

<b>Case Number:</b>	CM14-0165426		
<b>Date Assigned:</b>	10/10/2014	<b>Date of Injury:</b>	11/27/2013
<b>Decision Date:</b>	11/25/2014	<b>UR Denial Date:</b>	09/25/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	10/07/2014

### 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 Occupational 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:

According to the records made available for review, this is a 37-year-old female with an 11/27/13 date of injury. At the time (8/20/14) of request for authorization for Synapryn (no strength or quantity given), Deprizine (no strength or quantity given), Dicopanol (no strength or quantity given), Tabradol (no strength or quantity given), Fanatrex (no strength or quantity given), Ketoprofen cream (no strength or quantity given), Cyclobenzaprine (no strength or quantity given), Physical therapy 3x6 to cervical and thoracic spine, Chiropractic therapy 3x6 to cervical, thoracic, lumbar spine, Acupuncture 3x6 to cervical and thoracic spine, EMG/NCV to bilateral lower extremities, and Thoracic spine MRI, there is documentation of subjective (radiating neck pain and spasms and radiating low back pain that is moderate to severe with spasms) and objective (tenderness to palpation at the suboccipital region and trapezius muscles, decreased cervical spine range of motion, diminished sensation over the C5-T1 dermatomes, 4/5 muscle strength in the upper extremities, tenderness and spasms over the thoracic spine, tenderness and spasms over the lumbar spine, decreased lumbar spine range of motion, and diminished sensation over the L4-S1 dermatomes) findings, current diagnoses (cervicalgia, pain in thoracic spine, low back pain, and lumbar region radiculopathy), and treatment to date (physical therapy, chiropractic treatment, acupuncture treatment, and medications (including ongoing treatment with Deprizine, Dicopanol, Fanatrex, Synapryn, Tabradol, Cyclobenzaprine, and Ketoprofen cream)). Medical report identifies that medications offer the patient temporary relief of pain and improve the ability to have restful sleep; and that medications will be monitored closely for effectiveness and possible dependency. The number of previous physical therapy treatments, chiropractic treatments, and acupuncture treatments cannot be determined. Regarding Synapryn (no strength or quantity given), there is no documentation that the prescriptions are from a single practitioner and are taken as directed; the lowest possible dose is

being prescribed; and there will be ongoing review and documentation of pain relief, functional status, appropriate medication use, and side effects; and functional benefit or improvement as a reduction in work restrictions; an increase in activity tolerance; and/or a reduction in the use of medications as a result of Synapryn use to date. Regarding Cyclobenzaprine (no strength or quantity given), there is no documentation of acute exacerbation of chronic low back pain; and functional benefit or improvement as a reduction in work restrictions; an increase in activity tolerance; and/or a reduction in the use of medications as a result of Cyclobenzaprine use to date. Regarding Thoracic spine MRI, there is no documentation red flag diagnoses where plain film radiographs are negative; objective findings that identify specific nerve compromise on the neurologic examination, failure of conservative treatment, and consideration for surgery; and a condition/diagnosis (with supportive subjective/objective findings) for which an MRI is indicated (Thoracic spine trauma: with neurological deficit).

### **IMR ISSUES, DECISIONS AND RATIONALES**

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

**Synapryn (no strength or quantity given): Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 74-80; 113. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: Title 8, California Code of Regulations, section 9792.20

**Decision rationale:** MTUS Chronic Pain Medical Treatment Guidelines identifies documentation that the prescriptions are from a single practitioner and are taken as directed; the lowest possible dose is being prescribed; and there will be ongoing review and documentation of pain relief, functional status, appropriate medication use, and side effects; as criteria necessary to support the medical necessity of Opioids. In addition, specifically regarding Tramadol, MTUS Chronic Pain Medical Treatment Guideline identifies documentation of moderate to severe pain and Tramadol used as a second-line treatment (alone or in combination with first-line drugs), as criteria necessary to support the medical necessity of Tramadol. MTUS-Definitions identifies that any treatment intervention should not be continued in the absence of functional benefit or improvement as a reduction in work restrictions; an increase in activity tolerance; and/or a reduction in the use of medications or medical services. Within the medical information available for review, there is documentation of diagnoses of cervicgia, pain in thoracic spine, low back pain, and lumbar region radiculopathy. In addition, there is documentation of moderate to severe pain and Synaprin used as a second-line treatment. However, despite documentation that medications will be monitored closely for effectiveness and possible dependency, there is no documentation that the prescriptions are from a single practitioner and are taken as directed; the lowest possible dose is being prescribed; and there will be ongoing review and documentation of pain relief, functional status, appropriate medication use, and side effects. In addition, given documentation of ongoing treatment with Synapryn and despite documentation that medications offer the patient temporary relief of pain and improve the ability to have restful sleep, there is no documentation of functional benefit or improvement as a reduction in work restrictions; an

increase in activity tolerance; and/or a reduction in the use of medications as a result of Synapryn use to date. Furthermore, there is no documentation of the strength or quantity requested. Therefore, based on guidelines and a review of the evidence, the request for Synapryn (no strength or quantity given) is not medically necessary.

