

<b>Case Number:</b>	CM13-0035662		
<b>Date Assigned:</b>	02/07/2014	<b>Date of Injury:</b>	09/27/2011
<b>Decision Date:</b>	05/29/2014	<b>UR Denial Date:</b>	09/10/2013
<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 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 and Rehabilitation, has a subspecialty in Pain Medicine 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 58 year old female who was injured on 09/27/2011. The mechanism of injury is unknown. She presented with pain in the neck and left shoulder. Prior treatment history has included Omeprazole 20 mg twice per day, Benazepril 10 mg per day, Meloxicam 15 mg once or twice per day as needed for pain, Effexor 75 mg per day and AlerteC 10 mg per day. AME documented an exam which reveals tenderness to palpation in the trapezial musculature. There is no muscle spasm. She has some restricted neck motion. There is no significant neurological deficit. A request was made for a cervical epidural block on 05/16/2013. She had been seen by an orthopedic surgeon who recommended multiple medications including Naproxen Sodium, Omeprazole, Ondansetron, Cyclobenzaprine, Sumatriptan, Tramadol and Medrox pain relief ointment. She had been seen by an AME on 09/10/2012 who recommended conservative management including medications, physical therapy and referral to a pain management doctor. Office note dated 08/30/2013 states the patient has constant severe pain of the neck that radiates to the upper extremities with numbness and tingling. She is status post right hand surgery. She just took her cast off. She will attend a course of hand therapy. The symptomatology in the patient's lumbar spine is essentially unchanged. Objective findings on exam revealed tenderness at the cervical paravertebral muscles and upper trapezial muscles with spasm. Axial loading compression test and Spurling's maneuver are positive. There is painful and restricted cervical range of motion. There is dysesthesia at the C5 to C7 dermatomes. The bilateral wrists exam reveals a well-healed carpal tunnel release scar at the dorsal aspect of the thumb. There is still limited range of motion and weakness of the right hand. Neurovascular status remains intact. Examination of the left hand remains unchanged. There are positive Tinel and Phalen signs. There is pain with terminal flexion. There is dysesthesia at the radial digits. The lumbar spine exam reveals tenderness from the mid to distal lumbar segments. There is pain with terminal

motion; seated nerve root test is positive. There is dysesthesia from the L4 to S1 dermatomes on the right. The patient has failed cervical epidural steroid injections and conservative treatment. She is quite symptomatic. She continues having persistent neck pain with radicular symptoms with chronic headaches.

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

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

#### **MEDROX PATCH #30: Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Capsaicin, Salicylate Topicals, Topical Analgesics Page(s): 28-29; 105; 111-113.

**Decision rationale:** According to the California MTUS guidelines, topical analgesics are considered to be largely experimental in use with few randomized controlled trials to determine efficacy or safety. According to the references, Medrox patch is a product that contains methyl salicylate 5%, menthol 5%, and capsaicin 0.0375%. Per the guidelines, Capsaicin is recommended only as an option in patients who have not responded or are intolerant to other treatments. The medical records do not establish that to be the case of this patient, as it is documented that she is prescribed oral medications, and is able to tolerate other treatments. In addition, there have been no studies of a 0.0375% formulation of Capsaicin and there is no current indication that this increase over a 0.025% formulation would provide any further efficacy. Consequently, Medrox patch was not medically necessary.

#### **TRAMADOL HYDROCHLORIDE EXTENDED RELEASE (ER) 150 MG #90: Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Tramadol (Ultram®), Opioids Page(s): 113; 74-96.

**Decision rationale:** According to the CA MTUS Guidelines, Ultram is recommended as a second-line treatment (alone or in combination with first-line drugs). Tramadol is indicated for moderate to severe pain. The re-evaluation progress report of 7/23/2013 does not include subjective complaints and objective examination findings. There is no documentation of the patient's presenting subjective complaints, clinical examination findings, and documentation pertaining to the patient's response to her medication regimen. The presence of moderate to severe pain has not been established. Consequently, in absence of supportive documentation, the medical necessity of the request for Tramadol ER had not been established in accordance with the guidelines.

