

Case Number:	CM15-0193354		
Date Assigned:	10/07/2015	Date of Injury:	08/20/2012
Decision Date:	12/10/2015	UR Denial Date:	09/03/2015
Priority:	Standard	Application Received:	10/01/2015

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:

This is a 63 year old male with a date of injury of August 20, 2012. A review of the medical records indicates that the injured worker is undergoing treatment for lumbar spine sprain and strain rule out herniated nucleus pulposus, lumbago, lumbar radiculopathy, bilateral hip sprain and strain rule out internal derangement, left ankle and foot pain, anxiety disorder, mood disorder, and stress. Medical records dated June 10, 2015 indicate that the injured worker complained of lower back pain and muscle spasms rated at a level of 7 out of 10, associated numbness and tingling of the bilateral lower extremities, bilateral hip pain and muscle spasms rated at a level of 7 out of 10, anxiety, stress and depression. A progress note dated July 8, 2015 documented complaints similar to those reported on June 10, 2015 with pain levels rated at 6 to 7 out of 10. Records also indicate the injured worker complained of left ankle, foot and heel pain rated at a level of 7 out of 10. Per the treating physician (July 8, 2015), the employee was able to work full duty. The physical exam dated June 15, 2015 reveals tenderness to palpation at the lumbar paraspinal muscles, lumbosacral junction, quadratus lumborum with a trigger point, decreased range of motion of the lumbar spine, tenderness to palpation at the bilateral greater trochanters, decreased range of motion of the bilateral hips, decreased sensation to pinprick and light touch at the L4, L5 and S1 dermatomes bilaterally, and decreased motor strength at the lower extremities secondary to pain. The progress note dated July 8, 2015 documented a physical examination that showed no changes in the lumbar spine or bilateral hip examinations since the exam performed on June 10, 2015, tenderness to palpation over the left medial malleolus, tenderness at the left calcaneus, and decreased range of motion of the left ankle and

foot. Treatment has included an unknown number of physical therapy sessions, an unknown number of shockwave therapy sessions for the lumbar spine and hips, an unknown number of Localized Intense Neurostimulation Therapy sessions for the lumbar spine, and medications (Deprizine, Dicopanol, Fanatrex, Synapryn, Tabradol, Cyclobenzaprine, and Ketoprofen cream since at least June of 2015). The original utilization review (September 3, 2015) non-certified a request for Ketoprofen cream 20% 167gm, Cyclobenzaprine 5% 110gm, Synapryn 10mg in 1ml oral suspension 500ml, Tabradol 1mg/ml oral suspension 250ml, Deprizine 15mg in ml oral suspension 250ml, Dicopanol 5mg in ml oral suspension 150ml, Fanatrex 25mg in ml oral suspension 420ml, six session of localized intense neurostimulation therapy for the lumbar spine, and electromyogram-nerve conduction velocity of the bilateral lower extremities.

IMR ISSUES, DECISIONS AND RATIONALES

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

Ketoprofen cream 20% 167gm: 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): Topical Analgesics.

Decision rationale: The request is for the use of a topical NSAID for pain relief. There are specific criteria require for use based on the guidelines. The MTUS states the following: 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 indicated above, the patient would not qualify for the use of this medication based on the treatment duration. As such, the request is not medically necessary.

Cyclobenzaprine 5% 110gm: 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): Topical Analgesics.

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 use of the topical muscle relaxant is not indicated for use for the patient's condition. The MTUS states the following regarding muscle relaxants used topically: "Baclofen: Not recommended. There is currently one Phase III study of Baclofen-Amitriptyline- Ketamine gel in cancer patients for treatment of chemotherapy-induced peripheral neuropathy. There is no peer-reviewed literature to support the use of topical baclofen. Other muscle relaxants: There is no evidence for use of any other muscle relaxant as a topical product." As indicated above, due to inadequate clinical evidence of efficacy, the request is not medically necessary.

Synapryn 10mg/1ml oral suspension 500ml: 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 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 medically necessary.

