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| <b>Case Number:</b>   | CM15-0098545 |                              |            |
| <b>Date Assigned:</b> | 05/29/2015   | <b>Date of Injury:</b>       | 12/01/2009 |
| <b>Decision Date:</b> | 07/07/2015   | <b>UR Denial Date:</b>       | 04/17/2015 |
| <b>Priority:</b>      | Standard     | <b>Application Received:</b> | 05/21/2015 |

### 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: 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 50 year old female who reported an industrial injury on 12/1/2009. Her diagnoses, and/or impressions, are noted to include: chronic pain syndrome; cervical sprain/strain, spondylosis with myelopathy, stable degenerative disc disease, and status-post discectomy and fusion surgery on 11/17/10. No current imaging studies are noted. Her treatments have included acupuncture treatments, effective; medication management; and rest from work. The progress notes of 3/27/2015 reported a follow-up visit with complaints of constant, mild-moderate neck and upper back pain; headaches; and muscle stiffness/weakness; aggravated by activities and improved by medications. Objective findings were noted to include myospasms at the bilateral superior trapezius, and positive "TTP" occipital region. The physician's requests for treatments were noted to include the continuation of Vicodin, Colace, Pamelor, Cymbalta and Sonata.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Vicodin 5/500mg QTY15:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids, specific drug list, criteria for use of opioids Page(s): 76-80, 91 and 124.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Criteria for use of Opioids Page(s): 76-78, 88-89.

**Decision rationale:** The patient presents with pain and weakness in her neck and upper extremity. The patient is s/p discectomy and fusion surgery on 11/17/10. The request is for Vicodin 5/500mg #15. RFA is dated on 04/06/15. Per 03/27/15 progress report, the patient is taking Vicodin, Sonata, Cymbalta, Pamelor and Colace. "The patient meet the 4 A's of ongoing opioid use. This medication reduces pain, increase activity, no side effects, no abuse or aberrant behavior. The patient has a signed medication agreement with this office". Per 11/20/14 progress report, "Meds decrease pain from 6/10 to 3/10". The patient has been utilizing Vicodin since at least 09/24/14. Regarding work statue, the treater states that that patient is permanent and stationary. Regarding chronic opiate use, MTUS guidelines page 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. MTUS guidelines page 90 states that "Hydrocodone has a recommended maximum dose of 60mg/24 hours". In this case, the treater documents aberrant behavior/side-effects and analgesia with pain going from 8/10 to 6/10. The treater provides a general statement, stating, "Increase activity". But the treater does not address all 4 A's as required by MTUS guidelines. No specific ADL changes are noted showing significant functional improvement. No outcome measures are provided as required by MTUS. Urine drug screen is not mentioned either. Given the lack of sufficient documentation demonstrating efficacy for chronic opiate use, the patient should slowly be weaned as outlined in MTUS guidelines. The request is not medically necessary.

**Colace 250mg QTY 30:** Overturned

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines criteria for use of opioids, prophylactic treatment of constipation Page(s): 77.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Constipation Page(s): 77.

**Decision rationale:** The patient presents with pain and weakness in her neck and upper extremity. The patient is s/p discectomy and fusion surgery on 11/17/10. The request is for Colace 250mg #30. RFA is dated on 04/06/15. Per 03/27/15 progress report, the patient is taking Vicodin, Sonata, Cymbalta, Pamelor and Colace. "Meds decrease pain, allow for increase in activity tolerance, improve sleep, no side effect". Regarding work statue, the treater states that that patient is permanent and stationary. MTUS Guidelines page 76-78 discusses prophylactic medication for constipation when opiates are used. In this case, the patient has been on Vicodin and given the guidelines support for prophylactic use of stool softeners when opiates are used, the request appears to be reasonable. The patient has been utilizing Colace since at least 09/24/15 along with opiates being prescribed. Given the guidelines support for prophylactic use of medication for constipation when opiates are used, the request is medically necessary.

**Pamelor 10mg QTY 90: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Antidepressants for chronic pain, Specific Antidepressants Page(s): 15.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines antidepressant medications Page(s): 13-16.

