

Case Number:	CM14-0139257		
Date Assigned:	10/13/2014	Date of Injury:	02/28/2014
Decision Date:	11/28/2014	UR Denial Date:	08/16/2014
Priority:	Standard	Application Received:	08/28/2014

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 Family Medicine 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:

This is a 42-year-old male who reported an industrial injury to the back on 3/11/2014, eight (8) months ago, attributed to the performance of his usual and customary job tasks. The patient pushed a heavy object away from a coworker and subsequently reported low back pain. The patient is being treated for the diagnoses of status post lumbar microdiscectomy; low back pain; and rule out lumbar disc displacement/herniated nucleus pulposus. The patient complains of burning, radicular low back pain, and muscle spasms. The patient reports numbness and tingling of the bilateral lower extremities especially in the right side. The objective findings on examination included well healed surgical incision; normal gait; not able to heel-to walk due to pain; tenderness to palpation at the paralumbar muscles; diminished range of motion to the lumbar spine; straight leg raise reported as positive bilaterally; sensation with diminished pinprick and light touch a L4, L5, and S1 dermatomes bilaterally; motor strength is reported to be diminished due to pain; reflexes are 2+ and symmetrical; pulses are 2+ and symmetrical in the bilateral lower extremities. The treatment plan included a prescription for Deprizine; Dicopanol; Fanatrex; Synapryn; Tabradol; Ketoprofen cream; x-ray of the lumbar spine postoperatively; TENS unit purchase; 12 sessions of ESWT to the lumbar spine; Terocin patches topically; and a hot cold unit.

IMR ISSUES, DECISIONS AND RATIONALES

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

Unknown Prescription Deprizine: 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 Medications for Chronic pain Page(s): 60-61. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain chapter--medical foods

Decision rationale: Evidence-based guidelines report that medical foods are not evaluated for safety or efficacy by the federal FDA. According to the FDA, medical foods have significant health risk that can lead to permanent injury or death. The California state legislature stated: the legislature hereby declares the need to remove the financial incentive for prescribing costly and questionable compounded drugs, co-packs, and medical foods and create a new process for the prescription of compounded drugs, co-packs, and medical foods. The prescribed medical food Deprizine is not demonstrated to be medically necessary for the treatment of the cited diagnoses of this patient. Deprizine (Ranitidine) 150 mg is prescribed for GERD or stomach discomfort when NSAIDs are being prescribed; however, there is no objective evidence that the H2 inhibitor is as effective at protecting the mucosal layer of the stomach as the recommended proton pump inhibitors. Generally, the proton pump inhibitors are prescribed to protect the stomach lining from the chemical effects of NSAIDs. There are no prescribed NSAIDs in the current medical documentation. There are no documented GI issues or side effects to prescribed medications. There is no demonstrated medical necessity for Ranitidine. The protection of the stomach lining from NSAIDs is appropriately provided with the proton pump inhibitors such as Omeprazole. There is no objective evidence provided by provider to support the medical necessity of the prescribed Deprizine: Ranitidine Capsule - Oral for the treatment of the patient as the H2 blocker is not as effective in protecting the GI mucosa from the effects of NSAIDs as the PPIs. Therefore, this request is not medically necessary.

Unknown Prescription Dicopanol: 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 Medications for Chronic pain Page(s): 60-61. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain chapter--medical foods

Decision rationale: There is no medical necessity for the prescribed Dicopanol by for the cited diagnoses. It is not clear why a patient is prescribed medical foods as opposed to conventional medications. There is no documentation of failure of conventional medications. The medical foods are prescribed are not demonstrated to be medically necessary. The compounded medications prescribed by are not demonstrated to be medically necessary for the treatment of the patient and are not supported with subjective/objective evidence or current evidence-based guidelines. There is no demonstrated medical evidence to support the medical necessity of a compounded Benadryl solution for the treatment of the effects of the industrial injury. There is no demonstrated medical necessity for the oral solution containing Benadryl to be prescribed for sleep in order to treat the effects of the industrial injury. The same diphenhydramine is available

