

Case Number:	CM15-0019846		
Date Assigned:	02/09/2015	Date of Injury:	01/15/2011
Decision Date:	06/11/2015	UR Denial Date:	01/26/2015
Priority:	Standard	Application Received:	02/02/2015

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, Arizona
 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 57 year old female, who sustained an industrial injury on 01/15/2011. Medical records provided by the treating physician did not indicate the injured worker's mechanism of injury. Diagnoses include cervical spine herniated nucleus pulposus, cervical spine degenerative disc disease, rule out cervical spine radiculopathy, status post right shoulder surgery with residual pain, right shoulder tendonitis, acromioclavicular arthrosis, right shoulder bursitis, low back pain, lumbar spine herniated nucleus pulposus, lumbar spine degenerative disc disease, rule out radiculitis to the lower extremity, right knee internal derangement, right knee lateral meniscal tear, right knee tendonitis, anxiety disorder, mood disorder, sleep disorder, and stress. Treatment to date has included medication regimen and above listed surgery. In a progress note dated 12/15/2014 the treating provider reports burning radicular neck pain with muscle spasms; constant, moderate to severe right shoulder pain; burning radicular low back pain with muscle spasms; constant, and moderate to severe, burning right knee pain with muscle spasms. The neck pain is rated an eight out of ten, right shoulder pain is rated a seven out of ten, the radicular low back pain is rated a seven out of ten, and the right knee pain is rated an eight out of ten. On 01/25/2015 Utilization Review non-certified the requested treatments of Ketoprofen 20% cream 167gms, Cyclobenzaprine 5% cream 110gms, Synapryn 10mg/1ml 500mg oral suspension, Tabradol 1mg/ml 250mg oral suspension, Deprizine 15mg/ml 250ml oral suspension, Dicopanol 5mg/ml 150ml oral suspension, and Fanatrex 25mg/ml 420ml oral suspension for the dates of 12/15/2014 to 03/09/2015, noting the California Chronic Pain Medical Treatment Guidelines (May 2009) and Official Disability Guidelines, Pain (Chronic).

IMR ISSUES, DECISIONS AND RATIONALES

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

Ketoprofen 20% cream 167gms: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Non-Steroidal Anti-Inflammatory Drugs (NSAIDs). Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain.

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. 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 Ketoprofen 20% cream 167gms is not medically necessary.

Cyclobenzaprine 5% cream 110gms: 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. Cyclobenzaprine Page(s): 111, 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 relaxants as there is no evidence for use of any other muscle relaxant as a topical product. There was a lack of documentation indicating a necessity for both a topical and oral form of cyclobenzaprine. There was a lack of documentation indicating the injured worker had trialed and failed antidepressants and anticonvulsants. The request as submitted failed to indicate the frequency and body part to be treated. Given the above, the request for Cyclobenzaprine 5% cream 110gms is not medically necessary.

Synapryn 10mg/1ml 500mg oral suspension: 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 Glucosamine Sulfate, Ongoing Management, Tramadol Page(s): 50, 78, 82, 93, & 94. Decision based on Non-MTUS Citation Synapryn online drug insert.

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 indicate the injured worker had arthritis. There was a lack of documentation of objective functional improvement, an objective decrease in pain, and documentation the injured worker was being monitored for aberrant drug behavior and side effects. There was a lack of documentation indicating the injured worker had an inability to swallow or tolerate pills. The request as submitted failed to indicate the frequency and the specific dosage for the medication. Given the above, the request for Synapryn 10mg/1ml 500mg oral suspension is not medically necessary.

Tabradol 1mg/ml 250mgl oral suspension: 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 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. The clinical documentation submitted for review failed to provide documentation for a necessity for a topical and oral form of the medication. There was a lack of documentation of exceptional factors. The

request as submitted failed to indicate the frequency and the specific dosage. Given the above, the request for Tabradol 1mg/ml 250mg oral suspension is not medically necessary.

Deprizine 15mg/ml 250ml oral suspension: 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 NSAIDS, does 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: The California Medical Treatment Utilization Schedule Guidelines recommends 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 secondary to NSAID therapy. There was a lack of documentation indicating the injured worker had a necessity for a liquid and had an inability to swallow or tolerate a pill. The request as submitted failed to indicate the frequency and the dosage for the requested medication. Given the above, the request for Deprizine 15mg/ml 250ml oral suspension is not medically necessary.

Dicopanol 5mg/ml 150ml 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).

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 Treatments 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 failed to provide documentation of exceptional factors as the medication is not noted to be safe and effective per the FDA. 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 specific dosage for the requested medication. Given the above, the request for Dicopanl 5mg/ml 150ml oral suspension is not medically necessary.

Fanatrex 25mg/ml 420ml oral suspension: 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 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 been 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 indicate the injured worker had an inability to swallow or tolerate a pill. There was a lack of documentation of exceptional factors to warrant non-adherence to guideline recommendations. The request as submitted failed to indicate the frequency and specific dosing for the medication. Given the above, the request for Fanatrex 25mg/ml 420ml oral suspension is not medically necessary.