

<b>Case Number:</b>	CM14-0204870		
<b>Date Assigned:</b>	12/17/2014	<b>Date of Injury:</b>	09/08/2009
<b>Decision Date:</b>	02/04/2015	<b>UR Denial Date:</b>	11/25/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	12/08/2014

### 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 Rehab, 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 injured worker is a 42 year-old male with a date of injury of September 8, 2009. The patient's industrially related diagnoses include cervical spine sprain/strain, status post crush injury to the left upper extremity with symptoms of left brachial plexopathy versus complex regional pain syndrome, cervical radiculopathy left C5, C6, and C7, right shoulder pain, right elbow pain, depression and post-traumatic stress disorder, obstructive sleep apnea, and low back pain with L5-S1 3-4 mm central to left paracentral disc protrusion with bilateral lower extremity radicular pain. The disputed issues are prescriptions for MiraLax 71g/8oz #527g, Laxacin 50/8.6mg #120, Ketoprofen/Gabapentin/Lidocaine #240g, Norco 10/325mg #60, Fluoxetine 20mg #30, and Lyrica 150mg #90. A utilization review determination on 11/25/2014 had non-certified these requests. The stated rationale for the denial of MiraLax and Laxacin was: "The claimant experiences intermittent episodes of constipation due to the pain medication regimen. However, without establishing the medical necessity of Norco, prophylactic treatment of constipation is not established. In order to consider this medication for certification upon subsequent review, evidence of concurrent opioid use or specific documentation of gastrointestinal complaints including constipation will be required." The stated rationale for the denial of Ketoprofen/Gabapentin/Lidocaine was: "The cited guidelines do not support Gabapentin and a non-dermal patch formulation of Lidocaine for topical application as there is little to no evidence proving safety and efficacy." The stated rationale for the denial of Norco 10/325mg was: "Without evidence of objective functional benefit with prior medication use, and due to noncompliance with medication guidelines, the medical necessity is not supported. Although the claimant should have already been completely weaned from Norco based on warnings provided from previous reviews, it is the provider's responsibility to use his/her own judgment and/or protocol, based on the individual needs of the claimant, which may or may not

include additional weaning through the provider." The stated rationale for the denial of Fluoxetine was: "The provider notes that the claimant has improvement with depression and mood with the use of Fluoxetine. The claimant has been able to cope with the chronic pain with Fluoxetine. However, despite prior warning, there is no evidence of objective functional gains supporting the subjective improvement. Without evidence of objective function benefit with prior medication use, and due to noncompliance with medication guidelines, the medical necessity is not supported." The stated rationale for the denial of Lyrica was: "The claimant is able to participate better in the activities of daily living. However, despite prior warning, there is no documentation of objective functional improvement in range of motion or objective measures of function."

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

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

**Miralax 71g/8oz #527g:** Overturned

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

**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, Opioid Induced Constipation Treatment.

**Decision rationale:** Regarding the request for the oral laxative MiraLax (Polyethylene Glycol 3350), the California MTUS does not contain criteria regarding constipation treatment. ODG states that opioid induced constipation is recommended to be treated by physical activity, maintaining appropriate hydration, and following a diet rich in fiber. Over-the-counter medication such as stool softeners may be used as well. Second line treatments include prescription medications. In the supplemental report dated 12/16/2014, which was in response to the Utilization Review denial on 11/25/2014, the treating physician noted that the injured worker has chronic pain for which he takes pain medication, and complains of constipation with the use of his pain medication. The documentation indicates that the injured worker tried adjusting his diet but symptoms of constipation persisted. Only with the combination of both MiraLax and Laxacin has the injured worker been able to have normal bowel movements. This report clearly indicates that the injured worker has responded to the treatment with MiraLax. Furthermore, medical necessity was established for Norco. Based on this recent documentation and since Norco was determined to be medically necessary, medical necessity for the requested MiraLax 71g/8 ounces #527g has been established.

**Laxacin 50/8.6mg #120:** Overturned

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

**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, Opioid Induced Constipation Treatment.

**Decision rationale:** Regarding the request for the oral laxative and stool softener Laxacin (Docusate Sodium and Senna), the California MTUS does not contain criteria regarding constipation treatment. ODG states that opioid induced constipation is recommended to be treated by physical activity, maintaining appropriate hydration, and following a diet rich in fiber. Over-the-counter medication such as stool softeners may be used as well. Second line treatments include prescription medications. In the supplemental report dated 12/16/2014, which was in response to the Utilization Review denial on 11/25/2014, the treating physician noted that the injured worker has chronic pain for which he takes pain medication, and complains of constipation with the use of his pain medication. The documentation indicates that the injured worker tried adjusting his diet but symptoms of constipation persisted. Only with the combination of both MiraLax and Laxacin has the injured worker been able to have normal bowel movements. This report clearly documents that the injured worker has responded well to the treatment with Laxacin for the management of opioid induced constipation. Based on this recent documentation and since Norco was determined to be medically necessary, medical necessity for the requested Laxacin 50/8.6 mg #120 has been established.

