

<b>Case Number:</b>	CM15-0194372		
<b>Date Assigned:</b>	10/08/2015	<b>Date of Injury:</b>	06/01/2011
<b>Decision Date:</b>	11/20/2015	<b>UR Denial Date:</b>	09/29/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	10/02/2015

### 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 35 year old male, who sustained an industrial injury on 6-1-2011. He reported developing pain in the left, right shoulder, and low back. Diagnoses include cervicalgia, neuropathy, and limb pain. Treatments to date include activity modification, medication therapy (medication dose, frequency, and length of time prescribed not clearly documented), physical therapy, and joint injections. On 9-22-15, he reported improved sleep with use of Belsomra. He also reported taking less of other medications while taking buprenorphine. The current medications listed included Buprenorphine 8mg, Butrans 20mcg-hr patch, Lyrica, Gralise, Belsomra, and Nucynta. The records did not documented objective assessment of medication efficacy or improvement in functional ability with use. The physical examination documented cervical tenderness. There was allodynia documented with shoulder range of motion with flinching. All fibromyalgia tender points were positive. The plan of care included radiographic imaging of the neck, and prescriptions as previously prescribed. The appeal requested authorization for Nucynta 75mg #240, Gralise 600mg #90, and Lyrica 75mg #90. The Utilization Review dated 9-29-15, modified the request to allow Nucynta 75mg #120, Gralise 600mg #45, and Lyrica 75mg #45.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Nucynta 75 mg Qty 240:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Opioids (Classification). Decision based on Non-MTUS Citation Official Disability Guidelines: Pain - Tapentadol (Nucynta).

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

**Decision rationale:** Based on a 9/22/15 progress report provided by the treating physician this patient presents with improved sleep, and better pain control. The treater has asked for Nucynta 75 mg qty 240 on 9/22/15. The diagnoses per request for authorization dated 9/22/15 include neuropathy, limb pain, and neck pain. The patient is currently using Belsomra which is working, and has improved sleep per 9/22/15 report. The patient ran out of Buprenorphine but it helped while he was taking it per 9/22/15 report. Per physical exam on 9/22/15, the patient has tight neck muscles and pain at end of range of motion of cervical rotation. Per QME dated 4/27/15, the patient is s/p unspecified right wrist surgery from 2010. The patient is currently employed with the same employer working on modified duty; however, he is currently not working due to non-available accommodation per QME dated 4/27/15. MTUS, criteria for use of opioids section, 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, criteria for use of opioids section, 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. MTUS, criteria for use of opioids section, p77, states that "function should include social, physical, psychological, daily and work activities, and should be performed using a validated instrument or numerical rating scale." MTUS, medications for chronic pain section, page 60 states that "Relief of pain with the use of medications is generally temporary, and measures of the lasting benefit from this modality should include evaluating the effect of pain relief in relationship to improvements in function and increased activity." The treater does not discuss this request in the reports provided. Patient does not have a prior history of taking Nucynta. Utilization review letter dated 9/29/15 modifies request from #240 to #120 but does not provide a rationale. The patient is currently using Buprenorphine and Butrans patches, but it is unknown when the prescription was initiated. MTUS requires appropriate discussion of all the 4A's; however, in addressing the 4A's, the treater does not discuss how this medication significantly improves patient's activities of daily living. No validated instrument is used to show analgesia. There is no UDS, no CURES and no opioid contract provided. The treater is requesting Nucynta concurrently with Buprenorphine and Butrans patches. Given the lack of documentation as required by MTUS, the request does not meet the specifications given by the guidelines. Therefore, the request is not medically necessary.