OTC in 25 mg tablets for allergies or sleep. There is no demonstrated medical necessity for the compound oral solution form of Benadryl. Evidence-based guidelines report that medical foods are not evaluated for safety or efficacy by the federal FDA. According to the FDA, medical foods have significant health risk that can lead to permanent injury or death. The California state legislature stated: the legislature hereby declares the need to remove the financial incentive for prescribing costly and questionable compounded drugs, co-packs, and medical foods and create a new process for the prescription of compounded drugs, co-packs, and medical foods. The prescribed medical food Dicopanol is not demonstrated to be medically necessary for the treatment of the cited diagnoses of this patient. Therefore, this request is not medically necessary.

Unknown Prescription for Fanatrex: 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 Medications for Chronic pain Page(s): 60-61. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain chapter--medical foods

Decision rationale: Evidence-based guidelines report that medical foods are not evaluated for safety or efficacy by the federal FDA. According to the FDA, medical foods have significant health risk that can lead to permanent injury or death. The California state legislature stated: "the legislature hereby declares the need to remove the financial incentive for prescribing costly and questionable compounded drugs, co-packs, and medical foods and create a new process for the prescription of compounded drugs, co-packs, and medical foods." The prescribed medical food Fanatrex is not demonstrated to be medically necessary for the treatment of the cited diagnoses of this patient. The California MTUS and the Official Disability Guidelines and the California MTUS state that there is insufficient evidence to support the use of Gabapentin for the treatment of non-neuropathic pain. The prescription for Gabapentin in the form of Fanatrex appears to be prescribed for the treatment of back with no evidence of a neuropathic pain. There is no evidence of a nerve impingement radiculopathy or neuropathic pain to justify the use of Gabapentin. There is no objective evidence to support the medical necessity of Gabapentin for the cited diagnoses for this patient. The prescription of Gabapentin/Fanatrex for chronic knee pain due to reported back pain s/p microdiscectomy was not supported with objective findings on physical examination, as there were no demonstrated neurological deficits. There is no objective evidence on examination for significant neurogenic pain issues. There were no demonstrated neurological deficits along a dermatomal distribution. The use of Gabapentin is not documented to be for neuropathic pain and is prescribed by for subjective pain and arthritic pain issues. There is no demonstrated medical necessity for the medical food Fanatrex. The prescription of Gabapentin/Fanatrex is recommended for neuropathic pain and is used to treat postherpetic neuralgia and painful polyneuropathy such as diabetic polyneuropathy. The patient is not demonstrated to have neuropathic pain. Anti-epilepsy drugs (AEDs) are recommended on a trial basis (Gabapentin/Pregabalin) as a first-line therapy for painful polyneuropathy such as diabetic polyneuropathy. The prescription of Gabapentin for neuropathic pain was not supported with objective findings on physical examination. There is no objective evidence that the

recommended conservative treatment with the recommended medications have been provided prior to the prescription of Gabapentin for chronic pain. The use of Gabapentin should be for neuropathic pain. Presently, there is documented no objective evidence of neuropathic pain for which the use of Gabapentin is recommended. Mechanism of action: This medication appears to be effective in reducing abnormal hypersensitivity (allodynia and hyperalgesia), to have anti-anxiety effects, and may be beneficial as a sleep aid. Specific pain states: "There is limited evidence to show that this medication is effective for postoperative pain, where there is fairly good evidence that the use of gabapentin and gabapentin-like compounds results in decreased opioid consumption. This beneficial effect, which may be related to an anti-anxiety effect, is accompanied by increased sedation and dizziness." (Peng, 2007) (Buvanendran, 2007) (Menigaux, 2005) (Pandey, 2005) Spinal cord injury: Recommended as a trial for chronic neuropathic pain that is associated with this condition. (Levendoglu, 2004) CRPS: Recommended as a trial. (Serpell, 2002) Fibromyalgia: Recommended as a trial. (Arnold, 2007) Lumbar spinal stenosis: Recommended as a trial, with statistically significant improvement found in walking distance, pain with movement, and sensory deficit found in a pilot study. (Yaksi, 2007) Side-Effect Profile: Gabapentin has a favorable side-effect profile, few clinically significant drug-drug interactions and is generally well tolerated; however, common side effects include dizziness, somnolence, confusion, ataxia, peripheral edema, and dry mouth. (Eisenberg, 2007) (Attal, 2006) Weight gain is also an adverse effect. It is believed that the pharmacology is related to its ability, documented in in-vitro experiments, to enhance the activity of gamma aminobutyric acid (GABA), the major inhibitory neurotransmitter in the central nervous system. These experiments have shown that tiagabine binds to recognition sites associated with the GABA uptake carrier. It is thought that, by this action, tiagabine blocks GABA uptake into presynaptic neurons, permitting more GABA to be available for receptor binding on the surfaces of post-synaptic cells. Evidence is available that it operates as a selective GABA reuptake inhibitor. There is no demonstrated medical necessity for the prescribed oral solution Fanatrex for the treatment of chronic low back pain status post microdiscectomy. Therefore, this request is not medically necessary.

