

<b>Case Number:</b>	CM15-0177780		
<b>Date Assigned:</b>	09/18/2015	<b>Date of Injury:</b>	11/08/1993
<b>Decision Date:</b>	11/12/2015	<b>UR Denial Date:</b>	08/12/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	09/09/2015

### 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: New York

Certification(s)/Specialty: Internal Medicine

### CLINICAL CASE SUMMARY

The expert reviewer developed the following clinical case summary based on a review of the case file, including all medical records:

This is a 74 year old male with a date of injury on 11-8-1993. A review of the medical records indicates that the injured worker is undergoing treatment for chronic low back pain with right greater than left leg pain, neuropathic pain symptoms right greater than left, myofascial pain-spasm and poor sleep hygiene due to pain. Medical records (2-11-2015 to 8-3-2015) indicate ongoing low back pain and right leg pain. He rated his average pain seven out of ten on 2-11-2015. He rated his average pain as six out of ten from 4-8-2015 through 8-3-2015. Functional level was rated six to seven out of ten. The physical exam (8-3-2015) revealed ongoing axial baseline pain in the low back and right leg. There was ongoing numbness and tingling in his right lower extremity. Gait was antalgic. Treatment has included lumbar surgery, transcutaneous electrical nerve stimulation (TENS) unit and medications. The injured worker has been prescribed Norco, Senokot-S, Cymbalta, Dexilant and Lyrica since at least 2-11-2015. On 4-16-2015, it was noted that Oxycontin had been replaced with Hysingla. Failed medications included Nucynta, Methadone, Ambien ER, Opana ER, Fentanyl patches and Celebrex. The original Utilization Review (UR) (8-12-2015) non-certified requests for Norco, Senokot-S, Cymbalta, Hysingla, Dexilant and Lyrica (fill all on 8-4-2015 and 9-3-2015).

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Norco 10/325mg #120 (fill on 8/4/15 and 9/3/15): 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 for chronic pain. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter- Opioids.

**Decision rationale:** The California MTUS chronic pain medical treatment guidelines recommend specific guidelines for the ongoing use of narcotic pain medication to treat chronic pain. "Recommendations include the lowest possible dose be used as well as ongoing review and documentation of pain relief, functional status, appropriate medication use and its side effects. It is also recommends that providers of opiate medication document the injured worker's response to pain medication including the duration of symptomatic relief, functional improvements, and the level of pain relief with the use of the medication." The CA MTUS Guidelines define functional improvement as "a clinically significant improvement in activities of daily living or a reduction in work restrictions as measured during the history and physical exam, performed and documented as part of the evaluation and management and a reduction in the dependency on continued medical treatment." Therapies should be focused on functional restoration rather than the elimination of pain. The medical records submitted for review does not include the above recommended documentation. There were no functional improvements noted with the use of the medication. There is no change on medical dependence. Of note, discontinuation of an opioid analgesic should include a taper, to avoid withdrawal symptoms. Therefore the requested treatment: Norco 10/325mg # 120 is not medically necessary.

**Senokot-S #100 (fill on 8/4/15 and 9/3/15): Upheld**

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

**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-constipation.

**Decision rationale:** This request for this prescription is evaluated in light of the Official Disability Guidelines (ODG) for constipation. Opioid-induced constipation is a common adverse effect of long-term opioid use because of the binding of opioids to peripheral opioid receptors in the gastrointestinal tract, resulting in absorption of electrolytes and reduction in small intestine fluid. According to ODG, if opioids are determined to be appropriate for the treatment of pain then prophylactic treatment of constipation should be initiated. Senokot is stool softener, a stimulant laxative and is used to relieve occasional constipation. In this case, with non-approval of opioid use, the medical necessity of Senokot is not established. The requested medication is not medically necessary.

**Cymbalta 60mg #60 (fill on 8/4/15 and 9/3/15): 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:** According to the California MTUS Guidelines, antidepressants are indicated for the treatment of chronic musculoskeletal pain. They are recommended as a first-line option for neuropathic pain and as a possibility for non-neuropathic pain. Cymbalta (Duloxetine) is a norepinephrine and serotonin reuptake inhibitor antidepressant (SNRI). It has FDA approval for treatment of depression, generalized anxiety disorder, and for the treatment of pain related to diabetic neuropathy. In this case, there is no documentation of objective functional benefit with prior medication use. The medical necessity for Cymbalta has not been established. The requested medication is not medically necessary.

**Hysingla 40mg #30 (fill on 8/4/15 and 9/3/15): Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG-TWC) Pain Procedure Summary Online Version last updated 7/15/2015.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Opioids for chronic pain. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter- Opioids.

**Decision rationale:** According to the CA MTUS and ODG, Hysingla is an opioid analgesic indicated for moderate to moderately severe pain, and is used to manage both acute and chronic pain. The treatment of chronic pain with any opioid analgesic requires review and documentation of pain relief, functional status, appropriate medication use, and side effects. A pain assessment should include current pain, intensity of pain after taking the opiate, and the duration of pain relief. In this case, there is no documentation of the medication's functional benefit. Medical necessity of the requested item has not been established. Of note, discontinuation of an opioid analgesic should include a taper, to avoid withdrawal symptoms. The requested medication is not medically necessary.

**Dexilant 60mg #30 (fill on 8/4/15 and 9/3/15): 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, GI symptoms & cardiovascular risk.

**Decision rationale:** The CA MTUS guidelines indicate that proton pump inhibitors are recommended in those patients who are at risk for gastrointestinal events and no cardiovascular

disease. The gastrointestinal event risk factors include: age over 65 years, history of peptic ulcer, GI (gastrointestinal) bleeding or perforation, concurrent use of ASA (aspirin), corticosteroids, and/or an anticoagulant, or high dose or multiple oral NSAID (non-steroidal anti-inflammatory drug) use. There is no evidence in the medical records that this injured worker is at risk of gastrointestinal events or has any concerning GI complaints. Also there is no evidence of a history of peptic ulcer, gastrointestinal bleeding or perforation, concurrent use of aspirin, corticosteroids, anticoagulants, or high dose or multiple oral NSAID use. Based on the available information provided for review, the request for Dexilant 60mg #30 is not medically necessary and has not been established.

**Lyrica 50mg #60 (fill on 8/4/15 and 9/3/15): 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): Pregabalin (Lyrica).

**Decision rationale:** According to California MTUS Guidelines, anti-epilepsy drugs (AEDs) are a first-line treatment for neuropathic pain. Lyrica is FDA approved for diabetic neuropathy and post-herpetic neuralgia and has been used effectively for the treatment of other neuropathic pain. The guidelines indicate a good to moderate response to the use of Lyrica is a 30-50% reduction in pain. This patient has been taking Lyrica, in addition to narcotic analgesics, with no significant improvement documented. Without evidence of improvement, the guidelines recommend changing to a different first-line agent (TCA, SNRI or AED). Medical necessity for the requested medication has not been established. Of note, discontinuation of Lyrica should include a taper, to avoid withdrawal symptoms. The requested medication: Lyrica 50mg #60 is not medically necessary.