

<b>Case Number:</b>	CM14-0065301		
<b>Date Assigned:</b>	07/11/2014	<b>Date of Injury:</b>	01/06/2002
<b>Decision Date:</b>	04/17/2015	<b>UR Denial Date:</b>	04/18/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	05/08/2014

### 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. 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:

The injured worker is a 52 year old male with an industrial injury dated 09/23/1982 to 09/02/2000, 09/02/2000, 10/02/2000 to 01/06/2002, 01/02/2002, 05/22/2002. His diagnoses include right shoulder impingement, bilateral upper extremity overuse tendinitis, lumbar discopathy, lumbar spine strain/sprain, hypertension, and status post bilateral carpal tunnel release. No recent diagnostic testing was submitted or discussed. Multiple laboratory results were submitted. Previous treatments have included conservative measures, medications, and surgeries. In a progress note dated 03/28/2014, the treating physician reports persistent aching and throbbing pain in the low back, muscle spasms and pain in the left hip, right shoulder pain with muscle spasms, and right hand pain. New complaints included dizziness and redness to the eyes. The objective examination revealed an antalgic gait, painful range of motion in the bilateral hands, tenderness to the carpal tunnel release scars, diffuse tenderness to the forearm, decreased sensation in the medial distribution, decreased strength in the wrist, slightly restricted range of motion to both elbows, and hands/wrists, tenderness in the paraspinal musculature of the lumbar spine on the left, midline tenderness of the lumbar spine, positive muscle spasm over the lumbar spine, restricted range of motion in the lumbar spine with spasm, decreased sensation in the left foot/toes, left sacroiliac tenderness on compression, positive sciatic nerve compression on the left, and positive straight leg raises. The treating physician is requesting multiple medications which were denied or modified by the utilization review. On 04/18/2014, Utilization Review non-certified a prescription for cyclobenzaprine 7.5mg #60, noting that the medication is not recommended for long term use, and that a urine drug screen showed that the injured worker was

inconsistent with the prescribed medication. The MTUS guidelines were cited. On 04/18/2014, Utilization Review non-certified a prescription for FluriFlex (flurbiprofen/cyclobenzaprine 15/10%) cream 180gm, Cartivisc 500/200/150mg #90, noting that topical medications are not supported by referenced guidelines, and that the compound contains at least one medication that is not recommended. The MTUS guidelines were cited. On 04/18/2014, Utilization Review non-certified/modified a prescription for Cartivisc 500/200/150mg #90, noting that this medication is used to treat arthritic conditions and the absence of documented arthritic conditions. The MTUS guidelines were cited. On 04/18/2014, Utilization Review non-certified/modified a prescription for TGHot (tramadol/gabapentin/menthol/camphor/capsaicin 8/10/2/2/0.5%) cream 180gm, noting that topical medications are not supported by referenced guidelines, and that the compound contains at least one medication that is not recommended. The MTUS guidelines were cited. On 04/18/2014, Utilization Review modified a prescription for hydrocodone/APAP 10/325mg #60 to the approval of hydrocodone/APAP 10/325mg one month supply for weaning, noting that there was insufficient documented objective improvement with use of this medication, and that a urine drug screen showed that the injured worker was inconsistent with the prescribed medication. The MTUS guidelines were cited. On 05/08/2014, the injured worker submitted an application for IMR for review of cyclobenzaprine 7.5mg #60, FluriFlex (flurbiprofen/cyclobenzaprine 15/10%) cream 180gm, Cartivisc 500/200/150mg #90, TGHot (tramadol/gabapentin/menthol/camphor/capsaicin 8/10/2/2/0.5%) cream 180gm, and hydrocodone/APAP 10/325mg #60.

### **IMR ISSUES, DECISIONS AND RATIONALES**

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

**Cyclobenzaprine 7.5mg, #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 Treatment Guidelines Muscle Relaxants Page(s): 63.