Unknown Prescription for Synapryn: Upheld

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

MAXIMUS guideline: Decision based on MTUS Acupuncture Treatment Guidelines, Chronic Pain Treatment Guidelines Medications for Chronic pain Page(s): 60-61. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain chapter--medical foods

Decision rationale: Evidence-based guidelines report that medical foods are not evaluated for safety or efficacy by the federal FDA. According to the FDA, medical foods have significant health risk that can lead to permanent injury or death. The California state legislature stated: the legislature hereby declares the need to remove the financial incentive for prescribing costly and questionable compounded drugs, co-packs, and medical foods and create a new process for the prescription of compounded drugs, co-packs, and medical foods. The prescribed medical food Synapryn is not demonstrated to be medically necessary for the treatment of the cited diagnoses of this patient. The prescription for Synapryn Oral (Tramadol Hcl/Glucosamine

Sulf/Compounding Vehicle Susp No.10) for pain is being continued as an opioid analgesic almost 10 years after the DOI. The chronic use of Tramadol is not recommended by the California MTUS; the ACOEM Guidelines, or the Official Disability Guidelines for the long-term treatment of back pain. There is no demonstrated medical necessity for opioid analgesics in the compounded form with glucosamine for the treatment of the post-operative back. There is no objective evidence provided by the treating physician for the prescription of this compounded medication over the prescription of conventional pharmaceuticals. The prescription of opiates on a continued long-term basis is inconsistent with the California MTUS and the Official Disability Guidelines recommendations for the use of opiate medications for the treatment of chronic pain. There is objective evidence that supports the use of opioid analgesics in the treatment of this patient over the use of NSAIDs for the treatment of chronic pain. The California MTUS recommends: Chronic back pain: Appears to be efficacious but limited for short-term pain relief, and long-term efficacy is unclear (greater than 16 weeks), but also appears limited. Failure to respond to a time-limited course of opioids has led to the suggestion of reassessment and consideration of alternative therapy. There is no evidence to recommend one opioid over another. In patients taking opioids for back pain, the prevalence of lifetime substance use disorders has ranged from 36% to 56% (a statistic limited by poor study design). Limited information indicated that up to one-fourth of patients who receive opioids exhibit aberrant medication-taking behavior. The ACOEM Guidelines updated chapter on chronic pain states, "Opiates for the treatment of mechanical and compressive etiologies: rarely beneficial. Chronic pain can have a mixed physiologic etiology of both neuropathic and nociceptive components. In most cases, analgesic treatment should begin with acetaminophen, aspirin, and NSAIDs (as suggested by the WHO step-wise algorithm). When these drugs do not satisfactorily reduce pain, opioids for moderate to moderately severe pain may be added to (not substituted for) the less efficacious drugs. A major concern about the use of opioids for chronic pain is that most randomized controlled trials have been limited to a short-term period (less than or equal to 70 days). This leads to a concern about confounding issues; such as, tolerance, opioid-induced hyperalgesia, long-range adverse effects such as hypogonadism and/or opioid abuse, and the influence of placebo as a variable for treatment effect." The prescription of Glucosamine for the chronic postoperative back pain is not demonstrated to be medically necessary or supported by objective evidence by the treating physician. Glucosamine is recommended for the treatment of osteoarthritis of the knee. The prescription is not consistent with the recommendations of the California MTUS, the ACOEM Guidelines, and the Official Disability Guidelines. Glucosamine has been demonstrated to have a small protective effect for the knee joint; however does not provide any significant pain relief. There are no recommendations for the use of glucosamine for post-operative back pain. Therefore, this request is not medically necessary.

