

<b>Case Number:</b>	CM14-0063724		
<b>Date Assigned:</b>	08/13/2014	<b>Date of Injury:</b>	10/15/2012
<b>Decision Date:</b>	09/11/2014	<b>UR Denial Date:</b>	04/15/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	05/06/2014

### 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 Physical Medicine and Rehabilitation, has a subspecialty in Interventional Spine and is licensed to practice in California. 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:

The patient is a 46-year-old male with a date of injury of 10/15/2012. The listed diagnoses per [REDACTED] are headaches, cervical disk displacement (HNP), rule out cervical spine radiculopathy, thoracic spine pain, lumbar disk displacement (HNP), and rule out lumbar radiculopathy. According to progress report 03/31/2014, the patient presents with sharp headaches, achy neck pain, radicular mid back pain, and stabbing low back pain with muscle spasms. The low back pain is moderate to severe and radiates to the right lower extremity with numbness and tingling to the right thigh. The patient states the symptoms persist, but the medications do offer him temporary relief and improve his ability to have restful sleep. Examination of the cervical spine revealed +2 tender suboccipital and decreased range of motion. Thoracic spine exam revealed tenderness over the bilateral thoracic paraspinals and joints. There is decreased range of motion and motor strength noted. Examination of the lumbar spine revealed bilateral lumbar paraspinal muscle guarding, decreased range of motion, and positive straight leg raise on the right at 50 degrees. There is diminished sensation at L3 and L4, the right lower extremity. The provider is requesting the patient continue chiropractic and acupuncture treatment 3 times a week for 6 weeks, localized intense neurostim therapy 1 time a week for 6 weeks, consultation with pain management specialist regarding epidural steroid injection for the lumbar spine, topical cream Ketoprofen 20% gel 120 g, topical cream Cyclophene 5% gel 120 g, Synapryn 10 mg/mL oral suspension 500 mL, Tabradol 1 mg/mL oral suspension 250 mL, Deprizine 15 mg/mL oral suspension 250 mL, Dicopanol 5 mg/mL oral suspension 150 mL, and Fanatrex 25 mg/mL oral suspension 450 mL. Utilization Review denied the requests on 04/15/2014.

## IMR ISSUES, DECISIONS AND RATIONALES

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

**Chiropractic therapy for the lumbar spine (frequency/duration unspecified): Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Manual therapy & manipulation Page(s): 58-60.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Manual therapy & manipulation Page(s): 58, 59.

**Decision rationale:** This patient presents with sharp headaches, achy neck pain, radicular mid back pain, and stabbing low back pain with muscle spasms. The provider is requesting "continue chiropractic and acupuncture treatment for cervical spine and lumbar spine 3 times 6 weeks." The MTUS Guidelines recommend as an optional trial of 6 visits over 2 weeks with evidence of objective functional improvement, total of up to 18 visits over 6 weeks. Review of the medical file indicates the patient has had prior chiropractic treatment. On 12/06/2013, provider recommended patient continue chiropractic therapy 3 times a week for 6 weeks. In this case, there is no documentation of improvement from prior treatment. Furthermore, the provider does not discuss return to work plan or decrease of medication from prior treatments. Given the lack of discussion of improvement from prior chiropractic visits, additional treatments cannot be recommended. Therefore, the request is not medically necessary.

**Acupuncture for lumbar spine (frequency/duration unspecified): Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Acupuncture Treatment Guidelines, Chronic Pain Treatment Guidelines.

**Decision rationale:** This patient presents with sharp headaches, achy neck pain, radicular mid back pain, and stabbing low back pain with muscle spasms. The provider is recommending the patient continue chiropractic and acupuncture treatment for the cervical spine and lumbar spine 3 times a week for 6 weeks. For acupuncture, MTUS page 8 recommends acupuncture for pain, suffering, and restoration of function. Recommended frequency and duration is 3 to 6 treatments to produce functional improvement 1 to 2 times per year with optimal duration of 1 to 2 months. Review of the medical file indicates on 07/15/2013, patient was prescribed refill of medication and acupuncture. Number of sessions prescribed is unnoted. On 07/31/2013, provider states, "The patient is to undergo a course of acupuncture treatment for the cervical and lumbar spine in a frequency of 3 times per week for period of 6 weeks." Report 12/06/2013 states "The patient is to continue with course of acupuncture and chiropractic treatment for the lumbar and cervical spine in a frequency of 3 times per week for 6 weeks." It is unclear of the exact number of treatments and the dates they were received. In this case, the provider does not provide a discussion of functional improvement with prior acupuncture treatment. MTUS allows for

treatments to be extended only when functional improvement has been shown. Therefore, the request is not medically necessary.

