

<b>Case Number:</b>	CM14-0073308		
<b>Date Assigned:</b>	07/16/2014	<b>Date of Injury:</b>	11/25/2013
<b>Decision Date:</b>	09/08/2014	<b>UR Denial Date:</b>	05/14/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	05/20/2014

### 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 Physical Medicine & Rehabilitation, has a subspecialty in Interventional Spine 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:

The patient is a 46-year-old male with a date of injury of 11/25/2013. The listed diagnoses per [REDACTED] are: 1. Sprain of neck. 2. Tear, medial meniscus, knee. 3. Sprain, lumbar region. 4. Sprain of knee and leg. 5. Sprain, rotator cuff. 6. Headaches. 7. Sprain, thoracic region. 8. Joint pain, left leg. 9. Anxiety state, NOS. According to progress report 04/10/2014, the patient presents with right knee, bilateral shoulder, and cervical, thoracic, and lumbar spine pain. Bilateral shoulder pain radiates to the cervical spine. The right knee revealed swelling, and patient reported difficulty with sleeping due to pain. Objective finding noted decreased range of motion of the cervical, thoracic, and right knee. There is tenderness to the paraspinals and right knee globally. Treating physician is requesting medications, naproxen 550 mg, pantoprazole 20 mg, cyclobenzaprine 7.5 mg, tramadol ER 150 mg, topical compound cream, and a followup in 4 weeks with [REDACTED]. Utilization review denied the request on 05/14/2014.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Flurbiprofen/capsaicin/menthol 10/0.025/2/1% 120gm:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines The MTUS has the following regarding topical creams(p111, chronic pain section):Topical AnalgesicsRecommended as an option as indicated below. Largely experimental in use with few randomized controlled trials to determine efficacy or safety. Primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. (Namaka, 2004) These agents are applied locally to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. (Colombo, 2006) Many agents are compounded as monotherapy or in combination for pain control (including NSAIDs, opioids, capsaicin, local anesthetics, antidepressants, glutamate receptor antagonists, -adrenergic receptor agonist, adenosine, cannabinoids, cholinergic receptor agonists, agonists, prostanoids, bradykinin, adenosine triphosphate, biogenic amines, and nerve growth factor). (Argoff, 2006) There is little to no research to support the use of many of these agents. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. The use of these compounded agents requires knowledge of the specific analgesic effect of each agent and how it will be useful for the specific therapeutic goal required. [Note: Topical analgesics work locally underneath the skin where they are applied. These do not include transdermal analgesics that are systemic agents entering the body through a transdermal means. See Duragesic (fentanyl transdermal system).]Non-steroidal antiinflammatory agents (NSAIDs): The efficacy in clinical trials for this treatment modality has been inconsistent and most studies are small and of short duration. Topical NSAIDs have been shown in meta-analysis to be superior to placebo during the first 2 weeks of treatment for osteoarthritis, but either not afterward, or with a diminishing effect over another 2-week period. (Lin, 2004) (Bjordal, 2007) (Mason, 2004) When investigated specifically for osteoarthritis of the knee, topical NSAIDs have been shown to be superior to placebo for 4 to 12 weeks. In this study the effect appeared to diminish over time and it was stated that further research was required to determine if results were similar for all preparations. (Biswal, 2006) These medications may be useful for chronic musculoskeletal pain, but there are no long-term studies of their effectiveness or safety. (Mason, 2004) 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). There is little evidence to utilize topical NSAIDs for treatment of osteoarthritis of the spine, hip or shoulder. Neuropathic pain: Not recommended as there is no evidence to support use. FDA-approved agents: Voltaren Gel 1% (diclofenac): Indicated for relief of osteoarthritis pain in joints that Page(s): 111.

**Decision rationale:** CA MTUS states, "the efficacy in clinical trials for this treatment modality has been inconsistent, and most studies are small and of short duration. Topical NSAIDs had been shown in the meta-analysis to be superior to placebo during the first 2 weeks of treatment for osteoarthritis. Indications for use are osteoarthritis and tendinitis (in particular, that of the knee and elbow) or other joints that are amendable to topical treatment." In this case, the patient does not meet the indication for the topical medication as he does not present with any osteoarthritis or tendonitis symptoms. The MTUS Guidelines p 111 has the following regarding topical creams, "topical analgesics are largely experimental and used with few randomized control trials to determine efficacy or safety." MTUS further states, "Any compounded product that contains at least one (or drug class) that is not recommended is not recommended." Therefore the request is not medically necessary.

