

Case Number:	CM14-0164763		
Date Assigned:	10/09/2014	Date of Injury:	08/17/2011
Decision Date:	11/10/2014	UR Denial Date:	09/17/2014
Priority:	Standard	Application Received:	10/06/2014

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 was injured on 08/17/11. Nexium, Butrans patch, and Nucynta are under review. She injured her right knee and back. The note dated 10/15/13 indicated she had been taking Prozac, Nexium, and Trazodone in combo for 10 years per her family physician. On 12/31/13, she was to continue Butrans patch, Temazepam, Tegaderm, Norco, Prozac, Nexium, and Trazodone and was also using Imitrex and ointment. She reported on 03/07/14 that she uses Butrans patch and alternates it with Norco. Her pain was 10/10 without medications and 8/10 with medications. She received refills of multiple medications. On 03/28/14, she stated she was taking Norco to manage her pain but it was giving her constipation. She was prescribed Colace. She had weakness and tiredness all over her body. She was given vitamin B12. She received a number of medications. There is no mention of continued Norco. On 04/25/14, she reported having breakthrough bloody stool which had worsened her anemia. She went to the ER but nothing was done. She was referred to a couple of GI specialists but they were unable to accept her under Worker's Compensation. A referral to a GI specialist was mentioned on multiple occasions in 2013 and 2014 without a clear description of the GI complaints. She reported rectal bleeding. She was taking aspirin on her own. She was having bloody stools. Reportedly the urine drug screen was inconsistent with the medications prescribed and she confirmed taking Oxymorphone for the severe kidney infection. She stated she was given it in the hospital for her kidney infection. She was to continue Butrans patch, Trazodone, Theramine, Gabadone, and was given it Tegaderm and Temazepam. On 05/27/14, she received Norco for breakthrough pain. Therapy was ordered. She received refills of Butrans patch and was to continue Tegaderm patch covers, Temazepam, Trazodone, Theramine, Gabadone and Nexium for GI reflux. On 06/17/14, she reported throbbing right knee pain and sciatic pain. She stated that the Norco she was given was generic and she was not getting the same effect. It would wear off after 4 hours and she

wanted brand name Norco. Her pain averaged 9/10 and without pain medications was 10/10 and with it 8/10. The note states her current medications relieved her pain and improved her function. She was to discontinue the medical foods and continue Butrans patch, Tegaderm patch cover, Temazepam, Nexium, Norco, and Colace. She received a vitamin B12 shot. On 07/24/14, she reported that she was having gastrointestinal issues and had not been sent to a gastrointestinal specialist. Her medications and injections had been denied. There is no description of ongoing gastrointestinal complaints. Her medications and injections were denied. Her pain was 8/10 and averaged 7/10. It was 10/10 without pain medications and with pain medications was 8/10. On 07/29/14, a urine drug screen was positive for hydrocodone, hydromorphone, and fluoxetine. The claimant had been doubling up on her morning dose of Norco and the pain was still persistent. She was taking 240 Norco per month and was also on 20 g of Butrans patch. Without her medications, her pain was 10/10 and with them it was 6/10. Diagnoses include status post right knee arthroscopic surgery with right knee pain and meralgia paresthetica, right sciatica and insomnia. She was being treated for a flare-up of her pain on 08/27/14. Injections had been denied although she did extremely well with these blocks one year before. She needed narcotic detoxification and pain control. Sacroiliac joint injection and right sciatic nerve block were requested. She was advised to discontinue Norco and start Nucynta every 6 hours. She was instructed not to take Norco and Nucynta together. She was given Butrans patch, Nexium, Temazepam/Lorazepam, Colace, and Fluriflex ointment. On 08/19/14, she reported that she was walking the night before and her right knee popped and was very painful since then. Her pain was 9/10 and averaged 8/10. Without pain medications it was 10/10 and with it was 7/10. Aquatic therapy was recommended. She received a Toradol injection and was to continue Butrans patch, Tegaderm patch cover, Temazepam, Nexium, ointment, Norco and injections and aquatic therapy were again requested. On 08/14/14, she complained of right knee and leg pain and low back pain. Her sciatic pain had flared and her knee was swelling. She had been trying to walk more. Her pain score was 8 1/2/10 since last visit and averaged 7/10. Without her pain medications it was 10/10 and with them it was 8/10. She was having trouble with land-based exercises. She was taking Butrans patches, Tegaderm patch cover, Temazepam, Nexium, and ointment and was to continue Norco. Aquatic therapy was recommended and she received a Toradol injection. She was advised to take continue Nexium for acid reflux. She has been treated with multiple medications, including opioids.

IMR ISSUES, DECISIONS AND RATIONALES

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

Nexium 40mg: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDS,GI symptoms & Cardiovascular risk.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Proton pump inhibitors Page(s): 102. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG): Formulary - Nexium

Decision rationale: The history and documentation do not objectively support the request for Nexium 40 mg, quantity unknown, at this time. The CA MTUS state on p. 102 re: PPIs "patients at intermediate risk for gastrointestinal events and no cardiovascular disease :(1) a non-selective NSAID with either a PPI (Proton Pump Inhibitor, for example, 20 mg omeprazole daily) or misoprostol (200g four times daily) or (2) a Cox-2 selective agent." The ODG state "a trial of omeprazole or Lansoprazole is recommended before Nexium therapy." In this case, there

is brief documentation that states the claimant has a history of acid reflux and has been taking Nexium for a prolonged period of time. However, there is no recent documentation that describes such symptoms and no description of the benefit that the claimant gets from the ongoing use of this medication. There is no history of trials of other first line PPIs prior to Nexium. The medical necessity of this request for Nexium 40 mg has not been clearly demonstrated.

30 Butrans 20mcg patches: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines buprenorphine Page(s): 57. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Formulary: BuTrans

Decision rationale: The history and documentation do not objectively support the request for Butrans patches 20 mcg, #30. The MTUS state "buprenorphine may be recommended for treatment of opiate addiction. Also recommended as an option for chronic pain, especially after detoxification in patients who have a history of opiate addiction." The ODG formulary states buprenorphine may be "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." There is no clear evidence that the claimant tried and failed all other reasonable first line drugs and her pattern of use of this medication is unclear. The medication has not always been provided to her and she reported alternating it with Norco which is not appropriate use of this type of medication. Detoxification was mentioned in the provider's notes, but there is no evidence that this medication was ever used for this specific purpose. There is no evidence that the ODG criteria have been met, in particular, that the claimant has a hyperalgesic component to her pain, centrally mediated pain, though she may be at high risk of non-adherence with standard opioid maintenance. She has been prescribed multiple other medications and states her medications, in general, are helpful, without specifics being noted relative to each medication. The medical necessity of this request for 30 Butrans patches 20 mcg has not been clearly demonstrated.

Nucynta 75mg #15: Upheld

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

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

Decision rationale: The history and documentation do not objectively support the request for Nucynta 75 mg #15, frequency unknown. 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 nonsteroidal 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 OxyIR, 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 OxyIR 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 her response specifically to this medication, including assessment of pain relief and functional benefit, has been or will be done. There is only general information about her response to her medications and she continues to have high pain levels despite the use of multiple medications. There is no evidence that the claimant has been involved in an ongoing rehab program to help maintain any benefits she receives from treatment measures. Additionally, 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. 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 and is being kept by the claimant and reviewed by the prescriber. As such, the medical nec