MAXIMUS Federal Services

Case Number:	CM15-0074598		
Date Assigned:	04/27/2015	Date of Injury:	08/28/2003
Decision Date:	08/11/2015	UR Denial Date:	04/03/2015
Priority:	Standard	Application Received:	04/20/2015

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. 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/Service. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

The Expert Reviewer has the following credentials:
State(s) of Licensure: New York
Certification(s)/Specialty: Internal Medicine

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 injured worker is a 34 year old female, who sustained an industrial injury on 8/28/2003. She reported low back pain. The injured worker was diagnosed as having lumbar sprain/strain with spondylolisthesis, neuropathic component of burning pain in the lower extremities, neurogenic claudication leg cramps, muscle spasms in back, and insomnia due to pain. Treatment to date has included medications, and home exercises. The request is for Baclofen, Promethazine HCL, Hydrocodone Bitartrate, Nortriptyline HCL, Thermacare heat patches, Belsomra, Rozerem, and Zohydro. On 2/25/2015, she complained of severe back pain, muscle spasms, and a burning sensation in both legs. She reported having 50% improvement in pain and function with the use of her current medications. She rated her pain as 8/10, at best 4/10 with medications and 10/10 without medications. She reports having increased sleep problems due to pain. The treatment plan included refilling the requested medications, and trying a new medication (Belsomra) for her insomnia.

IMR ISSUES, DECISIONS AND RATIONALES

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

Lidocaine patch 5% #60 x 2 refills: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111 to 113.

Decision rationale: According to the California MTUS Guidelines (2009), topical analgesics, such as the Lidoderm 5% Patch, are primarily recommended for neuropathic pain when trials of antidepressants and anti-convulsants have failed. These agents are applied topically to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. Many agents are compounded as mono-therapy or in combination for pain control, for example, NSAIDs, opioids or antidepressants. Lidoderm is the brand name for a lidocaine patch. 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. Further research is needed to recommend this treatment for chronic neuropathic pain disorders other than post-herpetic neuralgia. In this case, the treating provider indicates this injured worker has had some subjective improvements from this medication, but review of Medical Records do not indicate that previous use of this medication in this injured worker has been effective in maintaining any measurable functional improvement. Medical necessity of the requested item has not been established. The request is not medically necessary.

Temazepam 15mg #30 x 2 refills: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Benzodiazepines Page(s): 24.

Decision rationale: Restoril (Temazepam) is an intermediate-acting 3-hydroxy hypnotic of the benzodiazepine class of psychoactive drugs. It is approved for the short-term treatment of insomnia. According to CA MTUS Guidelines, benzodiazepines are prescribed for anxiety. They are not recommended for long-term use for the treatment of chronic pain because long-term efficacy is unproven and there is a risk of dependency. There are no guideline criteria that support the long-term use of benzodiazepines for sleep disturbances. Medical necessity for the requested medication has not been established. There is no compelling evidence presented by the treating provider that indicates this injured worker has had any significant improvements from this medication, and also review of Medical Records do not indicate that previous use of this medication has been effective in this injured worker for maintaining any measurable functional improvement. The requested medication is not medically necessary. Of note, discontinuation of medicine should include a taper, to avoid withdrawal symptoms, weaning is typically recommended.

Nortriptyline Hcl 25mg #30 x 2 refills: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines SPECIFIC ANTIDEPRESSANTS: Tricyclic antidepressants Page(s): 15. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter--Antidepressants for chronic pain.

Decision rationale: Antidepressants for chronic pain are recommended as a first line option for neuropathic pain, and as a possibility for non-neuropathic pain. Tricyclic antidepressants, such as Nortryptiline, 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. In addition, recent reviews recommended tricyclic antidepressants as a first-line option, especially if pain is accompanied by insomnia, anxiety, or depression. Indications in controlled trials have shown effectiveness in treating central post-stroke pain, post-herpetic neuralgia, painful diabetic and non-diabetic polyneuropathy, and post-mastectomy pain. Tricyclics are contraindicated in patients with cardiac conduction disturbances and/or decompensation (they can produce heart block and arrhythmias) as well as for those patients with epilepsy. For patients > 40 years old, a screening ECG is recommended prior to initiation of therapy. In this case, there is no compelling evidence presented by the treating provider that indicates this injured worker has had any significant improvements from this medication, and also review of Medical Records do not indicate that previous use of this medication has been effective in this injured worker for maintaining any measurable functional improvement. There is no documentation of medical need to continue the Nortryptiline. Medical necessity for the requested medication is not medically necessary.

