

Case Number:	CM15-0108066		
Date Assigned:	06/12/2015	Date of Injury:	03/08/2008
Decision Date:	09/24/2015	UR Denial Date:	05/08/2015
Priority:	Standard	Application Received:	06/04/2015

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: California

Certification(s)/Specialty: Emergency 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 49-year-old, male who sustained a work related injury on 3/8/08. The diagnoses have included lumbar spondylolisthesis, status post lumbar fusion and lumbar disc protrusion. Treatments have included inversion table treatment, medications and physical therapy. In the Follow-Up Visit note dated 4/27/15, the injured worker complains of moderate, persistent lower back pain with radiating leg pain. He complains that his pain has not dramatically improved. He feels that the OxyContin does help but is experiencing side effects that are too great to continue. He has stopped taking it. He states it is causing too much sedation and "spaciness." He feels overall lethargic. He is requesting something different. He has moderately restricted range of motion in lumbar spine. The treatment plan includes discontinuing OxyContin, starting Embeda, Flector patches prescription and refills of other medications.

IMR ISSUES, DECISIONS AND RATIONALES

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

Embeda 20 mg/0.8, #60: 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), Pain (updated 04/30/15) Online Version, Embeda (morphine/naltrexone).

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Embeda (morphine /naltrexone).

Decision rationale: The request is for Embeda. This is an opioid agonist/antagonist medication. The MTUS guidelines are silent regarding this topic. The ODG state the following: Recommended as an option for patients who are at risk for abuse of opioids by altering recommended oral use. This medication is designed to alter oral use and thus prevent patients from abusing opioids. As it is resistant to being crushed or dissolved, Embeda does not allow for nasal use (insufflation), chewing and /or intravenous use. Other tamper resistant agents on the market include Suboxone (buprenorphine/ naloxone), Opana (oxymorphone), Exalgo (hydromorphone), and OxyContin (oxycodone-controlled release). The FDA has approved morphine sulfate and naltrexone hydrochloride extended-release capsules (Embeda) for once- or twice-daily use in the management of moderate to severe pain when continuous, around-the-clock opioid analgesic therapy is warranted for an extended period. The capsules contain morphine pellets with a sequestered inner core of the opioid antagonist naltrexone that is released when the product is crushed or chewed, thereby discouraging tampering and drug abuse. Approval of the product was based on data from 12 clinical studies, including a phase 3 study showing that its use provided significant pain relief compared with placebo in patients with severe pain caused by osteoarthritis of the hip or knee. (FDA, 2009) In this RCT pain relief was statistically significantly superior for those treated with Embeda compared to the control group (Trevino, 2009) The FDA's latest list of drugs to monitor after having identified potential signs of serious risks or new safety information includes Embeda for withdrawal symptoms not associated with misuse. (FDA, 2011) Black Box Warning: Embeda is not intended for PRN use. Embeda can be abused in a manner similar to other opioid agonists. It is only recommended for opioid tolerant patients. Patients on this drug should not ingest alcohol, including that included in prescription and non-prescription medications. Fatal respiratory depression can occur with use. In this case, the use of this medication is not indicated. This is secondary to polypharmacy, with multiple opioid medications requested. The use of 4 medications in the opioid class would not be recommended. As such, the request is not certified.

Flector patch #60 with 3 refills: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-112.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 111-112.

Decision rationale: The request is for the use of a topical NSAID for pain relief. There are specific criteria require for use based on the guidelines. The MTUS states the following: The efficacy in clinical trials for this treatment modality has been inconsistent and most studies are small and of short duration. Topical NSAIDs have been shown in meta-analysis to be superior to placebo during the first 2 weeks of treatment for osteoarthritis, but either not afterward, or with a diminishing effect over another 2-week period. (Lin, 2004) (Bjordal, 2007) (Mason, 2004) When investigated specifically for osteoarthritis of the knee, topical NSAIDs have been shown to be superior to placebo for 4 to 12 weeks. Indications: Osteoarthritis and tendinitis, in particular, that of the knee and elbow or other joints that are amenable to topical treatment: Recommended for short-term use (4-12 weeks). There is little evidence to utilize topical NSAIDs for treatment of osteoarthritis of the spine, hip or shoulder. FDA-approved agents: Voltaren Gel 1% (diclofenac):

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 treatment of the spine, hip or shoulder. In this case, as indicated above, the patient would not qualify for the use of this medication based on the treatment duration. As such, the request is not certified.

