MAXIMUS Federal Services

Case Number:	CM14-0011953		
Date Assigned:	02/21/2014	Date of Injury:	05/13/2002
Decision Date:	03/05/2015	UR Denial Date:	12/30/2013
Priority:	Standard	Application Received:	01/29/2014

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. 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: California
Certification(s)/Specialty: Family Practice

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 43 year old female who sustained a work related injury to the lower back on May 13, 2002. There was no mechanism of injury documented. The injured worker underwent on a lumbar fusion (no date documented). As of 10/8/13, the patient's diagnoses include chronic postoperative pain, postoperative laminectomy syndrome, lumbar radiculitis, degenerative lumbar disc disease, myalgia and insomnia. Current medications are listed as Kadian, Cymbalta, Trazadone, Ibuprofen, Lunesta, Norco, Amitriptyline and Voltaren topical gel. The patient continues to experience low back pain, bilateral hip pain radiating to her left lower extremity with aching, numbness and tingling. Her provider states that she is unable to maintain any position or activity other than lying down for any significant period.The injured worker wears a back brace and walks with a hip-flexed gait. On examination there was no instability noted. Lumbar flexion was limited to 15 degrees, extension, left and right lateral bend was 0 degrees. The progress notes in the record from 2013 include references to earlier visits that make it clear that this patient has been taking Kadian, Cymbalta, trazadone, ibuprofen, Lunesta and amitriptyline since at least 8/28/12. The injured worker is Permanent & Stationary (P&S) and does not work.The physician requested authorization for Voltaren 1% topical gel- apply on affected skin daily, Lunesta 2 mg #60 -2 orally every night at bedtime for insomnia, Amitriptyline 25 mg #30 - 1 tablet orally every night at bedtime for insomnia, Norco 10/325 mg #180 - 1 tablet orally every 4 hours as needed for breakthrough pain.On December 30, 2013 Utilization Review denied certification for Voltaren 1% topical gel- apply on affected skin daily, Lunesta 2 mg #60 -2 orally every night at bedtime for insomnia, Amitriptyline 25 mg #30 - 1

tablet orally every night at bedtime for insomnia, Norco 10/325 mg #180 - 1 tablet orally every 4 hours as needed for breakthrough pain. No evidence was cited as a basis for the denials.

IMR ISSUES, DECISIONS AND RATIONALES

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

Lunesta 2 mg #60 -2 orally every night at bedtime for insomnia: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Medications for Chronic Pain Page(s): 60. Decision based on Non-MTUS Citation insomnia chapter UptoDate, an online evidence-based review service for practitioners (www.uptodate.com), Eszopicolone: Drug Information

Decision rationale: Lunesta is a brand-name eszopicolone, a non-benzodiazepine sedative-hypnotic used for the treatment of insomnia. Per the first guideline cited above, medications should be started individually while other treatments are held constant, with careful assessment of function. There should be functional improvement with each medication in order to continue it. Per the ODG reference above, treatment of insomnia should be based on its etiology. Pharmacological agents should only be used after careful evaluation of potential causes of sleep disturbance. Failure of sleep disturbance to resolve in a 7 to 10 day period may indicate a psychiatric and/or medical illness. Primary insomnia is generally addressed pharmacologically. Secondary insomnia may be treated with pharmacological and/or psychological measures. The specific components of insomnia should be addressed: (a) Sleep onset; (b) Sleep maintenance; (c) Sleep quality; & (d) Next-day functioning. Per the Up to Date reference, the lowest effective dose of Lunesta should be used, as higher doses of 2-3 mg are more likely to result in impairment of memory and coordination lasting up to 11 hours after dosing. The maximum recommended dose in debilitated and geriatric patients is 2 mg. Lunesta causes headaches in 15-21 % of patients. It also causes dizziness in 5-7% of patients, chest pain in over 1%, neuralgia in up to 3% and decreased libido in up to 3%.The clinical findings in this case do not support the use of Lunesta. There is no clear documentation that any evaluation for insomnia has ever been performed on this patient. It is not clear that the patient has primary insomnia. The patient has been taking Lunesta for years with no documentation of any improvement in sleep or daily function. She is taking 4 mg per day, which is over the dose recommended for debilitated patients. This patient's complete lack of ability to function and to perform any activity except lie down for a significant time period would classify her as debilitated. It seems quite likely that Lunesta's side effects may be contributing to her inability to function. Based on the evidence-based references cited and the clinical findings in this case, Lunesta 2 mg 2 at HS is not medically indicated. It is not medically necessary because the patient's functional level has not improved while taking it, because an appropriate evaluation of the patient’s insomnia has not been performed, because the dose prescribed is inappropriately high, and because Lunesta has a side effect profile that may be contributing to the patient's disability level.

Norco 10/325 mg #180 - 1 tablet orally every 4 hours as needed for breakthrough pain: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Medications for Chronic Pain, page 60, Criteria for Use of Opioids, Steps to Take Before a Thera.

