

<b>Case Number:</b>	CM13-0021637		
<b>Date Assigned:</b>	11/13/2013	<b>Date of Injury:</b>	05/12/2001
<b>Decision Date:</b>	01/08/2014	<b>UR Denial Date:</b>	08/30/2013
<b>Priority:</b>	Standard	<b>Application Received:</b>	09/09/2013

### 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 Anesthesiology 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 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:

The patient is a 76-year-old male who reported a work related injury on 05/12/2001 to his right shoulder. The mechanism of injury was noted as a fall with subsequent onset of shoulder and arm pain and, since then, over the years, the patient reported gradually increasing neck, hand, and wrist pain problems as well. The patient has not undergone surgery. His diagnoses include bicipital tendinitis, shoulder capsulitis, cubital tunnel syndrome, wrist pain, and chronic pain. MRI of the right shoulder dated 08/30/2007 revealed evidence of a rotator cuff tear. The patient reached maximum medical improvement on 11/28/2001.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Flector patch 180mg #60:** Upheld

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

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter, Flector Patch. .

**Decision rationale:** The clinical note dated 08/23/2013 stated the patient presented with right shoulder pain that he rated as 4/10. The patient reported there had been no change in his pain and

stated his pain was increased with walking, bending, and reaching, and nothing makes his pain better. Physical exam revealed right shoulder tenderness to posterior aspect of the shoulder. Minimal radiation to the upper extremities was noted and straight arm raise to about 20 degrees before causing pain into the shoulder was reported. Weakness was also noted, right compared to the left upper extremity. The patient's medications were listed as Flector patch 180 mg, hydrocodone 10/325 mg daily, naproxen 250 mg every 12 hours to 8 hours as needed, Senokot S 50/8.6 mg twice a day, ketoprofen/ketamine/lidocaine/Gabapentin rub cream, 1 half teaspoon to affected area 3 times a day, Voltaren gel 1% 4 times daily, and hydrocodone 2.5/325 mg twice a day as needed. The clinical note dated 09/23/2013 indicated the patient received authorization to see a surgeon. He still complained of shoulder pain that he rated as 3/10. The patient stated he did not want to use the Naprosyn because he was afraid of a gastric bleed. He reported that the creams do seem to help. The patient also complained that his right wrist was painful, along with his neck. The plan was noted to continue with his medications and to taper the patient's hydrocodone down to 7.5 mg. Official Disability Guidelines indicate that Flector patch is not recommended as a first line treatment. Topical diclofenac is recommended for osteoarthritis after failure of an oral NSAID or contraindications to oral NSAIDs, after considering the increased risk profile with diclofenac, including topical formulations. Flector patch is FDA indicated for acute strains, sprains, and contusions. The FDA issued warnings about the potential for elevation in liver function tests during treatment with all products containing diclofenac. Per the submitted documentation, the patient was not noted to be using the Flector patch for an acute strain, sprain, or contusion. It was not indicated in the submitted documentation where the Flector patch was being used on the patient. Guidelines further state that there is no data that substantiates Flector efficacy beyond 2 weeks. Given the above, the request for Flector patch 180 mg #60 is non-certified.

**Voltaren gel 1% four times a day (QID), as needed:** Upheld

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

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain Chapter, Voltaren Gel..

**Decision rationale:** The clinical note dated 08/23/2013 stated the patient presented with right shoulder pain that he rated as 4/10. The patient reported there had been no change in his pain and stated his pain was increased with walking, bending, and reaching, and nothing makes his pain better. Physical exam revealed right shoulder tenderness to posterior aspect of the shoulder. Minimal radiation to the upper extremities was noted and straight arm raise to about 20 degrees before causing pain into the shoulder was reported. Weakness was also noted, right compared to the left upper extremity. The patient's medications were listed as Flector patch 180 mg, hydrocodone 10/325 mg daily, naproxen 250 mg every 12 hours to 8 hours as needed, Senokot S 50/8.6 mg twice a day, ketoprofen/ketamine/lidocaine/Gabapentin rub cream, 1 half teaspoon to affected area 3 times a day, Voltaren gel 1% 4 times daily, and hydrocodone 2.5/325 mg twice a day as needed. The clinical note dated 09/23/2013 indicated the patient received authorization to see a surgeon. He still complained of shoulder pain and rated the pain as 3/10. The patient stated

he did not want to use the Naprosyn because he was afraid of a gastric bleed. He reported that the creams do seem to help. The patient also complained that his right wrist was painful, along with his neck. The plan was noted to continue with his medications and to taper the patient's hydrocodone down to 7.5 mg. Official Disability Guidelines indicate Voltaren gel is not recommended as a first line treatment. Voltaren gel is recommended for osteoarthritis after failure of an oral NSAID, or contraindications to oral NSAIDs, or for patients who cannot swallow solid oral dosage forms, and after considering the increased risk profile with diclofenac, including topical formulations. According to the FDA MedWatch, there have been reported cases of severe hepatic reactions, including liver necrosis, jaundice, fulminant hepatitis with and without jaundice, and liver failure with the use of Voltaren gel. The patient was not noted in the submitted documentation to have a contraindication to oral NSAIDs and it was not noted that he was not able to swallow a solid oral dosage form. Therefore, the request for Voltaren gel 1% four times a day (QID), as needed for joint pain is non-certified.

**Ketoprofen/Ketamine/Gabapentin topical cream** ½ tsp three times a day (TID) for shoulder/wrist achiness, QTY: 1: Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical analgesics Page(s): 111-113.

**Decision rationale:** The clinical note dated 08/23/2013 stated the patient presented with right shoulder pain that he rated as 4/10. The patient reported there had been no change in his pain and stated his pain was increased with walking, bending, and reaching, and nothing makes his pain better. Physical exam revealed right shoulder tenderness to posterior aspect of the shoulder. Minimal radiation to the upper extremities was noted and straight arm raise to about 20 degrees before causing pain into the shoulder was reported. Weakness was also noted, right compared to the left upper extremity. The patient's medications were listed as Flector patch 180 mg, hydrocodone 10/325 mg daily, naproxen 250 mg every 12 hours to 8 hours as needed, Senokot S 50/8.6 mg twice a day, ketoprofen/ketamine/lidocaine/Gabapentin rub cream, 1 half teaspoon to affected area 3 times a day, Voltaren gel 1% 4 times daily, and hydrocodone 2.5/325 mg twice a day as needed. The clinical note dated 09/23/2013 indicated the patient received authorization to see a surgeon. He still complained of shoulder pain and rated the pain as 3/10. The patient stated he did not want to use the Naprosyn because he was afraid of a gastric bleed. He reported that the creams do seem to help. The patient also complained that his right wrist was painful, along with his neck. The plan was noted to continue with his medications and to taper the patient's hydrocodone down to 7.5 mg. California Chronic Pain Medical Treatment Guidelines indicate topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. Primarily, they are recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. Many agents are compounded as monotherapy or in combination for pain control, and there is little to no research to support the use of many of these agents. Gabapentin is not recommended as a topical medication as there is no peer reviewed literature to support its use. Ketamine is only recommended for treatment of neuropathic pain in refractory cases in which all primary and secondary treatment has been

exhausted. Guidelines state that any compounded product that contains at least 1 drug (or drug class) that is not recommended is not recommended. Therefore, the request for Ketoprofen/Ketamine/Gabapentin topical cream 1/2 tsp three times a day (TID) for shoulder/wrist achiness QTY: 1: is non-certified.