

Case Number:	CM14-0117237		
Date Assigned:	08/06/2014	Date of Injury:	01/19/2012
Decision Date:	09/29/2014	UR Denial Date:	07/23/2014
Priority:	Standard	Application Received:	07/25/2014

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 North Carolina. 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 patient is a 45-year-old with a reported date of injury of 01/19/2012. The patient has the diagnoses of L2 spinal cord injury, status post L2 burst fracture, status post T12-L4 fusion, neurogenic bowel, neurogenic bladder, right S1 radiculopathy, right ischial gluteal bursitis. Past treatment modalities have included surgical intervention and function restoration program. Per the progress notes provided by the primary treating physician the patient continue to have pain that is markedly worse by sitting and continued neurogenic bowel and bladder. Physical exam hyperactive bowel sounds with suprapubic tenderness. There is tenderness over the paraspinal muscles in the cervical region and the patient is able to sit for a small amount of time before having to lie down. Treatment recommendations have included additional physical therapy and continuation of medications.

IMR ISSUES, DECISIONS AND RATIONALES

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

Colace 100mg #60 two (2) refills: Overturned

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids-(d) prophylactic treatment of constipation. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain Procedure Summary.

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

Decision rationale: The California chronic pain medical treatment guidelines section on the use of opioids states:(d) Prophylactic treatment of constipation should be initiated. In addition this patient has the diagnoses of neurogenic bowel. Per the notes provided by the gastroenterologist, the patient has a bowel movement every 3 days. The patient has undergone flexible sigmoidoscopy and anorectal manometry. The patient has the diagnoses of chronic constipation and rectocele that does not empty. Recommendations were for continued bowel regimen. The patient has not only met guideline recommendations for the treatment of constipation prophylactically when on opioids but also has recommendation from a GI specialist to continue bowel regimen to treat the chronic constipation and rectocele. For these reasons the request is medically necessary.

Vesicare 10mg #30 Two (2) refills: Overturned

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Drugs.com-www.drugs.com/price-guide/vesicare.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation WebMD, R list and FDA monogram.

Decision rationale: The California MTUS and the ACOEM do not address this specific request. Per Web MD and the FDA monogram, this drug is an anticholinergic used in the treatment of overactive bladder by relaxing smooth muscles in the bladder. It is also used for urinary incontinence and neurogenic bladder. This patient has the diagnoses of neurogenic bladder and actually has to do self-catheterization at times. The provided documentation states the medication is maintain the patient's symptoms. The provider does acknowledge that the medication side-effects may be contributing to the constipation but the need for the medication outweighs that side-effect. For these reasons the provider has established medical need for the medication and the request is medically necessary.

Flector patches 1.3% #60 two (2) refills: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain Procedure Summary.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-112.

Decision rationale: The California chronic pain medical treatment guidelines section on topical analgesics states:Recommended as an option as indicated below. Largely experimental in use with few randomized controlled trials to determine efficacy or safety. Primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. (Namaka, 2004) These agents are applied locally to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. (Colombo, 2006) Many agents are compounded as monotherapy or in combination for pain control (including NSAIDs,

opioids, capsaicin, local anesthetics, antidepressants, glutamate receptor antagonists, -adrenergic receptor agonist, adenosine, cannabinoids, cholinergic receptor agonists, agonists, prostanoids, bradykinin, adenosine triphosphate, biogenic amines, and nerve growth factor). (Argoff, 2006) There is little to no research to support the use of many of these agents. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Non-steroidal anti-inflammatory agents (NSAIDs): The efficacy in clinical trials for this treatment modality has been inconsistent and most studies are small and of short duration. Topical NSAIDs have been shown in meta-analysis to be superior to placebo during the first 2 weeks of treatment for osteoarthritis, but either not afterward, or with a diminishing effect over another 2-week period. (Lin, 2004) (Bjordal, 2007) (Mason, 2004) Indications: Osteoarthritis and tendinitis, in particular, that of the knee and elbow or other joints that are amenable to topical treatment: Recommended for short-term use (4-12 weeks). The long-term use of this medication of greater than 12 weeks is not recommended per the California MTUS. There is no provided documentation that indicates why continued use would be necessary versus other modalities. For these reasons, guideline recommendations have not been met and the request is not medically necessary.

