

Case Number:	CM15-0141469		
Date Assigned:	08/05/2015	Date of Injury:	07/03/2004
Decision Date:	09/18/2015	UR Denial Date:	07/20/2015
Priority:	Standard	Application Received:	07/21/2015

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: New York

Certification(s)/Specialty: Internal 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 60 year old female who sustained an industrial injury on 07-03-2004 resulting in injury to the cervical spine. Treatment provided to date has included: cervical fusion surgery (2014); acupuncture which has reportedly help decrease pain in the right trapezius and upper extremity; physical therapy (16 sessions) with some benefit; medications; and conservative therapies and care. Diagnostic testing was not available for review and was not discussed in the clinical notes. There were no noted comorbidities or other dates of injury noted. On 06/30/2015, physician progress report noted that the injured worker presented for periodic follow-up; however, there were no specific complaints of pain. The progress report did note that the injured worker had previous undergone a cervical fusion of the C4 and C5 levels in 2014, for which the clinical course had been complicated by dysphagia and lymphedema. Driving was reported to be very frustrating and difficult. The injured worker was noted to continue wearing a Jovie collar to help with swallowing. Current medications include Lidocaine patches, probiotic, Lyrica, Mobic, Senna, Ambien, levothyroxine, tramadol, and Flexeril. The physical exam revealed moderate distress and frustration with ongoing pain, and limited, painful and guarded range of motion (ROM) in the cervical spine. The provider noted diagnoses of disc displacement (not otherwise specified), sprains and strains of the neck, late effect of surgical and medical care complications, chronic pain syndrome (impaired sleep and mood), myofascial pain, status post anterior cervical discectomy fusion, and carpal tunnel syndrome (right greater than left). Plan of care includes pending occupational therapy evaluation for driving safety, refill of current medications, discontinue Gabapril, laboratory testing for medication monitoring, and pain management counseling extension, and follow-up in 6 weeks. The injured worker's work status

permanent and stationary and not working. The request for authorization and IMR (independent medical review) includes: complete blood count (CBC) with differential, comprehensive metabolic panel (CMP), pain management counseling, Lidocaine patch 5% #30 with 2 refills, Senna Plus 8.6-50mg #60 with 2 refills, Ambien 5mg #30 with 2 refills, meloxicam 15mg #30 with 2 refills, tramadol ER 100mg #60 with 2 refills, Flexeril 10mg #90 with 2 refills, Lyrica 100mg #30 with 2 refills, and Lyrica 25mg #60 with 2 refills.

IMR ISSUES, DECISIONS AND RATIONALES

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

Labs: CBC with differential: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation www.labtestsonline.org.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Antidepressants for chronic pain, Muscle Relaxants, NSAIDs (non-steroidal anti-inflammatory drugs), and Opioids & Topical analgesics Page(s): 13-20, 63-66, 67-73, 74-96 & 111-113. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Mental Illness & Stress, Insomnia; and Pain (chronic) Chapter, Opioid-induced constipation treatment.

Decision rationale: In regards to the laboratory test CBC with differential, the treating physician stated in the progress notes that laboratory testing was required for monitoring of medications. Upon review of the injured worker's current medications and referencing the MTUS and or ODG on each medication (including probiotic and levothyroxine), it was found that there are no recommendations from the MTUS or ODG for laboratory monitoring for any of the current medications. Medical records do not indicate, if this injured worker had previous lab tests. The requested treatment CBC with differential is not medically necessary.

Labs: Comprehensive metabolic panel: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation www.labtestsonline.org.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Antidepressants for chronic pain, Muscle Relaxants, NSAIDs (non-steroidal anti-inflammatory drugs), Opioids, and Topical analgesics Page(s): 16-20, 63-66, 67-73, 74-96, & 111-113. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (chronic) Chapter, Opioid-induced constipation treatment; and Mental Illness & Stress, Insomnia.

