

<b>Case Number:</b>	CM15-0195168		
<b>Date Assigned:</b>	10/13/2015	<b>Date of Injury:</b>	04/10/2000
<b>Decision Date:</b>	12/18/2015	<b>UR Denial Date:</b>	10/01/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	10/05/2015

### 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: California

Certification(s)/Specialty: Physical Medicine & Rehabilitation, Pain Management

### 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 65 year old, female who sustained a work related injury on 4-10-2000. A review of the medical records shows she is being treated for total body pain. Treatments have included medications and pool therapy. Current medications include Cymbalta, Anaprox, Gabapentin, Lyrica, Tramadol, Ondansetron, Sentra AM and Savella. In the progress notes, the injured worker reports continued "total body" pain, chronic fatigue and problems sleeping. She is very depressed. On physical exam dated 3-31-15, there is no new joint swelling. Neurologic exam is normal. She is not working. The treatment plan includes requests for medication refills, for a psychological evaluation and to continue pool therapy. In the Utilization Review dated 10-1-15, the requested treatments of Anaprox 550mg. #60, 3 refills, Gabapentin 550mg. #120. 3 refills, Lyrica 75mg. #60. 3 refills, Tramadol 50mg. #90, Ondansetron 4mg. #90, Sentra AM #60 and Savella 50mg. #60 are all not medically necessary.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Anaprox 550mg #60 #3 Refills DOS 8-27-15 DS: 120: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): NSAIDs (non-steroidal anti-inflammatory drugs).

**Decision rationale:** Regarding the request for this NSAID, Chronic Pain Medical Treatment Guidelines state that NSAIDs are recommended at the lowest dose for the shortest period in patients with moderate to severe pain. Within the documentation available for review, there is no indication that this medication is providing any specific analgesic benefits (in terms of percent pain reduction, or reduction in numeric rating scale), or any objective functional improvement. Given this, the current request is not medically necessary.

**Gabapentin 550mg #120 #3 Refills DOS 8-27-15 DS: 120:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Antiepilepsy drugs (AEDs).

**Decision rationale:** Regarding request for Gabapentin, Chronic Pain Medical Treatment Guidelines state that antiepilepsy drugs are recommended for neuropathic pain. They go on to state that a good outcome is defined as 50% reduction in pain and a moderate response is defined as 30% reduction in pain. Guidelines go on to state that after initiation of treatment, there should be documentation of pain relief and improvement in function as well as documentation of side effects incurred with use. The continued use of AEDs depends on improved outcomes versus tolerability of adverse effects. Within the documentation available for review, there is no identification of any specific analgesic benefit (in terms of percent reduction in pain or reduction of NRS), and no documentation of specific objective functional improvement. Additionally, there is no discussion regarding side effects from this medication. In the absence of such documentation, the current request is not medically necessary.

**Lyrica 75mg #60 #3 Refills DOS 8-27-15 DS: 120:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Pregabalin (Lyrica).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Antiepilepsy drugs (AEDs).

**Decision rationale:** Regarding request for pregabalin (Lyrica), Chronic Pain Medical Treatment Guidelines state that antiepilepsy drugs are recommended for neuropathic pain. They go on to state that a good outcome is defined as 50% reduction in pain and a moderate response is defined as 30% reduction in pain. Guidelines go on to state that after initiation of treatment, there should be documentation of pain relief and improvement in function as well as documentation of side effects incurred with use. The continued use of AEDs depends on improved outcomes versus tolerability of adverse effects. Within the documentation available for review, there is no

identification of any specific analgesic benefit (in terms of percent reduction in pain or reduction of NRS), and no documentation of specific objective functional improvement. Additionally, there is no discussion regarding side effects from this medication. In the absence of such documentation, the currently requested pregabalin (Lyrica) is not medically necessary.

**Tramadol 50mg #90 DOS 8-27-15 DS: 30: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Opioids, criteria for use, Opioids for chronic pain, Opioids, specific drug list.