**Localized intense neurostimulation therapy (LINT) for the lumbar spine:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Neuromuscular electrical stimulation (NMES devices) Page(s): 121.

**Decision rationale:** This patient presents with sharp headaches, achy neck pain, radicular mid back pain, and stabbing low back pain with muscle spasms. The provider is recommending the patient "continue the course of LINT, in a frequency of 1 x 6 weeks for the lumbar spine as well as 1 x 6 more weeks for the thoracic spine." The MTUS, ACOEM, and Official Disability Guidelines do not have discussions on LINT (localized intense neurostim therapy); however, for neuromuscular electrical stimulation, the MTUS Guidelines page 121 has the following, "not recommended. NMES is used primarily as part of a rehabilitation program following stroke and there is no evidence to support its use for chronic pain. There is no intervention trial suggesting benefit from NMES for chronic pain." In this case, there is no indication that this patient has suffered a stroke. Furthermore, MTUS does not support the use of neuromuscular electrical stimulation for chronic pain. The requested LINT therapy is not medically necessary.

**Lumbar steroid injection (Level unspecified):** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Epidural steroid injections Page(s): 46.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Criteria for the use of Epidural steroid injections Page(s): 46-47.

**Decision rationale:** This patient presents with sharp headaches, achy neck pain, radicular mid back pain, and stabbing low back pain with muscle spasms. The provider is requesting unspecified levels of epidural steroid injections to the lumbar spine. MTUS Guidelines page 46 and 47 recommends ESI as an option for treatment for radicular pain defined as pain in dermatomal distribution with corroborative findings of radiculopathy. In this case, there is not MRI to corroborate dermatomal distribution of pain/paresthsia. Furthermore, the provider has not specified the levels being requested for injections. MTUS does not allow for more than two levels to be injected at a time. Therefore, this request is not medically necessary.

**Ketoprofen 20% in PLO gel 120gms:** 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.

**Decision rationale:** This patient presents with sharp headaches, achy neck pain, radicular mid back pain, and stabbing low back pain with muscle spasms. The provider is requesting a compounded Ketoprofen gel 20% 120 g. Provider states patient is to apply thin layer to the affected area. Provider states "topical NSAIDs such as Ketoprofen have been widely accepted by the medical community and have been used in Europe for over 10 years." The MTUS Guidelines page 111 has the following regarding topical creams, "topical analgesics are largely experimental and used with few randomized controlled trials to determine efficacy or safety." The MTUS Guidelines page 112 supports the use of topical NSAID for peripheral joint arthritis or tendonitis. However, non-FDA approved agents like Ketoprofen is not recommended for any topical use. MTUS Guidelines further states that this agent is not currently FDA approved for topical application. "It has an extreme high incident of photo-contact dermatitis." Therefore, this request is not medically necessary.

**Cyclophene 5% in PLO gel, 120gms:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111.

**Decision rationale:** This patient presents with sharp headaches, achy neck pain, radicular mid back pain, and stabbing low back pain with muscle spasms. The provider is requesting a compounded Cyclophene 5% gel 120 g to be applied to the affected area. The provider states Cyclophene contains Cyclobenzaprine, Hydrochloride, and other proprietary ingredients. The provider goes on to state that Cyclobenzaprine has consistently been found to be effective in most clinical trials compared to other drugs in this class and it is effective in the treatment of musculoskeletal condition such as low back pain, neck pain, muscle spasms, neuropathic pain, and chronic persistent pain. The MTUS Guidelines p 111 has the following regarding topical creams, "topical analgesics are largely experimental and used with few randomized control trials to determine efficacy or safety." MTUS further states, "Any compounded product that contains at least one (or drug class) that is not recommended is not recommended." In this case, Cyclobenzaprine is a muscle relaxant and is not recommended for any topical formulation. Therefore, the request is not medically necessary.

