

Case Number:	CM15-0106550		
Date Assigned:	06/10/2015	Date of Injury:	03/25/2014
Decision Date:	09/23/2015	UR Denial Date:	05/20/2015
Priority:	Standard	Application Received:	06/02/2015

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: California
 Certification(s)/Specialty: Physical Medicine & Rehabilitation

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 57 year old female, who sustained an industrial injury on 3/25/2014. She reported developing acute low back pain and right shoulder after lifting activity. She also developed abdominal pain and high blood pressure. She presented to the Emergency Department on 1/8/15 with complaints of vomiting blood, gastric pain for ten days, and back pain. Diagnoses include low back pain, lumbar disc displacement, and radiculopathy. Treatments to date include activity modification, anti-inflammatory, analgesic, back brace, and physical therapy. Currently, she complained of low back pain with radiation to the right lower extremity. The pain was rated 9/10 VAS. There was right shoulder pain rated 8.10 VAS. On 4/30/15, the physical examination documented restricted lumbar range of motion with guarding. Seated nerve root test was positive. The right shoulder was tender to palpation with positive Hawkins and impingement signs. The medical records included results from the MRI of the shoulder dated 5/15/15 that revealed a full thickness and complete tear of the supraspinatus tendon with retraction to the level of the glenohumeral joint measuring 4.0 centimeters. The plan of care included medication therapy and epidural injection pending authorization. The appeal requested authorization for Tramadol ER 150 mg tablets, one tablet daily #90; Cyclobenzaprine Hydrochloride 75mg tablets, one tablet every 8 hours #120; Ondansetron 8mg, ODT, one tablet as needed, no more than two tablets daily #30; Fenoprofen Calcium (Nalfon) 400mg, one tablet three times a day #120; and Eszopiclone Tablets 1mg at bedtime #30.

IMR ISSUES, DECISIONS AND RATIONALES

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

Tramadol ER 150mg once a day PRN for severe pain #90: 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 Medications for chronic pain, criteria for use of opioids Page(s): 60, 61, 76-78, 88, 89.

Decision rationale: The patient was injured on 03/25/14 and presents with low back pain with radiation to the right lower extremity. The request is for Tramadol ER 150 MG once a day PRN for severe pain #90. The RFA is dated 05/18/15 and the patient has reached maximum medical improvement. The patient has been taking this medication as early as 01/14/15. MTUS Guidelines pages 88 and 89 under Criteria For Use of Opioids (Long-Term Users of Opioids): "Pain should be assessed at each visit, and functioning should be measured at 6-month intervals using a numerical scale or validated instrument." MTUS page 78 under Criteria For Use of Opioids-Therapeutic Trial of Opioids, also requires documentation of the 4As, analgesia, ADLs, adverse side effects, and adverse behavior, as well as "pain assessment" or outcome measures that include current pain, average pain, least pain, intensity of pain after taking the opioid, time it takes for medication to work and duration of pain relief. MTUS Guidelines, under Opioids For Chronic Pain, pages 80 and 81 state the following regarding chronic low back pain: "Appears to be efficacious but limited for short-term pain relief, and long-term efficacy is unclear (>16 weeks), but also appears limited." Long-term use of opiates may be indicated for nociceptive pain as it is "Recommended as the standard of care for treatment of moderate or severe nociceptive pain (defined as pain that is presumed to be maintained by continual injury with the most common example being pain secondary to cancer)." However, this patient does not present with pain that is "presumed to be maintained by continual injury." The 05/19/14 report states that the patient is tolerating [her] current medication. In this case, none of the 4 A's are addressed as required by MTUS Guidelines. There are no before and after medication pain scales provided. There are no examples of ADLs which demonstrate medication efficacy, nor are there any discussions provided on adverse behavior/side effects. No validated instruments are used either. There are no pain management issues discussed such as CURES report, pain contract, et cetera. No outcome measures are provided as required by MTUS Guidelines. There are no urine drug screens provided to see if the patient is compliant with her prescribed medications. The treating physician does not provide adequate documentation that is required by MTUS Guidelines for continued opiate use. Furthermore, the use of opiates is not supported for low back pain. The requested Tramadol is not medically necessary.

Cyclobenzaprine Hydrochloride tab 7.5mg 1 by mouth Q8hrs PRN pain and spasm #120: 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: The patient was injured on 03/25/14 and presents with low back pain with radiation to the right lower extremity. The request is for Cyclobenzaprine Hydrochloride TAB 7.5 MG 1 by mouth Q 8 hrs PRN pain and spasm #120. The RFA is dated 05/18/15 and the patient has reached maximum medical improvement. The patient has been taking this medication as early as 01/14/15. MTUS Guidelines, Muscle Relaxants, pages 63-66 states: "Muscle relaxants (for pain): Recommended non-sedating muscle relaxants with caution as a second-line option for short-term treatment of acute exacerbations in patients with chronic low back pain. The most commonly prescribed antispasmodic agents are carisoprodol, cyclobenzaprine, metaxalone, and methocarbamol, but despite the popularity, skeletal muscle relaxants should not be the primary drug class of choice for musculoskeletal conditions. Cyclobenzaprine (Flexeril, Amrix, Fexmid, generic available): Recommended for a short course of therapy." The patient has a restricted lumbar range of motion with guarding, a positive seated nerve root test. The right shoulder was tender to palpation with positive Hawkins and impingement signs. She is diagnosed with low back pain, lumbar disc displacement, and radiculopathy. MTUS Guidelines do not recommend the use of cyclobenzaprine for longer than 2 to 3 weeks. The patient has been taking this medication as early as 01/14/15, which exceeds the 2 to 3 weeks recommended by MTUS Guidelines. The requested Cyclobenzaprine is not medically necessary.

