

Case Number:	CM14-0104920		
Date Assigned:	08/06/2014	Date of Injury:	08/27/2002
Decision Date:	09/18/2014	UR Denial Date:	06/05/2014
Priority:	Standard	Application Received:	07/07/2014

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 Family 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:

This is a 51 year old female who reported an industrial injury on 8/27/2002, over 12 years ago, attributed to the performance of her customary job tasks as a Medical Tech Assistant when a prisoner pushed her backwards and she struck her neck/back on a desk/file unit. The industrial injury was accepted for the right elbow; right shoulder; bilateral wrists/hands; neck; lower back and Mental. The patient is working. The patient underwent a cervical fusion 8/26/2008; had a permanent SCS placed 7/6/2011; and received an ESI to the cervical spine on 4/23/2012. The patient complained of back pain radiating to the BLEs and neck pain radiating to the occiput. The patient was assessed as having somatic dysfunction to the cervical/thoracic/lumbar spine. The diagnoses were back pain; nonallopathic lesion of thoracic spine; neck pain. The patient was prescribed PT and massage therapy. The patient was prescribed Amitiza 8 mcg #90; Baclofen 20 mg #90; Flector 1.3 % patch #60; Lyrica 75 mg #180; Robaxin 500 mg #120; Voltaren 1% topical gel; Ambien CR 12/5 mg #30; Norco 10/325 mg #150; and Morphine Sulfate 60 mg #90. The patient was prescribed a topical compounded cream. The patient is being prescribed 220 mg to 240 mg/24 hrs MED with no documented sustained functional improvement.

IMR ISSUES, DECISIONS AND RATIONALES

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

Norco 10/325mg QTY 1.00: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 91.

MAXIMUS guideline: Decision based on MTUS ACOEM Chapter 12 Low Back Complaints Page(s): 300-306, Chronic Pain Treatment Guidelines Opioids Page(s): 74-97. Decision based on Non-MTUS Citation American College of Occupational and Environmental Medicine (ACOEM), 2nd Edition, (2004) Chapter 6 pages 114-116; Official Disability Guidelines (ODG) Pain chapter opioids.

Decision rationale: The provider has not establish functional improvement as a result of the current regimen of Norco 10/325 mg # unspecified directed to mechanical back/neck pain. As noted by evidence-based guidelines, opiates may be continued if the patient has returned to work and has improved functioning and pain. Additionally, there is no indication of an improvement in pain levels or functionality to substantiate ongoing utilization of opiate medication. Long-term use of opiates is not supported by current evidence based guidelines. ODG states: "Routine long-term opioid therapy is not recommended, and ODG recommends consideration of a one-month limit on opioids for new chronic non-malignant pain patients in most cases, as there is little research to support its use." The patient has been taking opiate medication on a long-term basis, which is not consistent with evidence-based guidelines. The prescription for Norco 10/325 mg for short acting pain is being prescribed as an opioid analgesic for the treatment of chronic pain to the back/neck for the date of injury 12 years ago. The patient is diagnosed with low back pain and neck pain s/p cervical spine fusion. The patient is being prescribed opioids for chronic back/neck pain, which is inconsistent with the recommendations of the CA MTUS. There is no objective evidence provided to support the continued prescription of opioid analgesics for the cited diagnoses and effects of the industrial claim. The chronic use of Norco is not recommended by the CA MTUS; the ACOEM Guidelines or the Official Disability Guidelines for the long term treatment of chronic back or neck pain. The prescription of opiates on a continued long-term basis is inconsistent with the CA MTUS and the Official Disability Guidelines recommendations for the use of opiate medications for the treatment of chronic pain. There is objective evidence that supports the use of opioid analgesics in the treatment of this patient over the use of NSAIDs for the treatment of chronic pain. The current prescription of opioid analgesics is inconsistent with evidence-based guidelines. The prescription of opiates on a continued long-term basis is inconsistent with the Official Disability Guidelines recommendations for the use of opiate medications for the treatment of chronic pain. There is objective evidence that supports the use of opioid analgesics in the treatment of this patient over the use of NSAIDs (non-steroidal anti-inflammatory drug) for the treatment of chronic pain issues. Evidence based guidelines necessitate documentation that the patient has signed an appropriate pain contract, functional expectations have been agreed to by the clinician and the patient, pain medications will be provided by one physician only, and the patient agrees to use only those medications recommended or agreed to by the clinician to support the medical necessity of treatment with opioids. The ACOEM Guidelines updated chapter on chronic pain states "Opiates for the treatment of mechanical and compressive etiologies: rarely beneficial. Chronic pain can have a mixed physiologic etiology of both neuropathic and nociceptive components. In most cases, analgesic treatment should begin with acetaminophen, aspirin, and NSAIDs (as suggested by the WHO step-wise algorithm). When these drugs do not satisfactorily reduce pain, opioids for moderate to moderately severe pain may be added to (not substituted for) the less efficacious drugs. A major concern about the use of opioids for chronic pain is that most randomized controlled trials have been limited to a short-term period (70 days). This leads