**Ketoprofen/cyclobenzaprine/lidocaine 105-3%/5% 120gm: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines The MTUS has the following regarding topical creams(p111, chronic pain section):Topical AnalgesicsRecommended as an option as indicated below. Largely experimental in use with few randomized controlled trials to determine efficacy or safety. Primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. (Namaka, 2004) These agents are applied locally to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. (Colombo, 2006) Many agents are compounded as monotherapy or in combination for pain control (including NSAIDs, opioids, capsaicin, local anesthetics, antidepressants, glutamate receptor antagonists, -adrenergic receptor agonist, adenosine, cannabinoids, cholinergic receptor agonists, agonists, prostanoids, bradykinin, adenosine triphosphate, biogenic amines, and nerve growth factor). (Argoff, 2006) There is little to no research to support the use of many of these agents. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. The use of these compounded agents requires knowledge of the specific analgesic effect of each agent and how it will be useful for the specific therapeutic goal required. [Note: Topical analgesics work locally underneath the skin where they are applied. These do not include transdermal analgesics that are systemic agents entering the body through a transdermal means. See Duragesic (fentanyl transdermal system).]Non-steroidal antiinflammatory agents (NSAIDs): The efficacy in clinical trials for this treatment modality has been inconsistent and most studies are small and of short duration. Topical NSAIDs have been shown in meta-analysis to be superior to placebo during the first 2 weeks of treatment for osteoarthritis, but either not afterward, or with a diminishing effect over another 2-week period. (Lin, 2004) (Bjordal, 2007) (Mason, 2004) When investigated specifically for osteoarthritis of the knee, topical NSAIDs have been shown to be superior to placebo for 4 to 12 weeks. In this study the effect appeared to diminish over time and it was stated that further research was required to determine if results were similar for all preparations. (Biswal, 2006) These medications may be useful for chronic musculoskeletal pain, but there are no long-term studies of their effectiveness or safety. (Mason, 2004) 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). There is little evidence to utilize topical NSAIDs for treatment of osteoarthritis of the spine, hip or shoulder. Neuropathic pain: Not recommended as there is no evidence to support use. FDA-approved agents: Voltaren Gel 1% (diclofenac): Indicated for relief of osteoarthritis pain in joints

Page(s): 111.

**Decision rationale:** The CA MTUS Guidelines p 111 has the following regarding topical creams, "topical analgesics are largely experimental and used with few randomized control trials to determine efficacy or safety." MTUS further states, "Any compounded product that contains at least one (or drug class) that is not recommended is not recommended." Per MTUS, Lidocaine is only allowed in a patch form and not allowed in cream, lotion or gel forms. Furthermore, Cyclobenzaprine is a muscle relaxant and not recommended in topical formulation. Therefore the request is not medically necessary.

