

<b>Case Number:</b>	CM15-0029758		
<b>Date Assigned:</b>	02/23/2015	<b>Date of Injury:</b>	05/30/2006
<b>Decision Date:</b>	04/14/2015	<b>UR Denial Date:</b>	02/03/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	02/17/2015

### 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: Indiana

Certification(s)/Specialty: Preventive Medicine, Occupational Medicine

### 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 45-year-old male, with a reported date of injury of 05/30/2006. The diagnoses include spinal cord injury, chronic pain syndrome, thoracic or lumbosacral neuritis or radiculitis, paraplegia, drug-induced constipation, neurogenic bladder, dysesthesia, muscle spasm, and myalgia and myositis. Treatments have included oral medications, home health care, and a wheelchair. The progress report dated 01/12/2015 indicates that the injured worker complained of chronic, burning, and aching low back and bilateral leg pain. He rated the pain 8-9 out of 10 without medications, and 6-9 out of 10 with medications. The medications reduced the pain by 30%-50%. The objective findings included point tenderness at bilateral L3-5. The treating physician requested Mirapex 0.25 mg #60, with three refills, phenazopyridine 100mg #180, with three refills, and Celebrex 200mg #30, with three refills. On 01/29/2015, Utilization Review (UR) modified the request for Mirapex 0.25 mg #60, with three refills, and denied the request for phenazopyridine 100mg #180, with three refills, and Celebrex 200mg #30, with three refills. The UR physician noted that generic Mirapex was recommended; there was no evidence of blood in the urine, difficulty urinating, or a recent urinary tract infection; and there was no evidence of a gastrointestinal (GI) diagnosis or recent GI symptoms to justify prescribing Celebrex. The MTUS Chronic Pain Guidelines, RxList, and the US National Library of Medicine were cited.

## IMR ISSUES, DECISIONS AND RATIONALES

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

**Mirapex 0.25mg #60 1-2 HS, PRN 3 refills:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation US National Library of Medicine website: <http://www.nlm.nih.gov/medlineplus/druginfo/meds/a697029.html>.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Leg and Knee, Restless legs syndrome (RLS) Other Medical Treatment Guideline or Medical Evidence: UpToDate.com, Ropinirole, Neuroprotective therapy for Parkinson disease, Restless Leg Syndrome.

**Decision rationale:** MTUS guidelines are silent with regards to Mirapex, so other guidelines were utilized. Mirapex is a dopamine agonist. ODG refers to Mirapex for Restless Leg Syndrome as a treatment option "(D) Dopamine agonists: Requip (ropinirole), Mirapex (pramipexole). These drugs are not considered first-line treatment and should be reserved for patients who have been unresponsive to other treatment. Adverse effects include sleepiness, nausea, dizziness, fatigue, insomnia, hallucinations, constipation, and peripheral edema;" Medical records do not indicate that first-line treatments were utilized prior to this medication. ODG further details Diagnostic Criteria for Restless Leg Syndrome "There are four essential criteria. (Allen, 2003) (1) An urge to move the legs, usually accompanied by uncomfortable and unpleasant sensations in the legs. Pain is often a primary component (reported as often as 50% of the time). Symptoms may involve the arms or other body parts. (2) The urge to move/unpleasant sensations become worse during periods of rest or inactivity. (3) Movement partially relieves the urge to move/unpleasant sensations (at least as long as the movement continues). & (4) The urge to move/unpleasant sensations are generally worse at night, or only occur at night." While the treating physician notes "lower extremity twitching and restlessness", there is not enough detailed information in the treatment notes to satisfy the diagnostic criteria for restless leg syndrome. Therefore, the request for Mirapex is not medically necessary.

**Phenazopyridine 100mg #180 5-6 QD 3 refills:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation <http://www.rxlist.com/pyridium-drug.htm>.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Medline Plus: Phenazopyridine: <http://www.nlm.nih.gov/medlineplus/druginfo/meds/a682231.html>.

**Decision rationale:** Medline state: "Phenazopyridine relieves urinary tract pain, burning, irritation, and discomfort, as well as urgent and frequent urination caused by urinary tract infections, surgery, injury, or examination procedures." The medical notes do not show any

urinary symptoms such as described above in the reference. Therefore, the request for Phenazopyridine 100mg #180 5-6 QD 3 refills is not medically necessary.

**Celebrex 200mg #30 QD 3 refills:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms & cardiovascular risk.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Anti-inflammatory drugs; Celebrex; NSAIDs Page(s): 22, 30, 70. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, NSAIDs, GI symptoms & cardiovascular risk.

**Decision rationale:** Anti-inflammatory medications are the traditional first line treatment for pain, but COX-2 inhibitors (Celebrex) should be considered if the patient has risk of GI complications, according to MTUS. The medical documentation provided does not indicate a reason for the patient to be considered high risk for GI complications. Risk factors for GI bleeding according to ODG include: (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 or multiple NSAID (e.g., NSAID + low-dose ASA). The medical records do not indicate that he is undergoing treatment for any of the FDA approved uses such as osteoarthritis, rheumatoid arthritis, juvenile rheumatoid arthritis in patients 2 years and older, ankylosing spondylitis, acute pain, and primary dysmenorrhea. As such, the request for Celebrex 200mg #30 QD 3 refills is not medically necessary.