**Grallae 600 mg Qty 90:** Upheld

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

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

**Decision rationale:** Based on the 9/22/15 progress report provided by the treating physician this patient presents with improved sleep, and better pain control. The treater has asked for Grallae [Gralise] 600 MG QTY 90 on 9/22/15. The diagnoses per request for authorization dated 9/22/15 include neuropathy, limb pain, and neck pain. The patient is currently using Belsomra which is working, and has improved sleep per 9/22/15 report. The patient ran out of Buprenorphine but it helped while he was taking it per 9/22/15 report. Per physical exam on 9/22/15, the patient has tight neck muscles and pain at end of range of motion of cervical rotation. Per QME dated 4/27/15, the patient is s/p unspecified right wrist surgery from 2010. The patient is currently employed with the same employer working on modified duty; however, he is currently not working due to non-available accommodation per QME dated 4/27/15. MTUS Guidelines, Gabapentin section on pg 18, 19 has the following: Gabapentin - Neurontin, Gabarone, generic available - has been shown to be effective for treatment of diabetic painful neuropathy and postherpetic neuralgia and has been considered as a first-line treatment for neuropathic pain. MTUS Guidelines, Medications for Chronic Pain section, pg. 60, 61 states: "Before prescribing any medication for pain the following should occur: (1) determine the aim of use of the medication; (2) determine the potential benefits and adverse effects; (3) determine the patient's preference. Only one medication should be given at a time, and interventions that are active and passive should remain unchanged at the time of the medication change. A trial should be given for each individual medication. Analgesic medications should show effects within 1 to 3 days, and the analgesic effect of antidepressants should occur within 1 week. A record of pain and function with the medication should be recorded. (Mens, 2005)" In regard to the continuation of Gralise for this patient's neuropathic pain, the requesting physician has not provided adequate documentation of analgesia. This patient has been prescribed Gralise since at least 4/27/15. Progress report dated 9/22/15, which is associated with this request, does not address the efficacy of this patient's analgesic medications. Given this patient's presentation, this medication would generally be considered a first-line treatment modality. However, MTUS guidelines require at least some clear documentation of medication efficacy to substantiate continuation. In this case, no such clear documentation is provided. Therefore, the request is not medically necessary.

**Lyrica 150 mg Qty 90:** Upheld

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

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

**Decision rationale:** Based on the 9/22/15 progress report provided by the treating physician this patient presents with improved sleep, and better pain control. The treater has asked for Lyrica 150 mg qty 90 on 9/22/15. The diagnoses per request for authorization dated 9/22/15 include neuropathy, limb pain, and neck pain. The patient is currently using Belsomra which is working,

and has improved sleep per 9/22/15 report. The patient ran out of Buprenorphine but it helped while he was taking it per 9/22/15 report. Per physical exam on 9/22/15, the patient has tight neck muscles and pain at end of range of motion of cervical rotation. Per QME dated 4/27/15, the patient is s/p unspecified right wrist surgery from 2010. The patient is currently employed with the same employer working on modified duty; however, he is currently not working due to non-available accommodation per QME dated 4/27/15. MTUS Guidelines, Antiepilepsy drugs (AEDs) section, page 19-20, under Lyrica states: "Pregabalin (Lyrica) 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. This medication is designated as a Schedule V controlled substance because of its causal relationship with euphoria. This medication also has an anti anxiety effect. Pregabalin is being considered by the FDA as treatment for generalized anxiety disorder and social anxiety disorder." MTUS Guidelines, Medications for Chronic Pain section, pg. 60, 61 states: "Before prescribing any medication for pain the following should occur: (1) determine the aim of use of the medication; (2) determine the potential benefits and adverse effects; (3) determine the patient's preference. Only one medication should be given at a time, and interventions that are active and passive should remain unchanged at the time of the medication change. A trial should be given for each individual medication. Analgesic medications should show effects within 1 to 3 days, and the analgesic effect of antidepressants should occur within 1 week. A record of pain and function with the medication should be recorded. (Mens, 2005)" In regard to the continuation of Lyrica for this patient's neuropathic pain, the requesting physician has not provided adequate documentation of analgesia. This patient has been prescribed Lyrica since at least 4/27/15. Progress report dated 9/22/15, which is associated with this request, does not address the efficacy of this patient's analgesic medications. MTUS guidelines require documentation of medication efficacy to substantiate continuation. In this case, no such clear documentation is provided. Therefore, the request is not medically necessary.