Unknown Prescription for Tabradol: 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 Medications for Chronic pain Page(s): 60-61. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain chapter--medical foods

Decision rationale: Evidence-based guidelines report that medical foods are not evaluated for safety or efficacy by the federal FDA. According to the FDA, medical foods have significant health risk that can lead to permanent injury or death. The California state legislature stated: the legislature hereby declares the need to remove the financial incentive for prescribing costly and questionable compounded drugs, co-packs, and medical foods and create a new process for the prescription of compounded drugs, co-packs, and medical foods. The prescribed medical food Tabradol is not demonstrated to be medically necessary for the treatment of the cited diagnoses of this patient. The prescription for Flexeril (Cyclobenzaprine) in the form of Tabradol in combination with Methylsulfonylmethane is not demonstrated to be medically necessary over the readily available alternatives. The chronic use of muscle relaxants is not recommended by the California MTUS, the ACOEM Guidelines, or the Official Disability Guidelines for the treatment of chronic pain. The use of muscle relaxants are recommended to be prescribed only briefly in a short course of therapy. There is no medical necessity demonstrated for the use of muscle relaxants for more than the initial short-term treatment of muscle spasms. The patient is prescribed Cyclobenzaprine daily on a routine basis in the form of a medical food. There is no demonstrated medical necessity for the prescription of muscle relaxers on a routine basis for chronic back pain. The continued prescription of a muscle relaxant was not consistent with the evidence-based guidelines, but was helpful for the treatment of the perceived chronic pain. The prescription was not consistent with the recommendations of evidence-based guidelines. The use of Methylsulfonylmethane is not medically necessary over the readily available anti-inflammatory agents and has no particular functional improvement if compounded with Cyclobenzaprine. Therefore, this request is not medically necessary.

Unknown Prescription for Ketoprofen Cream: 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, NSAIDs Page(s): 111-113, 22, 67-68, 71. Decision based on Non-MTUS Citation American College of Occupational and Environmental Medicine (ACOEM), 2nd Edition, (2004) Chapter 6 pages 114-15 and the Official Disability Guidelines (ODG) Pain Chapter topical analgesics; NSAIDs

Decision rationale: The topical NSAID, Ketoprofen cream is not medically necessary in addition to prescribed oral NSAIDs. The patient has been prescribed topical Ketoprofen 100% cream for chronic pain. The patient has received topical NSAID cream for a prolonged period of time exceeding the time period recommended by evidence-based guidelines. There is no demonstrated medical necessity for both an oral NSAID and a topical NSAID. There is no provided subjective or objective evidence that the patient has failed or not responded to other conventional and recommended forms of treatment for relief of the effects of the industrial injury. Only if the subjective/objective findings are consistent with the recommendations of the California MTUS, then topical use of topical preparations is only recommended for short-term use for specific orthopedic diagnoses. There is no documented functional improvement by the provider attributed to the topical NSAID. The use of topical NSAIDS is documented to have efficacy for only 2-4 weeks subsequent to injury and thereafter is not demonstrated to be as

