

Case Number:	CM14-0035405		
Date Assigned:	07/23/2014	Date of Injury:	07/31/2011
Decision Date:	09/08/2014	UR Denial Date:	02/21/2014
Priority:	Standard	Application Received:	03/21/2014

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 Psychiatry & Neurology, and Addiction Medicine, has a subspecialty in Geriatric Psychiatry 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:

Records reviewed include 265 pages of medical and administrative records. The injured worker is a 46 year old female whose date of injury is 07/31/11 which occurred while lifting heavy boxes. Her primary diagnosis is displacement of lumbar intervertebral disc without myelopathy. She is also being treated for degenerative lumbar/lumbar-sacral intervertebral disc, lumbago, and sciatica. On 07/25/14 a progress report by [REDACTED], of the [REDACTED], shows that the patient was experiencing back stiffness, numbness in the right and left leg, radicular pain in the right and left leg, and weakness in the right and left leg. She rated the severity as 6/10. Back pain was described as aching, burning, throbbing, shooting, spasming, stiff, sore, pressure, and shooting down the legs. Narcotics and stretching improves condition, extension/flexion of the back and hip worsens it. She had tried and failed conservative treatments. She had undergone spinal injections and had some relief from these; as such she was considered a potential candidate for fusion of the sacroiliac joint. Vital signs blood pressure 124/78, pulse 98, temperature 98.8. The patient attested to burning and nausea with ibuprofen and constipation with hydrocodone. At the time of this evaluation her medications included Butrans patch 15mcg/hr to skin for 7 days, aspirin 300mg one per day, Cymbalta 60mg once per day, Doss, Medrol, Norco 10-325mg one every 3 hours, nortriptyline 25mg two at bedtime, omeprazole, Topamax 25mg four twice per day, Tums, and Wellbutrin 100mg one three times per day. Review of systems for psychiatric described the patient as oriented x3 with mood and affect appropriate to situation. [REDACTED] medication treatment plan involved prescribing the same medications and did not include weaning the patient off of any of her medications or changing them. He made no changes to her Butrans or Norco. Flexeril was not included in this treatment plan, in fact Flexeril is not seen in any of the documentation at all after the patient's

visit of 03/19/2014. The patient's medications were essentially the same going back to approximately 08/2013, with Wellbutrin added around 12/2013. I did not see a discussion of the rationale for any of these medications in progress reports provided..

IMR ISSUES, DECISIONS AND RATIONALES

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

Butrans patch 20mcg/hour, #4: Overturned

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 26-27. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Procedure Summary-Pain, buprenorphine for chronic pain.

Decision rationale: The California MTUS does not address Butrans. Per ODG: Recommended as an option for treatment of chronic pain (consensus based) in selected patients (not first-line for all patients). Suggested populations: (1) Patients with a hyperalgesic component to pain; (2) Patients with centrally mediated pain; (3) Patients with neuropathic pain; (4) Patients at high-risk of non-adherence with standard opioid maintenance; (5) For analgesia in patients who have previously been detoxified from other high-dose opioids. Use for pain with formulations other than Butrans is off-label. Due to complexity of induction and treatment the drug should be reserved for use by clinicians with experience. Drug description: Buprenorphine is a schedule-III controlled substance. Its mechanism of action is complex, involving four different opioid receptors at central and peripheral sites. It is primarily classified as a partial mu-agonist and kappa antagonist. It blocks effects of subsequently administered opioid agonists. Proposed advantages of treatment: (1) An apparent antihyperalgesic effect (partially due to the effect at the kappa-receptor); (2) Ability to suppress opioid withdrawal; (3) Indications of safety for use in patients with renal impairment. There appears to be a ceiling effect for respiratory depression. Treatment of chronic pain: A waiver is not required for the off-label use of sublingual buprenorphine for the treatment of pain. An "X" should NOT be put before the DEA number. It is recommended that the words, "Chronic Pain Patient" and "Off-Label Use" be written on the prescription. The request for Butrans patch 20mcg/hr. #4 is medically necessary.

Cymbalta 60mg, #90: Overturned

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 43-44.

