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| <b>Case Number:</b>   | CM14-0189655 |                              |            |
| <b>Date Assigned:</b> | 12/02/2014   | <b>Date of Injury:</b>       | 08/17/1998 |
| <b>Decision Date:</b> | 01/20/2015   | <b>UR Denial Date:</b>       | 10/08/2014 |
| <b>Priority:</b>      | Standard     | <b>Application Received:</b> | 11/13/2014 |

### 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, has a subspecialty in Interventional Spine 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 a 66-year-old female with a date of injury of 08/17/1998. The listed diagnoses are LBS, DDD, and facet arthritis, multiple levels. According to progress report 10/01/2014, the patient presents with chronic low back pain that radiates into the legs, which worsens during the winter months. Patient reports an increase in pain with standing, walking, and lifting. Patient also experiences some right hip pain, especially with increased activity. Examination revealed "no changes." Physical examination was performed on 09/03/2014, which revealed increased spasms of the lumbar area, stiff rotation and extension, and decreased lordosis. There is positive right leg raising and decreased sensation noted on the right. Treatment plan is for a refill of medications that include Rozerem, omeprazole 20 mg, Celebrex 200 mg, Valium 5 mg, and Zohydro 40 mg. The utilization review denied the request on 10/08/2014. Treatment reports from 05/07/2014 through 10/01/2014 were provided for review.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Rozerem 8mg #30:** Upheld

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

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

**Decision rationale:** This patient presents with chronic low back pain that radiates into the right lower extremity. The current request is for Rozerem 8 mg #30. Rozerem is an herbal product containing melatonin/L-tryptophan. The ODG guidelines have the following regarding tryptophan, "This supplement has been found to be possibly effective in treatment of anxiety disorders, fibromyalgia, obesity and sleep disorders." Regarding Melatonin, ODG states "Melatonin-receptor agonist: Ramelteon (Rozerem) is a selective melatonin agonist (MT1 and MT2) indicated for difficulty with sleep onset; is nonscheduled (has been shown to have no abuse potential)." Review of the medical file indicates the patient has been prescribed this medication since at least 05/07/2014. None of the progress reports provided for review have any discussion of sleep issues in this patient. Given the patient does not have any difficulties with sleep, the requested Rozerem is not medically necessary.

**Omeprazole 20mg #30:** 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 NSAIDs, GI Symptoms & Cardiovascular Risk Page(s): 69.

**Decision rationale:** This patient presents with chronic low back pain that radiates into the right lower extremity. The current request is for omeprazole 20 mg #30. The MTUS Guidelines page 68 and 69 states that Omeprazole is recommended with precaution for patients at risk for gastrointestinal events: (1) Age is greater than 65, (2) History of peptic ulcer disease and GI bleeding or perforation, (3) Concurrent use of ASA or corticosteroid and/or anticoagulant, (4) High dose/multiple NSAID. The patient's medications include Rozerem, omeprazole 20 mg, Celebrex 200 mg, Valium 5 mg, and Zohydro 40 mg. In this case, there is no indication that the patient is taking NSAID to consider the use of omeprazole. Furthermore, the treating physician provides no discussion regarding GI issues such as gastritis, ulcers, or reflux that would require the use of this medication. Therefore, this request is not medically necessary.

**Celebrex 200mg #30:** Overturned

**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 Medications for Chronic Pain Page(s): 60, 61, 22.

**Decision rationale:** This patient presents with chronic low back pain that radiates into the right lower extremity. The current request is for Celebrex 200 mg #30. MTUS guidelines page 22 supports NSAIDs for chronic LBP but for Celebrex, it states, "COX-2 inhibitors (e.g., Celebrex)

may be considered if the patient has a risk of GI complications, but not for the majority of patients. Generic NSAIDs and COX-2 inhibitors have similar efficacy and risks when used for less than 3 months, but a 10-to-1 difference in cost."Review of the medical file indicates the patient has been prescribed this medication since at least 05/07/2014. According to progress report dated 08/04/2014, medication regimen "helps in controlling patient's pain level and enables her to complete her ADLs and have a fairly good quality of life." The requested Celebrex is medically necessary.

**Valium 5mg #30: 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 Benzodiazepines Page(s): 24.

**Decision rationale:** This patient presents with chronic low back pain that radiates into the right lower extremity. The current request is for Valium 5 mg #30. The MTUS Guidelines page 24 has the following regarding benzodiazepines, "benzodiazepines are not recommended for long-term use because long-term efficacies are unproven and there is a risk of dependence. Most guidelines limit 4 weeks. Review of the medical file indicates the patient has been prescribed Valium since at least 05/07/2014. The MTUS Guidelines recommend maximum use of 4 weeks due to "unproven efficacy and risk of dependence." The requested Valium is not medically necessary.

**Zohydro 40mg #60: 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): 88, 89, 76-78.

**Decision rationale:** This patient presents with chronic low back pain that radiates into the right lower extremity. The current request is for Zohydro 40mg #60. Zohydro is a brand name for hydrocodone. MTUS Guidelines pages 88 and 89 state, "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 4As (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. Review of the medical file indicates the patient has been utilizing Zohydro since 5/7/14. According to progress report dated 08/04/2014, the current medication regimen "helps in controlling patient's pain level and enables her to complete her ADLs and have a fairly good quality of life." There are no before and after scale to denote decrease in pain, no discussion of specific functional improvement, changes in ADL, or improvement in quality of life with taking long term opiate. There are no urine drug screens,

discussion of aberrant behaviors or possible side effects as required by MTUS for opiate management. The treating physician has failed to provide the minimum requirements of documentation that are outlined for MTUS for continued opiate use. The requested Hydrocodone is not medically necessary and recommendation is for slow weaning per MTUS.