effective as oral NSAIDs. There is less ability to control serum levels and dosing with the topicals. The patient is not demonstrated to have any GI issue at all with NSAIDs. The patient was prescribed an oral opioids and topical NSAID concurrently. The use of the topical creams/gels does not provide the appropriate therapeutic serum levels of medications due to the inaccurate dosing performed by rubbing variable amounts of creams on areas that are not precise. The volume applied and the times per day that the creams are applied are variable and do not provide consistent serum levels consistent with effective treatment. There is no medical necessity for the addition of creams to the oral medications in the same drug classes. There is no demonstrated evidence that the topicals are more effective than generic oral medications. The prolonged use of topical Ketoprofen cream is not supported by the applicable evidence-based guidelines. The continued use of topical NSAIDs for the current clinical conditions is not otherwise warranted or demonstrated to be medically necessary. The prescribed topical Ketoprofen cream is not demonstrated be medically necessary. Evidence-based guidelines report that medical foods are not evaluated for safety or efficacy by the federal FDA. According to the FDA, medical foods have significant health risk that can lead to permanent injury or death. The California state legislature stated: "the legislature hereby declares the need to remove the financial incentive for prescribing costly and questionable compounded drugs, co-packs, and medical foods and create a new process for the prescription of compounded drugs, co-packs, and medical foods." The prescribed topical analgesic Ketoprofen cream is not demonstrated to be medically necessary for the treatment of the cited diagnoses of this patient. Therefore, this request is not medically necessary.

X-Ray of Lumbar Spine: Upheld

Claims Administrator guideline: Decision based on MTUS ACOEM Chapter 12 Low Back Complaints Page(s): 303. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Low back (acute & chronic)

MAXIMUS guideline: Decision based on MTUS ACOEM Chapter 12 Low Back Complaints Page(s): 303-304. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Lower back--X-rays

Decision rationale: The requested Lumbar spine x-rays was not demonstrated to be medically necessary for the treatment of the patient for a lumbar sprain/strain. The obtained x-ray was inconsistent with the recommendations of the California MTUS and the ACOEM Guidelines and the Official Disability Guidelines based on the documentation that the patient in relation to the effects of the industrial injury. There are no objective findings documented to support the medical necessity of the requested lumbar spine x-ray series. There were no objective findings consistent with the recommended criteria for the authorization of lumbar spine x-rays. The x-rays to the lumbar spine are not demonstrated to be medically necessary for the treatment of the effects of the industrial injury. The patient is noted to have previously obtained x-rays of the lumbar spine. There are no documented changes in clinical status to suggest that repeated x-rays of the lumbar spine medically necessary. Prior imaging studies are documented in the AME evaluation. There are no AME recommendations for any repeated x-ray studies of the lumbar spine. The requested repeated x-rays of the lumbar spine are not demonstrated to be medically necessary. Therefore, the request is not medically necessary.

TENS Unit and Supplies: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines TENS, Chronic pain (transcutaneous electrical nerve stimulation).

MAXIMUS guideline: Decision based on MTUS ACOEM Chapter 12 Low Back Complaints, Chapter 9 Shoulder Complaints Page(s): 203; 300, Chronic Pain Treatment Guidelines TENS unit chronic pain Page(s): 114-117. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) forearm, wrist, hand--TENS unit; Pain chapter--TENS unit

