

<b>Case Number:</b>	CM13-0056322		
<b>Date Assigned:</b>	04/16/2014	<b>Date of Injury:</b>	05/03/2013
<b>Decision Date:</b>	05/27/2014	<b>UR Denial Date:</b>	11/04/2013
<b>Priority:</b>	Standard	<b>Application Received:</b>	11/22/2013

### 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 Physical Medicine & Rehabilitation 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:

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 32-year-old male who reported injury on 05/03/2013. The mechanism of injury was the injured worker was operating a pallet jack, when the jack became wedged in a pallet, and upon removal, the injured worker pulled his shoulder out. The documentation of 10/18/2013 revealed the injured worker had subjective complaints of burning radicular neck pain and muscle spasms that were constant and severe; burning bilateral shoulder pain radiating down the arms to the fingers, associated with spasm; and burning radicular mid-back pain and muscle spasms. The injured worker had tenderness to palpation at the occiput more on the right side, and the trapezius and levator scapula muscles. There was tenderness to palpation at the scalenes, splenius, and sternocleidomastoid muscles. The injured worker had decreased range of motion in the bilateral shoulders. The treatment to be rendered included an MRI (magnetic resonance imaging), x-rays, surgery, physical therapy, transcutaneous electrical nerve stimulation (TENS) unit, and shockwave, as well as medications.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**COMPOUNDED KETOPROFEN 20% TIMES 120 GR:** 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, and Section Ketoprofen Page(s): 111,112.

**Decision rationale:** The California MTUS indicates 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. The MTUS also states "any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended." Regarding the use of Ketoprofen: This agent is not currently Food and Drug Administration (FDA)-approved for a topical application. In this case, the clinical documentation submitted for review indicated the injured worker had neuropathic pain. There was lack of documentation indicating the injured worker had a trial and failure of antidepressants and anticonvulsants. As ketoprofen has not currently been FDA approved for topical application, the request would not be supported. The request as submitted failed to indicate the frequency for the requested medication. The duration of use for this medication could not be established. Given the above, the request for compounded ketoprofen 20% x120 gr is not medically necessary.

**COMPOUNDED CYCLOPENE 5% TIMES 120 GR:** 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, Topical Muscle Relaxants, Cyclobenzaprine Page(s): 111,113,41.

**Decision rationale:** The California MTUS indicates topical analgesics are experimental in use with few randomized controlled trials to determine efficacy or safety and are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. The California MTUS Guidelines do not recommend the topical use of Cyclobenzaprine as topical muscle relaxants as there is no evidence for use of any other muscle relaxant as a topical product. In this case, the clinical documentation submitted for review indicated the injured worker had neuropathic pain. However, 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 for the medication. The duration of use for this medication could not be established. The clinical documentation submitted for review failed to provide documentation of exceptional factors to warrant non-adherence to guideline recommendations. Given the above, the request for compounded Cyclophene 5% x120 gr is not medically necessary.

**SYNAPRN 10MG/1 M1 TIMES 500 ML:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Glucosamine, Section Sulfate, Section Ongoing Management, Section Tramadol, Page(s): 50,78,82, 93,. Decision based on Non-MTUS Citation FDA.gov.

**Decision rationale:** The California MTUS Guidelines recommend tramadol for pain; however, do not recommend it as a first-line oral analgesic. A thorough search of FDA.gov, did not indicate there was a formulation of topical Tramadol that had been FDA approved. The California MTUS guidelines 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 clinical documentation submitted for review failed to provide the necessity for an oral suspension which 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. The duration of use for this medication could not be established. The clinical documentation submitted for review failed to provide exceptional factors to warrant non-adherence to guideline recommendations. The clinical documentation submitted for review failed to indicate the injured worker had a necessity for a liquid formulation of the medication. However, it failed to indicate the injured worker had osteoarthritis to support the necessity for the use of the medication. There is 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 for the requested medication. Given the above, the request for Synaprin 10 mg/1 mL x500 mL is not medically necessary.

**TABRADOL 1 MG/ML X 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 Page(s): 41.

**Decision rationale:** The California MTUS indicate that Cyclobenzaprine (Flexeril®) is recommended for a short course of therapy. This medication is not recommended to be used for longer than 2-3 weeks. The addition of cyclobenzaprine to other agents is not recommended. The MTUS do not recommend the topical use of Cyclobenzaprine as topical muscle relaxants as there is no evidence for use of any other muscle relaxant as a topical product. Tabradol is a compounding kit for oral suspension of cyclobenzaprine and methylsulfonylmethane. A search of ACOEM, California MTUS 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 duration of use for this medication could not be established. The clinical documentation submitted for review failed to indicate the injured worker had a necessity for both the topical and

oral form of the medication. This request was concurrently being reviewed for a topical medication. 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 for the requested medication. Given the above, the request for Tabradol 1 mg/mL x250 mg is not medically necessary.

**DEPRIZINE 15MG/ML X 250 ML:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines non-steroidal anti-inflammatory drugs (NSAIDs) Page(s): 69.

**Decision rationale:** The California MTUS Guidelines recommends Histamine 2 blockers for treatment of dyspepsia secondary to non-steroidal anti-inflammatory drugs (NSAIDs) therapy. The clinical documentation submitted for review indicated the medication Deprizine includes ranitidine which is a Histamine 2 blocker and can be used for the treatment of dyspepsia. 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 duration of use for this medication could not be established. 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 indicating the injured worker had dyspepsia secondary to NSAID therapy. The request as submitted failed to indicate the frequency for the requested medication. Given the above, the request for Deprizine 15 mg/mL x250 mL is not medically necessary.