## **Naproxen 550mg: Overturned**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Medications for chronic pain (MTUS 60, 61) Recommended as indicated below. Relief of pain with the use of medications is generally temporary, and measures of the lasting benefit from this modality should include evaluating the effect of pain relief in relationship to improvements in function and increased activity. Before prescribing any medication for pain the following should occur: (1) determine the aim of use of the medication; (2) determine the potential benefits and adverse effects; (3) determine the patient's preference. Only one medication should be given at a time, and interventions that are active and passive should remain unchanged at the time of the medication change. A trial should be given for each individual medication. Analgesic medications should show effects within 1 to 3 days, and the analgesic effect of antidepressants should occur within 1 week. A record of pain and function with the medication should be recorded. (Mens, 2005) The recent AHRQ review of comparative effectiveness and safety of analgesics for osteoarthritis concluded that each of the analgesics was associated with a unique set of benefits and risks, and no currently available analgesic was identified as offering a clear overall advantage compared with the others. (Chou, 2006) There are multiple medication choices listed separately (not all recommended). See Anticonvulsants for chronic pain; Antidepressants for chronic pain; Anti-epilepsy drugs (AEDs); Anti-Inflammatories; Benzodiazepines; Boswellia Serrata Resin (Frankincense); Buprenorphine; Cannabinoids; Capsaicin; Cod liver oil; Curcumin (Turmeric); Cyclobenzaprine (Flexeril); Duloxetine (Cymbalta); Gabapentin (Neurontin); Glucosamine (and Chondroitin Sulfate); Green tea; Herbal medicines; Implantable drug-delivery systems (IDDSs); Injection with anaesthetics and/or steroids; Intrathecal drug delivery systems, medications; Intravenous regional sympathetic blocks (for RSD, nerve blocks); Ketamine; Methadone; Milnacipran (Ixel); Muscle relaxants; Nonprescription medications; NSAIDs (non-steroidal anti-inflammatory drugs); NSAIDs, GI symptoms & cardiovascular risk; Opioids (with links to multiple topics on opioids); Pycnogenol (maritime pine bark); Salicylate topicals; Topical analgesics; Topical analgesics, Compounded; Uncaria Tomentosa (Cat's Claw); Venlafaxine (Effexor); White willow bark; & Ziconotide (Prialt). Anti-inflammatory medications (p22, Chronic pain MTUS) For specific recommendations, see NSAIDs (non-steroidal anti-inflammatory drugs). Anti-inflammatories are the traditional first line of treatment, to reduce pain so activity and functional restoration can resume, but long-term use may not be warranted. (Van Tulder-Cochrane, 2000) A comprehensive review of clinical trials on the efficacy and safety of drugs for the treatment of low back pain concludes that available evidence supports the effectiveness of non-selective Page(s): 60, 61, 22, 67,68.

**Decision rationale:** This patient presents with right knee, bilateral shoulder, and cervical, thoracic, and lumbar spine pain. The treating physician is requesting a refill of Naproxen 550 mg #60. For anti-inflammatory medication, the MTUS Guidelines page 22 states, "anti-inflammatories are the traditional first line of treatment to reduce pain, so activity and functional restoration can resume, but long-term use may not be warranted." In this case, the treating physician states, "Treatments, medication, compound topical cream are helping." In this case,

given the patient's continued pain and treating physician's statement that medications including Naproxen are "helping," Therefore the request is not medically necessary.

### **Pantoprazole 20mg: 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 NSAIDs, GI symptoms & cardiovascular risk (MTUS pg 69) Recommend with precautions as indicated below. 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). Recent studies tend to show that H. Pylori does not act synergistically with NSAIDs to develop gastroduodenal lesions. Recommendations Patients with no risk factor and no cardiovascular disease: Non-selective NSAIDs OK (e.g, ibuprofen, naproxen, etc.) Patients at intermediate risk for gastrointestinal events and no cardiovascular disease: (1) A non-selective NSAID with either a PPI (Proton Pump Inhibitor, for example, 20 mg omeprazole daily) or misoprostol (200 g four times daily) or (2) a Cox-2 selective agent. Long-term PPI use (> 1 year) has been shown to increase the risk of hip fracture (adjusted odds ratio 1.44). Patients at high risk for gastrointestinal events with no cardiovascular disease: A Cox-2 selective agent plus a PPI if absolutely necessary. Patients at high risk of gastrointestinal events with cardiovascular disease: If GI risk is high the suggestion is for a low-dose Cox-2 plus low dose Aspirin (for cardioprotection) and a PPI. If cardiovascular risk is greater than GI risk the suggestion is naproxyn plus low-dose aspirin plus a PPI. (Laine, 2006) (Scholmerich, 2006) (Nielsen, 2006) (Chan, 2004) (Gold, 2007) (Laine, 2007) Cardiovascular disease: A non-pharmacological choice should be the first option in patients with cardiac risk factors. It is then suggested that acetaminophen or aspirin be used for short-term needs. An opioid also remains a short-term alternative for analgesia. Major risk factors (recent MI, or coronary artery surgery, including recent stent placement): If NSAID therapy is necessary, the suggested treatment is naproxyn plus low-dose aspirin plus a PPI. Mild to moderate risk factors: If long-term or high-dose therapy is required, full-dose naproxen (500 mg twice a day) appears to be the preferred choice of NSAID. If naproxyn is ineffective, the suggested treatment is (1) the addition of aspirin to naproxyn plus a PPI, or (2) a low-dose Cox-2 plus ASA. Cardiovascular risk does appear to extend to all non-aspirin NSAIDs, with the highest risk found for the Cox-2 agents. (Johnsen, 2005) (Lanas, 2006) (Antman, 2007) (Laine, 2007) Use with Aspirin for cardioprotective effect: In terms of GI protective effect: The GI protective effect of Cox-2 agents is diminished in patients taking low-dose aspirin and a PPI may be required for those patients with GI risk factors. (Laine, 2007) In terms of the actual cardioprotective effect of aspirin: Traditional NSAIDs (both ibuprofen and naproxen Page(s): 69.