Decision rationale: In regards to the laboratory test CBC with differential, the treating physician stated in the progress notes that laboratory testing was required for monitoring of medications. Upon review of the injured worker's current medications and referencing the MTUS and or ODG on each medication (including probiotic and levothyroxine), it was found that there are no recommendations from the MTUS or ODG for laboratory monitoring for any of the current

medications. Medical records do not indicate, if this injured worker had previous lab tests. The requested treatment Comprehensive metabolic panel is not medically necessary.

Pain management counseling: Overturned

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation ACOEM Practice Guidelines, Chapter 7: Independent Medical Examinations and Consultations.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation ODG Pain (chronic) Chapter, Pain management programs and chronic pain programs (functional restoration programs).

Decision rationale: The ODG states that chronic pain programs (including pain management referrals and programs) are recommended for those patients with conditions that have resulted in delayed recovery. Types of programs include: multi-disciplinary programs, multi-disciplinary pain clinics, pain clinics, modality-oriented clinics, and interdisciplinary pain programs. In this case, the injured worker is under the care of a physician who was part of a physical medicine and rehabilitation group. The injured worker has had an injury to the cervical spine resulting in surgical discectomy and fusion which was further complicated by dysphagia and lymphedema. It was noted that driving was difficult and transportation was being provided. The request for pain management counseling (per the progress notes) was requested as an extension due to the injured worker needing a MPN (medical provider network) closer to her home secondary to the inability and or decreased safety of driving to doctor appointments. As such, the request for a pain management counseling as an extension appears to be medically reasonable and necessary.

Lidocaine patch 5% #30 x 2 refills: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-113.

Decision rationale: According to the California MTUS Guidelines (2009), Topical Analgesics, such as the Lidoderm 5% Patch, are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. These agents are applied topically to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. Many agents are compounded as monotherapy or in combination for pain control, for example, NSAIDs, opioids or antidepressants. Lidoderm is the brand name for a lidocaine patch. The Lidoderm patch has been designated for orphan status (granting special status approval to a drug or biological product) by the FDA for neuropathic pain. Topical lidocaine may be recommended for localized peripheral pain after there has been evidence of a trial of first-line therapy (tri-cyclic or SNRI anti-depressants or an AED such as gabapentin or Lyrica). This is not a first-line treatment and is only FDA approved for post-herpetic neuralgia. Additionally, this medication is not generally recommended for treatment of myofascial

pain/trigger points. Further research is needed to recommend this treatment for chronic neuropathic pain disorders other than post-herpetic neuralgia. In this case, medical necessity of the Lidoderm patch has not been established as there is no diagnosis or evidence of post-herpetic neuralgia. Additionally, this medication is not recommended for myofascial pain or trigger points. Although, the injured worker has exhibited evidence of neuropathic pain and has previously been prescribed Lyrica, this medication is only recommended for the treatment of localized peripheral pain. Moreover, the injured worker has been prescribed this medication for several months and there is no documented evidence of decreased pain or improvement in function. As such, the requested 5% Lidocaine patches #30 are not medically necessary.

Senna plus 8.6/50mg #60 x 2 refills: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines, Pain.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Pain (chronic) Chapter, Opioid-induced constipation treatment.

Decision rationale: Senna plus is a stool softener and laxative combination. The MTUS does not address this issue; therefore the ODG was referenced in the review of this medication. The ODG states that laxative treatment for opioid induced constipation is recommended with ongoing opioid therapy secondary to increasing physical activity, maintaining proper hydration and following a diet rich in fiber as first line preventative therapy. If these fail, second-line treatments may be necessary. However, traditional constipation medications are not as effective because the issue is not from the gastrointestinal tract, but rather from the central nervous system. These treatments include: oral formulations of methylnaltrexone (Relistor) for opioid treatment of non-cancer related pain, lubiprostone (Amitiza), and Lubiprostone. In this case, there is no evidence or complaints of ongoing constipation. Additionally, there was no mention of any discussion regarding first-line recommendations to prevent constipation. Furthermore, the medical necessity of continued opioid therapy was not found to be medically necessary. Therefore, the requested Senna Plus 8.6-50mg #60 with 2 refills is not medically necessary.

