

<b>Case Number:</b>	CM15-0084872		
<b>Date Assigned:</b>	05/29/2015	<b>Date of Injury:</b>	04/23/2002
<b>Decision Date:</b>	09/22/2015	<b>UR Denial Date:</b>	04/07/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	05/04/2015

### 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 62-year-old female, who sustained an industrial injury on April 23, 2002. Treatment to date has included TENS unit, physical therapy and medications. Currently, the injured worker complains of pain throughout the body which is described as a numbness and tingling sensation. She reports the pain is always present throughout the day and worsens with certain activities. Rest and medication alleviate the pain. She rates her pain a 7 on a 10-point scale with medication and an 8-9 on a 10-point scale without medication. On physical examination, the injured worker has widespread trigger point pain throughout the cervical, thoracic and lumbar spine. She exhibits tenderness over the cervical spine and lumbar spine. She has widespread trigger point pain throughout her shoulders and arms bilaterally. Her left upper extremity has a decreased sensation and a weak grip. The diagnoses associated with the request include carpal tunnel syndrome, neck pain, fibromyalgia, chronic pain syndrome and upper limb causalgia. The treatment plan includes a refill of her oral medications and 4 additional percutaneous electrical nerve stimulation sessions.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Savella 100mg #60 with 2 refills:** Overturned

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines, Pain, Milnacipran (Savella).

**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 under Milnacipran (Savella).

**Decision rationale:** This patient presents with chronic neck and low back pain. The current request is for Savella 100mg #60 with 2 refills. The RFA is dated 03/03/15. Treatment to date has included TENS unit, physical therapy and medications. The patient is not working. Regarding Milnacipran -Savella-, ODG guidelines under the Pain Chapter states "FDA has now approved Milnacipran for the management of fibromyalgia. As there is little to no evidence that the cause of fibromyalgia is related to industrial injuries, the use of Savella should be restricted to documented cases of fibromyalgia as part of an appropriate treatment plan." According to progress report 03/18/15, the patient complains of pain throughout the body which is described as a numbness and tingling sensation. She rates her pain a 7/10 with medication and an 8-9/10 without medication. On physical examination, there was trigger point pain throughout the cervical, thoracic and lumbar spine, and tenderness over the cervical spine and lumbar spine. She has widespread trigger point pain throughout her shoulders and arms bilaterally and her left upper extremity has a decreased sensation and a weak grip. The listed diagnoses include carpal tunnel syndrome, neck pain, fibromyalgia, chronic pain syndrome and upper limb causalgia. The treater requests a refill of Savella as the patient responded significantly well with increased functionality and decrease in pain, for the management of her fibromyalgia. ODG guidelines indicate that Savella is an appropriate medication in those patients who possess a diagnosis of fibromyalgia as part of an appropriate treatment plan. Given the patient's diagnosis and documentation of medication efficacy, the requested Savella is medically necessary.

**Lyrice 75mg #60 with 2 refills:** Overturned

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Antiepilepsy drugs, Lyrica.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines pregabalin-Lyrica Page(s): 19-20.

**Decision rationale:** This patient presents with chronic neck and low back pain. The current request is for Lyrica 75mg #60 with 2 refills. The RFA is dated 03/03/15. Treatment to date has included TENS unit, physical therapy and medications. The patient is not working. MTUS Guidelines page 19-20 has the following regarding pregabalin-Lyrica, "pregabalin-Lyrica, no generic available, has been documented to be effective in treatment of diabetic neuropathy and postherpetic neuralgia, has FDA approval for both indications, and is considered first-line treatment for both." According to progress report 03/18/15, the patient complains of pain throughout the body which is described as a numbness and tingling sensation. She rates her pain a 7/10 with medication and an 8-9/10 without medication. On physical examination, there was trigger point pain throughout the cervical, thoracic and lumbar spine, and tenderness over the cervical spine and lumbar spine. She has widespread trigger point pain throughout her

shoulders and arms bilaterally and her left upper extremity has a decreased sensation and a weak grip. This is a request for refill of Lyrica. The patient has been prescribed Lyrica since 2011. Per report 01/22/15 and 03/03/15 Lyrica has provided the patient with "significant help with neuropathic pain." MTUS guidelines recommend Lyrica for neuropathic conditions, and this patient presents with symptoms consistent with neuropathy. In addition, the treater states that Lyrica decreases pain and provides "significant" help with her neuropathic pain. Therefore, the request is medically necessary.

**4 percutaneous electrical nerve stimulation sessions:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Percutaneous electrical nerve stimulation.

**MAXIMUS guideline:** Decision based on MTUS ACOEM Chapter 12 Low Back Complaints Page(s): 300. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter, under Percutaneous electrical nerve stimulation (PENS).

