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| <b>Case Number:</b>   | CM15-0086040 |                              |            |
| <b>Date Assigned:</b> | 05/08/2015   | <b>Date of Injury:</b>       | 02/23/2006 |
| <b>Decision Date:</b> | 06/12/2015   | <b>UR Denial Date:</b>       | 04/14/2015 |
| <b>Priority:</b>      | Standard     | <b>Application Received:</b> | 05/05/2015 |

### 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: Texas, New York, California  
 Certification(s)/Specialty: Preventive Medicine, Occupational 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 applicant is a represented 51-year-old who has filed a claim for chronic low back and neck pain reportedly associated with an industrial injury of February 23, 2006. In a Utilization Review report dated April 13, 2015, the claims administrator failed to approve requests for Zohydro (extended release hydrocodone). The claims administrator referenced an order form dated April 8, 2015 and associated progress notes of February 25, 2015 and January 14, 2015 in its determination. The applicant's attorney subsequently appealed. In a January 27, 2015 progress note, the applicant was described as having various chronic pain and depressive symptoms. The applicant was using Lexapro, Cymbalta, Norco, Elavil, Ambien, tramadol, Soma, Risperdal, and Klonopin, it was acknowledged. The applicant was placed off of work, on total temporary disability, from a mental health perspective owing to issues with depression resulting in a Global Assessment of Functioning (GAF) 40, it was reported. On April 8, 2015, the applicant reported multifocal complaints of neck, low back, knee, jaw, and facial pain, 8/10. The applicant's medications included Prilosec, Norco, Soma, Motrin, Ambien, Xanax, glucosamine, Cymbalta, Risperdal, Zanaflex, and Viagra. Multiple palpable tender points were noted. A topical compounded cream was furnished. Nexium, Zohydro, Brintellix, Norco, Soma, Motrin, Elavil, Ambien, Ultram, Colace, Xanax, Klonopin, Cymbalta, Dexilant, Risperdal, and Neurontin were all endorsed in conjunction with a cervical epidural steroid injection. It was not clearly stated whether the request for Zohydro was a first-time request or renewal request. It did not appear, however, that Zohydro had been prescribed on earlier notes of January 14, 2015 and December 17, 2014.

## IMR ISSUES, DECISIONS AND RATIONALES

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

**Zohydro ER (Hydrocodone Bitartrate) 20mg #60 (DOS: 4-8-15): Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 81, 79-80. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain Chapter.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Functional Restoration Approach to Chronic Pain Management Page(s): 7-8. Decision based on Non-MTUS Citation Food and Drug Administration Zohydro™ ER (hydrocodone bitartrate) Extended-Release Capsules, **INDICATIONS AND USAGE:** Zohydro ER is an opioid agonist 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.

**Decision rationale:** No, the request for Zohydro, a long-acting variant of hydrocodone, was not medically necessary, medically appropriate, or indicated here. Pages 7 and 8 of the MTUS Chronic Pain Medical Treatment Guidelines stipulate that an attending provider using a drug for non-FDA labeled purposes has the responsibility to be well informed regarding usage of the same and should, furthermore, furnish compelling evidence to support such usage. Here, the request for Zohydro appeared to represent a first-time request for the same, prescribed on or around April 8, 2015. As noted by the Food and Drug Administration (FDA), Zohydro extended release is an opioid agonist indicated for the pain severe enough to require around-the-clock analgesia in applicants in whom alternative treatment options are inadequate. Here, however, the attending provider did not clearly establish that alternative treatment option with first and/or second-line opioids had proven inadequate. There was no mention of the applicant's having failed more conventional long-acting opioids, such as extended release morphine. The attending provider failed to make a clear or convincing case for introduction of Zohydro. Therefore, the request was not medically necessary.