

<b>Case Number:</b>	CM15-0134271		
<b>Date Assigned:</b>	07/22/2015	<b>Date of Injury:</b>	09/19/2007
<b>Decision Date:</b>	09/25/2015	<b>UR Denial Date:</b>	06/12/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	07/10/2015

### 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, District of Columbia, Maryland  
 Certification(s)/Specialty: Anesthesiology, Pain Management

### 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 27 year old female who sustained an industrial injury on 09/19/2007. Mechanism of injury occurred while lifting boxes at work, and injuring her low back. Diagnoses include lumbar disc displacement. Treatment to date has included diagnostic studies, medications, lumbar facet block with mild benefit, epidural steroid injections, radio frequency ablation, and trigger point injections, use of H-wave unit, acupuncture, and physical therapy. On 09/24/2012 a Magnetic Resonance Imaging of the lumbar spine showed disc bulges but no neural foraminal narrowing or central canal narrowing. Current medications include Norflex, Ketamine 5% cream, Nucynta, and Flector 1.3% patch, Lyrica, Lorazepam, Prozac and Seroquel. A physician progress note dated 06/04/2015 documents the injured worker complains of chronic low back pain. She had a flare up of symptoms last week after she tripped over a stool at work and aggravated her back pain. Her pain is radiating down her right lower extremity. She is icing and using heat but this is not helping much and the Nucynta is not helping much with her pain. She has not worked the last two days due to the pain. She ambulates with an antalgic gait. There is tenderness to palpation at the lumbosacral junction, and range of motion is restricted. Sensations are decreased to light touch along eh right dorsal foot and right lateral calf compared to the left lower extremity. Straight leg raise was positive at the right lower extremity about 50 degrees. She has balance problems and complains of anxiety, depression and hallucinations but denies suicidal thoughts. The treatment plan includes contrast dye, IV sedation, lumbar epidurogram and right transforaminal lumbar epidural steroid injections. Treatment requested is

for Flector 1.3% patch, Ketamine 5% cream 60gr, Lyrica 25mg, Nucynta, Orphenadrine-Norflex ER Qty 1.00, and right transforaminal LESI at L4-L5.

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

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

#### **Right transforaminal LESI at L4-L5: Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Epidural Steroid Injections Page(s): 46.

**Decision rationale:** Per the MTUS CPMTG epidural steroid injections are used to reduce pain and inflammation, restoring range of motion and thereby facilitating progress in more active treatment programs and avoiding surgery, but this treatment alone offers no significant long-term benefit. The criteria for the use of epidural steroid injections are as follows: 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. The documentation submitted for review notes decreased sensation to light touch along the right dorsal foot and right lateral calf compared to the left lower extremity. Motor strength decreased with right floor dorsiflexion and EHL compared to left lower extremity. Deep tendon reflexes were symmetrical bilaterally to the patella and achilles. MRI of the lumbar spine dated 9/24/12 revealed at L5-S1 mild degenerative disc disease with a 1mm disc bulge. There was mild facet hypertrophy. There was no neural foraminal or central canal narrowing. Above mentioned citation conveys radiculopathy must be documented by physical examination and corroborated by imaging studies and/or electrodiagnostic testing. As the imaging studies do not corroborate radiculopathy, the request is not medically necessary.

#### **Orphenadrine-Norflex ER Qty 1.00: Upheld**

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

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

**Decision rationale:** With regard to muscle relaxants, the 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. (Chou, 2007) (Mens, 2005) (Van Tulder, 1998) (van Tulder, 2003) (van Tulder, 2006) (Schnitzer, 2004) (See, 2008) 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." Regarding Orphenadrine: This drug is similar to diphenhydramine, but has greater anticholinergic effects. The mode of action is not clearly understood. Effects are thought to be secondary to analgesic and anticholinergic properties. This drug was approved by the FDA in 1959. Side Effects: Anticholinergic effects (drowsiness, urinary retention, dry mouth). Side effects may limit use in the elderly. This medication has been reported in case studies to be abused for euphoria and to have mood elevating effects. (Shariatmadari, 1975) As the guidelines do not recommend sedating muscle relaxants, the request is not medically necessary.