Thermacare heat patches #60 x 2 refills: Upheld

Claims Administrator guideline: Decision based on MTUS ACOEM.

MAXIMUS guideline: Decision based on MTUS ACOEM Chapter 8 Neck and Upper Back Complaints Page(s): 173-174. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Chapter-Low Back - Lumbar & Thoracic (Acute & Chronic)---Heat therapy.

Decision rationale: Per CA MTUS there is no high-grade scientific evidence to support the effectiveness or ineffectiveness of passive physical modalities such as heat/ cold applications. Official Disability Guidelines (ODG) state there is moderate evidence that heat wrap therapy provides a small short-term reduction in pain and disability in acute and sub-acute low-back pain, and that the addition of exercise further reduces pain and improves function. Heat therapy has been found to be helpful for pain reduction and return to normal function. The AHRQ draft comparative effectiveness review of noninvasive treatments for low back pain concluded that, for acute cases, superficial heat is effective. Thermacare web site states that thermacare is recommended for temporary relief from minor aches and joint pains associated with overextension and strains and sprains. The injured worker has chronic pain, no new injuries are reported. There is no such condition described in the medical records and in the request for which patches are prescribed. The above request is not medically necessary.

Belsomra 10mg #30 x 2 refills: 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)-TWC Mental Illness & Stress Procedure Summary.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Mental Illness & Stress -- Suvorexant (Belsomra).

Decision rationale: Official Disability Guidelines (ODG) state that Suvorexant (Belsomra) is not recommended as a first-line treatment due to adverse effects. FDA approved a first-in-class insomnia drug suvorexant (Belsomra, Merck) after the manufacturer lowered the dosages to satisfy the agency's safety concerns. Originally the FDA had declined to approve suvorexant until the starting dose for most patients was 10 mg. The agency also said that proposed upper-limit doses of 30 mg for elderly patients and 40 mg for nonelderly patients were unsafe. Drowsiness was the most commonly reported adverse event for clinical trial participants taking suvorexant, which is classified as a Schedule IV controlled substance. In next-day driving tests, both male and female participants who took the 20-mg dose proved to be impaired drivers. The FDA advises physicians to caution patients against next-day driving or other activities requiring full alertness. The injured worker states it works well and wakes up refreshed in the morning, but the submitted Medical records indicate no functional improvement in this worker. The request is not medically necessary.

Rozerem 8mg #30 x 2 refills: 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) - TWC Pain Procedure Summary.

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-- Sedative Hypnotics.

Decision rationale: Rozerem is in a class of sleep agents that selectively binds to MT1 and MT 2 receptors in the supra-chiasmatic nucleus instead of binding to GABA receptors such as, drugs like Zolpidem, Eszopicione and Zalepon. In this case there is documentation of a diagnosis of insomnia. Review of Medical Records show that previous use of this medication has not been effective for treating insomnia and there has been no functional improvement in this injured worker. In addition, there is documentation that this medication was previously denied. Medical necessity for the requested medication has not been established. Of note, discontinuation of medicine should include a taper, to avoid withdrawal symptoms, weaning is typically recommended. The request is not medically necessary.

Zohydro x 2 refills: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 91-97. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter-Opioids.

Decision rationale: Zohydro is an opioid analgesic. Opioid drugs are available in various dosage forms and strengths. These medications are generally classified according to potency and duration of dosage. The treatment of chronic pain with any opioid analgesic requires review and documentation of pain relief, functional status, appropriate medication use, and side effects. A pain assessment should include current pain, intensity of pain after taking the opiate, and the duration of pain relief. In this case, there is no compelling evidence presented by the treating provider that indicates this injured worker had any significant improvements from use of this medication, and also review of Medical Records do not indicate that in this injured worker, previous use of this medication has been effective in maintaining any measurable objective evidence of functional improvement. Medical necessity of the requested item has not been established. Of note, discontinuation of an opioid analgesic should include a taper, to avoid withdrawal symptoms. The requested medication is not medically necessary.

