

Case Number:	CM14-0178078		
Date Assigned:	11/10/2014	Date of Injury:	08/02/2007
Decision Date:	12/18/2014	UR Denial Date:	09/30/2014
Priority:	Standard	Application Received:	10/27/2014

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:

The claimant injured his low back on 08/02/07. Nucynta, DocuSoft, Ibuprofen, Norco, and Lidoderm patch are under review. He has been diagnosed with lumbar radiculopathy and disc disorder with chronic low back pain, depression, and anxiety. The mechanism of injury is unknown. On 05/20/14, he complained of low back pain, right shoulder pain, left knee pain, abdominal pain, right hamstring pain, and right calf pain and he had aching, throbbing, and shooting pain. His pain level was unchanged and level 6/10 with medication and 10/10 without. He had morning stiffness, muscle aches and weakness and reported the quality of his sleep was fair and he slept 4-6 hours per night. He was trying breathing/ relaxation and home exercises. He had used ice/heat and a pool/spa for pain relief. He was taking Valium. He had tenderness to the posterior iliac spine on both sides. His strength was 5/5 in all major muscle groups. There been no aberrant drug-seeking behaviors or side effects noted. His oral medications have been well tolerated. He was evaluated on 06/24/14 and was taking Nucynta, Valium, Doc-Q-Lace. Norco, Lidoderm and was receiving acupuncture treatments. On 05/20/14, he reported pain at level 5/10 that was unchanged. He was unable to function throughout the day without medications and his pain was level 10/10. Pain score with medication was 6/10 and within 20-30 minutes of taking his initial daily dose his pain would gradually decrease as he took the rest of his doses through the day. He could then get out of bed and perform his activities of daily living and function throughout the day. There was evidence of muscle wasting and weakness with pain and stiffness. He also had headache. Neurologic examination was intact. He was in no acute distress. He could sit comfortably on the exam table without difficulty or evidence of pain and could ambulate with no assistive device. He was referred to a neurologist to assess his increasing pain and sciatica. MSIR was prescribed and he was to continue Nucynta, Norco, and Lidoderm patches. His tox screen was within normal limits. He received MS Contin, Nucynta,

DocuSoft, and Valium. On 09/22/14, a Medrol dosepak was prescribed, also. On 08/14/14, his pain level was about the same. There was no significant change. His medications were continued. He was on Nucynta but not MSIR and laboratory studies were ordered. He was referred to a rheumatologist for rheumatoid arthritis. Chiropractic treatment was ordered and his medications were refilled. He was to continue home exercises. On 10/27/14, he was seen again. His Norco was being decreased down to 30 pills per month. He reportedly needed 240 pills every 30 days. His pain was slightly decreased since his last visit due to the anti-inflammatory injection he got at the last visit. His pain was 4-5/10 and he was otherwise unchanged. He stated his medications were working well. There were no side effects and he was not developing medication dependency. There was no suspected medication abuse. His urine drug screen was consistent with his prescribed meds. His pain without pain meds was 6-7/10 and with them was 4/10. He was able to function through the day with less difficulty with the medication. Again he was referred to a rheumatologist for rheumatoid arthritis. Additional chiropractic was ordered. His medications were continued. Physical examination was unremarkable. His motor testing was limited by pain. Urine drug screen dated 03/17/14 revealed consistent results including Norco, Nucynta, and Valium and tapentadol also was present.

IMR ISSUES, DECISIONS AND RATIONALES

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

Nucynta 50mg #120 with two refills: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 74-97.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids for Chronic Pain; Medications for Chronic Pain Page(s): 110;94.

Decision rationale: The history and documentation do not objectively support the request for Nucynta 50 mg, #120 with two refills. The MTUS states "a therapeutic trial of opioids should not be employed until the patient has failed a trial of non-opioid analgesics. Before initiating therapy, the patient should set goals, and the continued use of opioids should be contingent on meeting these goals." In these records, there is no documentation of trials and subsequent failure of or intolerance to first-line drugs such as acetaminophen or non-steroidal anti-inflammatory drugs or first line opioids. MTUS further explains, "pain assessment should include: current pain; the least reported pain over the period since last assessment; average pain; intensity of pain after taking the opioid; how long it takes for pain relief; and how long pain relief lasts." The ODG state "Nucynta is recommended only as second line therapy for patients who develop intolerable adverse effects with first line opioids. Three large RCTs concluded that tapentadol was efficacious and provided efficacy that was similar to oxycodone for the management of chronic osteoarthritis knee and low back pain, with a superior gastrointestinal tolerability profile and fewer treatment discontinuations. Tapentadol is a centrally acting oral analgesic. It has two mechanisms of action, combining mu-opioid receptor agonism and norepinephrine reuptake inhibition. (Johnson, 2008) Nucynta (tapentadol) was made a Schedule II controlled substance. Nucynta may be abused by crushing, chewing, snorting or injecting the product. These practices pose a significant risk to the abuser that could result in overdose and death. (FDA, 2009)

Nucynta has the same pain-relieving benefits of Oxy IR, as well as the same risks that come with any opioid, but shows a significant improvement in gastrointestinal tolerability compared with oxycodone; if patients on Oxy IR complain of constipation, nausea, and/or vomiting, Nucynta might be considered as a second-line choice." There is no indication that periodic monitoring of the claimant's pattern of use and his specific response to doses of this medication, including assessment of pain relief and functional benefit, has been or will be done. The claimant's pattern of use of Nucynta is unclear other than that he takes it and reports pain relief. There is no evidence that a signed pain agreement is on file at the provider's office, although the provider did say that he reviewed the rules about opioid use. There is no evidence that a pain diary has been recommended and is being kept by the claimant and reviewed by the prescriber. Typically, routine refills are not recommended for opioids as close medication monitoring is expected. As such, the medical necessity of the ongoing use of Nucynta 50 mg #120 with 2 refills has not been clearly demonstrated."

