

Case Number:	CM14-0012245		
Date Assigned:	02/21/2014	Date of Injury:	06/01/2003
Decision Date:	08/11/2014	UR Denial Date:	01/17/2014
Priority:	Standard	Application Received:	01/30/2014

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 Occupational 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 53 year-old male patient with an injury date of 6/1/2003. The exact mechanism of injury has not been described. The patient is being treated for major depressive disorder, anxiety disorder, lumbar failed back surgery syndrome with left L5 lumbar radiculopathy, lumbar spondylosis, and cervical spondylosis with intermittent radicular symptoms. The patient was seen on 7/8/13 and 7/30/13 by a urologist who noted the patient complained of constipation since the patient's lumbar surgery. He was noted to have possible neurogenic bladder and an inability to void until his bladder reached 300ccs. He was diagnosed with mildly enlarged prostate which would not cause any significant voiding dysfunction. His sexual dysfunction and voiding problems were attributed to the patient's medications as his urodynamic studies and cystoscopy revealed that the patient had neurogenic bladder but there was another cause for these symptoms. In addition, the Flomax was noted to be contributing to the patient's ejaculatory problems. The report stated once the Flomax was stopped the patient's retrograde ejaculation would stop. However, the patient was instructed to continue Tamsulosin to help empty his bladder. Syndrome of Inappropriate Antidiuretic Hormone Secretion (SIADH) was also entertained as a diagnosis. The GI review of systems is negative for constipation. The patient is noted to have nonspecific global pain, which is a 10/10 with his morphine. The patient is noted to be on morphine for several years for pain control. On an exam dated 10/31/2013 the patient complained of pain rated at 8-9/10 and reports of being more depressed recently. Physical exam showed decreased range of motion in all planes with tenderness to palpation of the lumbar paraspinous area. Positive straight leg raise testing was noted bilaterally at 30. Patellar deep tendon reflexes were noted. Diagnostic impression is thoracic/lumbosacral neuritis/radiculitis of unspecified origin. He was again seen on 12/23/13 with "pain all over the body" rated at 10/10. His heart rate was 72 and blood pressure was 147/82. He was in no signs of distress. The patient

was noted to be on Skelaxin, Lidoderm patches, and MS Contin 100 mg q 6 hrs, MSIR 30 mg q 4 hrs, Cymbalta and Fortesta. Treatment to date: Medication management, opiate detox program in 2006, and home exercise program. Urine Drug Screen 6/19/13: No illicit drugs noted. A UR decision on 1/17/2014 denied the request for 1) Lactulose Solution 10gm/15ml because the report did not describe any symptoms of constipation. 2) The request for testosterone Fortesta Gel metered dose 10mg #120 was denied because there was no documentation of the patient having low testosterone. 3) The request for Levitra 10mg #6 was denied because Levitra is indicated for erectile dysfunction and there was no documentation of any symptoms in the report. 4) The request for Metaxalone 800mg tablets #90 was denied because the reports do not show any presence of spasticity and there is no documentation of significant functional or vocational benefit with the use of muscle relaxants. 5) The request for Lidocaine 5% pads was denied because CA MTUS notes that application of topical medications is mostly experimental. Topical agents are primarily used for the treatment of neuropathic pain after primary and secondary agents have been tried. Lidocaine is only indicated in the form of Lidoderm patches. 6) The request for Omeprazole capsules 20mg #60 was denied. The documentation provided does not support the need for PPI therapy. The current documentation does not describe any GI symptoms or any previous treatment. There were no GI bleed risk factors to support use. 7) The request for Nuvigil tablets 150mg #30 was denied. There was no diagnosis in the documentation of narcolepsy, shift work disorder, or sleep apnea that would support that necessity. 8) The request for Ultracin lotion 120ml was denied. CA MTUS notes that topical agents are largely experimental and used primarily for neuropathic pain. The documentation does not describe any specific neuropathic pain that has failed the list of available oral agents of the antidepressant, antiepileptic, and NSAID classes. 9) The request for Morphine Sulfate ER 100mg #30 was denied. The CA MTUS requires ongoing review and documentation of pain relief, functional status, appropriate medication use, and side effects for patients on chronic opioid therapy. The documentation does not identify any measurable analgesic benefit by VAS scores with the use of opioids. There was no functional benefit with the ongoing use. Also, there are no urine drug screens to show compliance and screen for aberrant behavior. 10) The request for Tamsulosin .04mg #30 was denied. Tamsulosin is an alpha-adrenergic blocking agent. Its actions relax the muscles in the prostate making it easier to urinate. The documentation does not describe the patient having an enlarged prostate. 11) The request for Morphine Sulfate 30mg #180 is denied. Again, CA MTUS requires ongoing review and documentation of pain relief, functional status, appropriate use, and side effects for patients for chronic opioid therapy. The documentation does not identify measurable analgesic benefit through VAS scores with the use of opioids, and there is no documentation of functional benefit with ongoing use. There was no documentation of urine drugs screens performed to monitor compliance and screen for aberrant behavior.

