

<b>Case Number:</b>	CM15-0209941		
<b>Date Assigned:</b>	10/28/2015	<b>Date of Injury:</b>	04/03/2015
<b>Decision Date:</b>	12/30/2015	<b>UR Denial Date:</b>	10/14/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	10/26/2015

### 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

Certification(s)/Specialty: Anesthesiology

### CLINICAL CASE SUMMARY

The expert reviewer developed the following clinical case summary based on a review of the case file, including all medical records:

This 46 year old male sustained an industrial injury on 4-3-15. Documentation indicated that the injured worker was receiving treatment for thoracic spine pain, lumbar spine pain and myofascial pain. Previous treatment included physical therapy, acupuncture, trigger point injections and medications. In PR-2's dated 5-27-15, 6-10-15, 6-24-15, 7-15-15 and 8-4-15, the injured worker complained of pain rated 5 to 6 out of 10 on the visual analog scale. In a PR-2 dated 9-1-15, the injured worker rated his pain 4 out of 10 on the visual analog scale. The injured worker stated that he had gotten "some" benefit from recent acupuncture allowing him to increase walking time from 15 minutes every other day to 10 minutes once per week. The injured worker also stated that recent trigger point injections reduced his pain 30-40%. The injured worker also reported that Lidopro patches allowed him to increase sitting and standing time from 20 to 30 minutes. The treatment plan included home exercise and prescriptions for Omeprazole, Diclofenac and Lidopro. In a PR-2 dated 9-29-15, the injured worker stated that he was able to tolerate 15 minutes of walking daily. Objective findings were stated as "no exam". The physician stated that the injured worker was status post trigger point injections with improvement. The injured worker was pending authorization for physical therapy and acupuncture. The treatment plan included continuing home exercise and stretching and prescriptions for Omeprazole (since 5-7-15), Lidopro (since 8-4-15), and Diclofenac (since 5-7-15). On 10-14-15, Utilization Review noncertified a retrospective request for Lidopro patches #15, Omeprazole 20 mg #60, Diclofenac 100mg #60 for DOS 9-29-15 and noncertified a retrospective request for Lidopro patches #15, Omeprazole 20 mg #60, Diclofenac 100mg #60 for DOS 9-1-15.

## IMR ISSUES, DECISIONS AND RATIONALES

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

**Retro: Lidopro patches #15 (DOS 9/29/15): Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain chapter - Salicylate topicals.

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

**Decision rationale:** According to the California MTUS Guidelines (2009), topical analgesics are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. These agents are applied topically to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. Many agents are compounded as monotherapy or in combination for pain control including, for example, NSAIDs, opioids, capsaicin, muscle relaxants, local anesthetics or antidepressants. Guidelines indicate that any compounded product that contains at least 1 non-recommended drug (or drug class) is not recommended for use. Lidopro patches contain Capsaicin, Lidocaine, Menthol, and Methyl Salicylate. The CA MTUS states that Capsaicin is recommended only as an option in patients who have not responded or are intolerant to other treatments. Topical Lidocaine, in the formulation of a dermal patch (Lidoderm) is FDA approved for neuropathic pain and used off-label for diabetic neuropathy. No other Lidocaine topical creams or lotions are indicated for neuropathic or non-neuropathic pain. In addition, the ODG notes that a new alert from the FDA warns that topical over-the-counter (OTC) pain relievers that contain menthol, methyl salicylate, or capsaicin may, in rare instances, cause serious burns. Medical necessity for the requested medication was not established. The requested topical analgesic compound is not medically necessary.

**Retro: Omeprazole 20mg #60 (DOS 9/29/2015): Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): NSAIDs, GI symptoms & cardiovascular risk. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain chapter - Proton pump inhibitors (PPIs).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): NSAIDs, GI symptoms & cardiovascular risk. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) PPIs.

**Decision rationale:** According to the CA MTUS, proton pump inhibitors, such as Omeprazole (Prilosec), are recommended for patients taking NSAIDs with documented GI distress symptoms or specific GI risk factors. Risk factors include, age >65, history of peptic ulcer disease, GI bleeding, concurrent use of aspirin, corticosteroids, and/or anticoagulants or high-dose/multiple NSAIDs. There is no documentation indicating the patient has any GI symptoms or GI risk factors. In this case, Diclofenac was not found to be medically necessary. Therefore, medical necessity for Omeprazole was not established. The requested medication is not medically necessary.

