that pain on extension and/or rotation (facet loading) is a predictor of poor results from neurotomy. (Cohen2, 2007) The condition has been described as both acute and chronic. (Resnick, 2005) Radiographic findings: There is no support in the literature for the routine use of imaging studies to diagnose lumbar facet mediated pain. Studies have been conflicting in regards to CT and/or MRI evidence of lumbar facet disease and response to diagnostic blocks or neurotomy. (Cohen 2007) Degenerative changes in facets identified by CT do not correlate with pain and are part of the natural degenerative process. (Kalichman, 2008) See also Facet joint diagnostic blocks (injections); & Segmental rigidity (diagnosis). Suggested indicators of pain related to facet joint pathology (acknowledging the contradictory findings in current research): (1) Tenderness to palpation in the paravertebral areas (over the facet region); (2) A normal sensory examination; (3) Absence of radicular findings, although pain may radiate below the knee; (4) Normal straight leg raising exam. Indicators 2-4 may be present if there is evidence of hypertrophy encroaching on the neural foramen. For Facet joint diagnostic blocks for both facet joint and Dorsal Median Branches, ODG has the following: Recommend no more than one set of medial branch diagnostic

blocks prior to facet neurotomy, if neurotomy is chosen as an option for treatment (a procedure that is still considered "under study"). Diagnostic blocks may be performed with the anticipation that if successful, treatment may proceed to facet neurotomy at the diagnosed levels. Current research indicates.

**Decision rationale:** This patient presents with cervical area, bilateral upper extremity, low back, and bilateral lower extremity pain. The Provider includes in his progress report dated 06/14/2013 a treatment plan for "facet joint injection." ACOEM Guidelines do not discuss facet injections for treatment, but do discuss dorsal medial branch block as well as radiofrequency ablation on pages 300 and 301. ODG Guidelines also support facet diagnostic evaluations for patient presenting with paravertebral tenderness with non-radicular symptoms. Review of the medical file indicates the patient has sensation deficit in left L5-S1 distribution in the lower extremities. The patient also has diminished motor strength in the left lower extremities and has a diagnosis of lumbar radiculopathy. In this case, facet injections are not supported for patients that presents with radicular symptoms. Furthermore, the provider does not give location of injection or levels of injection that are being requested. Therefore the request for Facet Joint Injection is not medically necessary and appropriate.

**DOCLOFENAC SODIUM:** Overturned

**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 Anti-inflammatory medications page 22. For specific recommendations, see NSAIDs (non-steroidal anti-inflammatory drugs). Anti-inflammatories are the traditional first line of treatment, to reduce pain so activity and functional restoration can resume, but long-term use may not be warranted. (Van Tulder-Cochrane, 2000) A comprehensive review of clinical trials on the efficacy and safety of drugs for the treatment of low back pain concludes that available evidence supports the effectiveness of non-selective nonsteroidal anti-inflammatory drugs (NSAIDs) in chronic low back pain (LBP) and of antidepressants in chronic LBP. (Schnitzer, 2004) See also Nonprescription Medications. COX-2 inhibitors (e.g., Celebrex) may be considered if the patient has a risk of GI complications, but not for the majority of patients. Generic NSAIDs and COX-2 inhibitors have similar efficacy and risks when used for less than 3 months, but a 10-to-1 difference in cost. (Rate of overall GI bleeding is 3% with COX-2's versus 4.5% with ibuprofen.) (Homik, 2003) For precautions in specific patient populations, see NSAIDs, GI symptoms & cardiovascular risk. NSAIDs (non-steroidal anti-inflammatory drugs) (MTUS pages 67, 68) Specific recommendations: Osteoarthritis (including knee and hip): Recommended at the lowest dose for the shortest period in patients with moderate to severe pain. Acetaminophen may be considered for initial therapy for patients with mild to moderate pain, and in particular, for those with gastrointestinal, cardiovascular or renovascular risk factors. NSAIDs appear to be superior to acetaminophen, particularly for patients with moderate to severe pain. There is no evidence to recommend one drug in this class over another based on efficacy. In particular, there appears to be no difference between traditional NSAIDs and COX-2 NSAIDs in terms of pain relief. The main concern of selection is based on adverse effects. COX-2 NSAIDs have fewer GI side effects at the risk of increased cardiovascular side effects, although the FDA has concluded that long-term clinical trials are best interpreted to suggest that cardiovascular risk occurs with all NSAIDs and is a class effect (with Naproxyn being the safest drug). There is no evidence of long-term effectiveness for pain or function. (Chen, 2008) (Laine, 2008) Back Pain - Acute exacerbations of chronic pain: Recommended as a second-line treatment after acetaminophen. In general, there is conflicting evidence that NSAIDs are more effective than acetaminophen for acute LBP. (van