to a concern about confounding issues such as tolerance, opioid-induced hyperalgesia, long-range adverse effects such as hypogonadism and/or opioid abuse, and the influence of placebo as a variable for treatment effect." ACOEM guidelines state that opioids appear to be no more effective than safer analgesics for managing most musculoskeletal and eye symptoms; they should be used only if needed for severe pain and only for a short time. The long-term use of opioid medications may be considered in the treatment of chronic musculoskeletal pain, if: The patient has signed an appropriate pain contract; Functional expectations have been agreed to by the clinician and the patient; Pain medications will be provided by one physician only; The patient agrees to use only those medications recommended or agreed to by the clinician. ACOEM also notes, "Pain medications are typically not useful in the subacute and chronic phases and have been shown to be the most important factor impeding recovery of function." Evidence based guidelines recommend: Chronic 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. Failure to respond to a time-limited course of opioids has led to the suggestion of reassessment and consideration of alternative therapy. There is no evidence to recommend one opioid over another. In patients taking opioids for back pain, the prevalence of lifetime substance use disorders has ranged from 36% to 56% (a statistic limited by poor study design). Limited information indicated that up to one-fourth of patients who receive opioids exhibit aberrant medication-taking behavior. The ODG states that chronic pain can have a mixed physiologic etiology of both neuropathic and nociceptive components. In most cases, analgesic treatment should begin with acetaminophen, aspirin, and NSAIDs (as suggested by the WHO step-wise algorithm). When these drugs do not satisfactorily reduce pain, opioids for moderate to moderately severe pain may be added to (not substituted for) the less efficacious drugs. A major concern about the use of opioids for chronic pain is that most randomized controlled trials have been limited to a short-term period (70 days). This leads to a concern about confounding issues such as tolerance, opioid-induced hyperalgesia, long-range adverse effects such as hypogonadism and/or opioid abuse, and the influence of placebo as a variable for treatment effect. (Ballantyne, 2006) (Furlan, 2006) Long-term, observational studies have found that treatment with opioids tends to provide improvement in function and minimal risk of addiction, but many of these studies include a high dropout rate (56% in a 2004 meta-analysis). (Kalso, 2004) There is also no evidence that opioids showed long-term benefit or improvement in function when used as treatment for chronic back pain. (Martell-Annals, 2007) (ODG, Pain Chapter). There is no clinical documentation by the requesting provider with objective findings on examination to support the medical necessity of Norco for this long period of time 12 years status-post date of injury (DOI). There is no provided evidence that the patient has received benefit or demonstrated functional improvement with the prescribed Norco. There is no demonstrated medical necessity for the prescribed. Therefore, this request is not medically necessary.

Flector Patch 1.3% QTY 1.00: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 111-113.

MAXIMUS guideline: Decision based on MTUS ACOEM Chapter 3 Initial Approaches to Treatment Page(s): 47,128,Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-

113. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain chapter topical analgesics, topical analgesic compounded.

