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| <b>Case Number:</b>   | CM15-0067387 |                              |            |
| <b>Date Assigned:</b> | 04/15/2015   | <b>Date of Injury:</b>       | 08/22/2002 |
| <b>Decision Date:</b> | 05/19/2015   | <b>UR Denial Date:</b>       | 03/24/2015 |
| <b>Priority:</b>      | Standard     | <b>Application Received:</b> | 04/09/2015 |

### 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: Montana

Certification(s)/Specialty: Preventive Medicine, Occupational 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:

The injured worker (IW) is a 67-year-old female who sustained an industrial injury on 08/22/2002. Diagnoses include status post left total knee replacement, degenerative joint disease of the right knee, neck pain status post cervical spine fusion, impingement syndrome and rotator cuff tendinosis of the left and right shoulders and herniated disc of the lumbar spine. Treatment to date has included medications, cortisone and Synvisc knee injections, TENS unit and physical therapy. Diagnostics included x-rays and MRIs. According to the Primary Treating Physician's Initial Narrative Report dated 3/9/15, the IW reported constant sharp to burning low back pain, rated 4/10, which radiated into the buttocks and left hip and also constant mild to sharp pain in the left knee. A request was made for Nucynta 75mg, Lidoderm patches and Voltaren gel 1% for pain.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**One (1) prescription of Nucynta 75mg #90:** Overturned

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 75 and 78. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain, Nucynta.

**Decision rationale:** The ODG guidelines note that Nucynta ER (tapentadol) is recommended only as second line therapy for patients who develop intolerable adverse effects with first line opioids. The MTUS states that opioids are not recommended as first line therapy for neuropathic pain. Opioids are suggested for neuropathic pain that has not responded to first line recommendations including antidepressants and anticonvulsants. The MTUS states that reasonable alternatives to opioid use should be attempted. There should be a trial of non-opioid analgesics. When subjective complaints do not correlate with clinical studies a second opinion with a pain specialist and a psychological assessment should be obtained. The lowest possible dose should be prescribed to improve pain and function. Ongoing use of opioids requires review and documentation of pain relief, functional status, appropriate medication use, and side effects. Pain assessment should include: the least reported pain over the period since the last assessment; average pain; intensity of pain after taking the opioid; how long it takes for pain relief; and how long pain relief lasts. 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 non-adherent) 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. (Passik, 2000) In this case the medical records do document pain relief from 6-8/10 to 4-5/10, which has allowed some specific functional improvement. Utilization Review on 3/24/15 modified the request for Nucynta 75mg #90, approving 68 only. The records show that a pain contract is in place with no aberrant drug behaviors and urine drug screening has shown appropriate results. The injured worker is allergic to morphine, Demerol and hydrocodone. She is unable to use oral non-steroidal anti-inflammatory drugs. The request for Nucynta 75mg #90 is medically necessary.

**One (1) prescription of Lidoderm patches #30 with 2 refills:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Lidoderm (Lidocaine patch).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical analgesics Page(s): 111-112. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain, Lidoderm patches.

**Decision rationale:** The MTUS states that topical analgesics are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. Their use is largely experimental with few randomized controlled trials to determine efficacy or safety. Topical lidocaine, in the formulation of a dermal patch (Lidoderm) has been designated for orphan status by the FDA for neuropathic pain. Lidoderm is also used off label for diabetic neuropathy. No other commercially approved topical formulations of lidocaine are indicated for

