

<b>Case Number:</b>	CM15-0182776		
<b>Date Assigned:</b>	09/23/2015	<b>Date of Injury:</b>	08/31/1998
<b>Decision Date:</b>	11/06/2015	<b>UR Denial Date:</b>	08/20/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	09/17/2015

### 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: California, District of Columbia, Maryland  
 Certification(s)/Specialty: Anesthesiology, Pain Management

### 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 53 year old male, who sustained an industrial injury on 8-31-1998. The injured worker is being treated for failed anterior cervical fusion, posterior cervical fusion, cervical discogenic pain with radiculopathy, possible lumbar sprain-strain, bilateral lumbosacral radicular pain L5-S1, stress syndrome, posttraumatic metabolic syndrome, and rotator larynx secondary to spine surgery. Treatment to date has included surgical intervention (anterior C5-6 and C6-7 decompression, discectomy and fusion, 2000, and posterior cervical fusion and foraminotomy, 2002), diagnostics, medial branch blocks, radiofrequency ablation (RFA), cervical epidural steroid injections, spinal cord stimulator, cognitive behavioral therapy, medications, trigger point injections, physical therapy, and collagen injections. Per the Primary Treating Physician's Progress Report dated 7-29-2015, the injured worker presented for reevaluation. He reported low back pain with radiation to the lower extremities, neck pain with on and off occipital area headache and pain radiating to both upper extremities, left more than right, right vocal cord paralysis related to complication of cervical spine surgery, stress syndrome and posttraumatic metabolic syndrome. Objective findings included cervical midline tenderness, bilateral trapezius tenderness and bilateral occipital tenderness. There was mild tenderness of the low back and bilateral lumbar facet tenderness. Thoracic and lumbar spine movements were painful. He has been prescribed Flurlido-A and Ultraflex-G since at last 6-02-2015. Per the medical records dated 6-02-2015 to 7-29-2015 there is no documentation of improvement in symptoms, increase in activities of daily living or decrease in pain level with the topical medications. Work status was permanent and stationary. The plan of care included, and

authorization was requested on 7-29-2015 for Risperdal, Wellbutrin, Cymbalta, Lyrica, ibuprofen, Lidoderm, Baclofen, psychiatrist evaluation, ENT surgeon referral, urine drug screen and reevaluation in 4-6 weeks. On 8-20-2015 Utilization Review non-certified the request for Flurido-A and Ultraflex-G citing lack of documented medical necessity.

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

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

**Flurido - A (flurbiprofen 20% lidocaine 5% amitriptyline 5%): Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009.

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

**Decision rationale:** Per MTUS with regard to Flurbiprofen (p112), "(Biswal, 2006) These medications may be useful for chronic musculoskeletal pain, but there are no long-term studies of their effectiveness or safety. 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." Flurbiprofen may be indicated. Per the article "Topical Analgesics in the Management of Acute and Chronic Pain" published in Mayo Clinic Proceedings (Vol 88, Issue 2, p 195-205), "Studies in healthy volunteers demonstrated that topical amitriptyline at concentrations of 50 and 100 mmol/L produced a significant analgesic effect ( $P<.05$ ) when compared with placebo and was associated with transient increases in tactile and mechanical nociceptive thresholds." Amitriptyline may be indicated. With regard to lidocaine MTUS p 112 states "Further research is needed to recommend this treatment for chronic neuropathic pain disorders and other than post-herpetic neuralgia" and "Non-neuropathic pain: Not recommended. There is only one trial that tested 4% lidocaine for treatment of chronic muscle pain. The results showed there was no superiority over placebo. (Scudds, 1995)". The injured worker has not been diagnosed with post-herpetic neuralgia. Lidocaine is not indicated. The MTUS Chronic Pain Medical Treatment Guidelines state that topical medications are "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,  $\alpha$ -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." Regarding the use of multiple medications, MTUS p60 states, "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." Therefore, it would be optimal to trial each medication individually. Because lidocaine is not indicated, the compound is not recommended. This request is not medically necessary.

**Ultraflex- G (gabapentin 10% cyclobenzaprine 6% tramadol 10%): Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009.

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

**Decision rationale:** Per MTUS p113 with regard to topical cyclobenzaprine, "There is no evidence for use of any muscle relaxant as a topical product." Per MTUS p113 with regard to topical gabapentin: "Not recommended. There is no peer-reviewed literature to support use." The MTUS is silent on the use of tramadol topically. However, note the statement on page 111: Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Regarding the use of multiple medications, MTUS p60 states "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." Therefore, it would be optimal to trial each medication individually. As none of the agents in the requested compound are recommended, the request is not medically necessary.