

Case Number:	CM13-0004863		
Date Assigned:	05/02/2014	Date of Injury:	12/27/1999
Decision Date:	06/10/2014	UR Denial Date:	07/15/2013
Priority:	Standard	Application Received:	07/31/2013

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 Physical Medicine and Rehabilitation 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:

The patient is a 59 year old female who was injured on 12/27/1999. The mechanism of injury is unknown. She complains of back pain radiating from low back down to the right leg. The patient's medications as of 03/10/2014 include Paxil 20 mg, Wellbutrin XL, Zanaflex 4 mg, Bisacodyl 5 mg, Senna-s Tablet, MiraLax Pdr, Tegaderm Dressing, Lidoderm 5% patch, Duragesic 50 mcg/hr patch, Neurontin 300 mg capsule, Neurontin 300 mg, Oxycodone 15 mg, and Protonix 20 mg. The patient's medications as of 04/03/2014 include Paxil 20 mg, Wellbutrin XL, Zanaflex 4 mg, Bisacodyl 5 mg, Senna-s Tablet, MiraLax Pdr, Tegaderm Dressing, Lidoderm 5% patch, Duragesic 50 mcg/hr patch, Neurontin 300 mg capsule, Neurontin 300 mg, and Norco. Lyrica gives her incontinence and Oxycodone makes her short of breath therefore they have been discontinued. Urine drug screen tested positive for Fentanyl, Norfentanyl, Oxycodone, Noroxycodone, Oxymorphone, and Gabapentin. PR2 dated 04/03/2014 indicates the patient reports low backache. The pain level has remained unchanged since the last visit. There are no new problems or side-effects. Quality of sleep is poor. She is not trying any other therapies for pain relief. She denies any new injury since the last visit. Her activity level has decreased. The patient states she is frustrated and tearful due to denials of medications. She only received the TDF patch. Her pain score is a 10/10 today, she has been bedridden all month due to lack of medications. On exam, the patient has a right-sided antalgic gait that is awkward, slow and assisted by can and wheel-chair. On inspection of the lumbar spine, there is loss of normal lordosis with straightening of the lumbar spine and surgical scar. Range of motion is restricted with flexion limited to 15 degrees and extension is limited to 5 degrees. On palpation, paravertebral muscles, spasm, tenderness and tight muscle band is noted on both sides. FABER test is positive on the right. There is tenderness to palpation over the right greater trochanter and right posterior superior iliac spine. There are numerous myofascial

points of tenderness in buttocks and paraspinals. Motor testing is limited by pain. On sensory examination, light touch sensation is intact to bilateral lower extremities; Straight leg raise test is negative. The right lower extremity exhibits shaking. Diagnoses are post lumbar laminect syndrome; hip bursitis, spinal/lumbar DDD; low back pain; sacroiliac pain; myalgia and myositis NOS; right buttock and low back pain consistent with right greater trochanteric bursitis and sacroiliac pain. The treatment and plan includes: Duragesic patch for long acting pain control; Norco for breakthrough pain for breakthrough pain to be using in conjunction with the Duragesic patch; Wellbutrin XL for decreased mood secondary to pain; Paxil for decreased mood secondary to pain; Tegaderm dressings to increase adherence of TDF; Lidoderm Patches for topical and analgesia relieve burning on top of right; Neurontin for neuropathic pain down the right lower extremity which she reports to be significantly decreased while taking Neurontin; Zanaflex for muscle spasm; Bisacodyl for constipation secondary to pain medication; Senna-S for constipation secondary to pain medication; MiraLax for constipation secondary to pain medication. Her Oxycodone was discontinued as she reports shortness of breath.

IMR ISSUES, DECISIONS AND RATIONALES

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

DURAGESIC DIS 100MCG/HOUR: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids, Duragesic (Fentanyl Transdermal System) Page(s): 74-96; 11.

