

<b>Case Number:</b>	CM14-0029735		
<b>Date Assigned:</b>	06/16/2014	<b>Date of Injury:</b>	11/19/2013
<b>Decision Date:</b>	08/20/2014	<b>UR Denial Date:</b>	02/18/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	03/07/2014

### 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 and Rehabilitation, has a subspecialty in Pain Medicine 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 injured worker is a 60-year-old male who reported an injury on 11/19/2013. The mechanism of injury was noted as a fall. The clinical note dated 12/17/2013 noted the injured worker complained of burning left shoulder pain rated 7/10. The injured worker described the pain as constant, moderate to severe and aggravated by gripping, gasping, reaching, pulling, lifting and doing work at above shoulder level. The physical examination of the left shoulder revealed trigger points at the trapezius, levator scapula and rhomboid muscles. Diagnostic studies included an MRI of the left shoulder which was performed on 12/13/2013 and an MRI of the left shoulder which was performed on 02/10/2014. The injured worker was diagnosed with left shoulder internal derangement and left shoulder AC arthrosis. Previous treatments included physical therapy. Medications were noted as naproxen; however, the dosage and frequency were not provided in the medical records submitted for review. The provider's request for 1 bottle of Tabradol 1 mg/mL oral suspension, 250 mL, 1 container of ketoprofen 20% in PLO gel 120 grams, 1 bottle of Synapryn 10 mg/mL oral suspension 500 mL, and 1 container of cyclophene 5% in PLO gel 120 grams was noted on clinical note dated 12/17/2013. The request for authorization and the rationales for the requests were not provided within the medical records.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**1 BOTTLE OF TABRADOL 1MG/ML ORAL SUSPENSION 250ML:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Muscle Relaxants (for Pain), page(s) 63-64 Page(s): 63-64. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Compounded Drugs.

**Decision rationale:** The injured worker has a history of left shoulder pain. Tabradol contains cyclobenzaprine hydrochloride 1 mg/mL, in an oral suspension with MSM. The California MTUS Guidelines recommend non-sedating muscle relaxants with caution as a second line option for short term treatment of acute exacerbations in patients with chronic low back pain (LBP). The guidelines further state cyclobenzaprine is recommended for a short course of therapy as there are limited, mixed-evidence that does not allow for a recommendation for chronic use. The guidelines do not recommend using cyclobenzaprine longer than 2-3 weeks. The Official Disability Guidelines (ODG) do not recommend compounded drugs as a first-line therapy for most patients, but recommended as an option after a trial of first-line FDA-approved drugs, if the compound drug uses FDA-approved ingredients that are recommended in ODG. The guidelines note compounded medications should include at least one drug substance that is the sole active ingredient in an FDA-approved prescription drug, include only bulk ingredients that are components of FDA-approved drugs that have been made in an FDA-registered facility and have an NDC code, not include a drug that was withdrawn or removed from the market for safety reasons, and they should not be a copy of a commercially available FDA-approved drug product. The documentation provided noted the patient complained of left shoulder pain & difficulty reaching overhead and behind his back; however, there is a lack of documentation to indicate significant muscle spasms were present upon physical examination to warrant the use of a muscle relaxant. The documentation provided did not indicate the physician's rationale for providing an oral suspension as opposed to traditional forms of medication. There is no documentation indicating the injured worker has difficulty taking other forms of medication. There is no documentation indicating the injured worker's need for a compounded medication. Additionally, the request does not indicate the frequency at which the medication is prescribed and the prescribed dosage of the medication in order to determine the necessity of the medication. As such, the request for 1 Bottle of Tabradol 1 mg/ml oral suspension 250 ml is not medically necessary.

**1 CONTAINER OF KETOPROFEN 20% IN PLO GEL 120 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) 111-112 Page(s): 111-112.

**Decision rationale:** The injured worker has a history of left shoulder pain and has participated in physical therapy for treatment. The California MTUS Guidelines state topical analgesics are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. The guidelines note any compounded product that contains at least 1 drug (or drug

class) that is not recommended is not recommended. The guidelines recommend the use of topical NSAIDs for osteoarthritis and tendinitis, in particular that of the knee and elbow or other joints that are amenable to topical treatment, the guidelines recommend topical NSAIDs short term use (4 weeks to 12 weeks). There is little evidence to utilize topical NSAIDs for treatment of osteoarthritis of the spine, hip, or shoulder. The California MTUS Guidelines state ketoprofen is not currently FDA approved for a topical application as it has an extremely high incidence of photocontact dermatitis. The documentation provided noted the patient complained of left shoulder pain & difficulty reaching overhead and behind his back; however, there is a lack of documentation to indicate trials of antidepressants and anticonvulsants have failed to provide symptomatic relief. There is a lack of documentation indicating the injured worker has a diagnosis of osteoarthritis or tendinitis, particularly to a site which would lend itself to topical treatment. The guidelines note there is little evidence to use NSAIDs for topical application to the shoulder. Additionally, the request does not indicate the frequency at which the medication is prescribed or the site at which it is to be applied in order to determine the necessity of the medication. As such, the request for 1 container of Ketoprofen 20% in PLO gel 120 grams is not medically necessary.

