

<b>Case Number:</b>	CM13-0035617		
<b>Date Assigned:</b>	12/13/2013	<b>Date of Injury:</b>	12/17/2011
<b>Decision Date:</b>	03/12/2014	<b>UR Denial Date:</b>	10/09/2013
<b>Priority:</b>	Standard	<b>Application Received:</b>	10/17/2013

### HOW THE IMR FINAL DETERMINATION WAS MADE

MAXIMUS Federal Services sent the complete case file to a physician reviewer. He/she has no affiliation with the employer, employee, providers or the claims administrator. The physician reviewer is Board Certified in Internal Medicine & Emergency Medicine and is licensed to practice in Florida. 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 physician 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 patient is a 54 year-old with a date of injury of 12/17/11. A progress report included by [REDACTED] dated 08/28/13, identified subjective complaints of neck pain radiating into the upper extremities. Objective findings included tenderness of the cervical spine with decreased range-of-motion. Motor and sensory functions were "unchanged". Diagnoses included cervical disc degeneration with radiculitis. Treatment has included NSAIDs (Non-steroidal anti-inflammatory drug). A PR-2 report in December of 2012 indicates the use of ketoprofen spray and that he was still having some pain. A Utilization Review determination was rendered on 10/09/13 recommending non-certification of "Ketop/Lidoc/Cap/Tram 15%/1%/0.0125%/5% liquid, #1, Qty 60 15-days spray to affected area 2-3 x daily; Flur/Cyclo/Caps/Lid (New) 10%/2%/0,0125%/1% liquid, ref#1, Qty 120, 30days spray to affected area 2-3 x daily and Escitalopram 10mg Ref#3 Qty 45, 30 days 1 tab in the morning".

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Ketop/Lidoc/Cap/Tram 15%/1%/0.0125%/5% liquid, #1, Qty 60 15-days spray to affected area 2-3 x daily: 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:** Ketoprofen 15% is an NSAID (Non-steroidal anti-inflammatory drug) being used as a topical analgesic. The California Medical Treatment Utilization Schedule (MTUS) Chronic Pain section states that topical analgesics are primarily recommended when other modalities could not be tolerated or have failed. They are primarily recommended for neuropathic pain. The efficacy of topical NSAIDs in osteoarthritis has been inconsistent. They have been shown to be superior to placebo during the first two weeks of treatment, but either not afterward, or with diminishing effect over another two week period. The Guidelines also state that there is little evidence to utilize topical NSAIDs for treatment of osteoarthritis of the spine, hip or shoulder. In neuropathic pain, they are not recommended as there is no evidence to support their use. The only FDA approved topical NSAID is diclofenac. The Guidelines further state: "Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." Therefore, there is no necessity for the addition of ketoprofen in the topical formulation for this patient. Lidocaine is a topical anesthetic. The California Medical Treatment Utilization Schedule (MTUS) Chronic Pain section states that topical analgesics are primarily recommended when other modalities could not be tolerated or have failed. They are primarily recommended for neuropathic pain. Lidocaine as a dermal patch has been used off-label for neuropathic pain. However, the guidelines note that no other form (creams, lotions, gels) are indicated. Further, the Guidelines note that lidocaine showed no superiority over placebo for chronic muscle pain. Also, the FDA has issued warnings about the safety of these agents. The Guidelines further state: "Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Therefore, in this case, there is no demonstrated medical necessity for lidocaine as a spray.

**Flur/Cyclo/Caps/Lid (New) 10%/2%/0,0125%/1% liquid, ref#1, Qty 120, 30days spray to affected area 2-3 x daily:** 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:** Flurbiprofen 15% is an NSAID being used as a topical analgesic. The California Medical Treatment Utilization Schedule (MTUS) Chronic Pain section states that topical analgesics are primarily recommended when other modalities could not be tolerated or have failed. They are primarily recommended for neuropathic pain. The efficacy of topical NSAIDs in osteoarthritis has been inconsistent. They have been shown to be superior to placebo during the first two weeks of treatment, but either not afterward, or with diminishing effect over another two week period. The Guidelines also state that there is little evidence to utilize topical NSAIDs for treatment of osteoarthritis of the spine, hip or shoulder. In neuropathic pain, they are not recommended as there is no evidence to support their use. The only FDA approved topical NSAID is diclofenac. The Guidelines further state: "Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." Therefore, there is

no necessity for the addition of flurbiprofen in the topical formulation for this patient. Cyclobenzaprine 2% is a topical analgesic that is a muscle relaxant. The California Medical Treatment Utilization Schedule (MTUS) states that topical analgesics are primarily recommended when other modalities could not be tolerated or have failed. They are primarily recommended for neuropathic pain. The MTUS Guidelines state that there is no evidence for any muscle relaxant as a topical product. The Guidelines further state: "Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." Therefore, there is no necessity for the addition of cyclobenzaprine in the topical formulation for this patient.

**Escitalopram 10mg Ref#3 Qty 45, 30 days 1 tab in the morning:** 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 Antidepressants Page(s): 13-16.

**Decision rationale:** Lexapro (escitalopram) is an SSRI (selective serotonin reuptake inhibitor) class antidepressant. The California Medical Treatment Utilization Schedule (MTUS) Chronic Pain Guidelines note that some antidepressants are: "Recommended as a first line option for neuropathic pain, and as a possibility for non-neuropathic pain (Feurstein, 1977) (Perrot, 2006)." The tricyclic agents are generally considered first-line unless they are ineffective, poorly tolerated or contraindicated. Assessment of treatment efficacy should include not only pain outcomes, but also an evaluation of function, changes in the use of other analgesics, sleep quality and duration as well as a psychological assessment. The optimal duration of therapy is not known. The Guidelines recommend that assessment of treatment efficacy begin at one week with a recommended trial of at least 4 weeks. It is recommended that if pain is in remission for 3-6 months, a gradual tapering of the antidepressants occur. The long-term effectiveness of antidepressants has not been established. For neuropathic pain, tricyclics agents are recommended as first-line. Recent reviews also list tricyclics and SNRIs (duloxetine and venlafaxine) as first-line options. Antidepressants are listed as an option in depressed patients with non-neuropathic pain, but effectiveness is limited. The Guidelines note that non-neuropathic pain is generally treated with analgesics and anti-inflammatories. Multiple controlled trials have found limited effectiveness with antidepressants in fibromyalgia, with the exception of duloxetine. The Guidelines state that in low back pain: "... tricyclic antidepressants have demonstrated a small to moderate effect on chronic low back pain (short-term pain relief), but the effect on function is unclear. SSRIs have not shown to be effective for low back pain (there was not a significant difference between SSRIs and placebo) and SNRIs (Serotonin norepinephrine reuptake inhibitor) have not been evaluated for this condition (Chou, 2007)." They further state that "SSRIs do not appear to be beneficial." No studies have specifically studied the use of antidepressants to treat pain from osteoarthritis. The Guidelines do note that in depressed patients with osteoarthritis, improving depression symptoms was found to decrease pain and improve functional status. The Guidelines state that tricyclic antidepressants specifically "... are recommended over selective serotonin reuptake inhibitors (SSRIs), unless adverse reactions are a problem." SNRIs are recommended as a first-line option for diabetic

neuropathy. They note that there is no high quality evidence to support the use of duloxetine (SNRI) for lumbar radiculopathy. Related to SSRIs, the Guidelines state: "Selective serotonin reuptake inhibitors (SSRIs), a class of antidepressants that inhibit serotonin reuptake without action on noradrenaline, are controversial based on controlled trials (Finnerup, 2005) (Saarto-Cochrane, 2005). It has b