

<b>Case Number:</b>	CM14-0115274		
<b>Date Assigned:</b>	09/16/2014	<b>Date of Injury:</b>	08/09/2001
<b>Decision Date:</b>	10/15/2014	<b>UR Denial Date:</b>	07/10/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	07/23/2014

### 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 Physical Medicine and Rehabilitation, 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 patient is 59-year-old female who sustained an injury of 8/9/01. As per 8/27/14 report she had a recent flare up of neck, right shoulder, bilateral upper extremities and tailbone pain rated at 9-10/10 and 7-8/10 with medications. C-spine exam revealed significant guarding with restricted painful movement and c-spine pain in any position. Recent c-spine x-ray from 1/15/14 revealed anterior plate C5-C7 and posterior instrumentation C6-7. MRI from 4/4/14 revealed extensive post-surgical changes with 2mm posterior lateral herniation extending into left neural foramen on left C6-7, 2mm disc protrusion into the neural foramen right side at C4-5, and minimal spinal stenosis at C3-4 and C4-5. She had cervical epidural steroid injections and home interferential unit. She is currently on Nucynta, Oxymorphone and Amlodipine Besylate. Her constipation was well controlled with Colace and she had stopped the Diclofenac per its side effects She had previous modified certification for Nucynta and Oxymorphone ER 20 mg #60 on 07/09/14. Diagnoses: Status post anterior cervical discectomy and fusion, C5-6 and C6-7 with development of a nonunion at C6-7, status post posterior fusion with instrumentation at C6-7, status post repair of type 2 slap lesion; arthroscopic subacromial decompression; placement of pain pump catheter, intractable pain syndrome, and history of hypertension and fibromyalgia. The request for Nucynta 100 mg #120 was modified to Nucynta 100 mg #60 and Oxymorphone ER 20 mg #60 was modified to Oxymorphone ER 20mg #42 on 09/12/14.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Nucynta 100 mg #120:** 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: Tapentadol (Nucynta)

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

**Decision rationale:** CA MTUS guidelines do not address the issue. Per guidelines, 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. Guidelines indicate "four domains have been proposed as most relevant for ongoing monitoring of chronic pain patients on opioids; pain relief, side effects, physical and psychosocial functioning, and the occurrence of any potentially aberrant (or non-adherent) drug-related behaviors. There is little to no documentation of any significant improvement in pain level (i.e. VAS) or function with prior use to demonstrate the efficacy of this medication. There is no evidence of urine drug test in order to monitor compliance. The medical documents do not show failure of first line therapy. Furthermore, therefore, the medical necessity for Nucynta has not been established based on guidelines and lack of documentation.

**Oxymorphone ER 20 mg #60:** Upheld

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

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation (ODG), Pain, Oxymorphone

**Decision rationale:** CA MTUS guidelines do not address the issue. Per ODG Oxymorphone Extended Release (Opana ER), is a controlled, extended and sustained release preparations that is not recommended. Due to issues of abuse and Black Box FDA warnings, Oxymorphone is recommended as second line therapy for long acting opioids. Oxymorphone products do not appear to have any clear benefit over other agents, should be reserved for patients with chronic pain, who are need of continuous treatment. Regarding opioids, guidelines indicate "four domains have been proposed as most relevant for ongoing monitoring of chronic pain patients on opioids; pain relief, side effects, physical and psychosocial functioning, and the occurrence of any potentially aberrant (or non-adherent) drug-related behaviors. In this case, there is no documentation of failure of first line therapy. There is little to no documentation of any significant improvement in pain level (i.e. VAS) or function with prior use to demonstrate the efficacy of this medication. There is no evidence of urine drug test in order to monitor compliance. Therefore, the medical necessity for Oxymorphone ER has not been established according to guidelines and based on documentation.