**1 BOTTLE OF SYNAPRYN 10MG/1ML ORAL SUSPENSION 500 ML: Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids, Opioids, criteria for use, page(s) 78 and Glucosamine (and Chondroitin Sulfate), page(s) 50 Page(s): 78, 50. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Compounded Drugs.

**Decision rationale:** The injured worker has a history of left shoulder pain. Synapryn is comprised of tramadol hydrochloride 10 mg/mL, in an oral suspension with glucosamine. The California MTUS Guidelines state, before beginning a therapeutic trial of opioids, first attempt to determine if the pain is nociceptive or neuropathic and also attempt to determine if there are underlying contributing psychological issues. Neuropathic pain may require higher doses of opioids, and opioids are not generally recommended as a first line therapy for some neuropathic pain. Additionally, a therapeutic trial of opioids should not be employed until the patient has failed a trial of non-opioid analgesics. The guidelines also state, before beginning the trial, a baseline pain and functional assessment should be made including social, physical, psychological, daily and work activities. Pain related assessment should include history of pain treatment and effect of pain and function. Furthermore, consider the use of a urine drug screen to assess for the use or the presence of illegal drugs. The California MTUS guidelines note Glucosamine is recommended as an option given its low risk, in patients with moderate arthritis pain, especially for knee osteoarthritis. The Official Disability Guidelines (ODG) do not recommend compounded drugs as a first-line therapy for most patients, but recommended as an option after a trial of first-line FDA-approved drugs, if the compound drug uses FDA-approved ingredients that are recommended in ODG. The guidelines note compounded medications should include at least one drug substance that is the sole active ingredient in an FDA-approved prescription drug, include only bulk ingredients that are components of FDA-approved drugs that

have been made in an FDA-registered facility and have an NDC code, not include a drug that was withdrawn or removed from the market for safety reasons, and they should not be a copy of a commercially available FDA-approved drug product. The documentation provided noted the patient complained of left shoulder pain & difficulty reaching overhead and behind his back. There is a lack of documentation indicating the injured worker failed a trial of non-opioid medications. The documentation submitted for review did not provide an adequate and complete pain assessment and functional assessment prior to beginning a trial of opioid medications. The requested treatment plan did not indicate if a urine drug screen was performed to provide baseline testing. The documentation provided did not indicate the physician's rationale for providing an oral suspension as opposed to traditional forms of medication. There is no documentation indicating the injured worker has difficulty taking other forms of medication. There is no documentation indicating the injured worker's need for a compounded medication. Additionally, the request does not indicate the frequency at which the medication is prescribed as well as the prescribed dosage of the medication in order to determine the necessity of the medication. As such, the request for 1 Bottle of Synapryn 10 mg/1ml oral suspension 500 ml is not medically necessary.

**1 CONTAINER OF CYCLOPHENE 5% IN PLO GEL 120 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 Page(s): 111-113.

**Decision rationale:** The injured worker has a history of left shoulder pain. The documentation submitted for review noted that cyclophene contains cyclobenzaprine. The California MTUS Guidelines state topical analgesics are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. The guidelines note any compounded product that contains at least 1 drug (or drug class) that is not recommended is not recommended. The guidelines state that there is no evidence for use of any other muscle relaxant for topical application. Documentation provided noted the injured worker complained of left shoulder pain & difficulty reaching overhead and behind his back. There is a lack of documentation to indicate previous trials of antidepressants and anticonvulsants have failed to provide symptomatic relief. There is also a lack of documentation to indicate the presence of muscle spasms were present upon physical examination. The clinical note dated 02/24/2014 noted that there was no paraspinal tenderness or spasm upon palpation of the left shoulder. As the guidelines note muscle relaxants are not recommended for topical application, and the guidelines also indicate, any compounded product that contains at least 1 drug (or drug class) that is not recommended is not recommended, the medication would not be indicated. Additionally, the request does not indicate the frequency and dosage at which the medication is prescribed, as well as the site at which it is to be applied, in order to determine the necessity of the medication. As such, the request for 1 container of cyclophene 5% in PLO gel 120 grams is not medically necessary.