Decision rationale: The requesting provider did not provide subjective/objective evidence to support the medical necessity of the TENS Unit or the electronic muscle stimulator for the treatment of the back other than the recommended 30-day trial rental. The ACOEM Guidelines do not recommend the use of TENS Units for neck, shoulder, elbow, or wrist as there is no objective evidence available to support their use. There is no demonstrated medical necessity for a TENS unit as a freestanding treatment modality without the documentation of a functional restoration effort. It is recommended that the patient undergo a 30-day trial to demonstrate functional improvement prior to the purchase of a TENS unit for the treatment of the lumbar spine chronic pain issues. There is no justification for the use of the 4-lead TENS unit as required by the California MTUS. The use of the TENS unit for the treatment for the wrist/hand/forearm is not recommended by the California MTUS, or the ACOEM Guidelines. There is no objective evidence provided to support the medical necessity of the requested TENS Unit or electric muscle stimulator for the treatment of the back for the effects of the industrial injury. There was no documented functional improvement with use of a TENS unit in physical therapy; no documented 30-day trial rental; and no documented ongoing restoration program directed to the lower back. The TENS unit is directed to chronic back pain issues with a date of injury eight (8) months ago. The California MTUS and the Official Disability Guidelines only recommends the use of the TENS unit for chronic lower back pain with a demonstrated exercise program for conditioning and strengthening. The TENS Unit is recommended for only chronic intractable pain. There was no provided documentation that the patient was participating in a self-directed home exercise program. The ACOEM Guidelines revised back chapter 4/07/08 does recommend the use of the TENS Unit for the treatment of chronic lower back pain; however, it must be as an adjunct to a functional rehabilitation program and ongoing exercise program. The California MTUS only recommend the use of the TENS unit for chronic lower back pain with a demonstrated exercise program for conditioning and strengthening. There are no recommendations for the use of the TENS Unit in the treatment of the back. There is no objective evidence provided by the requesting provider that the same results cannot be achieved with a home exercise program established for functional rehabilitation with strengthening and conditioning directed to the hand. There is no demonstrated medical necessity for the purchase of a TENS for the rehabilitation of the chronic pain to the lower back without an initial 30-day trial to demonstrate evidence of functional improvement. Therefore, this request is not medically necessary.

12 Shockwave Therapy Visits 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 (ODG), Low back (acute & chronic)

MAXIMUS guideline: Decision based on MTUS ACOEM Chapter 9 Shoulder Complaints, Chapter 10 Elbow Disorders (Revised 2007) Page(s): 29; 203; 235. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) shoulder---ESWT

Decision rationale: The request for ESWT to the bilateral postoperative back does not provide any objective evidence to support the medical necessity of the requested ESWT. The requested treatment is not demonstrated to be medically necessary and is not consistent with the recommendations of the California MTUS. There is no rationale provided to support the medical necessity of the requested ESWT. Evidence-based guidelines recommend ESWT to the knees only for the diagnosis of calcific tendinitis of the patellar tendon or patellar bursitis. The use of ESWT to the lower back s/p microdiscectomy is not consistent with the recommendation of evidence-based guidelines is not demonstrated to be medically necessary. The treatment of the lower back with ESWT is not recommended by the California MTUS, the ACOEM Guidelines, or the Official Disability Guidelines unless certain criteria are met with specific diagnoses. The provider did not provide any objective evidence to support the use of ESWT for the diagnosed chronic low back pain that was demonstrated on the physical examination as only tenderness to palpation. There is no provided objective evidence that the use of ESWT for the symptoms related to the objective findings documented for this patient is medically necessary or leads to functional improvement. The California MTUS is silent on the use of ESWT. The Official Disability Guidelines only recommend the use of ESWT to the shoulder, elbow, and knee under certain clinical situations directed to the treatment of a calcific tendonitis or a prepatellar bursitis. It is not clear that the requesting provider has demonstrated a failure of conservative care and the decision to proceed with the requested treatment against the recommendations of the currently accepted guidelines is not demonstrated to be medically necessary. The use of conservative treatment must be performed for at least 6 months with documentation of treatment failure. There is no demonstrated medical necessity for the requested ESWT to the lower back for chronic pain status post microdiscectomy. Therefore, this request is not medically necessary.

Unknown Prescription for Terocin Patches: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Lidocaine topical, Capsaicin topical, Salicylate topicals, and Men.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Salicylate; Topical Analgesics; Anti-Inflammatory Medications Page(s): 105; 111-113; 67-. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Chronic Pain, Salicylate Topicals