IMR ISSUES, DECISIONS AND RATIONALES

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

Lactulose Solution 10 GM / 15 ML: Upheld

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

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: Drugs.com see Lactulose Sol.

Decision rationale: The documentation does not report that the patient is currently experiencing constipation. He was noted to be on Lactulose in March 2013. However, the patient was noted to have constipation in July 2013. There is no evidence he has failed any first line therapies such as stool softeners (i.e. Colace) or GI motility agents such as Senna. There is no documentation regarding this medication and the patient's bowel habits. The efficacy and rationale of this medication is unclear. In addition the opioids are being recommended for discontinuation and Prophylaxis would not be required. Therefore, the request for Lactulose Solution 10gm/15ml is not medically necessary.

Testosterone-Fortesta Gel Metered 10 Mg, Quantity 120: Upheld

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

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

Decision rationale: CA MTUS states that testosterone replacement for hypogonadism (related to opioids) is recommended in limited circumstances for patients taking high-dose long-term opioids with documented low testosterone levels. In addition, the FDA states that Androderm is an androgen indicated for replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone. However, there was no mention in the reports of low testosterone levels or hypogonadism. Therefore, the request for Testosterone-Forstesta gel metered 10mg quantity 120 is not medically necessary.

Levitra 10 Mg, Quantity 6: Upheld

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

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: Drugs.com see FDA Levitra.

Decision rationale: Levitra is indicated for treatment of erectile dysfunction. The patient was documented to have retrograde ejaculation and erectile dysfunction in July 2013 secondary to medication use, namely Tamsulosin. There is no diagnosis besides medication induced ejaculation difficulty, and it is unclear why the patient is staying on the medications that are causing his ejaculatory difficulty. In addition, there is no discussion with regard to the patient's sexual habits, or whether a PDE 5 inhibitor such as Viagra has worked for him in the past. Therefore, the request for Levitra 10mg, quantity 6 is not medically necessary.

Metaxalone Tablets 800 Mg, Quantity 90: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 63-66.

Decision rationale: CA MTUS Chronic Pain Medical Treatment Guidelines recommends sedating muscle relaxants with caution as a second-line option for short-term treatment of acute exacerbations in patients with chronic low back pain. In addition muscle relaxants may be effective in reducing pain and muscle tension, and increasing mobility. However, in most low back pain cases, they show no benefit beyond NSAIDs in pain and overall improvement, and no additional benefit has been shown when muscle relaxants are used in combination with NSAIDs. Efficacy appears to diminish over time, and prolonged use of some medications in this class may lead to dependence. This patient was on Skelaxin chronically, and it is unclear if he was using Skelaxin concurrently as he was noted to be on it from November 2013 to January 2014. There were no documented benefits with either sedating muscle relaxant, and no rationale for two sedating muscle relaxants. In addition, the patient has exceeded the treatment guidelines with regard to centrally acting muscle relaxants and duration of use. In addition, the documentation does not report any signs of spasticity and there is no documentation of significant functional benefit with the use of a muscle relaxant. Therefore, the request for Metaxalone tablets 800mg quantity 90 is not medically necessary.

Lidocaine Pad 5 %, Quantity 90: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 56-57.

Decision rationale: CA MTUS states that topical Lidocaine may be recommended for localized peripheral pain after there has been evidence of a trial of first-line therapy (Tricyclic or SNRI anti-depressants or an anti-epilepsy drug such as Gabapentin or Lyrica). Official Disability Guidelines (ODG) states that Lidoderm is not generally recommended for treatment of osteoarthritis or treatment of myofascial pain/trigger points. CA MTUS states that topical agents are primarily recommended for neuropathic pain that has failed primary and secondary oral agents. The patient describes pain everywhere and a 10/10 despite his medications. He was on Cymbalta, but this medication is meant for minor aches and pains, not 10/10 constant global pain. The patient has been on this medication chronically yet his VAS is still 10 and there is no evidence of ongoing functional gains. There was no documentation of neuropathic pain that failed the trials of antidepressant, antiepileptic, or non-steroidal anti-inflammatory agents. Also, the only available form of Lidocaine 5% is in a patch. Therefore, the request for Lidocaine pad 5% quantity 90 is not medically necessary.

Omeprazole Capsules 20 Mg, Quantity 60: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDS, GI symptoms and cardiovascular risk Page(s): 68.