**Ketoprofen/Gabapentin/Lidocaine #240g:** Upheld

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

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

**Decision rationale:** Regarding the request for topical Ketoprofen/Gabapentin/Lidocaine #240g, Chronic Pain Medical Treatment Guidelines states that Gabapentin is not recommended because there is no peer-reviewed literature to support its use. The guidelines further state that if one drug or drug class of a compounded formulation is not recommended, then the entire compounded formulation is not recommended. Given these guidelines, the request for topical Ketoprofen/Gabapentin/Lidocaine #240g is not medically necessary.

**Norco 10/325mg #60:** Overturned

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 75-80.

**Decision rationale:** Regarding the request for Norco 10/325mg (hydrocodone/acetaminophen), the California Chronic Pain Medical Treatment Guidelines state that Norco is an opiate pain medication. The DEA has reclassified Norco as of October 6, 2014 as a Schedule II Controlled

Medication. Because of this reclassification, refills are not allowed, and closer monitoring is encouraged. Due to high abuse potential, close follow-up is recommended with documentation of analgesic effect, objective functional improvement, side effects, and discussion regarding any aberrant use. Guidelines go on to recommend discontinuing opioids if there is no documentation of improved function and pain. The rationale that the UR provided for denial of Norco 10/325mg was: "Without evidence of objective functional benefit with prior medication use, and due to noncompliance with medication guidelines, the medical necessity is not supported." In the supplemental report dated 12/16/2014, which was in response to the Utilization Review denial on 11/25/2014, the treating physician noted that the injured worker does obtain objective functional improvement with Norco. Pain level was reported to be reduced by 30% and functional level was improved by 40% with specific examples provided to support the functional improvement. The treating physician indicated that there are no adverse side effects and the discussion regarding possible aberrant behavior indicated that the injured worker was at low risk for abuse. He continued to comply to the pain medication agreement, which he has signed and demonstrated compliance as seen with the department of justice CURES report and random urine drug screen. In light of this additional documentation, the four domains for ongoing monitoring of chronic pain patients on opioids (also known as the four A's) have been adequately addressed. Therefore, the currently requested Norco 10/325mg is medically necessary.

**Fluoxetine 20mg #30: Overturned**

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

**MAXIMUS guideline:** Decision based on MTUS ACOEM Chapter 15 Stress Related Conditions Page(s): 395,396 and 402, Chronic Pain Treatment Guidelines Page(s): 107.

**Decision rationale:** Regarding the request for Fluoxetine, Chronic Pain Medical Treatment Guidelines state that selective serotonin reuptake inhibitors (SSRIs) may have a role in treating secondary depression. Additionally, guidelines recommend follow-up evaluation with mental status examinations to identify whether depression is still present. Guidelines indicate that a lack of response to antidepressant medications may indicate other underlying issues. The rationale provided by the UR for the denial of Fluoxetine was: "The provider notes that the claimant has improvement with depression and mood with the use of Fluoxetine. The claimant has been able to cope with the chronic pain with Fluoxetine. However, despite prior warning, there is no evidence of objective functional gains supporting the subjective improvement." In the supplemental report dated 12/16/2014, which was in response to the Utilization Review denial on 11/25/2014, the treating physician noted that the injured worker was previously evaluated by a psychiatrist who diagnosed him with depression due to industrial causation. Furthermore, the treating physician documented that the injured worker has responded well to the current Fluoxetine treatment stating that the SSRI has been beneficial in improving the injured worker's depression and mood and enabling him to better cope with his chronic pain. With this improvement in depression, there is documentation that the injured worker's functional level is improved with specific examples provided as being able to participate in meaningful activities with his family. In light of the additional documentation and based on the guidelines, medical necessity for Fluoxetine 20mg has been established.

**Lyrica 150mg #90:** Overturned

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 16-21.

**Decision rationale:** Regarding request for Lyrica, Chronic Pain Medical Treatment Guidelines state that antiepilepsy drugs are recommended for neuropathic pain. They go on to state that a good outcome is defined as 50% reduction in pain and a moderate response is defined as 30% reduction in pain. Guidelines go on to state that after initiation of treatment, there should be documentation of pain relief and improvement in function as well as documentation of side effects incurred with use. The continued use of AEDs depends on improved outcomes versus tolerability of adverse effects. In the supplemental report dated 12/16/2014, which was in response to the Utilization Review denial on 11/25/2014, the treating physician documented both specific analgesic benefit and objective functional improvement. The treating physician stated that Lyrica not only reduced the injured worker's neuropathic pain by at least 40%, but also provided 30-40% improvement in function with the reduction of the neuropathic pain. He further provides specific examples of functional improvement with the use of Lyrica. Based on this additional documentation, the currently requested Lyrica 150mg #90 is medically necessary.