

Case Number:	CM15-0022954		
Date Assigned:	02/12/2015	Date of Injury:	03/19/2011
Decision Date:	05/21/2015	UR Denial Date:	01/15/2015
Priority:	Standard	Application Received:	02/06/2015

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: Physical Medicine & Rehabilitation

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 50-year-old male who reported injury on 03/19/2011 with the mechanism of injury being the injured worker was stepping down off a moving truck and sustained an injury to the right ankle and foot. Prior treatments included surgical intervention of a talocalcaneal fusion and repair of the lateral talar process for a nonunion of the fracture on 12/09/2011. The injured worker received shockwave therapy and physical therapy, as well as an Orthofix bone stimulator. The injured worker was noted to have utilized the medication Dicopanol, Deprizine, Fanatrex, Synapryn, and Tabradol since 09/14/2013. The documentation of 12/16/2014 revealed the injured worker was status post right ankle surgery in 12/2011. The injured worker had pain that was frequent, constant, and moderate to severe. The injured worker was noted to have difficulty sleeping and was often awoken at night due to pain. The injured worker indicated medications offered temporary relief of pain and improved his ability for a restful sleep. The injured worker had +2 edema at the mortise joint. The injured worker had tenderness to palpation at the medial and lateral malleolus with decreased range of motion of the right ankle. The injured worker had a positive anterior and posterior drawer and varus and valgus stress test. The diagnoses included status post ORIF of the right ankle with residual pain and sleep disorder. The treatment plan included Deprizine, Dicopanol, Fanatrex, Synapryn, Tabradol, capsaicin, flurbiprofen, menthol, cyclobenzaprine, and gabapentin.

IMR ISSUES, DECISIONS AND RATIONALES

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

Compound Ketoprofen 20% in PLO Gel, 120 grams: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-112.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics. Ketoprofen Page(s): 111,112.

Decision rationale: The California Medical Treatment Utilization Schedule Guidelines indicate that topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety and any compounded product that contains at least 1 drug (or drug class) that is not recommended is not recommended, and are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. Ketoprofen is not currently FDA approved for a topical application. The clinical documentation submitted for review failed to provide the duration of use. There was a lack of documentation of exceptional factors to warrant non-adherence to guideline recommendations. There was a lack of documentation indicating the injured worker had a trial and failure of antidepressants and anticonvulsants. The request as submitted failed to indicate the frequency and the body part to be treated. Given the above, the request for Compound Ketoprofen 20% in PLO Gel, 120 grams is not medically necessary.

Compound Cyclophene 5% in PLO Gel, 120gram: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-113.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines cyclobenzaprine Page(s): 41.

Decision rationale: The California Medical Treatment Utilization Schedule Guidelines indicate that topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety, topical analgesics are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. Any compounded product that contains at least 1 drug (or drug class) that is not recommended is not recommended. The guidelines do not recommend the topical use of cyclobenzaprine as a topical muscle relaxant as there is no evidence for use of any other muscle relaxant as a topical product. The clinical documentation submitted for review failed to provide the rationale for both a topical and oral form of the requested medication. There was a lack of documentation indicating the injured worker had a trial and failure of antidepressants and anticonvulsants. The request as submitted failed to indicate the frequency and body part to be treated. Given the above, the request for Compound Cyclophene 5% in PLO Gel, 120gram is not medically necessary.

Deprizine 15mg/ml Oral Suspension 250ml: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 68.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDS, not specifically address Deprizine, however it does address H-2 Blockers Page(s): 69. Decision based on Non-MTUS Citation www.drugs.com/search.php?searchterm=Deprizine.

Decision rationale: 4. The California Medical Treatment Utilization Schedule Guidelines recommend histamine 2 blockers for treatment of dyspepsia secondary to NSAID therapy. The medication Deprizine includes ranitidine, which is a histamine 2 blocker and can be used for the treatment of dyspepsia. However, per Drugs.com, Deprizine: Generic Name: ranitidine hydrochloride has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. The use of an oral suspension medication is only supported in the instances when the drug is unavailable in tablet or capsule form or when the patient's condition substantiates their inability to swallow or tolerate a pill. The clinical documentation submitted for review failed to provide documentation the injured worker had dyspepsia. Additionally, there was a lack of documentation of efficacy for the requested medication as it was utilized since 2013. There was a lack of documentation indicating the injured worker had an inability to swallow or tolerate a pill. The request as submitted failed to indicate the frequency and the specific dosage. Given the above, the request for Deprizine 15mg/ml Oral Suspension 250ml is not medically necessary.

Dicopanol (diphenhydramine) 5mg/ml Oral Suspension: 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), 13th edition (web), 215, Pain Chapter, Insomnia Treatment.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter, Insomnia Treatment and Other Medical Treatment Guidelines www.drugs.com/search.php?searchterm=Dicopanol.

