

<b>Case Number:</b>	CM14-0131769		
<b>Date Assigned:</b>	08/20/2014	<b>Date of Injury:</b>	07/12/1996
<b>Decision Date:</b>	09/22/2014	<b>UR Denial Date:</b>	08/12/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	08/18/2014

### 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 Anesthesiology, has a subspecialty in Pain Management and is licensed to practice in Tennessee. 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:

This is a 72-year-old male with a 7/12/96 date of injury. The mechanism of injury was not noted. There were not any progress notes provided for review. A report dated 8/7/14 was noted in the UR decision dated 8/12/14 but was not provided for review. According to the 8/7/14 examination, the patient began methadone but had an increase in pain or shortness of breath and a general sluggish feeling. The patient has been using a morphine pump. He used Opana, but was not able to tolerate it due to side effects. He found Norco most helpful for pain control. His pain level was 9/10 with medications. He would like to use long-acting hydrocodone for pain. Examination revealed that the patient uses a walker and transfers with stiffness and guarding. He had limited ROM of the lower extremities due to pain and decreased sensation to light touch. His lower back ROM was limited in all directions. Diagnostic impression: right elbow lateral epicondylitis, bilateral carpal tunnel syndromes, bilateral wrist/hand osteoarthritis, chronic lumbar pain syndrome, multilevel lumbar degenerative disc disease. Treatment to date: medication management, activity modification, surgery. A UR decision dated 8/12/14 denied the requests for Zohydro ER and Nuedexta. Regarding Zohydro ER, the records do not establish a medical rationale for the addition of a long-acting oral opioid in addition to the patient's intrathecal morphine pump nor an indication that the patient has failed short-acting hydrocodone. Regarding Nuedexta, the records do not establish a diagnosis or objective findings suggestive of pseudobulbar affect. During the peer to peer discussion, the provider said that Nuedexta was added as an additional adjuvant for the patient's pain. Although the patient, has failed Neurontin, the records do not indicate that the patient has failed another AED such as Lyrica

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Zohydro ER 10mg #30: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines:Pain Chapter, Zohydro.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Guidelines 9792.24.2 Page(s): 78-81. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: FDA (Zohydro ER).

**Decision rationale:** CA MTUS Chronic Pain Medical Treatment Guidelines do not support ongoing opioid treatment unless prescriptions are from a single practitioner and are taken as directed; are prescribed at the lowest possible dose; and unless there is ongoing review and documentation of pain relief, functional status, appropriate medication use, and side effects. According to the FDA, Zohydro ER is an opioid agonist, extended-release, oral formulation of hydrocodone bitartrate indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. The patient is currently utilizing a morphine pump, and the provider has not provided a rationale as to why another long-acting opioid is required for this patient. In addition, there is no documentation of significant pain reduction or improved activities of daily living. Furthermore, there is no documentation of lack of aberrant behavior or adverse side effects, an opioid pain contract, urine drug screen, or CURES monitoring. Therefore, the request for Zohydro ER 10 mg #30 was not medically necessary.

**Nuedexta 20/10 #60: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation According to webmd: Nuedexta oral Uses.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation FDA (Nuedexta).

**Decision rationale:** CA MTUS and ODG do not address this issue. According to the FDA, Nuedexta is the first and only FDA-approved treatment for pseudobulbar affect (PBA). Nuedexta is an innovative combination of two well-characterized components; dextromethorphan hydrobromide (20 mg), the ingredient active in the central nervous system, and quinidine sulfate (10 mg), a metabolic inhibitor that enables dextromethorphan to reach therapeutic concentrations. There is no documentation that the patient has symptoms suggestive of pseudobulbar affect. A specific rationale identifying why the patient requires this particular medication was not provided. Therefore, the request for Nuedexta 20/10 #60 was not medically necessary.