Decision rationale: The CA MTUS guidelines state Fentanyl is an opioid analgesic with potency eighty times that of morphine. Fentanyl transdermal (Duragesic®; generic available) is indicated for management of persistent chronic pain, which is moderate to severe requiring continuous, around-the-clock opioid therapy. The pain cannot be managed by other means (e.g., NSAIDS). Note: Duragesic® should only be used in patients who are currently on opioid therapy for which tolerance has developed. Analgesic dose: The previous opioid therapy for which tolerance has occurred should be at least equivalent to Fentanyl 25mcg/h. Patches are worn for a 72 hour period. The MED dosage exceeds CA MTUS recommendation of maximum 120 mg morphine daily equivalent dose. According to the medical records, the patient indicates she is essentially non-functional without Duragesic patch at 75 or 100mcg dosage, attempts to reduce to 50 mcg were not successful, per the patient. The recent urine toxicology screen indicates significantly positive for fentanyl and oxycodone metabolites. However, there is no demonstrated objective functional improvement with this medication. The medical records do not establish this patient obtained clinically significant pain relief despite significant opioid medications. In the absence of documented pain relief, opioids should not be continued. It is clear that the 4 A's have not been met. The request for Duragesic DIS 100MCG/Hour is not medically necessary.

LIDODERM 5 PERCENT PATCH: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Lidoderm (Lidocaine Patch); Topical Analgesics Page(s): 56; 111-113.

Decision rationale: The guidelines state 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. In the 11/21/2013 medical report, the patient claims that use of Lidoderm patch reduces her right dorsal foot pain from 10/10 to 6/10. However, there is no documented objective benefit with use. It is noted that there is no reduction in opioid medications nor improved function. It also appears that she continued prescriptions for other Neurontin as well. Measurable subjective and/or functional benefit as result of this medication is not demonstrated. It is not clear she has failed trials of standard anti-convulsants. The medical necessity of Lidoderm patch is not established.

WELLBUTRIN XL 300MG: Upheld

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 For Chronic Pain; Bupropion (Wellbutrin) Page(s): 16; 27.

Decision rationale: According to the CA MTUS guidelines, Wellbutrin is a second-generation non-tricyclic antidepressant (a noradrenaline and dopamine reuptake inhibitor) that has been shown to be effective in relieving neuropathic pain of different etiologies in a small trial. It is generally a third-line medication for diabetic neuropathy and may be considered when patients have not had a response to a tricyclic or SNRI. Ongoing efficacy with Wellbutrin has not been demonstrated. The request for Wellbutrin XL 300MG is not medically necessary.

PAXIL 20MG: Upheld

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

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain, Anxiety Medications In Chronic Pain.

Decision rationale: CA MTUS do not address the issue in dispute and hence ODG have been consulted. The ODG recommends diagnosing and controlling anxiety as an important part of chronic pain treatment, including treatment with anxiety medications based on specific DSM-IV diagnosis as described below. Definition of anxiety disorders: Anxiety disorders for this entry include (1) generalized anxiety disorder (GAD); (2) panic disorder (PD); (3) post-traumatic

stress disorder (PTSD); (4) social anxiety disorder (SAD); & (5) obsessive-compulsive disorder (OCD). Many antidepressants, in particular the Selective Serotonin Reuptake Inhibitors (SSRIs) are considered first-line agents in the treatment of most forms of anxiety. Paxil is an SSRI, recommended for treatment of GAD, PD, SAD, OCD, and PTSD as well as major depressive disorder. Ongoing efficacy such as measurable subjective and/or functional benefit with use is not evident. The medical records do not include any recent objective psychological or mental assessment with documentation of the patient's report of how or whether the medication is effective. The medical necessity of Paxil has not been established.

BISACODYL 5MG: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Mosby's Drug Consult; Veterans Health Administration: Clinical Practice Guideline For The Management Of Opioid Therapy For Chronic Pain.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Long-Term Users Of Opioids Page(s): 88.

Decision rationale: As per CA MTUS guidelines; Long-term Users of Opioids (6-months or more): Re-assess (e) Document adverse effects: constipation, nausea, vomiting, headache, dyspepsia, pruritis, dizziness, fatigue, dry mouth, sweating, hyperalgesia, sexual dysfunction, and sedation. Regarding long-term opioid management, the guidelines recommend routine re-assessment should include documentation of any adverse effects with the medications. The medical records do not appear to document any current complaints of constipation. Furthermore, ongoing chronic use of opioids is not supported. The medical necessity for a laxative is not established. The request for Bisacodyl 5MG is not medically necessary.