Decision rationale: Norco 10/325 is a brand-name Hydrocodone 10 mg with acetaminophen 325 mg. Hydrocodone is an opioid analgesic. Per the MTUS recommendations cited above, medications should be trialed one at a time while other treatments are held constant, with careful assessment of function, and there should be functional improvement with each medication in order to continue it. Opioids should not be started without an evaluation of the patient's current status in terms of pain control and function. An attempt should be made to determine if the patient's pain is nociceptive or neuropathic. Red flags indicating that opioid use may not be helpful should be identified, as should risk factors for abuse. Opioids should be discontinued if there is no improvement in function. There is no good evidence that opioids are effective for radicular pain. If long-term use of opioids occurs, there is a need for ongoing pain and function assessments, as well as assessments for side effects, of concurrent other treatments, and of concurrent psychological issues. The clinical findings in this case do not demonstrate that any of the above guidleines have been followed. Although there is no documentation regarding how long this patient has been taking Norco, she has clearly been taking it for at least 12 months, and probably for years. There is no documentation of evaluation of whether or not the patient's pain is nociceptive or neuropathic. Given this patient's diagnoses of lumbar radiculitis, it is quite likely that her pain includes a significant neuropathic component, which is not necessarily likely to respond to an opioid. No assessment is documented of whether or not opioid use was likely to be helpful in this patient, or of her potential for abuse. No specific functional goals were set or followed. Most importantly, Norco was not discontinued when it became clear that it has not produced any functional improvement. The patient's status has remained at totally disabled, with inability to do even the lightest sedentary work. Based on the evidence-based guidelines cited above, and the clinical documentation provided for my review, Norco 10/325 is not medically necessary. It is not medically necessary because of the lack of appropriate documentation of the patient’s status prior to beginning it, because of the failure to set and monitor functional goals, and because of the failure to discontinue it when it became clear that it has not produced any functional recovery.

Amitriptyline 25 mg #30 - 1 tablet orally every night at bedtime for insomnia: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Medications for chronic pain Page(s): 60. Decision based on Non-MTUS Citation Pain Chapter,

Insomnia Treatment UptoDate, an online evidence-based review service for practitioners (www.uptodate.com), Amitriptyline: Drug Information

Decision rationale: Amitriptyline is a tricyclic antidepressant. The MTUS citation above states that medications are to be given individually, one at a time, with assessment of specific benefit for each medication. Provision of multiple medications simultaneously is not recommended.The ODG guideline cited above recommends that treatment for insomnia be based on etiology. Pharmacological agents should only be used after careful evaluation of potential causes of sleep disturbance. Failure of sleep disturbance to resolve within 7 to 10 days may indicate a psychiatric and/or medical illness. Primary insomnia is generally addressed pharmacologically. Secondary insomnia may be treated with pharmacological and/or psychological measures. The specific components of insomnia should be addressed, including sleep onset, sleep maintenance, sleep quality, and next-day functioning. There are four main categories of pharmacologic treatment, which include benzodiazepines, non-benzodiazepines, melatonin and melatonin receptor agonists, and over-the-counter medications. The majority of studies have only evaluated short-term treatment of insomnia. Therefore more studies are necessary to evaluate the efficacy and safety of treatments of long-term treatment of insomnia. In 2007, the FDA requested that manufacturers of all sedative-hypnotic drugs strengthen product labeling regarding risks (i.e. severe allergic reactions and complex sleep-related behaviors, such as sleep driving). It is recommended that treatments for insomnia should reduce time to sleep onset, improve sleep maintenance, avoid residual effects and increase next-day functioning. The Up to Date reference states that amitriptyline is used for depression. Its off-label uses include chronic pain, diabetic neuropathy, interstitial nephritis, migraine headaches and post-traumatic stress disorder. It does not have an indication for insomnia. The clinical records in this case do not support the use of amitriptyline. There is no documentation of any evaluation of this patient's sleep disturbance and its possible causes. Even if she does have primary insomnia, amitriptyline is not indicated for its treatment. This patient has been taking amitriptyline for at least a year and has demonstrated no functional recovery whatsoever during that time. Based on the evidence-based citations above and on the clinical records provided to me, amitriptyline is not medically necessary and appropriate evaluation for insomnia was not made, because it is not indicated for the diagnosis of insomnia, and because its use has resulted in no functional improvement for this patient.

Voltaren 1% topical gel- apply on affected skin daily: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Medications for Chronic Pain, Topical analgesics, pages 111-113 Page(s): 111-113.

Decision rationale: Voltaren gel is a topical form of diclofenac, which is a non-steroidal anti-inflammatory drug (NSAID).The reference above states that topical NSAIDS may be recommended, but only for short-term use (4-12 weeks) for osteoarthritis of the knee, elbow and other joints, excluding osteoarthritis of the spine, hip or shoulder. They are not recommended for neuropathic pain, as there is no evidence to support their use. Topical diclofenac is indicated for relief of osteoarthritis pain in joints that lend themselves to topical treatment (ankle, elbow, foot,

hand, knee and wrist). It has not been evaluated for arthritis of the spine, hip or shoulder. No more that 8 grams per day should be used in the upper extremity or 16 grams in the lower extremity. Even topically, it is capable of causing GI, cardiac and renal side effects. The clinical documentation in this case does not support the use of Voltaren gel. The patient's pain is located primarily in her back and hip, which are not areas likely to respond to Voltaren gel as noted above. In addition, it appears that the patient's pain is at least partially neuropathic, and not likely to respond to a topical NSAID. Finally, this patient is also taking an oral NSAID, ibuprofen. When Voltaren is combined with it the patient is more likely to have adverse side effects such as gastritis, cardiac events, and renal failure. Based on the MTUS citations above and on the clinical information provided for my review, Voltaren gel is not medically necessary because it does not appear that the patient has a condition likely to respond to it, and because combining it with ibuprofen puts the patient at increased risk of adverse events due to NSAID use.