Pamelor 25mg #30 two (2) refills: Overturned

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Antidepressants Page(s): 13.

Decision rationale: The California chronic pain medical treatment guidelines section on antidepressants states: Recommended as a first line option for neuropathic pain, and as a possibility for non-neuropathic pain. (Feuerstein, 1997) (Perrot, 2006) Tricyclics are generally considered a first-line agent unless they are ineffective, poorly tolerated, or contraindicated. Analgesia generally occurs within a few days to a week, whereas antidepressant effect takes longer to occur. (Saarto- Cochrane, 2005) Assessment of treatment efficacy should include not only pain outcomes, but also an evaluation of function, changes in use of other analgesic medication, sleep quality and duration, and psychological assessment. The requested medication is a tricyclic antidepressant. This is a first line agent for the treatment of neuropathic pain. The patient has the diagnoses of neuropathic pain/neuropathy. Documentation provided espouses the efficacy of the medication. For these reasons, guideline recommendations have been met and the request is medically necessary.

Lidoderm patches 5% #60 two (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: Recommended as an option as indicated below. Largely experimental in use with few randomized controlled trials to determine efficacy or safety. Primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. (Namaka, 2004) These agents are applied locally to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. (Colombo, 2006) Many agents are compounded as monotherapy or in combination for pain control (including NSAIDs, opioids, capsaicin, local anesthetics, antidepressants, glutamate receptor antagonists, adrenergic receptor agonist, adenosine, cannabinoids, cholinergic receptor agonists, agonists, prostanoids, bradykinin, adenosine triphosphate, biogenic amines, and nerve growth factor). (Argoff, 2006) There is little to no research to support the use of many of these agents. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Lidocaine Indication: Neuropathic pain recommended for localized peripheral pain after there has been evidence of a trial of first-line therapy (tri-cyclic or SNRI antidepressants or an AED such as Gabapentin or Lyrica). Topical Lidocaine, in the formulation of a dermal patch (Lidoderm) has been designated for orphan status by the FDA for neuropathic pain. Lidoderm is also used off-label for diabetic neuropathy. No other commercially approved topical formulations of lidocaine (whether creams, lotions or gels) are indicated for neuropathic pain. Per the documentation the patient is currently on Gabapentin and a tricyclic antidepressant. Documentation provided espouses positive efficacy from these first-line treatment choices. There is no evidence of failure of other first line-agents. In the absence of failure with other first-line agent and the patient currently being on Gabapentin and Pamelor, guideline recommendations have not been met for the continued use of this medication. Therefore the request is not medically necessary.

Neurontin 600mg #90 two (2) refills: Overturned

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Anti-epilepsy drugs (AEDs).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines.

Decision rationale: The California chronic pain medical treatment guidelines section on the use of gabapentin states: Gabapentin (Neurontin, Gabarone, generic available) has been shown to be effective for treatment of diabetic painful neuropathy and postherpetic neuralgia and has been considered as a first-line treatment for neuropathic pain. (Backonja, 2002) (ICSI, 2007) (Knotkova, 2007)(Eisenberg, 2007) (Attal, 2006) This RCT concluded that gabapentin monotherapy appears to be efficacious for the treatment of pain and sleep interference associated with diabetic peripheral neuropathy and exhibits positive effects on mood and quality of life. (Backonja, 1998) It has been given FDA approval for treatment of post-herpetic neuralgia. The number needed to treat (NNT) for overall neuropathic pain is 4. It has a more favorable side-effect profile than Carbamazepine, with a number needed to harm of 2.5. (Wiffen-Cochrane, 2005) (Zaremba, 2006) Gabapentin in combination with morphine has been studied for treatment of diabetic neuropathy and postherpetic neuralgia. When used in combination the maximum tolerated dosage of both drugs was lower than when each was used as a single agent and better analgesia occurred at lower doses of each. (Gilron-NEJM, 2005) Recommendations involving combination therapy require further study. The patient has the diagnosis of neuropathic

