

Case Number:	CM15-0146281		
Date Assigned:	08/07/2015	Date of Injury:	08/07/2013
Decision Date:	10/06/2015	UR Denial Date:	06/30/2015
Priority:	Standard	Application Received:	07/27/2015

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:

The injured worker is a 60-year-old female who sustained an industrial injury on 08-07-13. She reported neck and shoulder pain. The injured worker is diagnosed with cervical muscle spasm-radiculopathy-stenosis, left rotator cuff tear-adhesive tendinitis-myospasm, status post surgery-left shoulder, and chronic pain. Diagnostic testing and treatment to date has included MRI, left shoulder surgery, physical therapy, cervical spine shockwave treatment, psychological evaluation, and medication management. Currently, the injured worker complains of constant, severe, sharp and stabbing cervical spine pain that radiates to the left shoulder with frequent stiffness. She has mild, dull, and achy left shoulder pain. Physical examination is remarkable for tenderness and painful decreased range of motion to the cervical spine, with paravertebral and left trapezius muscle spasm. The left shoulder is tender and has painful decreased range of motion; Supraspinatus Press causes pain. Requested treatments include Ketoprofen 20 percent cream 165 grams, cyclobenzaprine 5 percent cream 100 grams, Synapryn 10 MG/1 ML oral suspension 500 ML, Tabradol 1 Mg/ML oral suspension 250 ML, Deprizine 15 Mg /ML oral suspension 250 ML, Dicopanol 5 Mg/ML oral suspension 150 ML, and Fanatrex 25 Mg/ML oral suspension 420 ML. The injured worker is under modified work restrictions. Date of Utilization Review: 06-30-15.

IMR ISSUES, DECISIONS AND RATIONALES

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

Ketoprofen 20 Percent Cream 165 Grams: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics.

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

Decision rationale: As per MTUS Chronic pain guidelines, topical NSAIDs may be beneficial for osteoarthritic pain mostly on limbs. It has no benefit for spinal or shoulder pain. Patient's pain is all localized to spine and shoulder. Ketoprofen is not FDA approved for topical applications. The use of a non-FDA approved application of a medication when there are multiple other topical NSAIDs is not medically necessary. Ketoprofen cream is not recommended.

Cyclobenzaprine 5 Percent Cream 100 Grams: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics.

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

Decision rationale: As per MTUS Chronic pain guidelines, most topical medications especially compounded ones are considered experimental with little evidence of benefit. Cyclobenzaprine is an oral muscle relaxant. It is only FDA approved for oral use and is not FDA approved for topical use. There is no evidence of any efficacy or safety with topical. There is no justification in using an unapproved substance with unknown safety or efficacy with no supporting evidence. Cyclobenzaprine cream is not medically necessary.

Synapryn 10 MG/1 ML Oral Suspension 500 ML: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 76-79.

Decision rationale: "Synapryn" is not an FDA approved medication. It is a compounded substance containing Tramadol (a Mu-Agonist, an opioid-like medication), glucosamine and "other proprietary ingredients". MTUS guidelines have specific recommends concerning chronic opioid use which the provider's documentation fails to provide. Provider has failed to document anything concerning functional improvement in pain or function with this substance. There is no justification for using a non-FDA approved substance with unknown efficacy and unknown safety profile. There is no justification for a liquid formulation provided by the provider. There is a higher risk of overdose on liquid formulation. The requested amount of this substance is not

appropriate, as it is asking for 0.5 liters of this medication. The use of a compounded non-FDA approved substance like "Synapryn" is not medically necessary.

Tabradol 1 MG/ML Oral Suspension 250 ML: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Cyclobenzaprine (Flexeril) Page(s): 41-42.

Decision rationale: "Tabradol" is not an FDA approved medication. It is a compounded substance containing Cyclobenzaprine (a muscle relaxant) and "other proprietary ingredients". As per MTUS guidelines, evidence show that Cyclobenzaprine is better than placebo but is considered a second line treatment due to high risk of adverse events. It is recommended only for short course of treatment for acute exacerbation. Provider has failed to document anything concerning functional improvement in pain or function with this substance. There is no justification for using a non-FDA approved substance with unknown efficacy and unknown safety. There is no justification for a liquid formulation provided by the provider. The requested amount of this substance is not appropriate and excessive. The use of a compounded non-FDA approved substance like "Tabradol" is not medically necessary.

Deprizine 15 MG /ML Oral Suspension 250 ML: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms and cardiovascular risks Page(s): 68-69.

Decision rationale: "Deprizine" is not an FDA approved medication. It is a compounded substance containing ranitidine (a H2 blocker used for acid reduction for gastritis) and "other proprietary ingredients". As per MTUS guidelines, ranitidine may be used by patients at risk for GI bleed or active dyspepsia on NSAID therapy. There is no rationale provided for this substance. There is no justification for using a non-FDA approved substance with unknown efficacy and unknown safety profile. The requested amount of this substance is not appropriate. There is no justification for a liquid formulation provided by the provider. The use of a compounded non-FDA approved substance like "Deprizine" is not medically necessary.

Dicopanol 5 MG/ML Oral Suspension 150 ML: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Mental/Stress: Diphenhydramine (benadryl).

Decision rationale: "Dicopanl" is not an FDA approved medication. It is a compounded substance containing diphenhydramine (a Histamine blocker) and "other proprietary ingredients". Provider claims it is being used for "insomnia". MTUS and ACOEM guidelines do not deal with this topic. As per Official Disability Guidelines, chronic diphenhydramine use is not recommended. Chronic use significantly increase risk of dementia in older adults. There is no justification for using a non-FDA approved substance with unknown efficacy and unknown safety profile. The requested amount of this substance is not appropriate. There is no justification for a liquid formulation provided by the provider. The use of a compounded non-FDA approved substance like "Dicopanl" is not medically necessary.

Fanatrex 25 MG/ML Oral Suspension 420 ML: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Anti-epilepsy drugs (AEDs) Page(s): 18-19.

Decision rationale: "Fanatrex" is not an FDA approved medication. It is a compounded substance containing Gabapentin (an anti-epileptic drug (AED)) and "other proprietary ingredients". Gabapentin (Neurontin) is an anti-epileptic drug with efficacy in neuropathic pain. It is most effective in polyneuropathic pain. There is no documentation of any functional objective improvement or improvement in pain. There is no justification for using a non-FDA approved substance with unknown efficacy and unknown safety profile. The requested amount of this substance is not appropriate. There is no justification for a liquid formulation provided by the provider. The use of a compounded non-FDA approved substance like "Fanatrex" is not medically necessary.