

<b>Case Number:</b>	CM14-0070010		
<b>Date Assigned:</b>	07/14/2014	<b>Date of Injury:</b>	12/17/2011
<b>Decision Date:</b>	09/11/2014	<b>UR Denial Date:</b>	05/01/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	05/15/2014

### 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. The expert reviewer is Board Certified in Family Medicine 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:

This 55-year old male is being followed for multiple conditions felt to be due to repetitive physical stress at work, date of injury 12/17/11. He has a history of several other work-related injuries both before and after this date, including one in which he claimed injury to his neck because of sleeping in an awkward position due to fleabites which he had sustained at work. Current diagnoses include lumbar facet arthropathy, lumbar spinal stenosis, osteoarthritis, chronic pain, insomnia, hypertension, gastroesophageal reflux, gastritis, and "severe functional disability". Treatment has included medications, physical therapy, chiropractic treatment, right shoulder surgery, and a radiofrequency rhizotomy at L4-S1. The patient remains totally disabled, and has not worked since 12/17/11. There are several notes from a pain specialist in the available records. The patient's current medications include atenolol, Genicin capsules, Losartan, Omeprazole, Terocin patches, and multiple compounded topical medications. A pharmacy invoice was submitted for ingredients of a compounded topical medication containing Capsaicin, Lidocaine, Tramadol, Ketoprofen, and Glycerin. There was also a prescription request from a pharmacy dated 4/18/14 and accompanied by an undated order form for a compounded medication containing Ketoprofen, Lidocaine, Capsaicin, and Tramadol, and for another compounded medication containing Flurbiprofen, Cyclobenzaprine, and Capsaicin. These were denied in UR on 5/1/14 on the grounds that all three preparations contain ingredients which are not approved or not medically supported for topical use. The note by the reviewer states that the primary treating physician's office informed an administrator at the insurance carrier that this patient was last seen by the primary provider, under whose name the above prescriptions were requested, in February of 2013. An IMR was received from the primary provider on 5/15/14. The accompanying medical records contain no medical reports from the primary physician.

## IMR ISSUES, DECISIONS AND RATIONALES

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

### **Ketoprofen/Lidocaine/Capsaicin/Tramadol:** 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(s): 111-113.

**Decision rationale:** According to the guideline cited above, topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. Topical analgesics are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Ketoprofen: This agent is not currently FDA approved for a topical application. It has an extremely high incidence of photo contact dermatitis. Lidocaine is indicated for localized neuropathic pain if there is evidence of a trial of first-line therapy (tri-cyclic or SNRI anti-depressants or an AED such as Gabapentin or Lyrica). Only FDA-approved products are indicated, and no other commercially approved topical formulations of Lidocaine (whether creams, lotions or gels) are indicated for neuropathic pain. Topical Lidocaine is not indicated for non-neuropathic pain. The requested topical medication, which is apparently being prescribed by a provider who has not seen the patient since 2/2012, contains two medications that are not recommended in the above guideline. Topical Ketoprofen is not FDA approved, and is not recommended due to its extremely high incidence of photo contact dermatitis. Lidocaine in any other form besides Lidoderm patches (the only FDA-approved form of topical Lidocaine) is not recommended. Even Lidoderm patches are recommended for neuropathic pain only after a trial of a first-line oral agent has occurred. There is no documentation in the record that such a trial has taken place. Also of major concern is that all 3 topical preparations prescribed contain duplicative ingredients. All three contain Lidocaine and Capsaicin, and two contain Ketoprofen and Tramadol. The patient is also applying Terocin patches, which contain Lidocaine. This raises concerns about possible toxicity, particularly of Lidocaine, which can be cardio toxic or cause seizures when too much is applied topically. There is no clear evidence that the primary provider is even aware that these prescriptions are being filled, since he has not seen the patient for more than a year, or that he is monitoring the situation. The guideline quoted above and the clinical records in this case do not support the use of topical Ketoprofen/Lidocaine/Capsaicin/Tramadol. Use of this product is not medically necessary due to the presence of two medications in the product which are not supported or recommended by high-quality evidence-based guidelines, and the fact that its ingredients are duplicated in prescriptions being ordered and/or used at the same time, which could cause toxicity to the patient.

### **Retrospective Request for Capsaicin/Lidocaine/Tramadol/Ketoprofen/Glycerine:** 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(s): 111-113.