pain/radiculopathy. The requested medication is a first-line choice in the treatment of neuropathic pain. Documentation states the medication helps greatly with the back and leg pain. This medication is recommended choice for neuropathic pain and documentation is positive for its efficacy. Therefore the medication is medically necessary.

Percocet 5/325mg #30 two (2) refills: Overturned

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): 76-84.

Decision rationale: The California chronic pain medical treatment guidelines section on ongoing use of opioids states: On-Going Management. Actions Should Include: (a) Prescriptions from a single practitioner taken as directed, and all prescriptions from a single pharmacy. (b) The lowest possible dose should be prescribed to improve pain and function. (c) Office: 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, or improved quality of life. Information from family members or other caregivers should be considered in determining the patient's response to treatment. The 4 A's for Ongoing Monitoring: Four domains have been proposed as most relevant for ongoing monitoring of chronic pain patients on opioids: pain relief, side effects, physical and psychosocial functioning, and the occurrence of any potentially aberrant (or non-adherent) drug-related behaviors. These domains have been summarized as the "4 A's" (analgesia, activities of daily living, adverse side effects, and aberrant drug-taking behaviors). The monitoring of these outcomes over time should affect therapeutic decisions and provide a framework for documentation of the clinical use of these controlled drugs. (Passik, 2000) (d) Home: To aid in pain and functioning assessment, the patient should be requested to keep a pain diary that includes entries such as pain triggers, and incidence of end-of-dose pain. It should be emphasized that using this diary will help in tailoring the opioid dose. This should not be a requirement for pain management. (e) Use of drug screening or inpatient treatment with issues of abuse, addiction, or poor pain control. (f) Documentation of misuse of medications (doctor-shopping, uncontrolled drug escalation, drug diversion). (g) Continuing review of overall situation with regard to nonopioid means of pain control. (h) Consideration of a consultation with a multidisciplinary pain clinic if doses of opioids are required beyond what is usually required for the condition or pain does not improve on opioids in 3 months. Consider a psych consult if there is evidence of depression, anxiety or irritability. Consider an addiction medicine consult if there is evidence of substance misuse. When to Continue Opioids (a) If the patient has returned to work (b) If the patient has improved functioning and pain (Washington, 2002) (Colorado, 2002) (Ontario, 2000) (VA/DoD, 2003) (Maddox-AAPM/APS, 1997) (Wisconsin, 2004) (Warfield, 2004) Per the documentation the patient is using this medication only in the instance of break through pain and failure of other first-line choices. The patient is currently working (though a partial schedule) and there is notation of improvement in functioning and pain when using the

medication. For these reasons guideline criteria as listed above for the ongoing and continued use of the medication have been met. Therefore the request is medically necessary.

Miralax #30 two (2) refills: Overturned

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids-(d) prophylactic treatment of constipation. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain Procedure Summary.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 77.

Decision rationale: The California chronic pain medical treatment guidelines section on the use of opioids states:(d) Prophylactic treatment of constipation should be initiated. In addition this patient has the diagnoses of neurogenic bowel. Per the notes provided by the gastroenterologist, the patient has a bowel movement every 3 days. The patient has undergone flexible sigmoidoscopy and anorectal manometry. The patient has the diagnoses of chronic constipation and rectocele that does not empty. Recommendations were for continued bowel regimen. The patient has not only met guideline recommendations for the treatment of constipation prophylactically when on opioids but also has recommendation from a GI specialist to continue bowel regimen to treat the chronic constipation and rectocele. For these reasons the request is medically necessary.