Tabradol 1mg/ml oral suspension 250ml: 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): Muscle relaxants (for pain).

Decision rationale: The request is for the use of a muscle relaxant to aid in pain relief. The MTUS guidelines state that the use of a medication in this class is indicated as a second-line option for short-term treatment of acute exacerbations of low back pain. Muscle relaxants may be effective in reducing pain and muscle tension, which can increase mobility. However, in most LBP cases, they show no benefit beyond NSAIDs in pain improvement. Efficacy appears to diminish over time, and prolonged use may lead to dependence. (Homik, 2004) Due to inadequate documentation of a recent acute exacerbation and poor effectiveness for chronic long- term use, the request is not medically necessary.

Deprizine 15mg/ml oral suspension 250ml: 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 (Chronic)/Compounded drugs.

Decision rationale: The request is for the use of a compounded medication. The official disability guidelines state the following regarding this topic: Not recommended as a first-line therapy. In general, commercially available, FDA-approved drugs should be given an adequate trial. If these are found to be ineffective or are contraindicated in individual patients, compound drugs that use FDA-approved ingredients may be considered. (Wynn, 2011) See specific entries for each ingredient. See also Topical analgesics, compounded. Pharmacy compounding has traditionally involved combining drug ingredients to meet the needs of specific patients for medications that are not otherwise commercially available, and it is undertaken on a patient-by-patient basis for patients who, for example, might be allergic to inactive ingredients in FDA-approved drugs or may need a different dosage strength or route of administration. Unlike commercially available drugs, these products are not approved by the FDA but rather are regulated by the state pharmacy board and state law governing the practice of pharmacy. The FDA does not regulate pharmacy-compounded products in recognition of the important public health function performed by traditional compounding. Recently, some pharmacies have been making and marketing stock compound drugs for the WC patient population. Among the FDA "Red Flags" for Enforcement Action on Compounded Drugs is: "Compounding drugs in anticipation of receiving prescriptions, except in very limited quantities in relation to amounts compounded after receiving valid prescriptions." (FDA, 2011) Compound topical analgesics may provide relief by acting locally over the painful site with lower risk of systemic adverse effects on the gastrointestinal system and drug interactions than oral NSAIDs. The issues surrounding compound drugs are due to uncertainties regarding whether the products are medically appropriate and whether payments are reasonable, with the latter issue possibly also involving who dispenses the drug. Medical necessity should be based on the patient's needs combined with the medical and scientific evidence presented in ODG. ODG does not address pricing and fee schedules, but in general there should be consistency within a pharmacy fee schedule for products containing the same active ingredients, so that there is not an inappropriate incentive to use compounding. (Wynn, 2011) See also Co-pack drugs; Medical foods; Physician-dispensed drugs; Repackaged drugs; & Topical analgesics, compounded. Criteria for Compound drugs: (1) Include at least one drug substance (or active ingredient) that is the sole active ingredient in an FDA-approved prescription drug, not including OTC drugs. (2) Include only bulk ingredients that are components of FDA-approved drugs that have been made in an FDA-registered facility and have an NDC code. (3) Is not a drug that was withdrawn or removed from the market for safety reasons. (4) Is not a copy of a commercially available FDA-approved drug product. (5) Include only drug substances that have been supported as safe and effective for the prescribed indication by the FDA-approval process and/or by adequate medical and scientific evidence in the medical literature. This would allow off-label usage when supported by medical evidence. See specific entries for each ingredient in ODG for the medical and scientific evidence. (6) Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. The use of compounded agents requires knowledge of the specific analgesic effect of each agent and how it will be useful for the specific therapeutic goal required. See also Topical analgesics, compounded. (Wynn, 2011) As stated above the use of this medication is not indicated. This is

secondary to no documentation which states that there has been a failure of first-line FDA approved drug therapy or any explanation as to why this compounded formula is superior in efficacy. As such, the request is not medically necessary.

Dicopanol 5mg/ml oral suspension 150ml: 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) Mental Illness and Stress/Diphenhydramine (Benadryl).

