

<b>Case Number:</b>	CM15-0121459		
<b>Date Assigned:</b>	07/09/2015	<b>Date of Injury:</b>	01/01/2014
<b>Decision Date:</b>	10/06/2015	<b>UR Denial Date:</b>	06/09/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	06/22/2015

### 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: Emergency 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 is a 49-year-old female, who sustained an industrial injury on 01/01/2014. On provider visit dated 04/07/2015, the injured worker has reported right shoulder pain, bilateral wrist pain with numbness and tingling. On examination of the right shoulder range of motion was decreased. The diagnoses have included rotator cuff syndrome-right shoulder and bilateral carpal tunnel syndrome. Treatment to date has included medication. The injured worker received a Toradol and Vitamin B12 injection during visit. The provider requested Cyclobenzaprine Hydrochloride, Xanax, Naproxen Sodium, Norco, Tramadol, Terocin-Capsaicin, Terocin pain patch, Theramine, Sentra AM, Sentra PM, Gabadone and Toradol/B12 injection.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Cyclobenzaprine Hydrochloride 7.5mg #60:** Upheld

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

C. C. R. 9792.20 - 9792.26 (Pages: 41-42 of 127).

**Decision rationale:** The request is for the use of Cyclobenzaprine. This medication is classified as a muscle relaxant and central nervous system depressant with side effects including drowsiness and dizziness. The MTUS guidelines states that it is indicated for short term use for low back pain. The effect seems to be greatest the first 4 days of use, which suggests that treatment should be brief. In this case, due to the duration of treatment, further use would not be indicated. As such, the request is not medically necessary.

**Xanax 1mg #60:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 8 C. C. R. 9792.20 - 9792.26(pages 24 of 127).

**Decision rationale:** The request is for the use of a medication in the category of benzodiazepines. It is usually indicated to treat anxiety disorders but has been used short-term as a muscle relaxant. The MTUS guidelines state the following: Not recommended for long-term use because long-term efficacy is unproven and there is a risk of dependence. Most guidelines limit use to 4 weeks. Their range of action includes benzodiazepines are the treatment of choice in very few conditions. Tolerance to hypnotic effects develops rapidly. Tolerance to anxiolytic effects occurs within months and long-term use may actually increase anxiety. A more appropriate treatment for anxiety disorder is an antidepressant. Tolerance to anticonvulsant and muscle relaxant effects occurs within weeks. (Baillargeon, 2003) (Ashton, 2005) In this case, a medication in this class would not be advised for continued use due to the duration of therapy. As such, the request is not medically necessary. All benzodiazepine medications should be titrated down slowly to prevent an acute withdrawal syndrome.

**Naproxen Sodium 550mg #60:** Upheld

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

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic) NSAIDs (non-steroidal anti-inflammatory drugs).

**Decision rationale:** The request is for the use of a medication in the NSAID class. The ODG state the following regarding this topic: Specific recommendations: Osteoarthritis (including knee and hip): Recommended at the lowest dose for the shortest period in patients with moderate to severe pain. Acetaminophen may be considered for initial therapy for patients with mild to moderate pain, and in particular, for those with gastrointestinal, cardiovascular or renovascular risk factors. NSAIDs appear to be superior to acetaminophen, particularly for patients with moderate to severe pain. There is no evidence to recommend one drug in this class over another based on efficacy. In particular, there appears to be no difference between traditional NSAIDs and COX-2 NSAIDs in terms of pain relief. The main concern of selection is based on adverse effects. COX-2 NSAIDs have fewer GI side effects at the risk of increased cardiovascular side effects, although the FDA has concluded that long-term clinical trials are best interpreted to suggest that cardiovascular risk occurs with all NSAIDs and is a class effect

