

<b>Case Number:</b>	CM15-0162400		
<b>Date Assigned:</b>	08/31/2015	<b>Date of Injury:</b>	12/17/2004
<b>Decision Date:</b>	10/07/2015	<b>UR Denial Date:</b>	07/23/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	08/18/2015

### 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

Certification(s)/Specialty: Physical Medicine & Rehabilitation

### 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 43 year old male, who sustained an industrial injury on 12-17-04. He reported injury to his lower back after a slip and fall accident. The injured worker was diagnosed as having lumbar degenerative disc disease, myofascial pain and lumbar radiculopathy. Treatment to date has included a TENS unit, a home exercise program, Soma, Naproxen and Trazodone. Current medications include Diclofenac, Omeprazole and Gabapentin since at least 12-22-14 and LidoPro cream. On 4-24-15 the injured worker rated his pain a 5 out of 10. He is working full-time, but feels depressed. On 5-30-15 the injured worker rated his pain a 5 out of 10. The treating physician noted that PHQ-9 score was 24. As of the PR2 dated 7-6-15, the injured worker reports low back pain that radiates down his right leg. He rates his pain a 5 out of 10. He indicated that current medications help with pain over 80% and maintain his functionality. The treating physician requested Diclofenac 100mg #60, Gabapentin 300mg #60, LidoPro cream 121gm, Omeprazole 20mg #60 and TENS patches #4.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Diclofenac 100 mg Qty 60: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Anti-inflammatory medications. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (chronic) chapter under Diclofenac.

**Decision rationale:** The 43 year old patient complains of lower back pain radiating down the right lower leg, rated at 5/10, as per progress report dated 07/06/15. The request is for Diclofenac 100 mg Qty 60. The RFA for this case is dated 07/06/15, and the patient's date of injury is 12/17/04. Diagnoses, as per progress report dated 07/06/15, included lumbar degenerative disc disease, myofascial pain, lumbar radiculopathy, depression and sleep disorder. Medications included Diclofenac, Gabapentin, Omeprazole, Lidopro cream, and TENS patches. Diagnoses, as per progress report dated 07/13/15, included mild major depressive episode. The patient is currently working, as per the same progress report. MTUS Chronic Pain Medical Treatment Guidelines 2009, page 67 and 68 and Anti-inflammatory medications section, Chronic Pain Medical Treatment Guidelines 2009, recommend NSAIDs (non-steroidal anti-inflammatory drugs) as an option for short-term symptomatic relief. ODG guidelines, Pain (chronic) chapter under Diclofenac state: Not recommended as first line due to increased risk profile. A large systematic review of available evidence on NSAIDs confirms that diclofenac, a widely used NSAID, poses an equivalent risk of cardiovascular events to patients as did rofecoxib (Vioxx), which was taken off the market. According to the authors, this is a significant issue and doctors should avoid diclofenac because it increases the risk by about 40%. It goes on to state that there is substantial increase in stroke. In this case, a prescription for Diclofenac is first noted in progress report dated 08/11/14. It is not clear when this medication was initiated. As per progress report dated 07/06/15, medications help reduce the patient's pain by 80% and maintain functionality without any side effects. The patient does HEP with exercise ball every day. The patient has a pain level of 5-6/10 but continues to work 40 hours per week with the help of medications, as per the 07/13/15 report. In an appeal letter dated 08/12/15, the treater essentially states the guidelines but does not provide any details that are specific to the use of Diclofenac in this case. While the medication does appear to benefit the patient, ODG does not support the use of this medication unless other NSAIDs have failed as it increases the risk of stroke by about 40%. Hence, the request is not medically necessary.

**Gabapentin 300 mg Qty 60:** Overturned

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Antiepilepsy drugs (AEDs).

**Decision rationale:** The 43 year old patient complains of lower back pain radiating down the right lower leg, rated at 5/10, as per progress report dated 07/06/15. The request is for Gabapentin 300 mg Qty 60. The RFA for this case is dated 07/06/15, and the patient's date of injury is 12/17/04. Diagnoses, as per progress report dated 07/06/15, included lumbar

degenerative disc disease, myofascial pain, lumbar radiculopathy, depression and sleep disorder. Medications included Diclofenac, Gabapentin, Omeprazole, Lidopro cream, and TENS patches. Diagnoses, as per progress report dated 07/13/15, included mild major depressive episode. The patient is currently working, as per the same progress report. MTUS Chronic Pain Medical Treatment Guidelines 2009, pg 18, 19, Specific Anti-epilepsy Drugs section states: "Gabapentin (Neurontin, Gabarone, generic available) has been shown to be effective for treatment of diabetic painful neuropathy and post-therapeutic neuralgia and has been considered as a first-line treatment for neuropathic pain." In this case, Gabapentin was initiated during the 12/15/14 visit. As per progress report dated 07/13/15, Gabapentin elevated the patient's mood and helped him sleep better. The treater states "Gabapentin helps him with his back pain and improves his sleep and he has a better sense of well-being". The patient has a pain level of 5-6/10 but continues to work 40 hours per week with the help of medications, as per the 07/13/15 report. As per progress report dated 07/06/15, medications help reduce his pain by 80% and maintain functionality without any side effects. The patient does HEP with exercise ball every day. In an appeal letter dated 08/12/15, the treater essentially states the guidelines but does not provide any details that are specific to the use of Gabapentin in this case. Nonetheless, given the efficacy of the medication on the patient's pain, sleep and anxiety, the request appears reasonable and is medically necessary.