Tulder, 2006) (Hancock, 2007) For patients with acute low back pain with sciatica a recent Cochrane review (including three heterogeneous randomized controlled trials) found no differences in treatment with NSAIDs vs. placebo. In patients with axial low back pain this same review found that NSAIDs were not more effective than acetaminophen for acute low-back pain, and that acetaminophen had fewer side effects. (Roelofs-Cochrane, 2008) The addition of NSAIDs or spinal manipulative therapy does not appear to increase recovery in patients with acute low back pain over that received with acetaminophen treatment and advice from their physician. (Hancock, 2007) Back Pain - Chronic low back pain: Recommended as an option for short-term symptomatic relief. A Cochrane review of the literature on drug relief for low back pain (LBP) suggested that NSAIDs were no more effective than other drugs such as acetaminophen, narcotic analgesics, and muscle relaxants. The review also found that NSAIDs had more adverse effects than placebo and acetaminophen but fewer effects than muscle relaxants and narcotic analgesics. In addition, evidence from the review suggested that no one NSAID, including COX-2 inhibitors, was clearly more effective than another. (Roelofs-Cochrane, 2008) See also Anti-inflammatory medications. Neuro.

**Decision rationale:** This patient presents with cervical area, bilateral upper extremity, low back, and bilateral lower extremity pain. The provider is initiating medication, Diclofenac Sodium 50 mg. Utilization Review denied the request stating guidelines and standard of practice confirms that nonsteroidal anti-inflammatory agents should be reserved for the treatment of acute exacerbation of chronic pain as a second line after use of acetaminophen. For anti-inflammatory medications, the MTUS Guidelines page 22 has the following: "Anti-inflammatories are the traditional first line of treatment to reduce pain, so activity and functional restoration can resume, but long-term use may not be warranted." In this case, the provider is initiating a trial of NSAIDs for patient's continued pain. NSAIDs are the first line of treatment for chronic low back pain therefore the request for Doclofenac Sodium is medically necessary and appropriate.

**IBUPROFEN 800 MG:** 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 Medications for chronic pain (MTUS 60, 61) Recommendation as indicated. 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) The recent AHRQ review of comparative effectiveness and safety of analgesics for osteoarthritis concluded that each of the analgesics was associated with a unique set of benefits and risks, and no currently available analgesic was identified as offering a clear overall advantage compared with the others. (Chou, 2006) There is multiple medication choices listed separately (not all recommended). See Anticonvulsants for chronic pain; Antidepressants for chronic pain;

Anti-epilepsy drugs (AEDs); Anti-Inflammatories; Benzodiazepines; Boswellia Serrata Resin (Frankincense); Buprenorphine; Cannabinoids; Capsaicin; Cod liver oil; Curcumin (Turmeric); Cyclobenzaprine (Flexeril®); Duloxetine (Cymbalta®); Gabapentin (Neurontin®); Glucosamine (and Chondroitin Sulfate); Green tea; Herbal medicines; Implantable drug-delivery systems (IDDSs); Injection with anesthetics and/or steroids; Intrathecal drug delivery systems, medications; Intravenous regional sympathetic blocks (for RSD, nerve blocks); Ketamine; Methadone; Milnacipran (Ixel®); Muscle relaxants; Nonprescription medications; NSAIDs (non-steroidal anti-inflammatory drugs); NSAIDs, GI symptoms & cardiovascular risk; Opioids (with links to multiple topics on opioids); Pycnogenol (maritime pine bark); Salicylate topicals; Topical analgesics; Topical analgesics, Compounded; Uncaria Tomentosa (Cat's Claw); Venlafaxine (Effexor®); White willow bark; & Ziconotide (Prialt®). Anti-inflammatory medications (page 22, Chronic pain MTUS) for specific recommendations, see NSAIDs (non-steroidal anti-inflammatory drugs). Anti-inflammatories are the traditional first line of treatment, to reduce pain so activity and functional restoration can resume, but long-term use may not be warranted. (Van Tulder-Cochrane, 2000) A comprehensive review of clinical trials on the efficacy and safety of drugs for the treatment of low back pain concludes that available evidence supports the effectiveness of non-selective nonsteroidal anti-inflammatory drugs (NSAIDs) in chronic low back pain (LBP) and of antidepressants in chronic LBP. (Schnitzer, 2004) See also Nonprescription Medications. COX-2 inhibitors (e.g., Celebrex) may be considered if the patient has a risk of GI complications, but not for the majority of patients. Generic NSAIDs and COX-2 inhibitors have similar efficacy and risks when used for less than 3 months, but a 10-to-1 difference in cost. (Rate of overall GI bleeding is 3% with COX-2's versus 4.5% with ibuprofen.) (Homik, 2003) For precautions in specific patient populations, see NSAIDs, GI symptoms & cardiovascular risk. NSAIDs (non-steroidal anti-inflammatory drugs) (MTUS pages 67, 68) Specific recommendations: Osteoarthritis (including knee and hip): Recommended at the lowest dose for the shortest period in patients with moderate to severe pain. Acetaminophen may be considered for initial therapy for patients with mild to moderate.