Decision rationale: The Official Disability Guidelines indicate that sedating antihistamines have been suggested for sleep aids (for example, diphenhydramine) and that tolerance seems to develop within a few days. Per Drugs.com, Dicopanol is diphenhydramine hydrochloride and it was noted this drug has not been found by the FDA to be safe and effective and the labeling was not approved by the FDA. The use of an oral suspension medication is only supported in the instances when the drug is unavailable in tablet or capsule form or when the patient's condition substantiates their inability to swallow or tolerate a pill. The clinical documentation submitted for review indicated the injured worker had difficulty sleeping and the medication helped. However, there was a lack of documentation of quantification of specifically how the medication helped as far as duration of sleep and ability to stay asleep. There was a lack of documentation indicating the injured worker had an inability to swallow or tolerate a pill. Additionally, this medication has not been found to be safe, per the FDA, and, as such, would not be supported. The request as submitted failed to indicate the frequency and the specific dosage. Given the

above, the request for Dicopan^{ol} (diphenhydramine) 5mg/ml Oral Suspension is not medically necessary.

Terocin Patches (strength & qty unk.): Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 111-113.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Salicylate Topicals, Topical Analgesic, Lidocaine Page(s): 105,111,112. Decision based on Non-MTUS Citation dailymed.nlm.nih.gov/dailymed/lookup.cfm?setid=100ceb76-8ebe-437b-a8de-37cc76ece9bb.

Decision rationale: The California Medical Treatment Utilization Schedule Guidelines indicate that topical analgesics are largely experimental in use with few randomized control trials to determine efficacy or safety are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. Any compounded product that contains at least 1 drug (or drug class) that is not recommended is not recommended. The guidelines indicate that topical lidocaine (Lidoderm) may be recommended for localized peripheral pain after there has been evidence of a trial of first line therapy (tricyclic or SNRI antidepressants or an AED such as gabapentin or Lyrica). No other commercially approved topical formulations of lidocaine (whether creams, lotions or gels) are indicated for neuropathic pain. The guidelines recommend treatment with topical salicylates. Per dailymed.nlm.nih.gov, Terocin patches are topical lidocaine and menthol. The clinical documentation submitted for review failed to indicate the injured worker had a trial and failure of antidepressants and anticonvulsants. There was a lack of documentation of a trial and failure of first line therapy including antiepilepsy drugs or antidepressants. There was a lack of documentation of exceptional factors as lidocaine is not recommended except in the form of Lidoderm patches. The request as submitted failed to indicate the frequency, quantity, and strength, as well as the body part to be treated. Given the above, the request for Terocin Patches (strength & qty unk.) is not medically necessary.

Functional Capacity Evaluation: 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), 15th Edition (web), 2013, Fitness for Duty Functional Capacity Evaluation (FCE).

MAXIMUS guideline: Decision based on MTUS ACOEM Chapter 5 Cornerstones of Disability Prevention and Management Page(s): 89-92. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Fitness for Duty Chapter, FCE.

Decision rationale: The American College of Occupational and Environmental Medicine Guidelines indicate there is a functional assessment tool available and that is a Functional Capacity Evaluation; however, it does not address the criteria. As such, secondary guidelines were sought. The Official Disability Guidelines indicate that a Functional Capacity Evaluation is appropriate when a worker has had prior unsuccessful attempts to return to work. The clinical

documentation submitted for review failed to provide documentation the injured worker had a failed attempt to return to work. The original date of request could not be established. Given the above, the request for Functional Capacity Evaluation is not medically necessary.

Chiropractic Manipulation (body part, frequency & duration unk.): Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Manual Therapy & Manipulation Page(s): 58.

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

Decision rationale: The California Medical Treatment Utilization Schedule Guidelines state that manual therapy and manipulation is recommended for chronic pain if caused by musculoskeletal conditions. For the low back, therapy is recommended initially in a therapeutic trial of 6 sessions, and with objective functional improvement, a total of up to 18 visits over 6 to 8 weeks may be appropriate. Treatment for flare ups requires a need for re-evaluation of prior treatment success. Treatment is not recommended for the ankle and foot, carpal tunnel syndrome, the forearm, wrist and hand, or the knee. If chiropractic treatment is going to be effective, there should be some outward sign of subjective or objective improvement within the first 6 visits. Treatment beyond 4 to 6 visits should be documented with objective improvement in function. The maximum duration is 8 weeks, and at 8 weeks patients should be re-evaluated. Care beyond 8 weeks may be indicated for certain chronic pain patients in whom manipulation is helpful in improving function, decreasing pain and improving quality of life. The clinical documentation submitted for review failed to provide a rationale for the requested chiropractic manipulation. There was a lack of documentation indicating if this was the initial or subsequent chiropractic treatment. Additionally, the request as submitted failed to indicate the body part, frequency, and duration. Given the above and the lack of documentation, the request for Chiropractic Manipulation (body part, frequency & duration unk.) is not medically necessary.

Acupuncture (body part, frequency & duration unk.): Upheld

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

MAXIMUS guideline: Decision based on MTUS Acupuncture Treatment Guidelines.