SENNA: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Mosby's Drug Consult; Veterans Health Administration: Clinical Practice Guideline For The Management Of Opioid Therapy For Chronic Pain.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Long-Term Users Of Opioids Page(s): 88.

Decision rationale: As per CA MTUS guidelines; Long-term Users of Opioids (6-months or more): Re-assess (e) Document adverse effects: constipation, nausea, vomiting, headache, dyspepsia, pruritis, dizziness, fatigue, dry mouth, sweating, hyperalgesia, sexual dysfunction, and sedation. Regarding long-term opioid management, the guidelines recommend routine re-assessment should include documentation of any adverse effects with the medications. The medical records do not appear to document any current complaints of constipation. Furthermore, ongoing chronic use of opioids is not supported. The medical necessity for a laxative is not established. The request for Senna is not medically necessary.

TEGADERM DRESSING: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Blue Cross Of California Medical Policy Durable Medical Equipment; http://www.ncmedical.com/item_1780.html.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation <http://www.3m.com/product/information/nexcare-tegaderm-transparent-dressing.html>.

Decision rationale: CA MTUS and ODG do not address the issue in dispute and hence other evidence based guidelines have been consulted. According to manufacturer, Nexcare's Tegaderm Dressing is the #1 hospital brand in transparent dressings. Tegaderm Dressing can be worn for up to 7 days, making it ideal for securing IV catheters or other tubing, and for post-surgical dressings. Apparently, this product has been used to keep the Duragesic patch in place. This is not the intended use of this product. Furthermore, the medical records do not establish the request for Duragesic patch is medically necessary. The request for Tegaderm dressing is not medically necessary.

ZANAFLEX 4MG: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Muscle Relaxants For Pain Page(s): 63-64.

Decision rationale: The CA MTUS recommend non-sedating muscle relaxants with caution as a second-line option for short-term treatment of acute exacerbations in patients with chronic LBP. Recommended for a short course of therapy. Zanaflex is FDA approved for management of spasticity; unlabeled use for low back pain. The medical report does not demonstrate an acute exacerbation is present. Review of the medical records indicates chronic use of muscle relaxants, which is not recommended under the guidelines. The request for Zanaflex 4MG is not medically necessary.

MIRALAX: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Mosby's Drug Consult; Veterans Health Administration: Clinical Practice Guideline For The Management Of Opioid Therapy For Chronic Pain.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Long-Term Users Of Opioids Page(s): 88.

Decision rationale: As per CA MTUS guidelines; Long-term Users of Opioids (6-months or more): Re-assess (e) Document adverse effects: constipation, nausea, vomiting, headache, dyspepsia, pruritis, dizziness, fatigue, dry mouth, sweating, hyperalgesia, sexual dysfunction, and sedation. Regarding long-term opioid management, the guidelines recommend routine re-assessment should include documentation of any adverse effects with the medications. The medical records do not appear to document any current complaints of constipation. Furthermore, ongoing chronic use of opioids is not supported. The medical necessity for a laxative is not established. The request for Miralax is not medically necessary.

NORCO 10/325: 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: CA MTUS states Hydrocodone/Acetaminophen (Anexsia®[®], Co-Gesic®[®], Hycet®[®]; Lorcet®[®], Lortab®[®]; Margesic-H®[®], Maxidone®[®]; Norco®[®], Stagesic®[®], Vicodin®[®], Xodol®[®], Zydone®[®]; generics available) is indicated for moderate to moderately severe pain. Hydrocodone is a semi-synthetic opioid which is considered the most potent oral opioid that does not require special documentation for prescribing in some states (not including California). Short-acting opioids: also known as "normal-release" or "immediate-release" opioids are seen as an effective method in controlling chronic pain. They are often used for intermittent or breakthrough pain. These agents are often combined with other analgesics such as acetaminophen and aspirin. Guidelines indicate "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 nonadherent) 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 progress reports do not reflect there has been any notable pain relief and improved function with chronic use of opioids. The guidelines do not support continuing opioid therapy in the absence of benefit with use. Consequently, the medical necessity of Norco has not been established.