Decision rationale: CA MTUS and the FDA support proton pump inhibitors in the treatment of patients with GI disorders such as gastric/duodenal ulcers, GERD, erosive esophagitis, or patients utilizing chronic NSAID therapy. The reports do not provide medical support for the need of PPI therapy. There were not stated GI problems or any reported risk for GI bleed to support PPI use. In addition, the patient is not currently on a NSAID chronically. Therefore, the request for Omeprazole 20mg is not medically necessary.

Nuvigil Tablets 150 Mg, Quantity 30: Upheld

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

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.

Decision rationale: CA MTUS does not address this issue. Official Disability Guidelines (ODG) states that Nuvigil is not recommended solely to counteract sedation effects of narcotics. Armodafinil is used to treat excessive sleepiness caused by narcolepsy or shift work sleep disorder. It is very similar to Modafinil. Studies have not demonstrated any difference in efficacy and safety between Armodafinil and Modafinil. However, there is no clinical evidence of narcolepsy in the documentation. There is no rationale for use of this medication in this patient, as he has no diagnosis of narcolepsy and the most recent progress reports do not describe any fatigue. In addition, Nuvigil is not meant to be used to counteract the side effects of this patient's high chronic opiate use. Therefore, the request for Nuvigil tablets 150mg quantity 30 is not medically necessary.

Ultracin Lotion, Quantity 120: 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. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: Drugs.com see Ultracin Lotion.

Decision rationale: CA MTUS states that topical applications of medications are still experimental. Topical agents are primarily recommended for treatment of neuropathic pain that

has failed primary and secondary oral agents. This medication contains topical Methyl Salicylate, Menthol, and 0.025% Capsaicin, which is approved for use per MTUS guidelines in patient's minor aches and pains. This patient has non-specific global pain, 10/10 despite a medication above 500, which is not controlled by his morphine; hence the rationale for this medication is unclear. There is a lack of documentation regarding ongoing functional gain and a decrease in pain with this medication. Therefore, the request for Ultracin Lotion quantity 120 is not medically necessary.

Morphine Sulfate Extended Release 100 Mg, Quantity 120: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines opiates Page(s): 78-81.

Decision rationale: CA MTUS Chronic Pain Medical Treatment Guidelines do not support ongoing opioid treatment unless prescriptions are from a single practitioner and are taken as directed; are prescribed at the lowest possible dose; and unless there is ongoing review and documentation of pain relief, functional status, appropriate medication use, and side effects. The patient has a 2003 date of injury. He has been on morphine long term since his back surgery for years and his medication is well above 120, which puts him at risk for an adverse drug reaction. The documentation did not show any ongoing review, documentation of pain relief on VAS scale, or ongoing improvement in function with this medication. He has side effects such as decreased libido and energy loss. There is no documented long term pain management. Therefore, the request for Morphine Sulfate Extended Release 100mg quantity 120, date of service: 12/02/13 is not medically necessary.

Tamsulosin .04 Mg, Quantity 30: Upheld

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

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence:Drugs.com see Tamsulosin.

Decision rationale: Tamsulosin is an alpha adrenergic blocker. It relaxes smooth muscle in the prostate and the bladder making urination easier. It is used to improve problems with urination in patients with benign prostatic hypertrophy (BPH). The patient was noted to have a mildly enlarged prostate in June 2013 in a urology visit. However, it was noted that his prostate was unlikely to be contributing to his difficulty voiding and that neurogenic bladder and other medications were the culprit. In addition, Tamsulosin was said to be the culprit with regard the patient's ejaculatory problems. It is unclear why the patient would need a medication for difficulty voiding with BPH when his BPH is mild as was noted to not be causing difficult

voiding in this patient, as well as causing ejaculatory side effects. Therefore, the request for Tamsulosin 0.4mg quantity 30 is not medically necessary.

Morphine Sulfate Tab 30 Mg, Quantity 180: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines opiates Page(s): 78-81.

Decision rationale: CA MTUS Chronic Pain Medical Treatment Guidelines do not support ongoing opioid treatment unless prescriptions are from a single practitioner and are taken as directed; are prescribed at the lowest possible dose; and unless there is ongoing review and documentation of pain relief, functional status, appropriate medication use, and side effects. The patient has a 2003 date of injury. He has been on morphine long term since his back surgery for years and his medication is well above 120, which puts him at risk for an adverse drug reaction. The documentation did not show any ongoing review, documentation of pain relief on VAS scale, or ongoing improvement in function with this medication. He has side effects such as decreased libido and energy loss. There is no documented long term pain management. Therefore, the request for Morphine Sulfate Extended Release 100mg quantity 120 is not medically necessary.