**Deprizine (no strength or quantity given): Upheld**

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**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, Co-pack drugs Other Medical Treatment Guideline or Medical Evidence:  
<http://www.drugs.com/pro/deprizine.html>

**Decision rationale:** Medical Treatment Guideline identifies Deprizine as Ranitidine hydrochloride in oral suspension kit. MTUS does not address the issue. ODG identifies that co-packs are convenience packaging of a medical food product and a generic drug into a single package that requires a prescription. While the generic drug is FDA-approved, the co-pack of a medical food and FDA-approved drug is not unless the manufacturer obtains FDA approval for the product as a new drug. There are no high quality medical studies to evaluate co-packs on patient outcomes. Therefore, based on guidelines and a review of the evidence, the request for Deprizine (no strength or quantity given) is not medically necessary.

**Dicopanorl (no strength or quantity given): Upheld**

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**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, Co-pack drugs Other Medical Treatment Guideline or Medical Evidence:  
<http://www.drugs.com/pro/dicopanorl.html>

**Decision rationale:** Medical Treatment Guideline identify Dicopanorl as Diphenhydramine hydrochloride in oral suspension - compounding kit. MTUS does not address the issue. ODG identifies that co-packs are convenience packaging of a medical food product and a generic drug into a single package that requires a prescription. While the generic drug is FDA-approved, the co-pack of a medical food and FDA-approved drug is not unless the manufacturer obtains FDA approval for the product as a new drug. There are no high quality medical studies to evaluate co-packs on patient outcomes. Therefore, based on guidelines and a review of the evidence, the request for Dicopanorl (no strength or quantity given) is not medically necessary.

**Tabradol (no strength or quantity given): Upheld**

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

**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, Co-pack drugs Other Medical Treatment Guideline or Medical Evidence:  
<http://dailymed.nlm.nih.gov/dailymed/archives/fdaDrugInfo.cfm?archiveid=22434>

**Decision rationale:** Medical Treatment Guidelines identify Tabradol as cyclobenzaprine hydrochloride, in oral suspension with MSM - compounding kit. MTUS does not address the issue. ODG identifies that co-packs are convenience packaging of a medical food product and a generic drug into a single package that requires a prescription. While the generic drug is FDA-approved, the co-pack of a medical food and FDA-approved drug is not unless the manufacturer obtains FDA approval for the product as a new drug. There are no high quality medical studies to evaluate co-packs on patient outcomes. Therefore, based on guidelines and a review of the evidence, the request for Tabradol (no strength or quantity given) is not medically necessary.

**Fanatrex (no strength or quantity given): Upheld**

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**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, Co-pack drugs Other Medical Treatment Guideline or Medical Evidence:  
<http://www.drugs.com/pro/fanatrex.html>

**Decision rationale:** Medical Treatment Guidelines identify Fanatrex as gabapentin, in oral suspension kit. MTUS does not address the issue. ODG identifies that co-packs are convenience packaging of a medical food product and a generic drug into a single package that requires a prescription. While the generic drug is FDA-approved, the co-pack of a medical food and FDA-approved drug is not unless the manufacturer obtains FDA approval for the product as a new drug. There are no high quality medical studies to evaluate co-packs on patient outcomes. Therefore, based on guidelines and a review of the evidence, the request for Fanatrex (no strength or quantity given) is not medically necessary.

**Ketoprofen cream (no strength or quantity given): Upheld**

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation ODG (Official Disability Guidelines): Topicals

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

**Decision rationale:** MTUS Chronic Pain Medical Treatment Guidelines identifies that many agents are compounded as monotherapy or in combination for pain control; that ketoprofen,

lidocaine (in creams, lotion or gels), capsaicin in a 0.0375% formulation, baclofen and other muscle relaxants, and gabapentin and other antiepilepsy drugs are not recommended for topical applications; and that any compounded product that contains at least one drug (or drug class) that is not recommended, is not recommended. Within the medical information available for review, there is documentation of diagnoses of cervicgia, pain in thoracic spine, low back pain, and lumbar region radiculopathy. However, the requested Ketoprofen cream (no strength or quantity given) contains at least on drug (ketoprofen) that is not recommended. Therefore, based on guidelines and a review of the evidence, the request for Ketoprofen cream (no strength or quantity given) is not medically necessary.

