

Case Number:	CM15-0023093		
Date Assigned:	02/12/2015	Date of Injury:	05/01/2013
Decision Date:	05/21/2015	UR Denial Date:	01/20/2015
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 55 year old female, who sustained an industrial injury on 5/1/2013. The mechanism of injury was cumulative trauma to the neck, upper and lower back, bilateral hips, and right knee. The injured worker was diagnosed as having cervical spine multi-level disc displacement, cervical spine multi-level disc degeneration, cervical spinal stenosis, cervical radiculopathy, thoracic spine pain, thoracic spine multi-level disc degeneration, low back pain, lumbar radiculopathy, lumbar spine herniated nucleus pulposus, bilateral hip internal derangement, and bilateral knee sprain/strain. Treatment to date has included magnetic resonance imaging, trigger point injections, epidural steroid injections, LINT therapy, and medications. The request is for Synapryn, Tabradol, Deprizine, Dicopanol, and Fanatrex. On 1/2/2015, she complained of continued pain of the neck, mid back, low back, bilateral hips, and right knee pain. She rated her pain as: neck 8-9/10, mid back 8-9/10, low back 8-9/10, bilateral hips 8-9/10, and right knee 8-9/10. She reports that medications give her temporary relief of pain and help her to sleep. The treatment plan included: Terocin patches, pain management consultation, orthopedic surgeon consultation, continue medications: Deprizine, Dicopanol, Fanatrex, Synapryn, Tabradol, Capsaicin, Flurbiprofen, Menthol, Cyclobenzaprine, and Gabapentin. The documentation of 11/24/2014 revealed the injured worker had complaints of burning radicular midback, neck, and low back pain with associated muscle spasms. The injured worker had tenderness to palpation at the suboccipital region and over both trapezius and scalene muscles. The injured worker had decreased range of motion of the cervical spine. The injured worker had a positive distraction and compression test. The injured worker had spasms in the

thoracic spine and lumbar spine. The injured worker had decreased range of motion of the lumbar spine. The diagnosis included thoracic spine pain, thoracic spine multilevel disc degeneration, low back pain, lumbar spine herniated nucleus pulposus and lumbar radiculopathy, along with mood disorder, sleep disorder, and anxiety disorder. The treatment plan included Terocin patches for pain relief, and a continuation of deprezine, 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:

Synapryn 10mg/1ml oral suspension 500ml: 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) Compound drugs.

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

Tabradol 1mg/mg oral suspension 250ml: 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) Compound drugs.

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 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 the dosage for the requested medication. Given the above, the request for Tabradol 1mg/mg oral suspension 250ml is not medically necessary.

Deprizine 15mg/ml oral suspension 250ml: 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) Compound drugs.

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 indicate the injured worker had dyspepsia. There was a lack of documentation of exceptional factors. Additionally, this medication has not been found by the FDA to be safe and effective, and labeling has not been approved by the FDA. As such, this medication would not be supported. Additionally, 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 for the medication. Given the above, the request for Deprizine 15mg/ml oral suspension 250ml is not medically necessary.

Dicopanol 5mg/ml oral suspension 150ml: 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) Compound drugs.

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 the efficacy for the requested medication. There was a lack of documentation of exceptional factors as this medication has not been found to be safe and effective per the Federal Drug Administration There was a lack of documentation indicating the injured worker had an inability to swallow a tablet or capsule. The request as submitted failed to indicate the frequency and the specific dosage. Given the above, the request for Dicopanol 5mg/ml oral suspension 150ml is not medically necessary.

Fanatrex 25mg/ml oral suspension 420ml: 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) Compound drugs.

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 documentation of exceptional factors for non-adherence to the Federal Drug Administration recommendations, which indicates that Fanatrex is an oral suspension of gabapentin that is not approved. 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 Fanatrex 25mg/ml oral suspension 420ml is not medically necessary.