#### **SUMATRIPTAN SUCCINATE TABLETS 25MG #9 X 2: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation ODG Treatment.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG)Head, Imitrex® (Sumatriptan), Triptans.

**Decision rationale:** According to the Official Disability Guidelines, Triptans are recommended for migraine sufferers. At marketed doses, all oral triptans (e.g., sumatriptan, brand name Imitrex) are effective and well tolerated. The medical records do not include any clinical evidence of migraines. The medical records do not establish this patient has migraine headaches. Consequently, this medication would not be indicated or considered medically necessary for this patient.

#### **CYCLOBENZAPRINE HYDROCHLORIDE 7.5 MG #120: 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 Cyclobenzaprine (Flexeril®) Page(s): 41 & 64.

**Decision rationale:** According to California MTUS, Cyclobenzaprine (Flexeril®) is recommended as an option, using a short course of therapy. The addition of cyclobenzaprine to other agents is not recommended. The guidelines state antispasmodics are used to decrease muscle spasms. Flexeril is recommended as an option, using a short course. The re-evaluation progress report of 7/23/2013 does not include subjective complaints and objective examination findings. The medical records do not document the presence of muscle spasm on examination, and do not establish the patient presented with exacerbation unresponsive to first-line interventions. Furthermore, chronic use of muscle relaxants is not recommended by the guidelines. Consequently, Cyclobenzaprine was not medically necessary.

#### **ONDANSETRON (ODT) TABLETS 4 MG #60: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation ODG Treatment, Pain (Chronic).

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

**Decision rationale:** According to the Official Disability Guidelines, Antiemetics are not recommended for nausea and vomiting secondary to chronic opioid use. Ondansetron (Zofran®) is a serotonin 5-HT<sub>3</sub> receptor antagonist, FDA-approved for nausea and vomiting secondary to chemotherapy and radiation treatment. It is also FDA-approved for postoperative

use. Acute use is FDA-approved for gastroenteritis. According to the medical records, the patient had been prescribed Ondansetron (Zofran) on 07/23/2013. The re-evaluation progress report of 7/23/2013 does not include presenting complaints and objective examination findings. According to the guidelines, Zofran is FDA approved for nausea and vomiting secondary to chemotherapy and radiation treatment, postoperative use, and in acute use for gastroenteritis. It is acknowledged the patient had undergone surgery to the right wrist, however that was one week prior, and there is no reported subjective complaint of nausea/vomiting. In addition, the records do not document any history of diagnosed gastroenteritis. The medical records do not establish Ondansetron was appropriate and medically necessary for the treatment of this patient.

**OMEPRAZOLE DELAYED-RELEASE CAPSULES 20 MG #120: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation ODG, Integrated Treatment/Disability/Duration Guidelines, Pain (Chronic).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDS, GI Symptoms, And Cardiovascular Risk Page(s): 68.

**Decision rationale:** According to the California MTUS guidelines, PPI "Omeprazole" is recommended 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). The recent studies tend to show that H. Pylori does not act synergistically with NSAIDS to develop gastroduodenal lesions. Long-term PPI use (> 1 year) has been shown to increase the risk of hip fracture. The Official Disability Guidelines state, in general, the use of a PPI should be limited to the recognized indications and used at the lowest dose for the shortest possible amount of time. PPIs are highly effective for their approved indications, including preventing gastric ulcers induced by NSAIDs. Studies suggest, however, that nearly half of all PPI prescriptions are used for unapproved indications or no indications at all. The medical records do not reveal that the patient has any risk factors for potential GI events. In the absence of documented GI distress, any history of GI bleeding, concurrent use of ASA with corticosteroid and/or anticoagulant, or high dose or multiple NSAID, the request for Omeprazole was not medically necessary according to the guidelines.