(with naproxyn being the safest drug). There is no evidence of long-term effectiveness for pain or function. (Chen, 2008) (Laine, 2008) Back Pain - Acute low back pain & acute exacerbations of chronic pain: Recommended as a second-line treatment after acetaminophen. In general, there is conflicting to negative evidence that NSAIDs are more effective than acetaminophen for acute LBP. (van Tulder, 2006) (Hancock, 2007) For patients with acute low back pain with sciatica a recent Cochrane review (including three heterogeneous randomized controlled trials) found no differences in treatment with NSAIDs vs. placebo. In patients with axial low back pain this same review found that NSAIDs were not more effective than acetaminophen for acute low-back pain, and that acetaminophen had fewer side effects. (Roelofs-Cochrane, 2008) The addition of NSAIDs or spinal manipulative therapy does not appear to increase recovery in patients with acute low back pain over that received with acetaminophen treatment and advice from their physician. (Hancock, 2007) Back Pain - Chronic low back pain: Recommended as an option for short-term symptomatic relief. A Cochrane review of the literature on drug relief for low back pain (LBP) suggested that NSAIDs were no more effective than other drugs such as acetaminophen, narcotic analgesics, and muscle relaxants. The review also found that NSAIDs had more adverse effects than placebo and acetaminophen but fewer effects than muscle relaxants and narcotic analgesics. In addition, evidence from the review suggested that no one NSAID, including COX-2 inhibitors, was clearly more effective than another. (Roelofs-Cochrane, 2008) See also Anti-inflammatory medications. Neuropathic pain: There is inconsistent evidence for the use of these medications to treat long-term neuropathic pain, but they may be useful to treat breakthrough pain and mixed pain conditions such as osteoarthritis (and other nociceptive pain) in patients with neuropathic pain. (Namaka, 2004) (Gore, 2006) See NSAIDs, GI symptoms & cardiovascular risk; NSAIDs, hypertension and renal function; & Medications for acute pain (analgesics). Besides the above well-documented side effects of NSAIDs, there are other less well-known effects of NSAIDs, and the use of NSAIDs has been shown to possibly delay and hamper healing in all the soft tissues, including muscles, ligaments, tendons, and cartilage. (Maroon, 2006) The risks of NSAIDs in older patients, which include increased cardiovascular risk and gastrointestinal toxicity, may outweigh the benefits of these medications. (AGS, 2009) As stated above, acetaminophen would be considered first-line treatment for chronic pain. In this case, the use of an NSAID is not advised. This is secondary to the duration of use and significant side effect profile. Also, the use of NSAIDs is known to delay the healing of soft tissue including ligaments, tendons, and cartilage. As such, the request is not medically necessary.

**Norco 5/325mg #30:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids. C.C.R. 9792.20-9792.26 (page 78 of 127).

**Decision rationale:** The request is for the use of a medication in the opioid class. The MTUS guidelines state that for ongoing treatment with a pharmaceutical in this class, certain requirements are necessary. This includes not only adequate pain control, but also functional improvement. Four domains have been proposed for management of patients on opioids. This includes pain relief, side effects, physical and psychosocial functioning, and the occurrence of any potentially aberrant drug-related behaviors. In this case, there is inadequate documentation of persistent functional improvement which should eventually lead to medication discontinuation. As such, the request is not medically necessary. All opioid medications should be titrated down slowly in order to prevent a significant withdrawal syndrome.

**Tramadol 50mg #30:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines. The Expert Reviewer based his/her decision on the MTUS page 8 C. C. R. 9792.20 - 9792.26 (pages 80-83 of 127) Page(s): 8 C.C.R. 9792.20 - 9792.26 (pages 80-83 of 127).

**Decision rationale:** Tramadol is a pain medication in the category of a centrally acting analgesic. They exhibit opioid activity and a mechanism of action that inhibits the reuptake of serotonin and norepinephrine. Centrally acting drugs are reported to be effective in managing neuropathic type pain although it is not recommended as first line therapy. The side effect profile is similar to opioids. For chronic back pain, it appears to be efficacious for short term pain relief, but long term (>16 weeks) results are limited. It also did not appear to improve function. The use of tramadol for osteoarthritis is indicated for short term use only (<3 months) with poor long-term benefit. In this case, the patient does not meet the qualifying criteria. This is secondary to the duration of use, with this medication being indicated on a short-term basis only. As such, the request is not certified.