Baclofen 20mg #60 x 2 refills: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Muscle relaxants (for pain) Page(s): 63-65. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter --Muscle relaxants.

Decision rationale: The California MTUS Guidelines and the ODG recommends non-sedating muscle relaxants, such as Baclofen, with caution as a second-line option for short-term treatment of acute low back pain (LBP), and for short-term (<2 weeks) treatment of acute exacerbations in patients with chronic LBP. The mechanism of action is blockade of the pre and post-synaptic GABA receptors. It is recommended orally for the treatment of spasticity and muscle spasm related to multiple sclerosis and spinal cord injuries. It is also a first-line option for the treatment of dystonia. Baclofen has been noted to have benefits for treating lancinating, paroxysmal neuropathic pain. In this case, there is no documentation that this injured worker has maintained increase in function, or decrease in pain or spasm with the use of Baclofen. The duration of Baclofen use has far exceeded the guideline criteria (of 2-3 weeks). Medical necessity for the requested muscle relaxant has not been established. The requested medication is not medically necessary.

Promethazine Hcl 50mg #30 x 2 refills: 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) - TWC Pain Procedure Summary.

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--Antiemetics (for opioid nausea).

Decision rationale: Promethazine (Phenergan) is an anti-emetic. However, it is not recommended for nausea and vomiting secondary to chronic opioid use. Studies of opiate adverse effects including nausea and vomiting are limited to short-term duration (less than four weeks) and have limited application to long-term use. If nausea and vomiting remains prolonged, other etiologies of these symptoms should be evaluated for. In this case, there is no documentation of opioid related nausea and vomiting. Medical necessity for the requested medication has not been established. The requested medication is not medically necessary.

Hydrocodone Bitartrate #180 x 2 refills: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 91-97. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter--Opioids.

Decision rationale: Hydrocodone bitartrate is an opioid analgesic. Opioid drugs are available in various dosage forms and strengths. These medications are generally classified according to potency and duration of dosage. The treatment of chronic pain with any opioid analgesic requires review and documentation of pain relief, functional status, appropriate medication use, and side effects. A pain assessment should include current pain, intensity of pain after taking the opiate, and the duration of pain relief. In this case, there is no compelling evidence presented by the treating provider that indicates this injured worker had any significant improvements from use of this medication, and also review of Medical Records do not indicate that in this injured worker, previous use of this medication has been effective in maintaining any measurable objective evidence of functional improvement. Medical necessity of the requested item has not been established. Of note, discontinuation of an opioid analgesic should include a taper, to avoid withdrawal symptoms. The requested medication is not medically necessary.

Nortriptyline Hcl 10mg #60 x 2 refills: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines SPECIFIC ANTIDEPRESSANTS Page(s): 15. Decision based on Non-MTUS Citation Pain Chapter-Antidepressants for chronic pain, Tricyclic antidepressants.

Decision rationale: Antidepressants for chronic pain are recommended as a first line option for neuropathic pain, and as a possibility for non-neuropathic pain. Tricyclic antidepressants, such as Nortryptiline, 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. In addition, recent reviews recommended tricyclic antidepressants as a first-line option, especially if pain is accompanied by insomnia, anxiety, or depression. Indications in controlled trials have shown effectiveness in treating central post-stroke pain, post-herpetic neuralgia, painful diabetic and non-diabetic polyneuropathy, and post-mastectomy pain. Tricyclics are contraindicated in patients with cardiac conduction disturbances and/or decompensation (they can produce heart block and arrhythmias) as well as for those patients with epilepsy. For patients > 40 years old, a screening ECG is recommended prior to initiation of therapy. In this case, the patient has chronic burning pain in the lower extremities, neurogenic claudication leg cramps, muscle spasms in back, and insomnia due to pain. She has had prior use of Nortryptiline, however, there is no documentation of objective functional improvement as a result of this medication. There is no documentation of medical need to continue the Nortryptiline. Medical necessity for the requested medication is not established. The request is not medically necessary.