**Decision rationale:** According to the guideline cited above, topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. Topical analgesics are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Ketoprofen: This agent is not currently FDA approved for a topical application. It has an extremely high incidence of photo contact dermatitis. Lidocaine in any other form besides Lidoderm patches (the only FDA-approved form of topical Lidocaine) is not recommended. Even Lidoderm patches are recommend for neuropathic pain only after a trial of a first-line oral agent has occurred. There is no documentation in the record that such a trial has taken place for non-neuropathic pain. The topical medicine listed above appears to be the same medication discussed on page two, with the active ingredients listed in a different order, and the inactive ingredient glycerin added. It again contains two medications that are not recommended in the above guideline. To reiterate: Topical Ketoprofen is not FDA approved, and not recommended due to its extremely high incidence of photo contact dermatitis. Lidocaine in any other form besides Lidoderm patches (the only FDA-approved form of topical Lidocaine) is not recommended. Even Lidoderm patches are recommend for neuropathic pain only after a trial of a first-line oral agent has occurred. There is no documentation in the record that such a trial has taken place. Also of major concern is that 3 topical preparations prescribed contain duplicative ingredients. All three contain Lidocaine and Capsaicin, and two contain Ketoprofen and Tramadol. The patient is also applying Terocin patches, which contain Lidocaine. This raises concerns about possible toxicity, particularly of Lidocaine, which can be cardio toxic or cause seizures when too much is applied topically. There is no clear evidence that the primary provider is even aware that these prescriptions are being filled, since he has not seen the patient for more than a year, or that he is monitoring the situation. The guideline quoted above and the clinical records in this case do not support the use of topical Capsaicin/Lidocaine/Tramadol/Ketoprofen/Glycerine. Use of this product is not medically necessary due to the presence of two medications in the product which are not supported or recommended by high-quality evidence-based guidelines, and the fact that its ingredients are duplicated in prescriptions being ordered and/or used at the same time, which could cause toxicity to the patient.

**Flurbiprofen/Cyclobenzaprine/Capsaicin/Lidocaine:** 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(s): 111-113.

**Decision rationale:** According to the guideline cited above, topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. Topical analgesics are primarily recommended for neuropathic pain when trials of

antidepressants and anticonvulsants have failed. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Topical NSAIDs: may be recommended, but only for short-term use (4-12 weeks). There is little evidence to utilize topical NSAIDs for osteoarthritis of the spine, hip or shoulder, and they are not recommended for neuropathic pain, as there is no evidence to support their use. Lidocaine is indicated for localized neuropathic pain if there is evidence of a trial of first-line therapy (tri-cyclic or SNRI antidepressants or an AED such as Gabapentin or Lyrica). Only FDA-approved products are indicated, and no other commercially approved topical formulations of Lidocaine (whether creams, lotions or gels) are indicated for neuropathic pain. Topical Lidocaine is not indicated for non-neuropathic pain. Baclofen: Not recommended. Other muscle relaxants: There is no evidence for use of any other muscle relaxant as a topical product. The requested preparation listed above contains 3 medications that are not medically indicated per the guideline above. Topical Flurbiprofen, an NSAID, is not recommended for osteoarthritis of the hip, spine or shoulder; nor is it recommended for neuropathic pain. Although there is no documentation in the available records regarding what type of pain this patient is felt to have, there is documentation of both spinal arthritis and of radiculopathy, neither of which would be helped by topical Flurbiprofen. Cyclobenzaprine falls in the category of "other muscle relaxants" cited above, and is not recommended as a topical product. Lidocaine in any other form besides Lidoderm patches (the only FDA-approved form of topical Lidocaine) is not recommended. Even Lidoderm patches are recommended for neuropathic pain only after a trial of a first-line oral agent has occurred. There is no documentation in the record that such a trial has taken place. Also of major concern is that 3 topical preparations prescribed contain duplicative ingredients. All three contain Lidocaine and Capsaicin, and two contain Ketoprofen and Tramadol. The patient is also applying Terocin patches, which contain Lidocaine. This raises concerns about possible toxicity, particularly of Lidocaine, which can be cardio toxic or cause seizures when too much is applied topically. There is no clear evidence that the primary provider is even aware that these prescriptions are being filled, since he has not seen the patient for more than a year, or that he is monitoring the situation. The guideline quoted above and the clinical records in this case do not support the use of topical Flurbiprofen/Cyclobenzaprine/Capsaicin/Lidocaine. Use of this product is not medically necessary due to the presence of three medications in the product which are not supported or recommended by high-quality evidence-based guidelines, and the fact that its ingredients are duplicated in prescriptions being ordered and/or used at the same time, which could cause toxicity to the patient.