Decision rationale: The request is for the use of Diphenhydramine which is in the category of an antihistamine. The MTUS guidelines are silent regarding this topic. The ODG states the following regarding its use: Not recommended. See Insomnia treatment, where sedating antihistamines are not recommended for long-term insomnia treatment. The AGS updated Beers criteria for inappropriate medication use includes diphenhydramine. (AGS, 2012) Anticholinergic drugs, including diphenhydramine, may increase the risk for dementia by 50% in older adults. There is an obvious dose-response relationship between anticholinergic drug use and risk of developing dementia, but chronic use, even at low doses, would be in the highest risk category. While there is awareness that these drugs may cause short-term drowsiness or confusion, which is included in the prescribing information, there is no mention of long-term effects on cognition, and generally awareness of this issue is very low, and both the public and doctors need to be encouraged to use alternative treatments where possible. (Gray, 2015) As stated above, the use of this medication is not indicated for use in this patient for insomnia. There is inadequate documentation of the reasoning for its use for other indications. As such, the request is not medically necessary.

Fanatrex 25mg/ml oral suspension 420ml: 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 (Chronic)/Compounded drugs.

Decision rationale: The request is for the use of a compounded medication. The official disability guidelines state the following regarding this topic: Not recommended as a first-line therapy. In general, commercially available, FDA-approved drugs should be given an adequate trial. If these are found to be ineffective or are contraindicated in individual patients, compound drugs that use FDA-approved ingredients may be considered. (Wynn, 2011) See specific entries for each ingredient. See also Topical analgesics, compounded. Pharmacy compounding has traditionally involved combining drug ingredients to meet the needs of specific patients for medications that are not otherwise commercially available, and it is undertaken on a patient-by-patient basis for patients who, for example, might be allergic to inactive ingredients in FDA-approved drugs or may need a different dosage strength or route of administration. Unlike commercially available drugs, these products are not approved by the FDA but rather are regulated by the state pharmacy board and state law governing the practice of pharmacy. The FDA does not regulate pharmacy-compounded products in recognition of the

important public health function performed by traditional compounding. Recently, some pharmacies have been making and marketing stock compound drugs for the WC patient population. Among the FDA "Red Flags" for Enforcement Action on Compounded Drugs is: "Compounding drugs in anticipation of receiving prescriptions, except in very limited quantities in relation to amounts compounded after receiving valid prescriptions." (FDA, 2011) Compound topical analgesics may provide relief by acting locally over the painful site with lower risk of systemic adverse effects on the gastrointestinal system and drug interactions than oral NSAIDs. The issues surrounding compound drugs are due to uncertainties regarding whether the products are medically appropriate and whether payments are reasonable, with the latter issue possibly also involving who dispenses the drug. Medical necessity should be based on the patient's needs combined with the medical and scientific evidence presented in ODG. ODG does not address pricing and fee schedules, but in general there should be consistency within a pharmacy fee schedule for products containing the same active ingredients, so that there is not an inappropriate incentive to use compounding. (Wynn, 2011) See also Co-pack drugs; Medical foods; Physician-dispensed drugs; Repackaged drugs; & Topical analgesics, compounded. Criteria for Compound drugs: (1) Include at least one drug substance (or active ingredient) that is the sole active ingredient in an FDA-approved prescription drug, not including OTC drugs. (2) Include only bulk ingredients that are components of FDA-approved drugs that have been made in an FDA-registered facility and have an NDC code. (3) Is not a drug that was withdrawn or removed from the market for safety reasons. (4) Is not a copy of a commercially available FDA-approved drug product. (5) Include only drug substances that have been supported as safe and effective for the prescribed indication by the FDA-approval process and/or by adequate medical and scientific evidence in the medical literature. This would allow off-label usage when supported by medical evidence. See specific entries for each ingredient in ODG for the medical and scientific evidence. (6) Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. The use of compounded agents requires knowledge of the specific analgesic effect of each agent and how it will be useful for the specific therapeutic goal required. See also Topical analgesics, compounded. (Wynn, 2011) As stated above the use of this medication is not indicated. This is secondary to no documentation which states that there has been a failure of first-line FDA approved drug therapy or any explanation as to why this compounded formula is superior in efficacy. As such, the request is not medically necessary.