Decision rationale: The California Medical Treatment Utilization Schedule Guidelines state that acupuncture is used as an option when pain medication is reduced or not tolerated and it is recommended as an adjunct to physical rehabilitation and/or surgical intervention to hasten functional recovery. Acupuncture can be used to reduce pain, reduce inflammation, increase blood flow, increase range of motion, decrease the side effect of medication induced nausea, promote relaxation in an anxious patient, and reduce muscle spasm. The time to produce functional improvement is 3 to 6 treatments and acupuncture treatments may be extended if functional improvement is documented, including either a clinically significant improvement in activities of daily living or a reduction in work restrictions. The clinical documentation

submitted for review indicated the injured worker had been monitored for aberrant drug behavior through urine drug screens and for side effects. However, there was a lack of documentation of objective functional improvement and an objective decrease in pain. Additionally, there was a lack of documentation indicating the injured worker had an inability to swallow or tolerate a pill. There was a lack of documentation indicating the injured worker had moderate arthritis pain. Additionally, the request as submitted failed to indicate the frequency and specific dosage for the requested medication. Given the above, the request for Acupuncture (body part, frequency & duration unk) is not medically necessary.

Synapryn (10mg/1ml Oral Suspension 500ml): Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 50, 76, 80-83.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Glucosamine Sulfate, Ongoing Management, Tramadol Page(s): 50,78,82, 93, & 94.

Decision rationale: The California Medical Treatment Utilization Schedule Guidelines recommend tramadol for pain; however, they do not recommend it as a first line oral analgesic and they recommend glucosamine sulfate for patients with moderate arthritis pain, especially knee osteoarthritis, and that only 1 medication should be given at a time. Synapryn, per the online package insert included tramadol and glucosamine sulfate. The use of an oral suspension medication is only supported in the instances when the drug is unavailable in tablet or capsule form or when the patient's condition substantiates their inability to swallow or tolerate a pill. As tramadol is a form of an opiate, the California Medical Treatment Utilization Schedule Chronic Pain Guidelines recommend opiates for chronic pain. There should be documentation of an objective improvement in function, an objective decrease in pain, and evidence that the patient is being monitored for aberrant drug behavior and side effects. The clinical documentation submitted for review failed to provide documentation the injured worker could not tolerate or swallow a pill. There was a lack of documentation of objective functional improvement, an objective decrease in pain. The injured worker was being monitored for aberrant drug behavior and side effects. There was a lack of documentation of exceptional factors as this medication is not supported by the Food and Drug Administration. The request as submitted failed to indicate the frequency and specific dosing. Given the above, the request for Synapryn (10mg/1ml Oral Suspension 500ml) is not medically necessary.

Fanatrex (Gabapentin) 25mg/ml Oral Suspension 420ml: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Chronic pain, Cyclobenzaprine Page(s): 41.

Decision rationale: Tabradol is a compounding kit for oral suspension of cyclobenzaprine and methylsulfonylmethane. A search of ACOEM, California Medical Treatment Utilization

Schedule Guidelines, and Official Disability Guidelines, along with the National Guideline Clearinghouse (NCG) and the PubMed database, returned no discussion on Tabradol. The use of an oral suspension medication is only supported in the instances when the drug is unavailable in tablet or capsule form or when the patient's condition substantiates their inability to swallow or tolerate a pill. There was a lack of evidence based literature for the oral compounding of cyclobenzaprine and methylsulfonylmethane over the commercially available oral forms and the lack of medical necessity requiring an oral suspension of these medications. There was a lack of documentation supporting the necessity for both an oral and topical form of the medication. There was a lack of documentation of exceptional factors. There was a lack of documentation indicating the injured worker could not swallow tablets or pills. The efficacy was not provided. The request as submitted failed to include the frequency and dosage. Given the above, the request for Tabradol 1mg/ml Oral Suspension 250ml is not medically necessary.

Tabradol 1mg/ml Oral Suspension 250ml: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 64.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Chronic pain does not address Fanatrex, Gabapentin Page(s): 16. Decision based on Non-MTUS Citation www.drugs.com/search.php?searchterm=Fanatrex.

Decision rationale: The California Medical Treatment Utilization Schedule Guidelines indicate that gabapentin is used in the treatment of neuropathic pain. Per Drugs.com, Fanatrex is an oral suspension of gabapentin that has not approved by the FDA. The use of an oral suspension medication is only supported in the instances when the drug is unavailable in tablet or capsule form or when the patient's condition substantiates their inability to swallow or tolerate a pill. The clinical documentation submitted for review failed to provide documented rationale for both oral and topical cyclobenzaprine. There was a lack of documentation indicating the injured worker had an inability to swallow or tolerate a pill. The objective functional benefit and objective pain relief were not noted. The request as submitted failed to indicate the frequency and specific dosage for the requested medication. Given the above, the request for Fanatrex (Gabapentin) 25mg/ml Oral Suspension 420ml is not medically necessary.