**Retro: Diclofenac 100mg #60 (DOS 9/29/2015): Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): NSAIDs (non-steroidal anti-inflammatory drugs), NSAIDs, specific drug list & adverse effects. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain chapter - Diclofenac.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): NSAIDs (non-steroidal anti-inflammatory drugs). Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) NSAIDs.

**Decision rationale:** According to California MTUS Guidelines, oral NSAIDs, such as Diclofenac, are recommended for the treatment of chronic pain and control of inflammation as a second-line therapy after acetaminophen. The ODG states that NSAIDs are recommended for acute pain, acute low back pain (LBP), and short-term pain relief in chronic LBP. There is no evidence of long-term effectiveness for pain or function. According to the ODG, there is inconsistent evidence for the use of NSAIDs to treat long-term neuropathic pain, but they may be useful to treat breakthrough pain in this condition. Physicians should measure transaminases periodically in patients receiving long-term therapy with Diclofenac. In this case, there was no documentation of a failure of first-line NSAIDs. Therefore, medical necessity for the requested medication was not established. The requested medication is not medically necessary for this date of service.

**Retro: Diclofenac 100mg #60 (DOS 9/1/2015): Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): NSAIDs, specific drug list & adverse effects, NSAIDs (non-steroidal anti-inflammatory drugs). Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain chapter - Diclofenac.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): NSAIDs (non-steroidal anti-inflammatory drugs). Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) NSAIDs.

**Decision rationale:** According to California MTUS Guidelines, oral NSAIDs, such as Diclofenac, are recommended for the treatment of chronic pain and control of inflammation as a second-line therapy after acetaminophen. The ODG states that NSAIDs are recommended for acute pain, acute low back pain (LBP), and short-term pain relief in chronic LBP. There is no evidence of long-term effectiveness for pain or function. According to the ODG, there is inconsistent evidence for the use of NSAIDs to treat long-term neuropathic pain, but they may be useful to treat breakthrough pain in this condition. Physicians should measure transaminases periodically in patients receiving long-term therapy with Diclofenac. In this case, there was no documentation of a failure of first-line NSAIDs. Therefore, medical necessity for the requested medication was not established. The requested medication is not medically necessary for this date of service.

**Retro: Omeprazole 20mg #60 (DOS 9/1/2015): Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): NSAIDs, GI symptoms & cardiovascular risk. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain chapter - Proton pump inhibitors (PPIs).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): NSAIDs, GI symptoms & cardiovascular risk. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) PPIs.

**Decision rationale:** According to the CA MTUS, proton pump inhibitors, such as Omeprazole (Prilosec), are recommended for patients taking NSAIDs with documented GI distress symptoms or specific GI risk factors. Risk factors include, age >65, history of peptic ulcer disease, GI bleeding, concurrent use of aspirin, corticosteroids, and/or anticoagulants or high-dose/multiple NSAIDs. There is no documentation indicating the patient has any GI symptoms or GI risk factors. In this case, Diclofenac was not found to be medically necessary. Therefore, medical necessity for Omeprazole was not established. The requested medication is not medically necessary.

**Retro: Lidopro Patches #15 (DOS 9/1/2015): Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Topical Analgesics. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain chapter-Salicylate topicals.

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

**Decision rationale:** According to the California MTUS Guidelines (2009), topical analgesics are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. These agents are applied topically to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. Many agents are compounded as monotherapy or in combination for pain control including, for example, NSAIDs, opioids, capsaicin, muscle relaxants, local anesthetics or antidepressants. Guidelines indicate that any compounded product that contains at least 1 non-recommended drug (or drug class) is not recommended for use. Lidopro patches contain Capsaicin, Lidocaine, Menthol, and Methyl Salicylate. The CA MTUS states that Capsaicin is recommended only as an option in patients who have not responded or are intolerant to other treatments. Topical Lidocaine, in the formulation of a dermal patch (Lidoderm) is FDA approved for neuropathic pain and used off-label for diabetic neuropathy. No other Lidocaine topical creams or lotions are indicated for neuropathic or non-neuropathic pain. In addition, the ODG notes that a new alert from the FDA warns that topical over-the-counter (OTC) pain relievers that contain menthol, methyl salicylate, or capsaicin may, in rare instances, cause serious burns. Medical necessity for the requested medication was not established. The requested topical analgesic compound is not medically necessary.