**Cyclobenzaprine (no strength or quantity given): 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 Muscle relaxants (for pain) Page(s): 63-64. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Muscle relaxants (for pain) Other Medical Treatment Guideline or Medical Evidence: Title 8, California Code of Regulations, section 9792.20

**Decision rationale:** MTUS Chronic Pain Medical Treatment Guidelines identifies documentation of acute exacerbation of chronic low back pain and used as a second line option for short-term treatment, as criteria necessary to support the medical necessity of muscle relaxant. MTUS-Definitions identifies that any treatment intervention should not be continued in the absence of functional benefit or improvement as a reduction in work restrictions; an increase in activity tolerance; and/or a reduction in the use of medications or medical services. ODG identifies that muscle relaxants are recommended for short-term (less than two weeks) treatment. Within the medical information available for review, there is documentation of diagnoses of cervicgia, pain in thoracic spine, low back pain, and lumbar region radiculopathy. In addition, there is documentation of Cyclobenzaprine used as a second line option. However, despite documentation of muscle spasms, and given documentation of an 11/27/13 date of injury, there is no documentation of acute muscle spasms or acute exacerbation of chronic low back pain. In addition, despite documentation that medications offer the patient temporary relief of pain and improve the ability to have restful sleep, there is no documentation of functional benefit or improvement as a reduction in work restrictions; an increase in activity tolerance; and/or a reduction in the use of medications as a result of Cyclobenzaprine use to date. Therefore, based on guidelines and a review of the evidence, the request for Cyclobenzaprine (no strength or quantity given) is not medically necessary.

**Physical therapy 3x6 to cervical and thoracic spine: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation ODG (Official Disability Guidelines); Physical Therapy

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines physical medicine Page(s): 98. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Neck and Upper Back; and Low Back-lumbar & thoracic, Physical therapy (PT) Other Medical Treatment Guideline or Medical Evidence: Title 8, California Code of Regulations, section 9792.20

**Decision rationale:** MTUS Chronic Pain Medical Treatment Guidelines support a brief course of physical medicine for patients with chronic pain not to exceed 10 visits over 4-8 weeks with allowance for fading of treatment frequency, with transition to an active self-directed program of independent home physical medicine/therapeutic exercise. MTUS-Definitions identifies that any treatment intervention should not be continued in the absence of functional benefit or improvement as a reduction in work restrictions; an increase in activity tolerance; and/or a reduction in the use of medications or medical services. ODG recommends a limited course of physical therapy for patients with a diagnosis of thoracic sprain/strain not to exceed 10 visits over 5 weeks; and patients with a diagnosis of cervicgia not to exceed 9 visits over 8 weeks. ODG also notes patients should be formally assessed after a "six-visit clinical trial" to see if the patient is moving in a positive direction, no direction, or a negative direction (prior to continuing with the physical therapy) and when treatment requests exceeds guideline recommendations, the physician must provide a statement of exceptional factors to justify going outside of guideline parameters. Within the medical information available for review, there is documentation of diagnoses of cervicgia, pain in thoracic spine, low back pain, and lumbar region radiculopathy. In addition, there is documentation of previous physical therapy treatments, functional deficits, and functional goals. However, there is no documentation of the number of previous physical therapy sessions and, if the number of treatments have exceeded guidelines, remaining functional deficits that would be considered exceptional factors to justify exceeding guidelines. In addition, there is no documentation of functional benefit or improvement as a reduction in work restrictions; an increase in activity tolerance; and/or a reduction in the use of medications or medical services as a result of physical therapy provided to date. Therefore, based on guidelines and a review of the evidence, the request for Physical therapy 3x6 to cervical and thoracic spine is not medically necessary.

**Chiropractic therapy 3x6 to cervical, thoracic, lumbar spine:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation CA MTUS Guidelines; ACOEM text, page 173

**MAXIMUS guideline:** Decision based on MTUS ACOEM Chapter 8 Neck and Upper Back Complaints Page(s): 298-299, Chronic Pain Treatment Guidelines Manual Therapy & manipulation Page(s): 58.