Ambien 5mg #30 x 2 refills: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Mental Illness & Stress, Insomnia.

Decision rationale: The MTUS (Medical Treatment Utilization Schedule) is silent in regards to the use of Ambien (zolpidem); therefore, alternative guidelines were consulted in the review and decision of this medication. The ODG states: "Recommend that treatment be based on the etiology, with the medications recommended below. Pharmacological agents should only be used after careful evaluation of potential causes of sleep disturbance. Failure of sleep disturbance to

resolve in a 7 to 10 day period may indicate a psychiatric and/or medical illness." The ODG recommends Ambien, a short-acting non-benzodiazepine hypnotic, for the short-term (7-10 days) treatment of insomnia. This medication is not recommended for long-term use as it can be habit-forming, and may impair function and memory more than opioid pain relievers. "There is also concern that it may increase pain and depression over the long-term." In this case, there are no ongoing complaints of insomnia. Additionally, the injured worker has been prescribed this medication for several months, and this medication is not recommended for long-term use (longer than 7-10 days). As such, the request for Ambien 5mg #30 is not medically necessary.

Meloxicam 15mg #30 x 2 refills: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs (non-steroidal anti-inflammatory drugs) Page(s): 67-73.

Decision rationale: Meloxicam (Mobic) is a non-steroidal anti-inflammatory drug (NSAID) used to treat symptoms of osteoarthritis (OA) and rheumatoid arthritis (RA). MTUS-Definitions identifies that any treatment intervention should not be continued in the absence of functional benefit or improvement as a reduction in work restrictions; an increase in activity tolerance; and/or a reduction in the use of medications or medical services. The MTUS recommends NSAIDs as the first line of treatment to reduce pain so the activity and functional restoration can resume or improve, but is not recommended as a long-term treatment option as there is no evidence of long-term effectiveness for pain or function, and long-term use increases risks for cardiovascular, gastrointestinal and renal function problems. After review of the clinical documentation submitted, it was noted that the injured worker had a been prescribed Mobic (meloxicam) for several months with no noted measurable improvement in function, improved quality of life or reduction in pain in relation to use of this medication. Additionally, there was no evidence or diagnoses of OA or RA. As such, meloxicam 15mg #30 with 2 refills is not medically necessary as requested.

Tramadol ER 100mg #60 x 2 refills: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 74-96.

Decision rationale: Ultram (tramadol) is an opioid medication used to treat moderate to severe pain. MTUS discourages long-term usage unless there is evidence of ongoing review and documentation of pain relief, functional status, appropriate medication use, and side effects. Pain assessment should include: current pain; the least reported pain over the period since last assessment; average pain; intensity of pain after taking the opioid; how long it takes for pain relief; and how long pain relief lasts. Satisfactory response to treatment may be indicated by the

patient's decreased pain, increased level of function, return to work, or improved quality of life. Opioids are to be weaned and discontinued if there is no overall improvement in function, unless there are extenuating circumstances. After reviewing the clinical documentation submitted for review, it is found that the treating physician does not document: 1) the least reported pain over the period since last assessment; 2) intensity of pain after taking the opioid; 3) how long it takes for pain relief; 4) how long pain relief lasts; 5) improvement in pain; or 6) improvement in function. These are necessary to meet MTUS guidelines. Additionally, the progress reports show that the injured worker has been prescribed this medication for several months with no decrease in pain levels since the initiation of the tramadol. As such, the request for tramadol ER 100mg #60 with 2 refills is not medically necessary.

Flexeril 10mg #90 x 2 refills: 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 Muscle Relaxants Page(s): 63-66.

