

<b>Case Number:</b>	CM14-0061866		
<b>Date Assigned:</b>	08/08/2014	<b>Date of Injury:</b>	10/22/1999
<b>Decision Date:</b>	09/11/2014	<b>UR Denial Date:</b>	04/22/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	05/03/2014

### 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. The expert reviewer is Board Certified in General Preventive Medicine and is licensed to practice in Indiana. 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/services. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

### 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 employee is a 51 year old male with date of injury of 10/22/1999. A review of the medical records indicates that the patient is undergoing treatment for lumbar disc displacement without myelopathy and knee pain. Subjective complaints include back and knee pain. Objective findings include L4-L5 1.5 mm diffuse disc bulge, and spasm and guarding in lumbar spine; right knee joint line tenderness. Treatment has included Lidoderm patch, Ketamine cream, Protonix, Mirtazapine, Nabumetone, and Tramadol/APAP, and a TENS unit. The utilization review dated 4/22/2014 non-certified a Lidoderm patch, Ketamine cream, Protonix, Mirtazapine, Nabumetone, and Tramadol/APAP.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Lidoderm 5% patch (DOS: 03/17/14): Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Lidoderm patches Page(s): 56-57. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: UpToDate.com, Lidocaine (topical).

**Decision rationale:** Chronic Pain Medical Treatment Guidelines state "Lidoderm is the brand name for a lidocaine patch produced by Endo Pharmaceuticals. Topical lidocaine may be recommended for localized peripheral pain after there has been evidence of a trial of first-line therapy (tri-cyclic or SNRI anti-depressants or an AED such as gabapentin or Lyrica). This is not a first-line treatment and is only FDA approved for post-herpetic neuralgia. Further research is needed to recommend this treatment for chronic neuropathic pain disorders other than post-herpetic neuralgia. Formulations that do not involve a dermal-patch system are generally indicated as local anesthetics and anti-pruritics. For more information and references, see Topical analgesics." ODG further details, "Criteria for use of Lidoderm patches:(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 anti-depressants 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.(i) Continued outcomes should be intermittently measured and if improvement does not continue, lidocaine patches should be discontinued."Medical documents provided do not indicate that the use would be for post-herpetic neuralgia. Additionally, treatment notes did not detail failures of other first-line therapy used and what the clinical outcomes resulted. As such, the request for Lidoderm 5% patches is not medically necessary.

**Ketamine 5% Cream 60 gm (DOS: 03/17/14): Upheld**

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

**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) Pain, Compound creams.

**Decision rationale:** ODG recommends usage of topical analgesics as an option, but also further details "primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed." The medical documents do not indicate failure of antidepressants or anticonvulsants. MTUS states, "There is little to no research to support the use of many of these agents. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." MTUS states regarding topical Ketamine, "Under study: Only recommended for treatment of neuropathic pain in refractory cases in which all primary and secondary treatment has been exhausted." Medical records do not indicate that all primary

and secondary treatment options have been exhausted. Therefore, Katamine 5% cream 60 gm is not medically necessary.

**Pantoprazole-Protonix 20 mg #60 (DOS: 03/17/14): Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms & cardiovascular risk.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms & cardiovascular risk Page(s): 68-69. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic), NSAIDs, GI symptoms & cardiovascular risk.

**Decision rationale:** MTUS states "Determine if the patient is at risk for gastrointestinal events: (1) age > 65 years; (2) history of peptic ulcer, GI bleeding or perforation; (3) concurrent use of ASA, corticosteroids, and/or an anticoagulant; or (4) high dose/multiple NSAID (e.g., NSAID + low-dose ASA)." And "Patients at intermediate risk for gastrointestinal events and no cardiovascular disease :(1) A non-selective NSAID with either a PPI (Proton Pump Inhibitor, for example, 20 mg omeprazole daily) or misoprostol (200 g four times daily) or (2) a Cox-2 selective agent. Long-term PPI use (> 1 year) has been shown to increase the risk of hip fracture (adjusted odds ratio 1.44)." ODG states "If a PPI is used, omeprazole OTC tablets or lansoprazole 24HR OTC are recommended for an equivalent clinical efficacy and significant cost savings. Products in this drug class have demonstrated equivalent clinical efficacy and safety at comparable doses, including esomeprazole (Nexium), lansoprazole (Prevacid), omeprazole (Prilosec), pantoprazole (Protonix), dexlansoprazole (Dexilant), and rabeprazole (Aciphex). (Shi, 2008) A trial of omeprazole or lansoprazole is recommended before Nexium therapy. The other PPIs, Protonix, Dexilant, and Aciphex, should also be second-line. According to the latest AHRQ Comparative Effectiveness Research, all of the commercially available PPIs appeared to be similarly effective. (AHRQ, 2011) ". The medical documents provided do not establish the patient has reflux diseases and the treating physician has provided no documentation of a failed trial of omeprazole or lansoprazole. As such, the request for Protonix 20 mg #60 is not medically necessary.

