MAXIMUS Federal Services

Case Number:	CM15-0170529		
Date Assigned:	09/11/2015	Date of Injury:	10/01/1999
Decision Date:	11/03/2015	UR Denial Date:	08/12/2015
Priority:	Standard	Application Received:	08/31/2015

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 62 year old female, who sustained an industrial injury on 10-01-1999 resulting in pain or injury to the low back. A review of the medical records indicates that the injured worker is undergoing treatment for chronic radiating low back pain, right lower extremity pain, myofascial pain and spasm, insomnia, and hypothyroidism. Medical records (02-18-2015 to 08-03-2015) indicate ongoing low back pain with bilateral lower extremity pain (right greater than left). Records also indicate decreased pain levels with slightly worsening of mood; but no changes in work status or activities of daily living. Per the treating physician's progress report, the injured worker has not returned to work. The physical exams, dated 07-08-2015 and 08-03-2015, revealed ongoing tenderness and pain over the right-sided sacroiliac joints, decreased sensation in the lower extremities with decreased patellar reflex on the right along with complaints of weakness and numbness with a pins & needle sensation, and restricted range of motion in the lumbar spine. Relevant treatments have included lumbar fusion surgery (2013), injections, physical therapy, acupuncture, work restrictions, and pain medications (oxycodone, OxyContin, Nucynta and Lorzone since at least 02-2015). The treating physician reported that the injured worker has been paying for her medications out-of-pocket, and that Gralise is helping, and that the injured worker had failed a trial of Neurontin in the past. It was also noted that the injured worker was asking for separate prescriptions because she had to use multiple pharmacies. The treating physician indicates that CT scans of the lumbar spine (2014) showed interval lateral plate and screw fusion from L2 through L4. The injured worker's most recent urine drug screen was noted to be consistent with prescribed medications. The request for

authorization (07-09-2015) shows that the following medications were requested: Nucynta ER 200mg #60, Lorzone 750mg #60, oxycodone 10mg #90, and OxyContin 15mg #30. The original utilization review (08-11-2015) denied or modified the following medications: partially approved Nucynta due to the absence of documented failed first-line therapy and lack of functional improvement; denied Lorzone due the medication no being recommended for long-term use and the absence of spasm relief; partially approved oxycodone due to the lack of functional improvement with prior use and to allow for weaning; and partially approved OxyContin due to lack of functional improvement and to allow for weaning.

IMR ISSUES, DECISIONS AND RATIONALES

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

Nucynta ER 200mg #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.

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. This is secondary to a lack of documented functional improvement seen with use as well as polypharmacy with 3 medications in the opiate class requested. There is also no documentation of a trial of an anti-epileptic medication other

then neurontin which was stated to be not tolerated. As such, it is not certified and therefore is not medically necessary.

Lorzone 750mg #60: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Muscle relaxants (for pain).

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 and therefore is not medically necessary.

Oxycodone 10mg #90: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Opioids, criteria for use.

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 and therefore is not medically necessary.

Oxycontin 15mg #30: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Opioids, criteria for use.

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 and therefore is not medically necessary.