Decision rationale: According to the California MTUS, duloxetine is recommended as an option in first-line treatment option in neuropathic pain. Duloxetine is a norepinephrine and serotonin reuptake inhibitor antidepressant (SNRIs). It has FDA approval for treatment of depression,

generalized anxiety disorder, and for the treatment of pain related to diabetic neuropathy, with effect found to be significant by the end of week 1 (effect measured as a 30% reduction in baseline pain). The starting dose is 20-60 mg/day, and no advantage has been found by increasing the dose to twice a day, except in fibromyalgia. The medication has been found to be effective for treating fibromyalgia in women with and without depression, 60 mg once or twice daily. (Arnold, 2005) The most frequent side effects include nausea, dizziness and fatigue. GI symptoms are more common early in treatment. The patient was diagnosed with sciatica and radicular pain (nociceptive) radiating down both lower extremities. Sciatica is a common form of radiculitis whose radiating pain is the result of nerve root irritation. Radicular pain is often described as aching, radiating, and can be accompanied by numbness, tingling, and weakness. Neuropathic pain is caused by disease/damage to the peripheral or central nervous system (e.g. spine injury), and can present as "electric shock" sensations, burning or coldness, numbness and tingling. She has been diagnosed with displacement of lumbar intervertebral disc, from which neuropathic pain could emanate. In her case there may be a mixed presentation of both radicular and neuropathic pain. Cymbalta has been shown to have some efficacy in neuropathic and nonneuropathic pain. This request for Cymbalta 60mg #90 is therefore medically necessary.

Flexeril 10mg, #120: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Muscle Relaxants (for pain).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 41-42.

Decision rationale: The California MTUS indicates that cyclobenzaprine (Flexeril) is recommended as an option, using a short course of therapy, the effect is modest and comes at the price of greater adverse effects. The effect is greatest in the first 4 days of treatment, suggesting that shorter courses may be better. (Browning, 2001) Treatment should be brief. There is also a post-op use. The addition of cyclobenzaprine to other agents is not recommended. (Clinical Pharmacology, 2008) Cyclobenzaprine-treated patients with fibromyalgia were 3 times as likely to report overall improvement and to report moderate reductions in individual symptoms, particularly sleep. (Tofferi 2004). Cyclobenzaprine is associated with a number needed to treat of 3 at 2 weeks for symptom improvement in LBP and is associated with drowsiness and dizziness. (Kinkade, 2007) Cyclobenzaprine is a skeletal muscle relaxant and a central nervous system (CNS) depressant. Progress reports between 08/13-03/14 show Flexeril in active medications and treatment plan medications prescribed. From April 2014 forward Flexeril is not mentioned. There are only two thoughts that can be postulated here, as there are no notations in the PR2's regarding the continuation/discontinuation of this medication. One of those is that the Flexeril was discontinued, the other that it was continued but that the physician forgot to document it in the treatment plan. That being said, given that all PR2's from March 2014 on indicate that Flexeril was not prescribed, this request for Flexeril 10mg #120 is not medically necessary.

Norco 10/325mg, #240: Upheld

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

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

Decision rationale: Norco is an opiate agonist. It is contraindicated in the face of the Butrans (Suboxone), which will render it useless. Norco: Indicated for moderate to moderately severe pain. Note: there are no FDA-approved hydrocodone products for pain unless formulated as a combination. Request for Norco 10/325mg #240 is not medically necessary.

Nortriptyline 25mg, #180: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 13-14.