**Decision rationale:** This patient presents with cervical area, bilateral upper extremity, low back, and bilateral lower extremity pain. The provider is requesting a refill of Ibuprofen 800 mg. For anti-inflammatory medications, the MTUS Guidelines page 22 has the following: "Anti-inflammatories are the traditional first line of treatment to reduce pain, so activity and functional restoration can resume, but long-term use may not be warranted." The medical file provided for review indicates the patient has been taking Ibuprofen since 02/04/2013. In this case, the provider gives a pain scale to account for the patient's pain. However, he does not correlate the reduction of pain with any specific medication. Furthermore, he does not provide functional improvement from taking long-term medications. MTUS page 60 requires documentation of pain assessment and functional changes where medications are used for chronic pain. The requested refill for Ibuprofen is not medically necessary.

**LIDODERM 5% PATCH:** 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 pages 56, 57 Lidoderm® is the brand name for a lidocaine patch produced by Endo Pharmaceuticals. Topical Lidocaine may be recommended for localized peripheral pain after there has been evidence of a trial of first-line therapy (tri-cyclic or Serotonin norepinephrine reuptake inhibitors (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. Further research is needed to recommend this treatment for chronic neuropathic pain disorders other than 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.

MTUS page 112: Lidocaine Indication: Neuropathic pain Recommended for localized peripheral pain after there has been evidence of a trial of first-line therapy (tri-cyclic or SNRI antidepressants or an AED such as gabapentin or Lyrica). Topical lidocaine, in the formulation of a dermal patch (Lidoderm®) has been designated for orphan status by the FDA for neuropathic pain. Lidoderm is also used off-label for diabetic neuropathy. No other commercially approved topical formulations of lidocaine (whether creams, lotions or gels) are indicated for neuropathic pain. Non-dermal patch formulations are generally indicated as local anesthetics and anti-pruritics. Further research is needed to recommend this treatment for chronic neuropathic pain disorders other than post-herpetic neuralgia. Formulations that do not involve a dermal-patch system are generally indicated as local anesthetics and anti-pruritics.

In February 2007 the FDA notified consumers and healthcare professionals of the potential hazards of the use of Topical Lidocaine. Those at particular risk were individuals that applied large amounts of this substance over large areas, left the products on for long periods of time, or used the agent with occlusive dressings. Systemic exposure was highly variable among patients. Only FDA-approved products are currently recommended. (Argoff, 2006) (Dworkin, 2007) (Khaliq-Cochrane, 2007) (Knotkova, 2007) (Lexi-Comp, 2008) Non-neuropathic pain: Not recommended. There is only one trial that tested 4% lidocaine for treatment of chronic muscle pain. The results showed there was no superiority over placebo (Scudds, 1995) pages 56, 57, 112.

**Decision rationale:** This patient presents with cervical area, bilateral upper extremity, low back, and bilateral lower extremity pain. The provider is requesting a refill of Lidoderm 5% patch. The MTUS Guidelines, page 112 states under lidocaine, "Indications are for neuropathic pain, recommended for localized peripheral pain after there has been evidence of trial of first line therapy. Topical Lidocaine in the formulation of a dermal patch has been designated for orphan status by the FDA for neuropathic pain. Lidoderm is also used off label for diabetic neuropathy. This patient does present with some radicular pain for which this medication is intended for. However, the provider does not discuss functional improvement or provide pain assessment as required by MTUS for long term medication use. MTUS page 60 requires documentation of pain assessment and functional changes where medications are used for chronic pain. Therefore the request for Lidoderm 5% Patch is not medically necessary and appropriate.