**Terocin 120ml: Capsaicin 0.025%:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 8 C. C. R. 9792.20 - 9792.26 (pages 111 to 113 of 127).

**Decision rationale:** The request is for the use of a compounded medication for topical use to aid in pain relief. These products contain multiple ingredients which each have specific properties and mechanisms of action. The MTUS guidelines state the following: "Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." In this case, the compounded topical treatment contains an NSAID. Qualifying factors for this product is indicated by the following per the guidelines: 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. Indications: Osteoarthritis and tendinitis, in particular, that of the knee and elbow or other joints that are amenable to topical treatment: Recommended for short-term use (4-12 weeks). There is little evidence to utilize topical NSAIDs for treatment of osteoarthritis of the spine, hip or shoulder. FDA-approved agents: Voltaren Gel 1% (diclofenac): Indicated 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. In this case, as stated above, the patient would not qualify for the use of a topical NSAID. This is based on the treatment duration. As such, the request is not medically necessary.

**Terocin pain patch #20:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 8 C. C. R. 9792.20-9792.26 (pages 111 to 113 of 127).

**Decision rationale:** The request is for the use of a compounded medication for topical use to aid in pain relief. These products contain multiple ingredients which each have specific properties and mechanisms of action. The MTUS guidelines state the following: "Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." In this case, the compounded topical treatment contains an NSAID. Qualifying factors for this product is indicated by the following per the guidelines: 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. Indications: Osteoarthritis and tendinitis, in particular, that of the knee and elbow or other joints that are amenable to topical treatment: Recommended for short-term use (4-12 weeks). There is little evidence to utilize topical NSAIDs for treatment of osteoarthritis of the spine, hip or shoulder. FDA-approved agents: Voltaren Gel 1% (diclofenac): Indicated 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. In this case, as stated above, the patient would not qualify for the use of a topical NSAID. This is based on the treatment duration. As such, the request is not medically necessary.

**Theramine #90:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Medical food section.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic)Theramine.

**Decision rationale:** The request is for the use of Theramine. The Official Disability Guidelines state the following regarding this topic: Not recommended for the treatment of chronic pain. Theramine is a medical food that contains 5-hydroxytryptophan 95%, choline bitartrate, L-arginine, histidine, L-glutamine, L-serine, gamma-aminobutyric acid (GABA), whey protein concentrates, grape seed extract 85%, cinnamon, and cocoa (theobromine 6%). It is intended for use in the management of pain syndromes that include acute pain, chronic pain, fibromyalgia, neuropathic pain, and inflammatory pain. The proposed mechanism of action is that it increases the production of serotonin, nitric oxide, histamine, and gamma-aminobutyric acid by providing these precursors. (Micromedex, 2015) See Medical food. Under this entry discussions of the various components of this product are given. The entries for 5-hydroxytryptophan, choline bitartrate, L-arginine, histidine, L-glutamine, L-serine and GABA are given and all indicate there is no role for these supplements as treatment for chronic pain. In this case, the use of this medication is not supported by the guidelines. This is secondary to poor clinical evidence regarding efficacy in chronic pain. As such, the request is not medically necessary.

**Sentra AM #60: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Medical food section.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) PainSentra.

**Decision rationale:** The request is for the use of Sentra which is a blend of multiple supplements. The Official Disability Guidelines state the following regarding this topic: Not recommended. Sentra PM is a medical food from [REDACTED], CA, intended for use in management of sleep disorders associated with depression. It is a proprietary blend of choline bitartrate, glutamate, and 5-hydroxytryptophan, hawthorn berry, cocoa, ginkgo biloba, and acetyl L-carnitine. See Medical food, Choline, Glutamic Acid, & 5-hydroxytryptophan. In this case, the use of this medication is not indicated. As stated above, there is limited evidence to support its effectiveness. As such, the request is not medically necessary.

**Sentra PM #60: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Medical food section.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Sentra.