Decision rationale: Cyclobenzaprine (brand names: Amrix, Flexeril and Fexmid; generic form: tabradol) is a centrally acting skeletal muscle relaxant. The MTUS recommends non-sedating muscle relaxants with caution as a second-line option for short-term treatment of acute exacerbations in patients with chronic LBP (low back pain) as they can reduce pain from muscle tension and possibly increase mobility. However, in most cases involving LBP, they provide no more benefit beyond NSAIDs in pain and overall improvement. Efficacy appears to diminish over time, and prolonged use of some medications in this class may lead to dependence. Cyclobenzaprine (Amrix, Flexeril, Fexmid and other generic forms) is recommended for a short course of treatment (with greatest effect within the first 4 days) and not recommended for long term use. Dosing recommendations: 5 mg three times a day can be increased to 10 mg three times a day. This medication is not recommended to be used for longer than 2-3 weeks. The clinical notes show that the injured worker has been prescribed cyclobenzaprine (Fexmid) for several months with insufficient evidence of spasms, reduction in pain, or improvement in function with the use of this medication. Furthermore, the MTUS does not recommend or support the long-term use of muscle relaxants. Therefore, Flexeril 10mg #90 with 2 refills 90 is not medically necessary.

Lyrica 100mg #30 x 2 refills: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Anti-epilepsy Drugs.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Antidepressants for chronic pain & Pregabalin (Lyrica) Page(s): 13-20, 99.

Decision rationale: Lyrica is an Anti-Epilepsy drug (AED) used to treat diabetic painful neuropathy and post herpetic neuralgia. According to California MTUS Guidelines, AEDs are a first-line treatment for neuropathic pain. Lyrica is FDA approved for diabetic neuropathy

and post-herpetic neuralgia and has been used effectively for the treatment of other neuropathic pain. The guidelines indicate a good to moderate response to the use of Lyrica is a 30-50% reduction in pain. The MTUS states; "A 'good' response to the use of AEDs has been defined as a 50% reduction in pain and a 'moderate' response as a 30% reduction. A lack of response of this magnitude may indicate the need for the following: (1) a switch to a different first-line agent (TCA, SNRI or AED are considered first-line treatment); or (2) combination therapy if treatment with a single drug agent fails." In regards to the current request for Lyrica, the injured worker has been taking Lyrica, in addition to narcotic analgesics, for several months with no significant measurable improvement in pain or function documented. Without evidence of improvement, Medical necessity for Lyrica has not been established. Therefore, the current request for Lyrica 100mg #30 with 2 refills is not medically necessary.

Lyrica 25mg #60 x 2 refills: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Anti-epilepsy Drugs.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Antidepressants for chronic pain & Pregabalin (Lyrica) Page(s): 13-20, 99.

Decision rationale: Lyrica is an Anti-Epilepsy drug (AED) used to treat diabetic painful neuropathy and post herpetic neuralgia. According to California MTUS Guidelines, AEDs are a first-line treatment for neuropathic pain. Lyrica is FDA approved for diabetic neuropathy and post-herpetic neuralgia and has been used effectively for the treatment of other neuropathic pain. The guidelines indicate a good to moderate response to the use of Lyrica is a 30-50% reduction in pain. The MTUS states; "A 'good' response to the use of AEDs has been defined as a 50% reduction in pain and a 'moderate' response as a 30% reduction. A lack of response of this magnitude may indicate the need for the following: (1) a switch to a different first-line agent (TCA, SNRI or AED are considered first-line treatment); or (2) combination therapy if treatment with a single drug agent fails." In regards to the current request for Lyrica, the injured worker has been taking Lyrica, in addition to narcotic analgesics, for several months with no significant measurable improvement in pain or function documented. Without evidence of improvement, Medical necessity for Lyrica has not been established. Therefore, the current request for Lyrica 100mg #30 with 2 refills and Lyrica 25mg #60 with 2 refills are not medically necessary.