**Synapryn 10mg/ml oral suspension 500ml:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 75.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Tramadol, Glucosamine (and Chondroitin Sulfate) Page(s): 50, 75.

**Decision rationale:** This patient presents with sharp headaches, achy neck pain, radicular mid back pain, and stabbing low back pain with muscle spasms. The provider is requesting Synapryn 10 mg/mL oral suspension 500 mL to be used 3 times a day as directed. The provider states Synapryn contains Tramadol and Glucosamine and is commonly used to treat neuropathic/fibromyalgia pain. The MTUS Guidelines page 75 states a small class of synthetic opioids, for example, Tramadol exhibits opiates activity and a mechanism of action that inhibits the re uptake of serotonin and Norepinephrine. Central analgesic drugs such as Tramadol are reported to be effective in managing neuropathic pain. Given the patient's continued pain, a synthetic opioid like Tramadol may be warranted. However, the provider is requesting Synapryn, a compound drug with Tramadol and Glucosamine without specifying the reason why both are needed. Glucosamine is indicated for painful arthritis of the knee which this patient does not suffer from. Therefore, this request is not medically necessary.

**Tabradol 1mg/ml oral suspension 250ml:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Cyclobenzaprine, Muscle relaxants (for pain) Page(s): 63, 64.

**Decision rationale:** This patient presents with sharp headaches, achy neck pain, radicular mid back pain, and stabbing low back pain with muscle spasms. The provider is requesting Tabradol 1 mg/mL oral suspension 250 mL to be taken 2 to 3 times per day. Provider states "the patient has failed to respond to a course of non-steroid anti-inflammatory medication, therefore, the addition of Tabradol to the patient's treatment is deemed to be necessary." Tabradol contains Cyclobenzaprine, Methylsulfonylmethane and other proprietary ingredients. The MTUS Guidelines page 64 states Cyclobenzaprine is recommended for short course of therapy, limited mixed evidence does not allow for recommendation for chronic use. In this case, the treating physician does not indicate that this is for short term management of spasm or acute pain. Furthermore, it is not known why the provider is prescribing oral suspension formulation for this drug. There is no documentation regarding the patient's inability to swallow pills. Therefore, this request is not medically necessary.

**Deprizine 15mg/ml oral suspension 250ml:** 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), Treatment Index, 9th edition (web), Chronic pain-medical food.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms & cardiovascular risk (MTUS pg 69) Recommend with precautions as indicated below. Clinicians should weight the indications for NSAIDs against both GI and cardiovascular risk factors. 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).

Recent studies tend to show that H. Pylori does not act synergistically with NSAIDs to develop gastroduodenal lesions. Recommendations Patients with no risk factor and no cardiovascular disease: Non-selective NSAIDs OK (e.g, ibuprofen, naproxen, etc.) 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). Patients at high risk for gastrointestinal events with no cardiovascular disease: A Cox-2 selective agent plus a PPI if absolutely necessary. Patients at high risk of gastrointestinal events with cardiovascular disease: If GI risk is high the suggestion is for a low-dose Cox-2 plus low dose Aspirin (for cardioprotection) and a PPI. If cardiovascular risk is greater than GI risk the suggestion is naproxyn plus low-dose aspirin plus a PPI. (Laine, 2006) (Scholmerich, 2006) (Nielsen, 2006) (Chan, 2004) (Gold, 2007) (Laine, 2007) Cardiovascular disease: A non-pharmacological choice should be the first option in patients with cardiac risk factors. It is then suggested that acetaminophen or aspirin be used for short-term needs. An opioid also remains a short-term alternative for analgesia. Major risk factors (recent MI, or coronary artery surgery, including recent stent placement): If NSAID therapy is necessary, the suggested treatment is naproxyn plus low-dose aspirin plus a PPI. Mild to moderate risk factors: If long-term or high-dose therapy is required, full-dose naproxen (500 mg twice a day) appears to be the preferred choice of NSAID. If naproxyn is ineffective, the suggested treatment is (1) the addition of aspirin to naproxyn plus a PPI, or (2) a low-dose Cox-2 plus ASA. Cardiovascular risk does appear to extend to all non-aspirin NSAIDs, with the highest risk found for the Cox-2 agents. (Johnsen, 2005) (Lanas, 2006) (Antman, 2007) (Laine, 2007) Use with Aspirin for cardioprotective effect: In terms of GI protective effect: The GI protective effect of Cox-2 agents is diminished in patients taking low-dose aspirin and a PPI may be required for those patients with GI risk factors. (Laine, 2007) In terms of the actual cardioprotective effect of aspirin: Traditional NSAIDs (both ibuprofen and napr Page(s): 69.