**Decision rationale:** Cyclobenzaprine HCl (Flexeril) is a skeletal muscle relaxant and a central nervous system (CNS) depressant with similar effects to tricyclic antidepressants. It has a central mechanism of action, but it is not effective in treating spasticity from cerebral palsy or spinal cord disease. According to CA MTUS Guidelines, muscle relaxants are not considered any more effective than nonsteroidal anti-inflammatory medications alone. Cyclobenzaprine is not recommended for the long-term treatment of chronic pain. This medication has its greatest effect in the first four days of treatment. This medication is not recommended to be used for longer than 2-3 weeks. In this case, there are muscle spasms documented on physical exam, however there is no documentation of objective functional improvement from any previous use of this medication. Based on the currently available information, the medical necessity for Cyclobenzaprine HCl, has not been established. The requested medication is not medically necessary.

**FluriFlex (Flurbiprofen/cyclobenzaprine 15/10%) cream 180gm: 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.

**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. In this case, there is no documentation of intolerance to other previous oral medications. MTUS guidelines state that Flurbiprofen and/or muscle relaxants (Cyclobenzaprine in this case) are not recommended for topical applications. Cyclobenzaprine is not recommended, as there is no evidence for the use of any muscle relaxant as a topical agent. In addition, there are no clinical studies to support the safety or effectiveness of Flurbiprofen in a topical delivery system (excluding ophthalmic). Medical necessity for this topical analgesic has not been established. The requested item is not medically necessary.

**TGHot (tramadol/gabapentin/menthol/camphor/capsaicin, 8/10/2/2/0.5%) cream 180gm:**  
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 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. In this case, the topical analgesic compound is TGHot cream, which contains Tramadol 8%, gabapentin 10%, menthol 2%, camphor 2%, and capsaicin 0.05%. Gabapentin is not recommended as a topical agent per CA MTUS Guidelines. There is no peer-reviewed literature to support its use. Tramadol is not recommended as a first line therapy. Capsaicin is recommended only as an option in patients who have not responded to or are intolerant to other treatments. Since the guidelines do not recommend several of the ingredients, there is no medical necessity for this compound. Additionally, the documentation submitted for

review does not provide evidence of the necessity for 2 topical analgesics. The request for TGHOT is not medically necessary.

**Hydrocodone/APAP 10/325mg #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 Treatment Guidelines Opioids for the treatment of chronic pain Page(s): 91-97.

**Decision rationale:** According to CA MTUS, Hydrocodone/Acetaminophen 10/325 (Vicodin) is a short-acting opioid analgesic indicated for moderate to moderately severe pain, and is used to manage both acute and chronic pain. The treatment of chronic pain with any opioid analgesic requires review and documentation of pain relief, functional status, appropriate medication use, and side effects. A pain assessment should include current pain, intensity of pain after taking the opiate, and the duration of pain relief. In this case, there is no documentation of the medication's pain relief effectiveness, functional status, or response to ongoing opioid analgesic therapy. In addition, the urine drug screen revealed that this patient was inconsistent with prescribed Hydrocodone/APAP. Medical necessity of the requested item has not been established. Of note, discontinuation of an opioid analgesic should include a taper, to avoid withdrawal symptoms. Medical necessity for the requested medication is not established. The requested medication is not medically necessary.

**Cartivisc 500/200/150mg, #90: 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 Glucosamine (and Chondroitin Sulfate) Page(s): 50.

**Decision rationale:** California MTUS guidelines state that Glucosamine/Chondroitin is recommended as an option, given its low risk, in patients with moderate arthritic pain, especially for knee osteoarthritis. Cartivisc consists of glucosamine and chondroitin sulfate. Studies have demonstrated a highly significant efficacy for crystalline glucosamine sulphate (GS) in all outcomes, including joint space narrowing, pain, mobility, safety, and response to treatment, but similar studies are lacking for glucosamine hydrochloride. The Glucosamine Chondroitin Arthritis Intervention Trial (GAIT) funded by the National Institutes of Health concluded that glucosamine hydrochloride (GH) and chondroitin sulfate were not effective in reducing knee pain in the study group overall; however, these may be effective in combination for patients with moderate to severe knee pain. In this case, although there is documentation of pain, there is no clear documentation of moderate arthritic pain. Medical necessity for the requested item is not established. The requested item is not medically necessary.