

<b>Case Number:</b>	CM15-0148441		
<b>Date Assigned:</b>	08/11/2015	<b>Date of Injury:</b>	04/22/1971
<b>Decision Date:</b>	09/08/2015	<b>UR Denial Date:</b>	07/12/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	07/30/2015

### 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: Massachusetts

Certification(s)/Specialty: Physical Medicine & Rehabilitation, 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 65 year old male, who sustained an industrial injury on April 22, 1971. The injured worker was transported for emergency medical care for neck fracture and a right traumatic knee amputation. Treatment to date has included left knee injection, physical therapy, CT scan, x-ray, MRI, surgery, hospitalization, halo, medication, physical rehabilitation admission, TENS unit, lumbar sympathetic block and steroid injection. Currently, the injured worker complains of increased back pain and bilateral leg pain. The injured worker is currently diagnosed with lumbar degenerative disc disease. A note dated September 9, 2014 states the injured worker experienced an 80% decrease in pain from the lumbar block and a 60% decrease in pain from the left knee steroid injection. The note further states the injured worker is experiencing adequate pain relief from his current medication regimen. A physical therapy note dated March 16, 2015 states the injured worker is able to engage in treatment. A note dated May 7, 2015 states the injured worker experienced pain relief from the TENS unit. A note dated June 3, 2015 states the injured worker reached all of his physical therapy goals during his admission. The following medications, Flector 1.3% #30 (for pain relief), Ondansetron 4 mg #60 (relief of nausea) and Modafinil 200 mg #30 (to improve daytime wakefulness and cognition) is requested.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Flector 1.3% #30:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-112.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines (1) Medications for chronic pain, p60 (2) Topical Analgesics, p111-113 Page(s): 60, 111-113.

**Decision rationale:** The claimant has a remote history of a work injury occurring in April 1971. He underwent multiple right knee surgeries ultimately undergoing an above knee amputation. He has a history of a C2 fracture with Halo placement and severe lumbar spinal stenosis. He continues to be treated for chronic pain including diagnoses of neurogenic claudication and CRPS. He is current being treated in a transitional living center program. When seen, he was doing well and being transitioned to a home-based and community program. He was having increasing fatigue of unclear etiology. Physical examination findings included appearing fatigued. He was somnolent but easily arousable. He had left lower extremity edema. He was not regularly taking lactulose and technicians included obtaining an ammonia level. Medical diagnoses include hepatic encephalopathy, morbid obesity, hepatitis, hypertension, chronic lymphedema, dyslipidemia, insomnia, and coronary artery disease. Topical non-steroidal anti-inflammatory medication can be recommended for patients with chronic pain where the target tissue is located superficially in patients who either do not tolerate, or have relative contraindications, for oral non-steroidal anti-inflammatory medications. In this case, the claimant has multiple co-morbid medical conditions that would contraindicate the use of an oral NSAID. However, a trial of generic topical diclofenac in a non-patch form would be indicated before consideration of use of a dermal-patch system. Flector is not medically necessary.

**Ondansetron 4mg #60:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation PDR, 2009, page 1688.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic), Antiemetics and Other Medical Treatment Guidelines Ondansetron prescribing information.

**Decision rationale:** The claimant has a remote history of a work injury occurring in April 1971. He underwent multiple right knee surgeries ultimately undergoing an above knee amputation. He has a history of a C2 fracture with Halo placement and severe lumbar spinal stenosis. He continues to be treated for chronic pain including diagnoses of neurogenic claudication and CRPS. He is current being treated in a transitional living center program. When seen, he was doing well and being transitioned to a home-based and community program. He was having increasing fatigue of unclear etiology. Physical examination findings included appearing fatigued. He was somnolent but easily arousable. He had left lower extremity edema. He was not regularly taking lactulose and technicians included obtaining an ammonia level. Medical diagnoses include hepatic encephalopathy, morbid obesity, hepatitis, hypertension, chronic lymphedema, dyslipidemia, insomnia, and coronary artery disease. Indications for prescribing

Zofran (ondansetron) are for the prevention of nausea and vomiting associated with cancer treatments or after surgery. The claimant has not had recent surgery and is not being treated for cancer. Ondansetron is not recommended for the treatment of opioid induced nausea. The use of this medication is not medically necessary.

**Modafinil 200mg #30: Upheld**

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

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic), Modafinil (Provigil) and Other Medical Treatment Guidelines Provigil Prescribing Information.

**Decision rationale:** The claimant has a remote history of a work injury occurring in April 1971. He underwent multiple right knee surgeries ultimately undergoing an above knee amputation. He has a history of a C2 fracture with Halo placement and severe lumbar spinal stenosis. He continues to be treated for chronic pain including diagnoses of neurogenic claudication and CRPS. He is current being treated in a transitional living center program. When seen, he was doing well and being transitioned to a home-based and community program. He was having increasing fatigue of unclear etiology. Physical examination findings included appearing fatigued. He was somnolent but easily arousable. He had left lower extremity edema. He was not regularly taking lactulose and technicians included obtaining an ammonia level. Medical diagnoses include hepatic encephalopathy, morbid obesity, hepatitis, hypertension, chronic lymphedema, dyslipidemia, insomnia, and coronary artery disease. Modafinil is a vigilance-promoting drug commonly used to treat narcolepsy and idiopathic hypersomnia. Although the precise mechanism of action remains unknown, it is believed that modafinil can inhibit GABA or increase glutamate levels in the nondopaminergic anterior hypothalamus, hippocampus, and amygdala. In this case, the claimant has multiple risk factors for his symptoms including obstructive sleep apnea and encephalopathy due to hepatic insufficiency. The claimant also has a significant cardiac history and caution should be exercised when prescribing this medication to patients with known cardiovascular disease. Prescribing modafinil without an adequate assessment of the claimant's medical condition is not appropriate or medically necessary.