**Decision rationale:** The request is for the use of Sentra which is a blend of multiple supplements. The Official Disability Guidelines state the following regarding this topic: Not recommended. Sentra PM is a medical food from [REDACTED], CA, intended for use in management of sleep disorders associated with depression. It is a proprietary blend of choline bitartrate, glutamate, and 5-hydroxytryptophan, hawthorn berry, cocoa, ginkgo biloba, and acetyl L-carnitine. See Medical food, Choline, Glutamic Acid, & 5-hydroxytryptophan. In this case, the use of this medication is not indicated. As stated above, there is limited evidence to support its effectiveness. As such, the request is not medically necessary.

**Gabadone #60: Upheld**

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

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic) Gabadone.

**Decision rationale:** The request is for the use of Gabadone. This is a medical food which is an amino acid blend. The Official Disability Guidelines state the following regarding this topic: Not recommended. GABAdone is a Medical food from Physician Therapeutics, Los Angeles, CA, that is a proprietary blend of choline bitartrate, glutamic acid, 5-hydroxytryptophan, GABA, grape seed extract, griffonia extract, whey protein, valerian extract, ginkgo biloba and cocoa. It is intended to meet the nutritional requirements for sleep disorders and sleep disorders associated with insomnia. See Medical food, Choline, Glutamic Acid, 5-hydroxytryptophan, and Gamma-aminobutyric acid (GABA). In these entries it is noted that there is no peer-reviewed research in humans to support the use of choline or glutamic acid for treatment of either anxiety or sleep disorder. There is inconclusive evidence for the use of 5-hydroxy tryptophan as a treatment for anxiety. GABA does not cross the blood-brain barrier so this supplement will not replace drugs that work in the brain by a GABA-related mechanism. There is no quality evidence to support use in anxiety. Sleep disorders: Not recommended for this indication based on limited available research. There is one randomized, placebo-controlled trial of GABAdone for treatment of sleep disorder in 18 subjects in a 7-day study. There is no analysis comparing the two groups. Improvement was noted in time to fall asleep-sleep latency. Hours slept improved in the treated group, but never reached the baseline level found in the placebo group (6.83 hours in the GABAdone group and 7.11 hours in the placebo group at day 7). The number of awakenings was associated with apneic events and decreased in the treated group. Again, there was no description of the baseline status of the subjects, including weight or history of sleep apnea. There were other numerous baseline differences for which statistical significance was not given (minutes awake during awakenings, restorative sleep and AM grogginess) or no description of baseline at all. The study was described as a "pilot" in the conclusion. (Shell, 2010) As stated above the use of this product is not recommended. This is secondary to poor clinical evidence regarding efficacy. As such, the request is not medically necessary.

**Toradol/B12 injection provided on 3/31/15: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain Chapter; Ketorolac (Toradol) and Vitamin B.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Pain (Chronic) NSAIDs, specific drug list & adverse effects Page(s): Pain (Chronic) NSAIDs, specific drug list & adverse effects.

**Decision rationale:** The request is for the use of ketorolac intramuscular injection for pain relief. The MTUS guidelines are silent regarding this issue. The ODG guidelines state the following: Ketorolac (Toradol, generic available): 10 mg. Boxed Warning: The oral form is only recommended for short-term (up to 5 days) in management of moderately severe acute pain that requires analgesia at the opioid level and only as continuation following IV or IM dosing, if necessary. This medication is not indicated for minor or chronic painful conditions. Increasing doses beyond a daily maximum dose of 40 mg will not provide better efficacy, and will increase the risk of serious side effects. The FDA boxed warning would relegate this drug to second-line use unless there were no safer alternatives. Dosing: Acute pain (transition from IV or IM) for adults < 65 years of age: 20mg PO followed by 10mg PO every 4 to 6 hours (max 40 mg/day). An oral formulation should not be given as an initial dose. (Toradol Package Insert) The FDA has approved a nasal formulation of ketorolac (Sprix) for short-term pain management. (FDA, 2010) As indicated above, this patient does not qualify for the use of ketorolac. This is secondary to the duration of use with the guidelines stating that it is not to be given for chronic painful conditions. As such, the request is not medically necessary.