Decision rationale: The prescribed topical anti-inflammatory patches (FLECTOR PATCHES) are not medically necessary for the treatment of the injured worker and are inconsistent with the recommendations of the CA MTUS and the Official Disability Guidelines. The patient has exceeded the 6-8 week recommendation for the use of topical NSAIDs. There is no demonstrated medical necessity for the use of the topical patches in addition to the prescribed oral NSAIDs or OTC NSAIDs. There is no evidence provided that Flector patches are medically necessary over the available OTC topical NSAIDs. There is no evidence based medicine or current literature to establish the effectiveness topical NSAIDs in patch form for chronic back pain or to establish functional capacity improvement. The use of topical NSAIDs is noted to be effective for only 2-4 weeks without any further demonstrated functional improvement. The use of Flector patches is not demonstrated to be medically necessary concurrently with the prescribed high dose opioids over the available OTC NSAIDs. The patient has been provided with a clinical trial of the Flector patches and there was no demonstrated functional improvement. There is no medical necessity for the prescription of Flector patches in addition to the prescribed medications. The objective findings documented by the requesting provider do not demonstrate ongoing myofascial or topical pain issues. The objective findings do not support the medical necessity for the prescribed Flector patches. The use of topical anti-inflammatory patches is not considered medically necessary for the treatment of chronic back or neck pain. The use of topical analgesic patches or transdermal compounds are not supported with objective evidence that is peer reviewed and accepted by the national medical community. There is no objective peer reviewed evidence available and only anecdotal evidence has been put forth to establish the use of the prescribed Flector Patches. There is no medical evidence provided to support the use of the topical analgesic patches for chronic pain over the use of prescribed oral medications. The use of topical transdermal applications such as the Flector Patch are not supported with objective evidence that is peer reviewed and accepted by the national medical community. The prescription of the Flector Patches for the treatment of the patient is not supported with objective medically based evidence to demonstrate medical necessity or establish functional capacity improvement. There is no objective peer reviewed evidence available to support the continued use of the Flector patches and only anecdotal evidence has been put forth to establish the use of these identified compounds. The use of topical NSAIDs has only been shown to be effective over a two week time period and only for Osteoarthritis. The prescription for Flector Patches topically is not demonstrated to be medically necessary for the treatment of the patient's back complaints. The prescription of Flector Patches as a topical NSAID is not recommended by the CA MTUS and the Official Disability Guidelines. The continued use of topical NSAIDs for the current clinical conditions is not otherwise warranted or appropriate-noting the specific comment, "There is little evidence to utilize topical NSAIDs for treatment of osteoarthritis of the spine, hip, or shoulder." The ODG states that the use of topical NSAIDs should be in the first 4-12 weeks of the injury and after the initial two weeks of treatment the use of topical NSAIDS becomes less effective. Therefore, this request is not medically necessary.

Ambien CR 12.5mg QTY 120: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines Treatment in Workers Compensation 10th Edition Treatment Index, Drug Formulary updated 9/30/12.

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-- insomnia and Zolpidem ; Other Medical Treatment Guideline or Medical Evidence.

Decision rationale: Zolpidem/Ambien CR12.5 mg #120 is recommended only for the short-term treatment of insomnia for two to six weeks. The Zolpidem/Ambien 12.5 mg has been prescribed to the patient for a prolonged period of time. The use of Zolpidem or any other sleeper has exceeded the ODG guidelines. The prescribing physician does not provide any rationale to support the medical necessity of Zolpidem for insomnia or documented any treatment of insomnia to date. The patient is being prescribed the Zolpidem for insomnia due to chronic back pain simply due to the rationale of chronic pain without demonstrated failure of OTC remedies. There is no provided subjective/objective evidence to support the use of Zolpidem 12.5 mg over the available OTC remedies. The patient has exceeded the recommended time period for the use of this short-term sleep aide. There is no demonstrated functional improvement with the prescribed Zolpidem/Ambien. There is no documentation of alternatives other than Zolpidem have provided for insomnia or that the patient actually requires sleeping pills. The patient is not documented with objective evidence to have insomnia or a sleep disorder at this point in time or that conservative treatment is not appropriate for treatment. There is no evidence that sleep hygiene, diet and exercise have failed for the treatment of sleep issues. There is no demonstrated failure of the multiple sleep aids available OTC. The CA MTUS and the ACOEM Guidelines are silent on the use of sleeping medications. The ODG does not recommend the use of benzodiazepines in the treatment of chronic pain. Zolpidem is not a true benzodiazepine; however, retains some of the same side effects and is only recommended for occasional use and not for continuous nightly use. There is no medical necessity for the prescribed Zolpidem. Therefore, this request is not medically necessary.

Baclofen 2%/Cyclobenzaprine 2%/Flurbiprofen 15%/ Ketamine 10%/Lidocaine 5% cream 120gm QTY 4.00: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 23, 64, 113.

MAXIMUS guideline: Decision based on MTUS ACOEM Chapter 3 Initial Approaches to Treatment Page(s): 47, Chronic Pain Treatment Guidelines Section on Topical Analgesics Page(s): 111-113. Decision based on Non-MTUS Citation American College of Occupational and Environmental Medicine (ACOEM), 2nd Edition 2004 Pain chapter 2008 pages 128; Official Disability Guidelines (ODG) Pain chapter topical analgesics, topical analgesic compounded.

