

Case Number:	CM14-0051315		
Date Assigned:	06/23/2014	Date of Injury:	12/17/2003
Decision Date:	07/25/2014	UR Denial Date:	03/08/2014
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 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 cervical spine on 12/17/03, and has post laminectomy syndrome and chronic pain. He was prescribed Nucynta and Flector. The Nucynta was modified and the Flector was not certified and the medications are under review. He also uses a transcutaneous electrical nerve stimulation (TENS) unit. He reportedly has chronic neck pain radiating down the right arm. Wellbutrin, trazodone, and Neurontin were certified on 03/05/14. He is status post surgery on 02/09/05 for a three (3) level discectomy and fusion. He was also taking tramadol and ibuprofen when he had a qualified medical exam (QME) on 02/06/08. He reported ongoing cervical pain that radiated into the left upper extremity. He also has a history of back pain. He saw [REDACTED] on 09/07/12. He was also receiving acupuncture. Several urine toxicology screens were inconsistent in 2011. He reported that his medications were working well. His medications were refilled. On 12/28/12, he reported pain at level 8/10 and stated he needed refills. He was taking Nucynta twice daily as needed and was using Flector patches. His medications were continued. He was advised on exercising. His medications have been continued on a chronic basis. On 02/14/14, he reported his medications were working well. His sleep was fair. He had restricted range of motion of the low back with tenderness over the sacroiliac (SI) joint. Light touch sensation was decreased over the right side in the C5 distribution. He was diagnosed with cervical and lumbar radiculopathy and postlaminectomy syndrome. He reported no side effects and there was no medication abuse suspected. In the past, he had used up to 300 mg daily of Darvocet to address daily flare-ups of pain. He was using Flector patches and stated it was effective to decrease his inflammation. In the past he had used ibuprofen two to three (2-3) times a day, which was effective, but caused gastrointestinal (GI) distress. He was still taking Neurontin, Wellbutrin XL, and trazodone. On 03/14/14, he reported pain with medications at level 6/10 and without as 10/10. His pain was worse. He was also

trying a TENS unit for pain relief. He then stated his medications were working well. They were refilled. On 04/10/14, 05/08/14, and 06/05/14, he reported benefit from the pain medications and high levels of pain without. When he has enough of his medications he can help take care of his children more and do his daily activities. He wanted to return to three (3) per day of Nucynta medication. The Nucynta was increased, due to his complaints of moderate to severe pain.

IMR ISSUES, DECISIONS AND RATIONALES

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

One (1) prescription of Nucynta 50mg #60: Overturned

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Long-term Users of Opioids (6-months or more). Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain (Chronic), Tapentadol (Nucynta).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Medications for Chronic Pain Page(s): 60-61. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Formulary: Nucynta.

Decision rationale: The history and documentation support the request for the opioid, Nucynta, but weaning should be instituted. The Official Disability Guidelines indicate that Nucynta is "recommended as second line therapy for patients who develop intolerable adverse effects with first line opioids. These recent 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. On November 21, 2008, the FDA approved tapentadol immediate-release tablets for relief of moderate to severe acute pain. Tapentadol, manufactured by [REDACTED], is a new centrally acting oral analgesic. It has two mechanisms of action, combining mu-opioid receptor agonism and norepinephrine reuptake inhibition. The guidelines also indicate that Nucynta (tapentadol) was made a Schedule II controlled substance. Such drugs are sought by drug abusers and people with addiction disorders. Diversion of Schedule II products is an act subject to criminal penalty. 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. Nucynta has the same pain-relieving benefits of OxyIR, as well as the same risks that come with any opioid, but shows a significant improvement in gastrointestinal tolerability compared with oxycodone, so if patients on OxyIR complain of constipation, nausea, and/or vomiting, Nucynta might be recommended as a second-line choice. The claimant has been taking this medication regularly for several years. The Chronic Pain Guidelines outline 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. The guidelines further explain, "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 close 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. Despite continued use of this medication, the claimant has also required the use of multiple other medications and has used a TENS unit. He states the medications work well, but he reports moderately high pain levels, even when he takes it. Additionally, the specifics of the 4A's "analgesia, activities of daily living, adverse side effects, and aberrant drug-taking behaviors" should be followed and documented per the guidelines. The claimant's pattern of use of Nucynta is unclear, other than he takes it twice a day and it was recently increased. There is no evidence that a signed pain agreement is on file at the provider's office and no evidence that a pain diary has been recommended. As such, the medical necessity of the ongoing use of Nucynta has not been clearly demonstrated. The request is not medically necessary.

One (1) prescription of Flector 1.3% #30: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical NSAIDs. Decision based on Non-MTUS Citation Official Disability Guidelines, Pain, Flector patch (diclofenac epolamine).

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

Decision rationale: The history and documentation do not objectively support the request for Flector patches. The Chronic Pain Guidelines indicate that "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. The claimant received refills of his other medications, which include an antidepressant and an antineuropathic medication. His pattern of use of this patch is not described including specifics of benefit to him, and the following have not been documented for this medications, as recommended by the guidelines: (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. Analgesic medication should show effects within one to three (1 to 3) days and the analgesic effect of antidepressants should occur within one (1) week. A record of pain and function with the medication should be recorded. He is taking multiple oral medications and the specific additional benefit to him of the use of this topical agent is unclear. The medical necessity of this request has not been clearly demonstrated. The request is not medically necessary.