Restoril 15 mg, #20: Upheld

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

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

Decision rationale: Not recommended for long-term use because long-term efficacy is unproven and there is a risk of dependence. Most guidelines limit use to 4 weeks. Their range of action includes benzodiazepines are the treatment of choice in very few conditions. Tolerance to hypnotic effects develops rapidly. Tolerance to anxiolytic effects occurs within months and long-term use may actually increase anxiety. A more appropriate treatment for anxiety disorder is an antidepressant. Tolerance to anticonvulsant and muscle relaxant effects occurs within weeks. (Baillargeon, 2003) (Ashton, 2005) In this case, a medication in this class would not be advised for continued use due to the duration of therapy. As such, the request is not certified. All benzodiazepine medications should be titrated down slowly to prevent an acute withdrawal syndrome.

Norco 10/325 mg, #150: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids, Specific Drug List, Hydrocodone/Acetaminophen, Opioids, Criteria for Use Page(s): 91, 93, 76-78, 78-80, 124.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 78.

Decision rationale: The request is for the use of a medication in the opioid class. The MTUS guidelines state that for ongoing treatment with a pharmaceutical in this class, certain requirements are necessary. This includes not only adequate pain control, but also functional improvement. Four domains have been proposed for management of patients on opioids. This includes pain relief, side effects, physical and psychosocial functioning, and the occurrence of any potentially aberrant drug-related behaviors. In this case, there is inadequate documentation of persistent functional improvement, which should eventually lead to medication discontinuation. As such, the request is not certified. All opioid medications should be titrated down slowly in order to prevent a significant withdrawal syndrome.

Dilaudid 4 mg, #60: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids, Specific Drug List, Hydromorphone, Opioids, Criteria for Use Page(s): 91, 93, 76-78, 78-80, 124.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines
Page(s): 78.

Decision rationale: The request is for the use of a medication in the opioid class. The MTUS guidelines state that for ongoing treatment with a pharmaceutical in this class, certain requirements are necessary. This includes not only adequate pain control, but also functional improvement. Four domains have been proposed for management of patients on opioids. This includes pain relief, side effects, physical and psychosocial functioning, and the occurrence of any potentially aberrant drug-related behaviors. In this case, there is inadequate documentation of persistent functional improvement which should eventually lead to medication discontinuation. As such, the request is not certified. All opioid medications should be titrated down slowly in order to prevent a significant withdrawal syndrome.

Nucynta ER 150 mg, #60: 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), Pain (updated 04/30/15) Online Version, Tapentadol (Nucynta).

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic), Tapentadol (Nucynta).

Decision rationale: The request is for the medication Nucynta. This is categorized as a centrally acting opioid agonist. The ODG guidelines state the following regarding its use: 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. (Afilalo, 2010) (Buynak, 2010) (Lange, 2010) 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. (Daniels, 2009) (Daniels2, 2009) (Hale, 2009) (Hartrick, 2009) (Stegmann, 2008) In one study, gastrointestinal adverse events led to discontinuation in 9% of the tapentadol group versus 22% of the oxycodone group. (Wild, 2010) This review questioned the opioid potency of tapentadol, and suggested that it affects pain modulation through inhibition of norepinephrine. (Prommer, 2010) But the manufacturer disagrees. (Nelson, 2011) In August 2011, FDA approved tapentadol extended release (Nucynta ER) for moderate to severe chronic pain. Nucynta was already approved for acute pain. (FDA, 2011) In this case, this medication is not indicated for use. This is secondary to polypharmacy with 4 medications in the opiate class requested. As such, it is not certified for use.

Soma 350 mg, #90 with 3 refills: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Muscle Relaxants (for pain) Page(s): 65.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 63.

Decision rationale: The request is for the use of a muscle relaxant to aid in pain relief. The MTUS guidelines state that the use of a medication in this class is indicated as a second-line option for short-term treatment of acute exacerbations of low back pain. Muscle relaxants may be effective in reducing pain and muscle tension, which can increase mobility. However, in most LBP cases, they show no benefit beyond NSAIDs in pain improvement. Efficacy appears to diminish over time, and prolonged use may lead to dependence. (Homik, 2004) Due to inadequate qualifying evidence and prolonged duration of use, the request is not certified. All muscle relaxant medications should be titrated down slowly to prevent an acute withdrawal syndrome.