DocuSoft 100mg Soft Gel Cap #90 with two refills: Overturned

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 77.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids for Chronic Pain Page(s): 110. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: PDR 2014, Colace

Decision rationale: The history and documentation support the ongoing use of DocuSoft during the weaning period from opioids. The claimant has reported problems with constipation which may be a result of chronic opioid use. The MTUS state "(d) Prophylactic treatment of constipation should be initiated. DocuSoft is typically recommended for the control/relief of constipation that may occur due to the chronic use of opioids. The claimant is likely still using Nucynta and Norco and is at risk of continued problems with constipation. The use of DocuSoft can be recommended during the weaning process and until the Norco and Nucynta have been discontinued.

Ibuprofen 600mg #90 with two refills: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs. Decision based on Non-MTUS Citation Official Disability Guidelines, web 2012, Pain

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs for Chronic Pain Page(s): 102.

Decision rationale: The history and documentation do not objectively support the request for continued use of Ibuprofen 600 mg #90 with 2 refills for the claimant's chronic pain. The MTUS state re: NSAIDs "Osteoarthritis (including knee and hip): Recommended at the lowest dose for the shortest period in patients with moderate to severe pain. Acetaminophen may be considered for initial therapy for patients with mild to moderate pain, and in particular, for those with gastrointestinal, cardiovascular or renovascular risk factors. NSAIDs appear to be superior to

acetaminophen, particularly for patients with moderate to severe pain. There is no evidence to recommend one drug in this class over another based on efficacy. In particular, there appears to be no difference between traditional NSAIDs and COX-2 NSAIDs in terms of pain relief. The main concern of selection is based on adverse effects. COX-2 NSAIDs have fewer GI side effects at the risk of increased cardiovascular side effects, although the FDA has concluded that long-term clinical trials are best interpreted to suggest that cardiovascular risk occurs with all NSAIDs and is a class effect (with naproxen being the safest drug). There is no evidence of long-term effectiveness for pain or function. Back Pain -Acute exacerbations of chronic pain: Recommended as a second-line treatment after acetaminophen. Neuropathic pain: There is inconsistent evidence for the use of these medications to treat long-term neuropathic pain, but they may be useful to treat breakthrough and mixed pain conditions such as osteoarthritis (and other nociceptive pain) in with neuropathic pain." In this case, there is evidence of radicular pain and degenerative disc disease of the low back. There is brief mention of a diagnosis of rheumatoid arthritis but it is not clear how that diagnosis was made and no symptoms of RA or physical findings supporting this diagnosis have been documented. The claimant's pattern of use of this medication is unclear, including when he takes it, what pain relief he receives, how long it lasts, or the objective measurable or functional benefit he receives from it. There is mention of a reduction in pain but it is not clear whether he gets this pain relief from the use of this medication or a combination of medications or how this has been determined. There is no evidence of significant inflammation to support its use prior to a trial of first line medication such as acetaminophen. It is not clear that the claimant is using this medication for breakthrough pain or acute flare ups of chronic back pain. The medical necessity of the use of ibuprofen 60 mg #90 with 2 refills for chronic pain has not been demonstrated.

Norco 10/325mg #30 with two refills: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 74-97.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids for Chronic Pain Page(s): 110.

Decision rationale: The history and documentation do not objectively support the request for the opioid, Norco 10/325 mg #3 with 2 refills. The MTUS outlines several components of initiating and continuing opioid treatment and states "a therapeutic trial of opioids should not be employed until the patient has failed a trial of non-opioid analgesics. Before initiating therapy, the patient should set goals, and the continued use of opioids should be contingent on meeting these goals." In these records, there is no documentation of trials and subsequent failure of or intolerance to first-line drugs such as acetaminophen or non-steroidal anti-inflammatory drugs. MTUS further explains, "pain assessment should include: current pain; the least reported pain over the period since last assessment; average pain; intensity of pain after taking the opioid; how long it takes for pain relief; and how long pain relief lasts." There is no indication that periodic monitoring of the claimant's pattern of use and response to this medication, including assessment of pain relief and functional benefit, has been or will be done. There is brief mention that his medications reduce his pain but it is not clear exactly what benefit he receives specifically from this medication, including whether the pain relief is received from each medication separately or

the combination of medications. The claimant's pattern of use of Norco is unclear other than he takes it. There is no evidence that a pain diary has been recommended and is being kept by the claimant and reviewed by the prescriber. As such, the medical necessity of the ongoing use of Norco with refills has not been clearly demonstrated.

Lidoderm 5% patch (700mg/patch) #30 with two refills: 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 Page(s): 143.

Decision rationale: The history and documentation do not objectively support the request for Lidoderm 5% patch (700mg/patch) #30 with two refills, frequency of use unknown. The CA MTUS state "topical agents may be recommended as an option [but are] largely experimental in use with few randomized controlled trials to determine efficacy or safety. Primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed." There is no evidence of failure of all other first line drugs. There is no documentation of failures of trials of first line drugs such as acetaminophen and also local modalities. The CA MTUS also state "before prescribing any medication for pain, the following should occur: (1) determine the aim of use of the medication; (2) determine the potential benefits and adverse effects; (3) determine the patient's preference. Only one medication to be given at a time, and interventions that are active and passive should remain unchanged at the time of the medication change. A trial should be given for each individual medication." There is no evidence that these criteria have been met for Lidoderm patches. The medical necessity of this request for Lidoderm patches 5% with refills has not been clearly demonstrated.