

<b>Case Number:</b>	CM15-0204010		
<b>Date Assigned:</b>	10/20/2015	<b>Date of Injury:</b>	12/12/2002
<b>Decision Date:</b>	12/02/2015	<b>UR Denial Date:</b>	09/18/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	10/16/2015

### 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: Montana, Oregon, Idaho

Certification(s)/Specialty: Orthopedic Surgery

### 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 injured worker is a 46 year old male who reported an industrial injury on 12-12-2002. His diagnoses, and or impressions, were noted to include: chronic low back and left knee; and insomnia due to chronic pain. The history noted multiple other work-related injuries Magnetic imaging studies of the lumbar spine were said to be done on 2-12-2005, 2-10-2014 & 4-28-2015; of the cervical spine and left shoulder on 1-30-2015; and of the brain on 2-1-2013. His treatments were noted to include: a complex comprehensive agreed medical evaluation on 8-17-2009; lumbar epidural steroid injections; lumbar medial branch blocks; bilateral sacral transforaminal epidurography; left knee arthroscopic surgery (3-22-12); TEN's unit therapy; medication management. The progress notes of 9-4-2015 reported: bilateral knee pain, neck pain, headaches; and low back pain. The objective findings were noted to include: lumbar 5-sacral 1 disc desiccations and bulging, with asymmetry over the left side, and some facet arthritic changes. The physician's requests for treatment were noted to include the reconsideration of Zohydro. The current dose of Zohydro ER was noted to be 40 mg, #45, down from #60 on 8-7-2015. Zohydro ER 40 mg twice a day was noted back 4-3-2015. The Request for Authorization, dated 9-10-2015, was noted to include the remaining #15 of Zohydro 40 mg, twice a day. The Utilization Review of 9-17-2015 non-certified the request for Zohydro ER 40 mg, #15.

### IMR ISSUES, DECISIONS AND RATIONALES

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

## **Zohydro ER 40mg #15: 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.

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

**Decision rationale:** CA MTUS is silent on the issue of Zorhydro. According to ODG, pain section, Zorhydro is not recommended. Zohydro ER (Zogenix Inc) is the first single-entity extended-release (ER) formulation of hydrocodone approved by the FDA; unlike Vicodin, Lortab and Norco, it is not buffered with acetaminophen or some other OTC medication. Each pill will be very potent, but Zohydro initially did not have abuse-deterrent technology. According to the FDA, Zohydro ER should be reserved for use in patients for whom alternative treatment options are ineffective. FDA's Drug Advisory Committee of independent experts voted 11 to 2 to recommend against approval of Zohydro for the treatment of moderate to severe chronic pain. Zohydro is not recommended as a first line drug in ODG. As the guidelines do not recommend Zorhydro, the request is not medically necessary.