**LidoPro Cream 121 gm: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics.

**Decision rationale:** The 43 year old patient complains of lower back pain radiating down the right lower leg, rated at 5/10, as per progress report dated 07/06/15. The request is for Lidopro cream 121 gm. The RFA for this case is dated 07/06/15, and the patient's date of injury is 12/17/04. Diagnoses, as per progress report dated 07/06/15, included lumbar degenerative disc disease, myofascial pain, lumbar radiculopathy, depression and sleep disorder. Medications included Diclofenac, Gabapentin, Omeprazole, Lidopro cream, and TENS patches. Diagnoses, as per progress report dated 07/13/15, included mild major depressive episode. The patient is currently working, as per the same progress report. The MTUS, Chronic Pain Medical Treatment Guidelines 2009, p111 and Topical Analgesics section state: 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 anti-depressants 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. In this case, a prescription for Lidopro cream is first noted in progress report dated 07/06/15. This appears to be the first prescription for this medication. There is no documentation of efficacy from prior use. The treater, however, does not specify how and where this cream will be used. In an appeal letter dated 08/12/15, the treater essentially states the guidelines but does not provide any details that are specific to the use of

Lidopro cream in this patient. Additionally, MTUS guidelines do not support any other formulation of Lidocaine other than the topical patch. Hence, the request is not medically necessary.

**TENS (transcutaneous electrical nerve stimulation) Patches, Qty 4: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Transcutaneous electrotherapy.

**Decision rationale:** The 43 year old patient complains of lower back pain radiating down the right lower leg, rated at 5/10, as per progress report dated 07/06/15. The request is for Tens (transcutaneous electrical nerve stimulation) patches, Qty 4. The RFA for this case is dated 07/06/15, and the patient's date of injury is 12/17/04. Diagnoses, as per progress report dated 07/06/15, included lumbar degenerative disc disease, myofascial pain, lumbar radiculopathy, depression and sleep disorder. Medications included Diclofenac, Gabapentin, Omeprazole, Lidopro cream, and TENS patches. Diagnoses, as per progress report dated 07/13/15, included mild major depressive episode. The patient is currently working, as per the same progress report. MTUS Chronic Pain Medical Treatment Guidelines 2009 guidelines, page 116, Criteria for the use of TENS section require: (1) Documentation of pain of at least three months duration. (2) There is evidence that other appropriate pain modalities have been tried (including medication) and failed. (3) A one-month trial period of the TENS unit should be documented (as an adjunct to ongoing treatment modalities within a functional restoration approach) with documentation of how often the unit was used, as well as outcomes in terms of pain relief and function; rental would be preferred over purchase during this trial. (4) Other ongoing pain treatment should also be documented during the trial period including medication usage. (5) A treatment plan including the specific short- and long-term goals of treatment with the Tens unit should be submitted. (6) A 2-lead unit is generally recommended; if a 4-lead unit is recommended, MTUS recommends TENS for neuropathic pain, CRPS, Multiple Sclerosis, Phantom pain, and spasticity pain. In this case, a prescription for TENS patches is noted in progress report dated 06/24/13. It is not clear when this treatment modality was initiated. The treater, however, does not document specific increase in function and reduction in pain due to prior use of the TENS unit and there is no discussion regarding treatment plan with short- and long-term goals. Hence, the request for TENS patches is not medically necessary.

**Omeprazole 20 mg Qty 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 Medical Treatment 2009, Section(s): NSAIDs, GI symptoms & cardiovascular risk.

**Decision rationale:** The 43 year old patient complains of lower back pain radiating down the right lower leg, rated at 5/10, as per progress report dated 07/06/15. The request is for Omeprazole 20 mg Qty 60. The RFA for this case is dated 07/06/15, and the patient's date of injury is 12/17/04. Diagnoses, as per progress report dated 07/06/15, included lumbar degenerative disc disease, myofascial pain, lumbar radiculopathy, depression and sleep disorder. Medications included Diclofenac, Gabapentin, Omeprazole, Lidopro cream, and TENS patches. Diagnoses, as per progress report dated 07/13/15, included mild major depressive episode. The patient is currently working, as per the same progress report. MTUS Chronic Pain Medical Treatment Guidelines 2009, pg 69, NSAIDs, GI symptoms & cardiovascular risk Section and Chronic Pain Medical Treatment Guidelines 2009 states, "Clinicians should weight the indications for NSAIDs against both GI and cardiovascular risk factors. Determine if the patient is at risk for gastrointestinal events: (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/multiple NSAID (e.g., NSAID + low-dose ASA)." "Treatment of dyspepsia secondary to NSAID therapy: Stop the NSAID, switch to a different NSAID, or consider H2-receptor antagonists or a PPI." In this case, a prescription for Omeprazole is first noted in progress report dated 06/24/13. The patient is also taking Diclofenac, an NSAID. Prophylactic use of PPI is indicated by MTUS. However, the treater has not provided GI risk assessment for prophylactic use of PPI, as required by MTUS. Provided progress reports do not show evidence of gastric problems, and there is no mention of GI issues. In an appeal letter dated 08/12/15, the treater essentially states the guidelines but does not provide any details that are specific to the use of Omeprazole in this case. Additionally, the request for Diclofenac is not authorized. Consequently, the request for Omeprazole is not medically necessary.