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| <b>Case Number:</b>   | CM14-0218610 |                              |            |
| <b>Date Assigned:</b> | 01/08/2015   | <b>Date of Injury:</b>       | 01/31/2003 |
| <b>Decision Date:</b> | 03/09/2015   | <b>UR Denial Date:</b>       | 12/08/2014 |
| <b>Priority:</b>      | Standard     | <b>Application Received:</b> | 12/30/2014 |

### 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. 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: Physical Medicine & Rehabilitation

### 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 68-year-old male, with a reported date of injury of 01/31/2003. The result of the injury was low back pain. The current diagnosis was not included in the medical records provided for review. The past diagnosis includes displacement of disc without myelopathy. Treatments have included chiropractic treatments, with tremendous relief, pain medication. The medical report dated 11/29/2014 indicates that the injured worker continued to have chronic low back pain with occasional intermittent flare-ups, as well as occasional pain that radiated down into his left foot. The physical examination findings included tenderness to palpation bilaterally about the lumbar paraspinal musculature, limited active voluntary range of motion of the thoracolumbar spine was limited, forward flexion at 45 degrees, extension at 10 degrees, lateral bending at 15 degrees, and negative straight leg raising test. The treating physician prescribed Vicoprofen 7.5/200mg #120. The rationale for the request was not documented. The injured worker remained permanent and stationary. On 12/08/2014, Utilization Review (UR) denied the request for Vicoprofen 7.5/200mg #120. The UR physician noted that the injured worker was no longer in an acute phase after the injury. The MTUS Guidelines were cited.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Vicoprofen 7.5/200mg #120:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines CRITERIA FOR USE OF OPIOIDS Page(s): 76-78,88-89. Decision based on Non-MTUS Citation Drug Formulary, Hydrocodone/Ibuprofen (Vicoprofen®)

**Decision rationale:** The patient presents with low back pain with occasional pain that radiates down into his left foot. The request is for VICOPROFEN 7.5/200 MG #120. Regarding chronic opiate use, MTUS guidelines page 78 and 89 states, "Pain should be assessed at each visit, and functioning should be measured at 6-month intervals using a numerical scale or validated instrument." MTUS page 78 also requires documentation of the 4A's (analgesia, ADLs, adverse side effects, and adverse behavior), as well as "pain assessment" or outcome measures that include current pain, average pain, least pain, intensity of pain after taking the opioid, time it takes for medication to work and duration of pain relief. ODG guidelines, under Drug Formulary, specifically discusses Hydrocodone/Ibuprofen (Vicoprofen) and "Recommended for short term use only. This combination opioid/NSAID has a low dose of ibuprofen (200mg) that is below the normal adult dose of 400 to 800 mg per dose and total max daily dose of 2400mg. Vicoprofen was approved only based on single dose, post-op pain and is approved to treat acute pain for generally less than 10 days. It may be considered an option for use at the time of injury, but the fixed dose of hydrocodone 7.5mg/ibuprofen 200mg and the maximum approved dose of 5 tablets daily may limit acute pain relief. Prescribing information also stresses that this product is not indicated for treating conditions such as rheumatoid arthritis or osteoarthritis. (Vicoprofen prescribing information) In addition, there is also a cost difference between the generic Vicodin (approx \$0.35/tab) and generic Vicoprofen (\$1.04/tab)."None of the reports provide any discussion on any change in the patient's pain and function. None of the 4A's are addressed as required by MTUS Guidelines. The treater fails to provide any pain scales. There are no examples of ADLs which demonstrate medication efficacy with the use of Norco. There are no discussions provided on adverse behaviors/side effects. There is no opiate management issues discussed such as CURES report, pain contracts, etc. No outcome measures are provided either as required by MTUS Guidelines. In addition, urine drug screen to monitor the medicine compliance has not been addressed. Furthermore, ODG Guidelines do not support Vicoprofen for long term use. The patient has been utilizing this medication since at least 06/17/14. Given the lack of sufficient documentation demonstrating efficacy for chronic opiate use, the patient should slowly be weaned as outlined in MTUS guidelines. The requested Vicoprofen IS NOT medically necessary.