**Decision rationale:** This patient presents with chronic neck and low back pain. The current request is for 4 percutaneous electrical nerve stimulation sessions. The RFA is dated 03/03/15. Treatment to date has included TENS unit, physical therapy and medications. The patient is not working. For PENS unit, ACOEM guidelines Chapter 12 page 300 states: 'Physical modalities such as massage, diathermy, cutaneous laser treatment, ultrasound, transcutaneous electrical neurostimulation (TENS) units, percutaneous electrical nerve stimulation (PENS) units, and biofeedback have no proven efficacy in treating acute low back symptoms. Insufficient scientific testing exists to determine the effectiveness of these therapies, but they may have some value in the short term if used in conjunction with a program of functional restoration. Insufficient evidence exists to determine the effectiveness of sympathetic therapy, a noninvasive treatment involving electrical stimulation, also known as interferential therapy.' ODG-TWC Guidelines, Pain Chapter, under Percutaneous electrical nerve stimulation (PENS) Section states, 'Not recommended as a primary treatment modality, but a trial may be considered, if used as an adjunct to a program of evidence-based functional restoration, after other non-surgical treatments, including therapeutic exercise and TENS, have been tried and failed or are judged to be unsuitable or contraindicated. There is a lack of high quality evidence to prove long-term efficacy.' The treater is seeking authorization for "additional PENS 4 sessions 30 days- previous session of PENS provided improvement in pain relief and functionality, greater than 60%, and although she had some pain, patient was able to perform her ADL's comfortably." A PENS unit for 30 day trial was recommended on 12/03/14. The patient has trialed a PENS unit with documented efficacy; however, ACOEM and ODG guidelines do not support this treatment modality for chronic pain or long term use. The requested additional sessions for the treatment of chronic pain, cannot be substantiated. This request is not medically necessary.

**Norflex 100mg (unspecified qty):** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Orphenate (Norflex), Muscle relaxants (for pain).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Muscle relaxants Page(s): 63. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic) Chapter, under Muscle relaxants (for pain).

**Decision rationale:** This patient presents with chronic neck and low back pain. The current request is for Norflex 100mg (unspecified qty). The RFA is dated 03/03/15. Treatment to date has included TENS unit, physical therapy and medications. The patient is not working. For muscle relaxants for pain, MTUS Guidelines page 63 states, "Recommended non-sedating muscle relaxants with caution as a second-line option for short-term treatment of acute exacerbation in patients with chronic low back pain. Muscle relaxants may be effective in reducing pain and muscle tension and increasing mobility; however, in most LBP cases, they show no benefit beyond NSAIDs in pain and overall improvement." A short course of muscle relaxants may be warranted for patient's reduction of pain and muscle spasms. MTUS Guidelines do not recommend long-term use of sedating muscle relaxants and recommends using it for 3 to 4 days for acute spasm and no more than 2 to 3 weeks. ODG-TWC, Pain (Chronic) Chapter, Muscle relaxants (for pain) states: Antispasmodics: Orphenadrine (Norflex, Banflex, Antiflex, Mio-Rel, Orphenate, generic available): This drug is similar to diphenhydramine, but has greater anticholinergic effects. The mode of action is not clearly understood. Effects are thought to be secondary to analgesic and anticholinergic properties. This medication has been reported in case studies to be abused for euphoria and to have mood elevating effects. The patient has been prescribed this medication since at least 12/04/14. Per report 03/03/15, Norflex was helpful for a while for muscle aches and spasms; "however, efficacy has been reduced recently." Norflex is a sedating muscle relaxant and only short-term use is recommended by MTUS. Guidelines state these muscle relaxants are "abused for euphoria and to have mood elevating effects." Furthermore, it appears this medication's efficacy is diminishing with continued use. Given this patient has been using this medication chronically, with no documentation of specific efficacy and functional benefit, the request is not medically necessary.

**Norco 10/325mg #120:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids, Hydrocodone/Acetaminophen (Norco).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Medications for chronic pain, Criteria for use of Opioids Page(s): 60, 61, 76-78, 88, 89.

**Decision rationale:** This patient presents with chronic neck and low back pain. The current request is for Norco 10/325mg #120. The RFA is dated 03/03/15. Treatment to date has included TENS unit, physical therapy and medications. The patient is not working. MTUS Guidelines pages 88 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 page 77 states, 'function should include social, physical,

psychological, daily and work activities, and should be performed using a validated instrument or numerical rating scale.' According to progress report 03/18/15, the patient complains of pain throughout the body which is described as a numbness and tingling sensation. She rates her pain a 7/10 with medication and an 8-9/10 without medication. This is a request for refill of Norco. The patient has been prescribed this medication since at least 12/04/14. Progress reports 12/04/14 through 05/19/15 provide a before and after pain scale to denote a decrease in pain with utilizing medication; however, there are no specific functional improvement, changes in ADL's or change in work status to document significant functional improvement with utilizing Norco. Furthermore, there are no discussions regarding aberrant behaviors or adverse side effects as required by MTUS for opiate management. This request is not medically necessary and recommendation is for slow weaning per MTUS.

**Gabapentin 300mg #90:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Gabapentin (Neurontin), Fibromyalgia.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Gabapentin Page(s): 18, 19.

**Decision rationale:** This patient presents with chronic neck and low back pain. The current request is for Gabapentin 300mg #90. The RFA is dated 03/03/15. Treatment to date has included TENS unit, physical therapy and medications. The patient is not working. MTUS has the following regarding Gabapentin on pg. 18, 19, Anti-epilepsy Drugs section: 'Gabapentin (Neurontin, Gabarone, generic available) has been shown to be effective for treatment of diabetic painful neuropathy and post-therapeutic neuralgia and has been considered as a first-line treatment for neuropathic pain.' According to progress report 03/18/15, the patient complains of pain throughout the body which is described as a numbness and tingling sensation. She rates her pain a 7/10 with medication and an 8-9/10 without medication. This is a request for refill of Gabapentin. The patient has been prescribed this medication since at least 12/04/14. Per report 01/22/15, Lyrica provided significant help with neuropathic pain, but therapy was interrupted due to denial. "The switch to Gabapentin did not provide similar efficacy." Although this patient meets the criteria for the use of Gabapentin, further use cannot be substantiated as there is no documentation of medication efficacy. The MTUS guidelines page 60 states, 'A record of pain and function with the medication should be recorded,' when medications are used for chronic pain. Given the lack of discussion regarding medication efficacy, this request is not medically necessary.