**Decision rationale:** MTUS reference to ACOEM identifies documentation of objective improvement with previous treatment, functional deficits, functional goals, and a statement identifying why an independent home exercise program would be insufficient to address any remaining functional deficits, as criteria necessary to support the medical necessity of additional chiropractic treatment. In addition, MTUS Chronic Pain Medical Treatment Guidelines supports a total of up to 18 visits over 6-8 weeks. Within the medical information available for review,

there is documentation of diagnoses of cervicalgia, pain in thoracic spine, low back pain, and lumbar region radiculopathy. In addition, there is documentation of previous chiropractic treatments, functional deficits, and functional goals. However, there is no documentation of the number of previous chiropractic therapy sessions and, if the number of treatments have exceeded guidelines, a statement identifying why an independent home exercise program would be insufficient to address any remaining functional deficits. In addition, there is no documentation of objective improvement with previous treatment. Therefore, based on guidelines and a review of the evidence, the request for Chiropractic therapy 3x6 to cervical, thoracic, lumbar spine is not medically necessary.

**Acupuncture 3x6 to cervical and thoracic spine:** Upheld

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

**MAXIMUS guideline:** Decision based on MTUS Acupuncture Treatment Guidelines.

**Decision rationale:** MTUS Acupuncture Medical Treatment Guidelines identifies that acupuncture may be used as an option when pain medication is reduced or not tolerated, it may be used as an adjunct to physical rehabilitation and/or surgical intervention to hasten functional recovery, to reduce pain, reduce inflammation, increase blood flow, increase range of motion, decrease the side effect of medication-induced nausea, promote relaxation in an anxious patient, and reduce muscle spasm. In addition, MTUS Acupuncture Medical Treatment Guidelines allow the use of acupuncture for musculoskeletal conditions for a frequency and duration of treatment as follows: Time to produce functional improvement of 3-6 treatments, frequency of 1-3 times per week, and duration of 1-2 months. Within the medical information available for review, there is documentation of diagnoses of cervicalgia, pain in thoracic spine, low back pain, and lumbar region radiculopathy. In addition, there is documentation of previous acupuncture treatments, functional deficits, and functional goals. However, there is no documentation of the number of previous acupuncture treatments. In addition, there is no documentation of functional improvement following previous treatment. Therefore, based on guidelines and a review of the evidence, the request for Acupuncture 3x6 to cervical and thoracic spine is not medically necessary.

**EMG/NCV to bilateral lower extremities:** Upheld

**Claims Administrator guideline:** Decision based on MTUS ACOEM Chapter 12 Low Back Complaints Page(s): 303.

**MAXIMUS guideline:** Decision based on MTUS ACOEM Chapter 12 Low Back Complaints Page(s): 303. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Low Back, Electrodiagnostic studies

**Decision rationale:** MTUS reference to ACOEM guidelines identifies documentation of focal neurologic dysfunction in patients with low back symptoms lasting more than three to four weeks, as criteria necessary to support the medical necessity of electrodiagnostic studies. ODG

identifies documentation of evidence of radiculopathy after 1-month of conservative therapy, as criteria necessary to support the medical necessity of electrodiagnostic studies. In addition, ODG does not consistently support performing nerve conduction studies when a patient is presumed to have symptoms on the basis of radiculopathy. Within the medical information available for review, there is documentation of diagnoses of cervicalgia, pain in thoracic spine, low back pain, and lumbar region radiculopathy. In addition, there is documentation of focal neurologic dysfunction in patients with low back symptoms lasting more than three to four weeks. However, given documentation of the associated requests for medications and physical modalities, there is no (clear) documentation of failure of 1-month of conservative therapy. Therefore, based on guidelines and a review of the evidence, the request for EMG/NCV to bilateral lower extremities is not medically necessary.

**Thoracic spine MRI: Upheld**

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**MAXIMUS guideline:** Decision based on MTUS ACOEM Chapter 12 Low Back Complaints Page(s): 303-304. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Low Back - Lumbar & Thoracic, Magnetic Resonance Imaging (MRI)

**Decision rationale:** MTUS reference to ACOEM Guidelines identifies documentation of red flag diagnoses where plain film radiographs are negative; objective findings that identify specific nerve compromise on the neurologic examination, failure of conservative treatment, and who are considered for surgery, as criteria necessary to support the medical necessity of an MRI. ODG identifies documentation of a condition/diagnosis (with supportive subjective/objective findings) for which an MRI is indicated (Thoracic spine trauma: with neurological deficit), as criteria necessary to support the medical necessity of a Thoracic MRI. Within the medical information available for review, there is documentation of a diagnosis of pain in thoracic spine. However, despite documentation of objective findings (tenderness and spasms over the thoracic spine), there is no documentation red flag diagnoses where plain film radiographs are negative; objective findings that identify specific nerve compromise on the neurologic examination, failure of conservative treatment, and consideration for surgery. In addition, there is no documentation of a condition/diagnosis (with supportive subjective/objective findings) for which an MRI is indicated (Thoracic spine trauma: with neurological deficit). Therefore, based on guidelines and a review of the evidence, the request for Thoracic spine MRI is not medically necessary.