**Decision rationale:** The MTUS Guidelines page 68 and 69 state, "Clinicians should weight the indications for NSAIDs against both GI and cardiovascular risk factors." MTUS recommends determining risk for GI events before prescribing prophylactic PPI or Omeprazole. GI risk factors include: (1) Age is greater than 65, (2) History of peptic ulcer disease and GI bleeding or perforation, (3) Concurrent use of ASA or corticosteroid and/or anticoagulant, (4) High

dose/multiple NSAID. In this case, the patient has been taking NSAID in a long-term basis, but the treating physician does not document dyspepsia or any GI issues. Routine prophylactic use of PPI without documentation of gastric issues is not supported by guidelines without GI-risk assessment. The request is not medically necessary.

**Cyclobenzaprine 7.5mg: Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines MTUS pg 64 Cyclobenzaprine (Flexeril, Amrix, Fexmid, generic available): Recommended for a short course of therapy. Limited, mixed-evidence does not allow for a recommendation for chronic use. Cyclobenzaprine is a skeletal muscle relaxant and a central nervous system depressant with similar effects to tricyclic antidepressants (e.g. amitriptyline). Cyclobenzaprine is more effective than placebo in the management of back pain, although the effect is modest and comes at the price of adverse effects. It has a central mechanism of action, but it is not effective in treating spasticity from cerebral palsy or spinal cord disease. Cyclobenzaprine is associated with a number needed to treat of 3 at 2 weeks for symptom improvement. The greatest effect appears to be in the first 4 days of treatment. (Browning, 2001) (Kinkade, 2007) (Toth, 2004) See Cyclobenzaprine. Cyclobenzaprine has been shown to produce a modest benefit in treatment of fibromyalgia. Cyclobenzaprine-treated patients with fibromyalgia were 3 times more likely to report overall improvement and to report moderate reductions in individual symptoms (particularly sleep). A meta-analysis concluded that the number needed to treat for patients with fibromyalgia was 4.8. (ICSI, 2007) (Tofferi, 2004) Side Effects: Include anticholinergic effects (drowsiness, urinary retention and dry mouth). Sedative effects may limit use. Headache has been noted. This medication should be avoided in patients with arrhythmias, heart block, heart failure and recent myocardial infarction. Side effects limit use in the elderly. (See, 2008) (Toth, 2004) Dosing: 5 mg three times a day. Can be increased to 10 mg three times a day. This medication is not recommended to be used for longer than 2-3 weeks. (See, 2008) Page(s): 64.

**Decision rationale:** The MTUS Guidelines page 64 states, "Cyclobenzaprine is recommended for short course of therapy. Limited, mixed evidence does not allow for recommendation for chronic use." In this case, review of the medical file does not provide a discussion of this medication. It is also excluded from the request for authorization. Utilization review denied the request stating there is no sufficient documentation or rationale for this pharmacy purchase. Review of the medical file including reports from 12/30/2013 through 05/08/2014 by 7 different treating physicians provides no discussion of this medication. Furthermore, dosing and quantity are not specified. An open-ended prescription cannot be recommended for a medication that is not recommended for long-term use. The request is not medically necessary.

