

<b>Case Number:</b>	CM15-0006701		
<b>Date Assigned:</b>	01/26/2015	<b>Date of Injury:</b>	05/08/2001
<b>Decision Date:</b>	03/17/2015	<b>UR Denial Date:</b>	12/18/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	01/13/2015

### 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: Colorado

Certification(s)/Specialty: Family Practice

### CLINICAL CASE SUMMARY

The expert reviewer developed the following clinical case summary based on a review of the case file, including all medical records:

This 68 year old woman sustained an industrial injury on 5/8/2001. The mechanism of injury is not detailed. Current diagnoses include bilateral shoulder tendonitis, lumbosacral sprain/strain with spinal cord stimulator, and internal derangement of bilateral knees. Patient also has depression and anxiety, migraines, and restless leg syndrome, though it is not clear if these are related to industrial injury. Treatment has included oral medication, opioid detoxification, and a spinal cord stimulator x 2. Physician notes dated 10/13/2014 show complaints of increased right knee pain with swelling and multiple chronic pain complaints involving her upper and lower extremities. Physician notes dated 10/13/2014 show another physician's request for authorization of six medications, one of them being the Imitrex 50 mg. Similar assessments and requests were also made on 11/3/2014 and 12/1/2014. On 12/18/2014, Utilization Review evaluated a prescription for Imitrex 50 mg #10, that was submitted on 1/2/2015. The UR physician noted lack of documentation of characteristics of the headaches or a clear diagnosis of migraines. Documentation does state that the spinal cord stimulator has caused muscle spasms radiating up toward the head, however, this is consistent with a tension headache and not a migraine. Further, documentation indicates that the worker has been taking Imitrex for a prolonged period of time, however, there is no documentation to support clinical efficacy and no monitoring noted. The MTUS, ACOEM (or ODG) Guidelines was cited. The request was denied and subsequently appealed to Independent Medical Review.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Imitrex 50mg #10:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation <http://www.accessdata.fda.gov/scripts>

**Decision rationale:** The MTUS and ACOEM do not address the use of Sumatriptan, so FDA recommendations were consulted. Sumatriptan succinate (Imitrex) is a selective 5HT1 agonist indicated for treatment of migraine headaches with or without aura. It has no evidence-based approved usage in basilar headaches or cluster headaches. Use of Imitrex requires a definite diagnosis of migraine. Imitrex is not recommended for use in patients with any ischemic cardiovascular or cerebral disorder or peripheral vascular disease. Imitrex is also not to be used in patients with uncontrolled high blood pressure. For the patient of concern, the records mention that patient has migraine headaches, but records do not describe characteristics of patient headaches or their response to Imitrex which has been prescribed for some time. The patient also has had issues with syncope and high blood pressure in the last year. The records supplied for review do not include any documentation of the work up on the syncope and/or resolution / management of same. There is also no documentation that patient migraines are related to her industrial injury, so would not be subject to approval through this system. Without more information about patient's headaches and efficacy of Imitrex for the patient, and with the concerning history of blood pressure issues and syncope incompletely addressed, the Imitrex is not currently medically indicated. Furthermore, there is no documented association between patient's industrial injury and her migraine headaches.

**Mirapex 0.5mg #60:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation <http://www.accessdata.fda.gov/scripts>

**Decision rationale:** The MTUS and ACOEM do not address the use of Mirapex, so FDA recommendations were consulted. Mirapex is a dopamine agonist used to treat Parkinson's Disease and Moderate to severe Primary Restless Leg Syndrome. The optimal dose recommended is 0.5mg daily. For the patient of concern, the records do not indicate if patient has moderate or severe restless leg syndrome, nor do the records address possible previous testing for other causes of leg symptoms, including iron and/or vitamin deficiencies. There is also no documentation of a relationship between patient's industrial injury and restless leg symptoms. Without verification that patient has primary restless leg syndrome (no underlying cause), and/or moderate to severe restless leg syndrome, and without documented association between the injury and symptoms, the Mirapex is not medically indicated.