**Decision rationale:** This patient presents with sharp headaches, achy neck pain, radicular mid back pain, and stabbing low back pain with muscle spasms. The provider is requesting Deprizine 5 mg/mL oral suspension 250 mL, 10 mL to be taken once daily. This medicine is a histamine H2-blocker. The MTUS, ACOEM, and Official Disability Guidelines do not specifically discuss Deprizine. However, MTUS page 69 recommends determining risk for GI events before prescribing prophylactic PPI or Omeprazole. GI risk factors include: (1) Age is greater than 65, (2) History of peptic ulcer disease and GI bleeding or perforation, (3) Concurrent use of ASA or corticosteroid and/or anticoagulant, (4) High dose/multiple NSAID. In this case, the provider states this medication is helpful in patient's that are taking NSAID. The medical file indicates the patient is not taking NSAIDs to require this medication. Furthermore, the provider provides no discussion as to why oral suspensions are being requested. Therefore, this request is not medically necessary.

**Dicopanol 5mg/ml oral suspension 150ml:** 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), Treatment Index, 9th edition (web), Chronic pain-medical food.

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

**Decision rationale:** This patient presents with sharp headaches, achy neck pain, radicular mid back pain, and stabbing low back pain with muscle spasms. The provider is requesting Dicopanol 5 mg/ml oral suspension 150 mL, 1 mL to be taken daily as bedtime. The provider states Dicopanol's sedative properties make it a great alternative for patient's insomnia. The MTUS, ACOEM, and Official Disability Guidelines guidelines do not discuss Dicopanol. The Official Disability Guidelines has the following regarding anti-Histamine for insomnia: (4) Over-the-counter medications: Sedating antihistamines have been suggested for sleep aids (for example, diphenhydramine). Tolerance seems to develop within a few days. Next-day sedation has been noted as well as impaired psychomotor and cognitive function. Side effects include urinary retention, blurred vision, orthostatic hypotension, dizziness, palpitations, increased liver enzymes, drowsiness, dizziness, grogginess and tiredness. The Official Disability Guidelines states that tolerance develops within a few days. It does not appear to be intended for a long-term use and the provider is requesting 150ml, 1ml to be taken once nightly. Furthermore, it is not known why the provider is prescribing oral suspension formulation for this drug. There is no documentation regarding the patient's inability to swallow pills. Therefore, this request is not medically necessary.

**Fanatrex 25 mg/mL oral suspension 420 mL, 5 mL to be taken daily:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Gabapentin Page(s): 18-20.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Gabapentin Page(s): 18-19.

**Decision rationale:** This patient presents with sharp headaches, achy neck pain, radicular mid back pain, and stabbing low back pain with muscle spasms. The provider is requesting Fanatrex 25 mg/mL oral suspension 420 mL, 5 mL to be taken daily. The provider states Fanatrex contains Gabapentin. The MTUS Guidelines page 18 and 19 has the following regarding Gabapentin, "Gabapentin has been shown to be effective for treatment of diabetic painful neuropathy and post-therapeutic neuralgia and has been considered a first-line treatment for neuropathic pain." This patient suffers from cervical and lumbar radiculopathy and Gabapentin is indicated for neuropathic pain. The Utilization review dated 12/24/2013 denied the request because the prescription as there is "no clear indication for use of suspension form over regular tablet." The provider really does not provide any discussion on why oral suspension. While the use of Gabapentin is indicated for neuropathic pain, it is not understood why the provider uses oral solutions for all medications. ACOEM guidelines page 492 considers apparent reasonableness of the treatment including "cost-effectiveness" when considering medical treatments. In this case, the provider does not explain why the patient must have use oral solution. Therefore, this request is not medically necessary.