Six session of localized intense neurostimulation therapy for the lumbar spine: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Low Back Lumbar & Thoracic (Acute & Chronic)/Hyperstimulation analgesia.

Decision rationale: The request is for Localized Intense Therapy to aid in pain relief. The MTUS guidelines are silent regarding this issue. The Official Disability Guidelines state the following: Not recommended until there are higher quality studies. Initial results are promising, but only from two low quality studies sponsored by the manufacturer [REDACTED] [REDACTED] Localized manual high-intensity neurostimulation devices are applied to small surface areas to stimulate peripheral nerve endings (A fibers), thus causing the release of endogenous endorphins. This procedure, usually described as hyperstimulation analgesia, has been investigated in several controlled studies. However, such treatments are time consuming

and cumbersome, and require previous knowledge of the localization of peripheral nerve endings responsible for LBP or manual impedance mapping of the back, and these limitations prevent their extensive utilization. The new device is capable of automatically measuring skin impedance in a selected body area and, immediately afterwards, of stimulating multiple points that are targeted according to differentiation in their electrical properties and proprietary image processing algorithms with high intensity yet non-painful electrical stimulation. The therapeutic neurostimulation pulse modulation of dense electrical pulses is applied locally to specific Active Trigger Points (ATPs) which are locations of nerve ending associated with pain, providing effective pain relief by stimulating the release of endorphins, the body's natural pain killers. The gate control theory of pain describes the modulation of sensory nerve impulses by inhibitory mechanisms in the central nervous system. One of the oldest methods of pain relief is generalized hyperstimulation analgesia produced by stimulating myofascial trigger points by dry needling, acupuncture, intense cold, intense heat, or chemical irritation of the skin. The moderate-to-intense sensory input of hyperstimulation analgesia is applied to sites over, or sometimes distant from, the pain. A brief painful stimulus may relieve chronic pain for long periods, sometimes permanently. The new device takes advantage of these same principles. Hyperstimulation analgesia with localized, intense, low-rate electrical pulses applied to painful active myofascial trigger points was found to be effective in 95% patients with chronic nonspecific low back pain, in a clinical validation study. (Gorenberg, 2013) The results of this current pilot study show that treatment with this novel device produced a clinically significant reduction in back pain in almost all patients after four treatment sessions. (Gorenberg, 2011) As stated above, this treatment is not indicated. This is secondary to poor high quality clinical evidence of effectiveness. As such, the request is not medically necessary.

One EMG/NCV of the bilateral lower extremities: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Lumbar & Thoracic (Acute & Chronic)/Nerve conduction studies (NCS).

Decision rationale: The request is for nerve conduction studies. The ODG state the following regarding this study: Not recommended. There is minimal justification for performing nerve conduction studies when a patient is presumed to have symptoms on the basis of radiculopathy. (Utah, 2006) This systematic review and meta-analysis demonstrate that neurological testing procedures have limited overall diagnostic accuracy in detecting disc herniation with suspected radiculopathy. (Al Nezari, 2013) In the management of spine trauma with radicular symptoms, EMG/nerve conduction studies (NCS) often have low combined sensitivity and specificity in confirming root injury, and there is limited evidence to support the use of often uncomfortable and costly EMG/NCS. (Charles, 2013) See also the Carpal Tunnel Syndrome Chapter for more details on NCS. Studies have not shown portable nerve conduction devices to be effective. EMGs (electromyography) are recommended as an option (needle, not surface) to obtain unequivocal evidence of radiculopathy, after 1-month conservative therapy, but EMG's are not necessary if radiculopathy is already clinically obvious. In this case, the patient does not meet criteria for the study requested. This is secondary to radiculopathy already diagnosed in the records. Pending receipt of information further clarifying how this would change the management rendered, the study is not medically necessary.