Decision rationale: According to the California MTUS, antidepressants for chronic pain are recommended as a first line option for neuropathic pain, and as a possibility for non-neuropathic pain. Nortriptyline is a 2nd generation tricyclic, and 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. 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. Side effects, including excessive sedation (especially that which would affect work performance) should be assessed. It is recommended that these outcome measurements should be initiated at one week of treatment with a recommended trial of at least 4 weeks. The optimal duration of treatment is not known because most double-blind trials have been of short duration (6-12 weeks). It has been suggested that if pain is in remission for 3-6 months, a gradual tapering of anti-depressants may be undertaken. Long-term effectiveness of anti-depressants has not been established. The effect of this class of medication in combination with other classes of drugs has not been well researched. Specifically studied underlying pain etiologies: Neuropathic pain: Recommended (tricyclic antidepressants) as a first-line option, especially if pain is accompanied by insomnia, anxiety, or depression. Other recent reviews recommended both tricyclic antidepressants and SNRIs (i.e., duloxetine and venlafaxine) as first line options. Non-neuropathic pain: Recommended as an option in depressed patients, but effectiveness is limited. Non-neuropathic pain is generally treated with analgesics and anti-inflammatories. Low Back Pain: Chronic: A systematic review indicated that tricyclic antidepressants have demonstrated a small to moderate effect on chronic low back pain (short-term pain relief), but the effect on function is unclear. This effect appeared to be based on inhibition of norepinephrine reuptake. Reviews that have studied the treatment of low back pain with tricyclic antidepressants found them to be slightly more effective than placebo for the relief of pain. A non-statistically significant improvement was also noted in improvement of functioning. Radiculopathy: Antidepressants are an option, but there are no specific medications

that have been proven in high quality studies to be efficacious for treatment of lumbosacral radiculopathy. The patient was diagnosed with sciatica and radicular pain (nociceptive) radiating down both lower extremities. Sciatica is a common form of radiculitis whose radiating pain is the result of nerve root irritation. Radicular pain is often described as aching, radiating, and can be accompanied by numbness, tingling, and weakness. Neuropathic pain is caused by disease/damage to the peripheral or central nervous system (e.g. spine injury), and can present as "electric shock" sensations, burning or coldness, numbness and tingling. She has been diagnosed with displacement of lumbar intervertebral disc, from which neuropathic pain could emanate. In her case there may be a mixed presentation of both radicular and neuropathic pain. There was no discussion in records provided of the rationale for this choice of medication as treatment for the patient's symptoms. There were no outcome measures instituted, no treatment efficacy discussed in terms of this medication in combination with other medications prescribed, along with any side effects present. It is unknown how long the patient has been on this agent. If the patient is in fact on Cymbalta, the use of nortriptyline then becomes redundant. This request for Nortriptyline 25mg #180 is therefore not medically necessary..

Wellbutrin 100mg, #90: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Antidepressants for chronic pain, Bupropion (Wellbutrin) Page(s): 16.

Decision rationale: According to the California MTUS, bupropion, a second-generation non-tricyclic antidepressant (a noradrenaline and dopamine reuptake inhibitor) has been shown to be effective in relieving neuropathic pain of different etiologies in a small trial (41 patients). (Finnerup, 2005) While bupropion has shown some efficacy in neuropathic pain there is no evidence of efficacy in patients with nonneuropathic chronic low back pain. (Katz, 2005) Furthermore, a recent review suggested that bupropion 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. (Dworkin, 2007). Side-effect profile: Headache, agitation, insomnia, anorexia, weight loss Dosing Information: Neuropathic pain (off-label indication): 100 mg once daily, increase by 100 mg per week up to 200 mg twice daily. (Maizels, 2005) The patient was diagnosed with sciatica and radicular pain (nociceptive) radiating down both lower extremities. Sciatica is a common form of radiculitis whose radiating pain is the result of nerve root irritation. Radicular pain is often described as aching, radiating, and can be accompanied by numbness, tingling, and weakness. Neuropathic pain is caused by disease/damage to the peripheral or central nervous system (e.g. spine injury), and can present as "electric shock" sensations, burning or coldness, numbness and tingling. She has been diagnosed with displacement of lumbar intervertebral disc, from which neuropathic pain could emanate. In her case there may be a mixed presentation of both radicular and neuropathic pain. Bupropion was added around 12/2013 for unclear reasons. There was no discussion in records provided of the rationale for this choice of medication as treatment for the patient's symptoms. In addition, bupropion has never carried an on or off label indication for radicular pain. There were no outcome measures instituted, no treatment efficacy discussed in terms of this medication in combination with other medications

prescribed, along with any side effects present. Bupropion, per CA-MTUS may be considered when patients have not had a response with tricyclics or SNRI's, but it is unclear from records provided whether or not this is the case. This request for Wellbutrin 100mg, #90 is therefore not medically necessary.