Decision rationale: The prescription for the topical compounded analgesic Baclofen 2%/Cyclobenzaprine 2%/Flurbiprofen 15%/Ketamine 10%/Lidocaine 5% cream 120gm QTY 4.00 is not medically necessary for the treatment of the patient for pain relief for the orthopedic

diagnoses of the patient. There is clinical documentation submitted to demonstrate the use of the topical gels or creams for appropriate diagnoses or for the recommended limited periods of time. It is not clear that the topical compounded medications are medically necessary in addition to prescribed oral medications. There is no provided subjective/objective evidence that the patient has failed or not responded to other conventional and recommended forms of treatment for relief of the effects of the industrial injury. Only if the subjective/objective findings are consistent with the recommendations of the ODG, then topical use of topical preparations is only recommended for short-term use for specific orthopedic diagnoses. There is no provided rationale supported with objective evidence to support the prescription of the topical compounded cream. There is no documented efficacy of the prescribed topical compounded analgesics with no assessment of functional improvement. The patient is stated to have reduced pain with the topical creams however there is no functional assessment and no quantitative decrease in pain documented. The use of topical NSAIDs is documented to have efficacy for only 2-4 weeks subsequent to injury and thereafter is not demonstrated to be as effective as oral NSAIDs. There is less ability to control serum levels and dosing with the topicals. The patient is not demonstrated to have any GI issue at all with NSAIDs. There is no demonstrated medical necessity for topical NSAIDs for chronic pain for a prolonged period of time. The request for the topical NSAID the topical compounded analgesic Baclofen 2%/Cyclobenzaprine 2%/Flurbiprofen 15%/Ketamine 10%/Lidocaine 5% cream 120gm QTY 4.00 is not medically necessary for the treatment of the patient for the diagnosis of the chronic pain to the neck and back. The use of the topical gels does not provide the appropriate therapeutic serum levels of medications due to the inaccurate dosing performed by rubbing variable amounts of gels on areas that are not precise. The volume applied and the times per day that the gels are applied are variable and do not provide consistent serum levels consistent with effective treatment. There is no medical necessity for the addition of gels to the oral medications in the same drug classes. There is no demonstrated evidence that the topicals are more effective than generic oral medications. The use of the topical compounded analgesic Baclofen 2%/Cyclobenzaprine 2%/Flurbiprofen 15%/Ketamine 10%/Lidocaine 5% cream 120gm QTY 4.00 is not supported by the applicable evidence based guidelines as cited above. The continued use of topical NSAIDs for the current clinical conditions is not otherwise warranted or demonstrated to be appropriate. There is no documented objective evidence that the patient requires both the oral medications and the topical analgesic medication for the treatment of the industrial injury. The prescription for the topical compounded analgesic Baclofen 2%/Cyclobenzaprine 2%/Flurbiprofen 15%/Ketamine 10%/Lidocaine 5% cream 120gm QTY 4.00 is not medically necessary for the treatment of the patient's chronic pain complaints. The prescription of the topical compounded analgesic Baclofen 2%/Cyclobenzaprine 2%/Flurbiprofen 15%/Ketamine 10%/Lidocaine 5% cream 120gm QTY 4.00 is not recommended by the CA MTUS; ACOEM guidelines, and the Official Disability Guidelines. The continued use of topical NSAIDs for the current clinical conditions is not otherwise warranted or appropriate - noting the specific comment that "There is little evidence to utilize topical NSAIDs for treatment of osteoarthritis of the spine, hip, or shoulder." The objective findings in the clinical documentation provided do not support the continued prescription of for the treatment of chronic pain of the neck and back. Therefore, this request is not medically necessary.

Abilify 2mg QTY 1.00: 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) Section Pain chapter anti-depressants for chronic pain.