**Tramadol ER 150mg: Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines MTUS on Long-term Opioid use, page 88-89 Opioids, long-term assessment CRITERIA FOR USE OF OPIOIDS Long-term Users of Opioids (6-months or more) 1) Re-assess (a) Has the diagnosis changed? (b) What other medications is the patient taking? Are they effective, producing side effects? (c) What treatments have been attempted since the use of opioids? Have they been effective? For how long? (d) Document pain and functional improvement and compare to baseline. Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function, or improved quality of life. Information from family members or other caregivers should be considered in determining the patient's response to treatment. Pain should be assessed at each visit, and functioning should be measured at 6-month intervals using a numerical scale or validated instrument. (e) Document adverse effects: constipation, nausea, vomiting, headache, dyspepsia, pruritis, dizziness, fatigue, dry mouth, sweating, hyperalgesia, sexual dysfunction, and sedation. (f) Does the patient appear to need a psychological consultation? Issues to examine would include motivation, attitude about pain/work, return-to-work, social life including interpersonal and work-related relationships. (g) Is there indication for a screening instrument for abuse/addiction. See Substance Abuse Screening. 2) Strategy for maintenance (a) Do not attempt to lower the dose if it is working (b) Supplemental doses of breakthrough medication may be required for incidental pain, end-of dose pain, and pain that occurs with predictable situations. This can be determined by information that the patient provides from a pain diary or evaluation of additional need for supplemental medication. (c) The standard increase in dose is 25 to 50% for mild pain and 50 to 100% for severe pain (Wisconsin) 3) Visit Frequency (a) There is no set visit frequency. This should be adjusted to the patient's need for evaluation of adverse effects, pain status, and appropriate use of medication, with recommended duration between visits from 1 to 6 months. (Washington, 2002) (Colorado, 2002) (Ontario, 2000) (VA/DoD, 2003) (Maddox-AAPM/APS, 1997) (Wisconsin, 2004) (Warfield, 2004) Outcomes measures: It is now suggested that rather than simply focus on pain severity, improvements in a wide range of outcomes should be evaluated, including measures of functioning, appropriate medication use, and side effects. Measures of pain assessment that allow for evaluation of the efficacy of opioids and whether their use should be maintained include the following: current pain; the least reported pain over the period since last assessment; average pain; intensity of pain after taking the opioid; how long it takes for pain relief; and how long pain relief lasts. (Nicholas, 2006) (Ballantyne, 2006) A recent epidemiologic study f Page(s): 88-89.

**Decision rationale:** Page 78 of MTUS requires "Pain Assessment" that should include, "current pain; the least reported pain over the period since last assessment; average pain; intensity of pain after taking the opioid; how long it takes for pain relief; and how long pain relief lasts." Furthermore, "The 4 A's for ongoing monitoring" are required that include analgesia, ADL's, adverse side effects and aberrant drug-seeking behavior. Review of the medical file indicates the patient has been taking this medication since 12/30/2013. Report 12/30/2013 indicates the patient is tolerating current medication regimen. Report 02/19/2014 indicates the patient has a pain level of 8/10. In this case, review of progress reports from 12/30/2013 through 05/08/2014 by 7 different treating physicians provides no discussion regarding functional improvement from taking Tramadol ER. Furthermore, no specific ADL changes are documented to determine whether or not significant functional improvements are achieved. Pain assessment information is not provided and opiate monitoring such as drug screening and aberrant behavior is not discussed. The request is not medically necessary.

**Follow -up in four (4) weeks with Hitendra Shah:** Overturned

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**MAXIMUS guideline:** Decision based on MTUS ACOEM Chapter 12 Low Back Complaints Page(s): 303.

**Decision rationale:** This patient presents with right knee, bilateral shoulder, and cervical, thoracic, and lumbar spine pain. The treating physician is requesting a follow up visit in 4 weeks. Utilization review denied the request but the rationale for the denial was not provided for review. ACOEM, chapter 12, low back pain page 303 has the following regarding follow up visits, "Patients with potentially work-related low back complaint should have follow up every 3 to 5 days by a mid-level practitioner or physical therapist who can counsel the patient about avoiding static positions, medication use, activity modification, and other concerns." In this case, given the patient's continued pain and medication intake, a follow up visit in 4 weeks is medically necessary.