Ondansetron 8mg ODT 1 PRN Upset Stomach/camping/nausea o more than 2/day #30:
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 Official Disability Guidelines (ODG) Pain (Chronic) Chapter, under Anti-emetics (for opioid nausea).

Decision rationale: The patient was injured on 03/25/14 and presents with low back pain with radiation to the right lower extremity. The request is for Ondansetron 8 MG ODT 1 PRN upset stomach/camping/nausea more than 2/day #30. The RFA is dated 05/18/15 and the patient has reached maximum medical improvement. The patient has been taking this medication as early as 01/14/15. MTUS guidelines are silent on antiemetic medications, though ODG Guidelines, Pain (Chronic) Chapter, under Anti-emetics (for opioid nausea) states "Not recommended for nausea and vomiting secondary to chronic opioid use. Ondansetron (Zofran): This drug is a serotonin 5-HT₃ receptor antagonist. It is FDA-approved for nausea and vomiting secondary to chemotherapy and radiation treatment. It is also FDA-approved for postoperative use. Acute use is FDA-approved for gastroenteritis." The patient has a restricted lumbar range of motion with guarding, a positive seated nerve root test. The right shoulder was tender to palpation with positive Hawkins and impingement signs. She is diagnosed with low back pain, lumbar disc displacement, and radiculopathy. The 04/23/15 report states that Ondansetron is being prescribed for nausea associated with the headaches that are present with chronic cervical spine pain. However, the treater has not indicated that the patient is postoperative, undergoing

chemotherapy and radiation, or has gastroenteritis, as recommended by ODG and the FDA. The request does not meet guideline indications. Therefore, the requested Ondansetron is not medically necessary.

Fenoprofen Calcium (Nalfon) 400mg 1 pill TID Inflammatory Pain #120: 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 Anti-inflammatory Medications Page(s): 22.

Decision rationale: The patient was injured on 03/25/14 and presents with low back pain with radiation to the right lower extremity. The request is for Fenoprofen Calcium (nalfon) 400 MG 1 pill TID inflammatory pain #120. The RFA is dated 05/18/15 and the patient has reached maximum medical improvement. The patient has been taking this medication as early as 04/23/15. MTUS Guidelines, Anti-inflammatory Medications, page 22 states: Anti-inflammatories are the traditional first line of treatment, to reduce pain so activity and functional restoration can resume, but long-term use may not be warranted. A comprehensive review of clinical trials on the efficacy and safety of drugs for the treatment of low back pain concludes that available evidence supports the effectiveness of non-selective nonsteroidal anti-inflammatory drugs (NSAIDs) in chronic LBP and of antidepressants in chronic LBP. MTUS page 60 also states, "A record of pain and function with the medication should be recorded," when medications are used for chronic pain. The 05/19/14 report states that the patient is tolerating [her] current medication. The patient has a restricted lumbar range of motion with guarding, a positive seated nerve root test. The right shoulder was tender to palpation with positive Hawkins and impingement signs. She is diagnosed with low back pain, lumbar disc displacement, and radiculopathy. In this case, the treater has not documented pain reduction or functional improvement resulting from using Fenoprofen. Given the lack of documentation as required by guidelines, the request is not medically necessary.

Eszopiclone tablets 1mg at bedtime PRN for sleep #30: 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 Official Disability Guidelines (ODG) Pain Chapter, under Eszopicolone (Lunesta).

Decision rationale: The patient was injured on 03/25/14 and presents with low back pain with radiation to the right lower extremity. The request is for Eszopiclone tablets 1 MG at bedtime prn for sleep #30. The RFA is dated 05/18/15 and the patient has reached maximum medical improvement. The patient has been taking this medication as early as 01/14/15. ODG Guidelines, Pain Chapter, under insomnia treatments states, "Eszopiclone (Lunesta) has demonstrated reduced sleep latency and sleep maintenance. The only benzodiazepine-receptor agonist FDA approved for used longer than 35 days. A randomized, double-blind controlled

clinical trial with 830 primary insomnia patients reported significant improvement in the treatment group when compared to the controlled group for sleep latency, wake after sleep onset, and total sleep time over a 6-month period." ODG Guidelines, Pain Chapter, under Eszopicolone (Lunesta), this medication is "Not recommended for long-term use, but recommended for short-term use." The patient has a restricted lumbar range of motion with guarding, a positive seated nerve root test. The right shoulder was tender to palpation with positive Hawkins and impingement signs. She is diagnosed with low back pain, lumbar disc displacement, and radiculopathy. In this case, the patient has been taking this medication since 01/14/15, which exceeds the short-term duration set by ODG guidelines. It would appear that this medication is prescribed on a long-term basis. In regards to Lunesta, ODG Guidelines do not recommend for long-term use, but recommended for short-term use. Therefore, the request is not medically necessary.