Decision rationale: The provider has prescribed Abilify due to the assessed increased depression not controlled with the medications prescribed. There is no demonstrated rationale for Abilify 12 years after the cited DOI. There are no mental status evaluations documented by the treating physician. The use of Ability for depression is to increase the effectiveness of an underlying previously prescribed antidepressant. There is no documented functional improvement with the prescribed Ability. The patient is treated with high dose opioids contrary to the recommendations of the CA MTUS. The provider has prescribed the name brand Abilify (Aripiprazole) for the treatment of cognitive difficulties associated with the effects of the industrial injury and as a result of the prescribed medications. The medication is being prescribed as an adjunct to depression medications; however there is no documentation of clinical efficacy with and without the medication. There is no rationale provided to support the medical necessity of the polypharmacy. Therefore, this request is not medically necessary.

MS Contin 60mg Extended Release QTY 90: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 93.

MAXIMUS guideline: Decision based on MTUS ACOEM Chapter 12 Low Back Complaints Page(s): 300-306, Chronic Pain Treatment Guidelines opioids Page(s): 74-97. Decision based on Non-MTUS Citation American College of Occupational and Environmental Medicine (ACOEM), 2nd Edition, (2004) chapter 6 pages 114-116; Official Disability Guidelines (ODG) pain chapter opioids.

Decision rationale: The prescription for MS Contin 60 mg #90 for short acting pain relief is being prescribed as an opioid analgesic for the treatment of chronic pain to the back and neck for the date of injury 12 years ago. The objective findings on examination do not support the medical necessity for continued opioid analgesics for the diagnosis of mechanical neck and back pain. The patient is being prescribed opioids for mechanical back/neck pain post operatively, which is inconsistent with the recommendations of the CA MTUS. There is no objective evidence provided to support the continued prescription of opioid analgesics for the cited diagnoses and effects of the industrial claim. The patient should be titrated down and off the prescribed MS Contin 60 mg #90. The patient is 12 years status-post date of injury with reported continued chronic pain issues. There is no demonstrated medical necessity for the continuation of opioids for the effects of the industrial injury. The chronic use of MS Contin 60 mg #90 is not recommended by the CA MTUS; the ACOEM Guidelines or the Official Disability Guidelines for the long-term treatment of chronic back or neck pain. The prescription of opiates on a continued long-term basis is inconsistent with the CA MTUS and the Official Disability Guidelines recommendations for the use of opiate medications for the treatment of chronic pain.

There is objective evidence that supports the use of opioid analgesics in the treatment of this patient over the use of NSAIDs for the treatment of chronic pain. The current prescription of opioid analgesics is inconsistent with evidence-based guidelines. The prescription of opiates on a continued long-term basis is inconsistent with the Official Disability Guidelines recommendations for the use of opiate medications for the treatment of chronic pain. There is objective evidence that supports the use of opioid analgesics in the treatment of this patient over the use of NSAIDs for the treatment of chronic pain issues. The ACOEM Guidelines updated chapter on chronic pain states "Opiates for the treatment of mechanical and compressive etiologies: rarely beneficial. Chronic pain can have a mixed physiologic etiology of both neuropathic and nociceptive components. In most cases, analgesic treatment should begin with acetaminophen, aspirin, and NSAIDs (as suggested by the WHO step-wise algorithm). When these drugs do not satisfactorily reduce pain, opioids for moderate to moderately severe pain may be added to (not substituted for) the less efficacious drugs. A major concern about the use of opioids for chronic pain is that most randomized controlled trials have been limited to a short-term period (70 days). This leads to a concern about confounding issues such as tolerance, opioid-induced hyperalgesia, long-range adverse effects such as hypogonadism and/or opioid abuse, and the influence of placebo as a variable for treatment effect." ACOEM guidelines state that opioids appear to be no more effective than safer analgesics for managing most musculoskeletal symptoms; they should be used only if needed for severe pain and only for a short time. The long-term use of opioid medications may be considered in the treatment of chronic musculoskeletal pain, if: The patient has signed an appropriate pain contract; Functional expectations have been agreed to by the clinician and the patient; Pain medications will be provided by one physician only; The patient agrees to use only those medications recommended or agreed to by the clinician. ACOEM also notes, "Pain medications are typically not useful in the subacute and chronic phases and have been shown to be the most important factor impeding recovery of function." There is no clinical documentation by with objective findings on examination to support the medical necessity of MS Contin 60 mg for this long period of time or to support ongoing functional improvement. There is no provided evidence that the patient has received benefit or demonstrated functional improvement with the prescribed MS Contin 60 mg. There is no demonstrated medical necessity for the prescribed Opioids. The continued prescription for MS Contin 60 mg #90 is not demonstrated to be medically necessary. Therefore, this request is not medically necessary.