neuropathic pain. Further research is needed to recommend this treatment for chronic neuropathic pain disorders other than postherpetic neuralgia. The ODG guidelines also state that Lidoderm patches are not a first-line treatment and are FDA approved only for postherpetic neuralgia. ODG Criteria for use of Lidoderm patches include: (a) Recommended for a trial if there is evidence of localized pain that is consistent with a neuropathic etiology. (b) There should be evidence of a trial of first-line neuropathy medications (tri-cyclic or SNRI antidepressants or an AED such as gabapentin or Lyrica). (c) This medication is not generally recommended for treatment of osteoarthritis or treatment of myofascial pain/trigger points. (d) An attempt to determine a neuropathic component of pain should be made if the plan is to apply this medication to areas of pain that are generally secondary to non-neuropathic mechanisms (such as the knee or isolated axial low back pain). One recognized method of testing is the use of the Neuropathic Pain Scale. (e) The area for treatment should be designated as well as number of planned patches and duration for use (number of hours per day). (f) A Trial of patch treatment is recommended for a short-term period (no more than four weeks). (g) It is generally recommended that no other medication changes be made during the trial period. (h) Outcomes should be reported at the end of the trial including improvements in pain and function, and decrease in the use of other medications. If improvements cannot be determined, the medication should be discontinued. In this case there is no documentation of failure of antidepressant or anticonvulsant treatment. There is no diagnosis of postherpetic neuralgia. A trial of short term use with specific documentation of outcomes related to its use is not provided. The request for Lidoderm patches #30 with 2 refills is not consistent with the guidelines noted above and is not medically necessary.

**One (1) prescription of Voltaren gel 1% 120gm with 2 refills:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical NSAIDs.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical analgesics Page(s): 111-113. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Voltaren Gel.

**Decision rationale:** Voltaren gel is a topical analgesic containing diclofenac, a non-steroidal anti-inflammatory (NSAID) drug. The MTUS recommends topical analgesics primarily for neuropathic pain when trials of antidepressants and anticonvulsants have failed. They are largely experimental in use with few randomized controlled trials to determine efficacy or safety. Topical analgesics have been shown to have some benefit in the first 2 weeks of treatment for osteoarthritis but with diminishing effect after that. The efficacy in clinical trials for this treatment modality has been inconsistent and most studies are small and of short duration. Topical NSAIDs have been shown in meta-analysis to be superior to placebo during the first 2 weeks of treatment for osteoarthritis, but either not afterward, or with a diminishing effect over another 2-week period. (Lin, 2004) (Bjordal, 2007) (Mason, 2004) When investigated specifically for osteoarthritis of the knee, topical NSAIDs have been shown to be superior to placebo for 4 to 12 weeks. Topical analgesics containing non-steroidal anti-inflammatory agents are recommended only as a short-term option for chronic musculoskeletal pain associated with arthritis and tendinitis but there is little evidence for use in osteoarthritis or musculoskeletal pain

involving the spine, hip or shoulder. It is also not recommended for neuropathic pain. Efficacy in clinical trials have been inconsistent with most studies being small and of short duration. There are no long-term studies of their effectiveness or safety. The FDA has approved Voltaren Gel 1% (diclofenac) with indications for relief of osteoarthritis pain in joints that lend themselves to topical treatment (ankle, elbow, foot, hand, knee, and wrist). It has not been evaluated for treatment of the spine, hip or shoulder. Maximum dose should not exceed 32 g per day (8 g per joint per day in the upper extremity and 16 g per joint per day in the lower extremity). The most common adverse reactions were dermatitis and pruritus. (Voltaren package insert). Additional adverse effects for NSAIDs include GI symptoms, cardiovascular risk, hypertension and impaired renal function. The ODG guidelines note that Voltaren Gel is not recommended as a first-line treatment. Voltaren Gel is recommended for osteoarthritis after failure of an oral NSAID, or contraindications to oral NSAIDs, or for patients who cannot swallow solid oral dosage forms, and after considering the increased risk profile with diclofenac, including topical formulations. According to FDA MedWatch, post-marketing surveillance of Voltaren Gel has reported cases of severe hepatic reactions, including liver necrosis, jaundice, fulminant hepatitis with and without jaundice, and liver failure. In this case the use of Voltaren Gel has been long term since at least January 2014. It is recommended for short-term use with no long-term studies of their effectiveness or safety. There is little evidence for use in osteoarthritis or musculoskeletal pain involving the spine, hip or shoulder. Continued use is not consistent with the MTUS and ODG guidelines. The request for Voltaren Gel 1% 120gm with 2 refills is not medically necessary.