**Decision rationale:** The patient presents with pain and weakness in her neck and upper extremity. The patient is s/p discectomy and fusion surgery on 11/17/10. The request is for PAMELOR 10MG #60. RFA is dated on 04/06/15. Per 03/27/15 progress report, the patient is taking Vicodin, Sonata, Cymbalta, Pamelor and Colace. Regarding work status, the treater states that that patient is permanent and stationary. Regarding antidepressants, MTUS guidelines page 13-16 recommends for neuropathic pain, and as a possibility for non-neuropathic pain. (Feuerstein, 1997) (Perrot, 2006) Tricyclics are generally considered a first-line agent unless they are ineffective, poorly tolerated, or contraindicated. Analgesia generally occurs within a few days to a week, whereas antidepressant effect takes longer to occur. (Saarto-Cochrane, 2005) Assessment of treatment efficacy should include not only pain outcomes, but also an evaluation of function, changes in use of other analgesic medication, sleep quality and duration, and psychological assessment. It is recommended that these outcome measurements should be initiated at one week of treatment with a recommended trial of at least 4 weeks. In this case, this patient has been utilizing Pamelor prior to 09/24/14. The 03/27/15 progress report mentions this medication's efficacy, stating "Meds decrease pain, allow for increase in activity tolerance, improve sleep, no side effect". However, MTUS guidelines require assessment of treatment efficacy including not only pain outcomes, but also an evaluation of function, changes in use of other analgesic medication, sleep quality and duration, and psychological assessment. Given the lack of sufficient documentation demonstrating efficacy for antidepressants use, the request is not medically necessary.

**Cymbalta 30mg QTY 30: Overturned**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Antidepressants for chronic pain Page(s): 13-16.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Antiepilepsy drugs (AEDs, Duloxetine (Cymbalta) Page(s): 16-17, 43-44.

**Decision rationale:** The patient presents with pain and weakness in her neck and upper extremity. The patient is s/p discectomy and fusion surgery on 11/17/10. The request is for Cymbalta 30mg #30. RFA is dated on 04/06/15. Per 03/27/15 progress report, the patient is taking Vicodin, Sonata, Cymbalta, Pamelor and Colace. Regarding work status, the treater states that that patient is permanent and stationary. MTUS guidelines page 16 and 17 state, "Duloxetine (Cymbalta) is FDA-approved for anxiety, depression, diabetic neuropathy, and fibromyalgia. Used off-label for neuropathic pain and radiculopathy. Duloxetine is recommended as a first-line option for diabetic neuropathy". MTUS guidelines page 43 and 44 states "The FDA notes

that although duloxetine was effective for reducing pain in patients with and without major depressive disorder, the degree of pain relief may have been greater in those with comorbid depression". In this case, this patient has been utilizing this medication since at least 09/24/14. The treater discusses this medication's efficacy, stating "decrease pain, allow for increase in activity tolerance, improve sleep, no side effect". Therefore, the requested Cymbalta is medically necessary.

**Sonata 10mg QTY 60:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) (updated 4/6/15), Online Version, Insomnia Treatment.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official disability guidelines Chapter Pain (Chronic) and Topic Insomnia.

**Decision rationale:** The patient presents with pain and weakness in her neck and upper extremity. The patient is s/p discectomy and fusion surgery on 11/17/10. The request is for Sonata 10mg #60. RFA is dated on 04/06/15. Per 03/27/15 progress report, the patient is taking Vicodin, Sonata, Cymbalta, Pamelor and Colace. Regarding work statue, the treater states that that patient is permanent and stationary. ODG guideline, Chapter Pain (Chronic) and Topic Insomnia, states that Sonata has "has a rapid onset of action. Short-term use (7-10 days) is indicated with a controlled trial showing effectiveness for up to 5 weeks." In this case, the patient has been utilizing Sonata prior to 09/24/14. The treater discusses this medication's efficacy, stating "decrease pain, allow for increase in activity tolerance, improve sleep, no side effect". However, ODG guidelines do not recommend long-term use of this medication. Therefore, the request is not medically necessary.