**Norco 10/325mg #45 Med 15:** 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 Pain Interventions and Treatments Page(s): 79-80, 85, 88-89, and 91.

**Decision rationale:** The Guidelines establish criteria for use of opioids, including long term use (6 months or more). When managing patients using long term opioids, the following should be addressed: Re-assess the diagnosis and review previous treatments and whether or not they were helpful. When re-assessing, pain levels and improvement in function should be documented. Pain levels should be documented every visit. Function should be evaluated every 6 months using a validated tool. Adverse effects, including hyperalgesia, should also be addressed each visit. Patient's motivation and attitudes about pain / work / interpersonal relationships can be examined to determine if patient requires psychological evaluation as well. Aberrant / addictive behavior should be addressed if present. Do not decrease dose if effective. Medication for breakthrough pain may be helpful in limiting overall medication. Follow up evaluations are recommended every 1-6 months. To summarize the above, the 4A's of Drug Monitoring (analgesia, activities of daily living, adverse side effects, and aberrant drug-taking Behaviors) have been established. The monitoring of these outcomes over time should affect therapeutic decisions and provide a framework for documentation of the clinical use of these controlled drugs. (Passik, 2000) Several circumstances need to be considered when determining to discontinue opioids: 1) Verify patient has not had failure to improve because of inappropriate dosing or under-dosing of opioids. 2) Consider possible reasons for immediate discontinuation including diversion, prescription forgery, illicit drug use, suicide attempt, arrest related to opioids, and aggressive or threatening behavior in clinic. Weaning from the medication over 30 day period, under direct medical supervision, is recommended unless a reason for immediate discontinuation exists. If a medication contract is in place, some physicians will allow one infraction without immediate discontinuation, but the contract and clinic policy should be reviewed with patient and consequences of further violations made clear to patient. 3) Consider discontinuation if there has been no improvement in overall function, or a decrease in function. 4) Patient has evidence of unacceptable side effects. 5) Patient's pain has resolved. 6) Patient exhibits 'serious non-adherence.' Per the Guidelines, Chelminski defines 'serious substance misuse' or non-adherence as meeting any of the following criteria: (a) cocaine or amphetamines on urine toxicology screen (positive cannabinoid was not considered serious substance abuse); (b) procurement of opioids from more than one provider on a regular basis; (c) diversion of opioids; (d) urine toxicology screen negative for prescribed drugs on at least two occasions (an indicator of possible diversion); & (e) urine toxicology screen positive on at least two occasions for substances not routinely prescribed. (Chelminski, 2005) 7) Patient requests discontinuing opioids. 8) Consider verifying that patient is in consultation with physician specializing in addiction to consider detoxification if patient continues to violate the medication contract or shows other signs of abuse / addiction. 9) Document the basis for decision to discontinue opioids. Likewise, when making the decision to continue opioids long term, consider the following: Has patient returned to work, Has patient had improved function and decreased pain

with the opioids. For the patient of concern, it is documented that patient has 30% pain reduction with medications, and is able to participate in activities of daily living with medications, though not without medications. The record indicates that patient has a pain contract and meets criteria for moderate risk of opioid abuse. The treating physician's notes indicate no aberrant drug taking behavior but acknowledge that patient failed detoxification program December 2013-January 2014. Furthermore, the records indicate patient was taking average 15 Norco per month through clinic visit October 2014, then suddenly increased use to 45 Norco per month by clinic visit November 2014. There is no discussion of the significant increase in use and no recommendation for such increase per the treating physicians. The 2 urine drug screens referenced in the records (one discussed in a clinic note and the other with results in the record for review) indicate patient positive for 3 separate controlled substances nowhere else mentioned in the record as prescribed medications. With evidence of significant opioid increase on her own, and failed detoxification, and with evidence of substances not prescribed positive on urine drug screen, the request for Norco is not medically indicated.