**Ketamine 5% cream 60gr:** 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 rationale:** With regard to Ketamine MTUS states: Under study: Only recommended for treatment of neuropathic pain in refractory cases in which all primary and secondary treatment has been exhausted. Topical ketamine has only been studied for use in non-controlled studies for CRPS I and post-herpetic neuralgia and both have shown encouraging results. Per the documentation submitted for review, the injured worker is being treated with Lyrica. As the injured worker is not refractory to treatment with AED, the request is not medically necessary.

**Nucynta ER 50mg:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 74-75.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 78.

**Decision rationale:** Per MTUS Chronic Pain Medical Treatment Guidelines p78 regarding ongoing management of opioids "Four domains have been proposed as most relevant for ongoing monitoring of chronic pain patients on opioids: Pain relief, side effects, physical and psychosocial functioning, and the occurrence of any potentially aberrant (or nonadherent) drug

related behaviors. These domains have been summarized as the '4 A's' (Analgesia, activities of daily living, adverse side effects, and any aberrant drug-taking behaviors). The monitoring of these outcomes over time should affect therapeutic decisions and provide a framework for documentation of the clinical use of these controlled drugs." The MTUS is silent on the use of Nucynta specifically. With regard to tapentadol (Nucynta), the ODG states: "Recommended as second line therapy for patients who develop intolerable adverse effects with first line opioids. These recent large RCTs concluded that tapentadol was efficacious and provided efficacy that was similar to oxycodone for the management of chronic osteoarthritis knee and low back pain, with a superior gastrointestinal tolerability profile and fewer treatment discontinuations." Per note dated 6/17/15, it was noted that the injured worker's medications including Nucynta ER continue to decrease pain and increase functional ability. She rated her pain as 7/10 without medication, which decreased to 5/10 with the use of medications. She stated that with the use of Nucynta she was able to perform her activities of daily living with less pain. She was tolerating Nucynta without any side effects. Efforts to rule out aberrant behavior (e.g. CURES report, UDS, opiate agreement) are necessary to assure safe usage and establish medical necessity. UDS report dated 3/31/15 was negative for opiates. CURES report dated 12/10/14 indicated that the injured worker had received prescription for Norco and Ambien from an outside physician, but she stated that she will continue to follow up in this clinic for ongoing management of her pain condition. She also signed an opiate pain contract on 2/19/15. As UDS did not corroborate appropriate usage, medical necessity cannot be affirmed. Therefore, the request is not medically necessary.

**Flector 1.3% patch:** 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): 111-112.

**Decision rationale:** Flector patches contain diclofenac, a nonsteroidal anti-inflammatory drug. With regard to topical NSAID agents, the MTUS CPMTG states: "These medications may be useful for chronic musculoskeletal pain, but there are no long-term studies of their effectiveness or safety. 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)." Per the guidelines, the indications of this medication are limited to joints that are amenable to topical treatment. The documentation submitted for review does not denote any indications for the request. The request is not medically necessary.

**Lyrica 25mg:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Lyrica Page(s): 19-20, 99.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Anti-epilepsy Drugs Page(s): 16-17, 99.

**Decision rationale:** Per MTUS CPMTG, "Pregabalin (Lyrica) has been documented to be effective in treatment of diabetic neuropathy and post-herpetic neuralgia, has FDA approval for both indications, and is considered first-line treatment for both. Pregabalin was also approved to treat fibromyalgia." Pregabalin is the prodrug of gabapentin and is often used when gabapentin is clinically not sufficiently effective. Per MTUS CPMTG, "Gabapentin (Neurontin) has been shown to be effective for treatment of diabetic painful neuropathy and post-herpetic neuralgia and has been considered as a first-line treatment for neuropathic pain." Per MTUS CPMTG p17, "After initiation of treatment there should be documentation of pain relief and improvement in function as well as documentation of side effects incurred with use. The continued use of AEDs depends on improved outcomes versus tolerability of adverse effects." With regard to medication history, the medical records indicate that the injured worker has been using this medication since at least 3/2015. The documentation submitted for review did not contain evidence of improvement in function. As such, medical necessity cannot be affirmed. Therefore, the request is not medically necessary.