**Decision rationale:** Tramadol is a centrally acting opioid agonist and also inhibits the reuptake of serotonin and norepinephrine. On July 2, 2014, the DEA published in the Federal Register the final rule placing tramadol into schedule IV of the Controlled Substances Act. This rule became effective on August 18, 2014. The CPMTG specifies that this is a second line agent for neuropathic pain. Given its opioid agonist activity, it is subject to the opioid criteria specified on pages 76-80 of the CPMTG. With regard to this request, the California Chronic Pain Medical Treatment Guidelines state the following about on-going management with opioids: "Four domains have been proposed as most relevant for ongoing monitoring of chronic pain patients on opioids: pain relief, side effects, physical and psychosocial functioning, and the occurrence of any potentially aberrant (or nonadherent) drug-related behaviors. These domains have been summarized as the '4 A's' (analgesia, activities of daily living, adverse side effects, and aberrant drug-taking behaviors). The monitoring of these outcomes over time should affect therapeutic decisions and provide a framework for documentation of the clinical use of these controlled drugs." Guidelines further recommend discontinuing opioids if there is no documentation of improvement in function and reduction in pain. In the progress reports available for review, the requesting provider did not adequately document monitoring of the four domains. Improvement in function was not clearly outlined. This can include a reduction in work restrictions or significant gain in some aspect of the patient's activities. Furthermore, there was no discussion regarding possible aberrant drug-related behavior. There was no documentation of a signed opioid agreement, no indication that a periodic urine drug screen (UDS) was completed, and no recent CURES report was provided to confirm that the injured worker is only getting opioids from one practitioner. Based on the lack of documentation, medical necessity of this request cannot be established at this time. Although tramadol is not medically necessary at this time, it should not be abruptly halted, and the requesting provider should start a weaning schedule as he or she sees fit or supply the requisite monitoring documentation to continue this medication.

**Ondansetron 4mg #90: 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), Pain Chapter.

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

**Decision rationale:** Regarding the request for Ondansetron (Zofran), California MTUS guidelines do not contain criteria regarding the use of antiemetic medication. ODG states that antiemetics are not recommended for nausea and vomiting secondary to chronic opioid use. Guidelines go on to recommend that Ondansetron is approved for postoperative use, nausea and vomiting secondary to chemotherapy, and acute use for gastroenteritis. Within the documentation available for review, there is no indication that the patient has nausea as a result of any of these diagnoses. Additionally, there are no subjective complaints of nausea in any of the recent progress reports provided for review. In the absence of clarity regarding those issues, the currently requested Ondansetron (Zofran) is not medically necessary.

**Sentra AM #60:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation ODG: Pain Chapter.

**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, Medical food.

**Decision rationale:** Regarding the request for Sentra AM, California MTUS does not address the issue. Per ODG, "There is no known medical need for choline supplementation except for the case of long-term parenteral nutrition or for individuals with choline deficiency secondary to liver deficiency." Additionally, "Glutamic Acid" is used for treatment of hypochlohydria and achlorhydria. Treatment indications include those for impaired intestinal permeability, short bowel syndrome, cancer and critical illnesses. It is generally used for digestive disorders in complementary medicine. Within the documentation available for review, there is no documentation of a condition for which the components of Sentra AM would be supported. In the absence of such documentation, the currently requested Sentra AM is not medically necessary.

**Savella 50mg #60 DOS 8-27-15 DS: 30:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Antidepressants for chronic pain.

**Decision rationale:** Regarding the request for Savella, guidelines state that antidepressants are recommended as a 1st line option for neuropathic pain and as a possibility for non-neuropathic pain. Guidelines go on to recommend a trial of at least 4 weeks. 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 should be further noted that Savella is FDA approved for the treatment of depression as well as fibromyalgia. Within the documentation available for review, it appears that this worker is very depressed and a note from March 2015 documents the intention of the provider to refer to psychiatry. However, there is no follow-up note circa the time of this request from August 2015. Although it is very likely appropriate, this needs to be documented. Any benefit from the use of Savella should also be noted. Given the lack of documentation, this request is not medically necessary.