**Mirtazapine-Remeron 15mg #60 (DOS: 03/17/14): Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Antidepressants for chronic pain and Specific Antidepressants.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Antidepressants for chronic pain Page(s): 13-16.

**Decision rationale:** Mirtazapine is an antidepressant. The above cited guidelines state that this class of medications are "recommended as a first line option for neuropathic pain, and as a possibility for non-neuropathic pain. (Feuerstein, 1997) (Perrot, 2006) Tricyclics are generally considered a first-line agent unless they are ineffective, poorly tolerated, or contraindicated. Analgesia generally occurs within a few days to a week, whereas antidepressant effect takes

longer to occur. (Saarto- Cochrane, 2005) 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 is recommended that these outcome measurements should be initiated at one week of treatment with a recommended trial of at least 4 weeks. The optimal duration of treatment is not known because most double-blind trials have been of short duration (6-12 weeks). It has been suggested that if pain is in remission for 3-6 months, a gradual tapering of anti-depressants may be undertaken."In this case, the medical documentation does not show an assessment of treatment efficacy from the previous use of this medication, including any comments on functional improvement, psychological assessment, or pain reduction. Therefore, Mirtazapine is not medically necessary.

**Nabumetone-Relafen 500 mg #90 (DOS: 03/17/14): Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs (non-steroidal anti-inflammatory drugs).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDS; Relafen Page(s): 67-72.

**Decision rationale:** MTUS recommends the use of NSAIDS for the acute exacerbation of back pain at the lowest effective dose for the shortest amount of time due to the increased cardiovascular risk, renal, hepatic and GI side effects associated with long term use. MTUS states "Nabumetone (Relafen, generic available): 500, 750 mg. Dosing: Osteoarthritis: The recommended starting dose is 1000 mg PO. The dose can be divided into 500 mg PO twice a day. Additional relief may be obtained with a dose of 1500 mg to 2000 mg per day. The maximum dose is 2000 mg/day. Patients weighing less than 50 kg may be less likely to require doses greater than 1000 mg/day. The lowest effective dose of nabumetone should be sought for each patient. Use for moderate pain is off-label. (Relafen Package Insert)". The patient has been prescribed Relafen without any documentation of improvement in pain, quality of life, or functionality. There is no documentation of continued acute exacerbations of back pain. As such, the request for Relafen 500 MG # 90 is not medically necessary.

**Tramadol/APAP 37.5/325 mg #90 (DOS: 03/17/14): Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Criteria for use for a therapeutic trial of opioids.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids, Tramadol, Ultram Page(s): 74-96, 113, 123. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic) - Medications for acute pain (analgesics), Tramadol (Ultram®).

**Decision rationale:** Ultram is the brand name version of tramadol, which is classified as central acting synthetic opioids. MTUS states regarding tramadol that "A therapeutic trial of opioids should not be employed until the patient has failed a trial of non-opioid analgesics. Before initiating therapy, the patient should set goals, and the continued use of opioids should be

contingent on meeting these goals." ODG further states, "Tramadol is not recommended as a first-line oral analgesic because of its inferior efficacy to a combination of Hydrocodone/acetaminophen." The treating physician did not provide sufficient documentation that the patient has failed his trial of non-opioid analgesics at the time of prescription or in subsequent medical notes. Additionally, no documentation was provided which discussed the setting of goals for the use of tramadol prior to the initiation of this medication. As such, the request for Tramadol/APAP #90 is not medically necessary.