Decision rationale: The prescription for Terocin patches is not medically necessary for the treatment of the patient for pain relief for the orthopedic diagnoses of the patient. There is no Orthopedic clinical documentation submitted to demonstrate the use of the topical patches for appropriate diagnoses or for the recommended limited periods of time. It is not clear that the

topical NSAID medications are medically necessary in addition to prescribed oral medications. There is no provided subjective/objective evidence that the patient has failed or not responded to other conventional and recommended forms of treatment for relief of the effects of the industrial injury. Only if the subjective/objective findings are consistent with the recommendations of the Official Disability Guidelines, then topical use of topical preparations is only recommended for short-term use for specific orthopedic diagnoses. There is no demonstrated medical necessity for the prescription of Terocin patches for the treatment of chronic low back pain due to degenerative disc disease. The request for Terocin patches is not medically necessary for the treatment of the patient for the diagnosis of chronic back pain. The patient is eight (8) months status post DOI and has exceeded the time period recommended for topical treatment. There are alternatives available OTC for the prescribed topical analgesics. The volume applied and the times per day that the patches are applied are variable and do not provide consistent serum levels consistent with effective treatment. There is no medical necessity for the addition of patches to the oral medications in the same drug classes. There is no demonstrated evidence that the topicals are more effective than generic oral medications. The prescription for Terocin patches is not medically necessary for the treatment of the patient's pain complaints. The prescription of Terocin patches is not recommended by the California MTUS and the Official Disability Guidelines. The continued use of topical NSAIDs for the current clinical conditions is not otherwise warranted or appropriate - noting the specific comment that "There is little evidence to utilize topical NSAIDs for treatment of osteoarthritis of the spine, hip, or shoulder." The objective findings in the clinical documentation provided do not support the continued prescription for the treatment of chronic pain. There is no documented medical necessity for the prescribed Terocin patches for the effects of the industrial injury in the treatment of chronic low back pain. Therefore, this request is not medically necessary.

Hot and Cold Unit: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines, Knee (acute and chronic), Continuous Flow Cryotherapy.

MAXIMUS guideline: Decision based on MTUS ACOEM Chapter 13 Knee Complaints Page(s): 300; 338, Chronic Pain Treatment Guidelines Physical Medicine Page(s): 98. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Knee and Leg Chapter, Cold Heat Packs; Continuous Flow Cryotherapy; Low Back Chapter Cold/Head Packs

Decision rationale: The use of the cold circulation units are recommended by evidence-based guidelines for hospital use but not for home use. There is no demonstrated medical necessity for this cold/hot therapy unit with appliance to be provided to the patient subsequent to the surgical intervention to the lumbar spine for home treatment as opposed to the conventional treatment with cold/hot packs. The medical necessity of the DME for the home treatment of the patient was not supported with objective evidence to support medical necessity. There is no objective evidence to support the home use of the requested cold/hot therapy system as opposed to the customary RICE for the treatment of pain and inflammation after the initially recommended seven (7) days of home therapy with a cold/hot therapy unit. There was no clinical documentation provided to support the medical necessity of the requested DME in excess of the

recommendations of the California MTUS. The use of a cold/hot circulation pump post-operatively is recommended for up to seven (7) days and not recommended for longer durations of time. There is no demonstrated medical necessity for the purchase of a cold/hot circulation unit for the treatment of the lumbar spine status post microdiscectomy. The cold/hot therapy units are not medically necessary for the treatment of the lumbar spine post operatively as alternatives for the delivery of heat and cold to the back are readily available. The request for authorization of the cold/hot therapy by name brand is not supported with objective medically based evidence to support medical necessity. There is no provided objective evidence to support the medical necessity of the requested cold/hot unit as opposed to the more conventional methods for the delivery of cold/hot for the cited surgical intervention rehabilitation. The California MTUS; the ACOEM Guidelines, and the Official Disability Guidelines recommend hot or cold packs for the application of therapeutic cold/hot or heat. The use of hot or cold/hot is not generally considered body part specific. The Official Disability Guidelines chapter on the knee and lower back states a good example of general use for hot or cold. The issue related to the request for authorization is whether an elaborate mechanical compression devise is necessary as opposed to the recommended hot or cold pack. There is no demonstrated medical necessity for the requested cold/hot unit for the treatment of the postoperative lumbar spine. There is no demonstrated medical necessity for the requested hot/cold unit for the treatment of the reported chronic low back pain status post microdiscectomy. Therefore, this request is not medically necessary.