**VOLTAREN 1% GEL:** 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 Topical Analgesics, page 111. Recommendation as an option is indicated below. Largely experimental in use with few randomized controlled trials to determine efficacy or safety. It is primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. (Namaka, 2004) These agents are applied locally to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. (Colombo, 2006) Many agents are compounded as monotherapy or in combination for pain control (including NSAIDs, opioids, capsaicin, local anesthetics, antidepressants, glutamate receptor antagonists, adrenergic receptor agonist, adenosine, cannabinoids, cholinergic receptor agonists, agonists,

prostanoids, bradykinin, adenosine triphosphate, biogenic amines, and nerve growth factor). (Argoff, 2006) There is little to no research to support the use of many of these agents. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. The use of these compounded agents requires knowledge of the specific analgesic effect of each agent and how it will be useful for the specific therapeutic goal required. [Note: Topical analgesics work locally underneath the skin where they are applied. These do not include transdermal analgesics that are systemic agents entering the body through a transdermal means. See Duragesic® (fentanyl transdermal system).] Non-steroidal anti-inflammatory agents (NSAIDs): The efficacy in clinical trials for this treatment modality has been inconsistent and most studies are small and of short duration. Topical NSAIDs have been shown in meta-analysis to be superior to placebo during the first 2 weeks of treatment for osteoarthritis, but either not afterward, or with a diminishing effect over another 2-week period. (Lin, 2004) (Bjordal, 2007) (Mason, 2004) When investigated specifically for osteoarthritis of the knee, topical NSAIDs have been shown to be superior to placebo for 4 to 12 weeks. In this study the effect appeared to diminish over time and it was stated that further research was required to determine if results were similar for all preparations. (Biswal, 2006) These medications may be useful for chronic musculoskeletal pain, but there are no long-term studies of their effectiveness or safety. (Mason, 2004) Indications: Osteoarthritis and tendinitis, in particular, that of the knee and elbow or other joints that are amenable to topical treatment: Recommended for short-term use (4-12 weeks). There is little evidence to utilize topical NSAIDs for treatment of osteoarthritis of the spine, hip or shoulder. Neuropathic pain: Not recommended as there is no evidence to support use. FDA-approved agents: Voltaren® Gel 1% (Diclofenac): Indicated for relief of osteoarthritis pain in joints that lends themselves to topical treatment (ankle, elbow, foot, hand, knee, and wrist). It has not been evaluated for treatment of the spine, hip or shoulder. Maximum dose should not exceed 32 g per day (8 g per joint per day in the upper extremity and 16 g per joint per day in the lower extremity). The most common adverse reactions were dermatitis and pruritus. (Voltaren® package insert) For additional adverse effects: See NSAIDs, GI symptoms and cardiovascular risk; & NSAIDs, hypertension and renal function. Non FDA-approved agents: Ketoprofen: This agent is not currently FDA approved for a topical application. It has an extremely high incidence of photocontact dermatitis. (Diaz, 2006) (Hindsen, 2006) Absorption of the drug depends on the base it is delivered in. (Gurol, 1996). Topical treatment can result in blood concentrations and systemic effect comparable to those from oral forms, and caution should be used for patients.

**Decision rationale:** This patient presents with cervical area, bilateral upper extremity, low back, and bilateral lower extremity pain. The provider is requesting a refill of Voltaren 1% gel. The MTUS Guidelines state, "efficacy in clinical trials for this topical NSAIDS modality has been inconsistent and most studies are small and of short duration. Indications are for osteoarthritis and tendinitis, in particular that of the knee and elbow and other joints that are amenable to topical treatment, recommended for short-term use 4 to 12 weeks. There is little evidence utilized topical NSAIDs for treatments of osteoarthritis of the spine, hip, or shoulder." In this case, the patient does not suffer from peripheral joint arthritis or tendinitis problems for which topical NSAIDs are indicated for. Therefore the request for Voltaren 1% Gel is not medically necessary and appropriate.









