MAXIMUS Federal Services

Case Number:	CM14-0005924		
Date Assigned:	02/07/2014	Date of Injury:	06/06/2013
Decision Date:	07/23/2014	UR Denial Date:	12/12/2013
Priority:	Standard	Application Received:	01/15/2014

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:

Patient is a 49-year-old male who has submitted a claim for hypertension, hypercholesterolemia, status post traumatic partial amputation of the right thumb, and right wrist pain associated with an industrial injury date of June 6, 2013. Medical records from 2013 to 2014 were reviewed. Patient complained of residual pain at the right thumb, graded 6 to 7/10 in severity, status post partial amputation of the distal phalanx. Patient likewise complained of right wrist pain, relieved with medications, rest, and activity restriction. Aggravating factors included grasping, reaching, and lifting. Physical examination revealed a well-healed scar, 1.5 inches amputation of the right thumb, and tenderness. Flexor pollicis longus was intact. Range of motion of both the right wrist and right thumb were normal. Motor strength was 4/5 in bilateral upper extremities. Reflexes and pulse were normal. Sensation was diminished along the distribution of the ulnar and radial nerve. Treatment to date has included right thumb surgery on 6/6/13, physical therapy, and medications such as thiazide, Lipitor, and topical products.Utilization review from December 12, 2013 denied the requests for ketoprofen 20% 120 gms qty 1; cyclophene 5% 120 gms qty 1; synapryn 10 mg 500 ml qty 1; tabradol 1 mg 250 ml qty 1; deprizine 15 mg 250 ml qty 1; dicopanol 5 mg 150 ml qty 1; and fanatrex 25 mg 420 ml qty 1 because compounded topical analgesics are experimental without proven efficacy. The requests for X-ray, MRI, EMG, and NCV were likewise denied because of unspecified body parts intended to be tested. Shock wave was non-certified due to non-specific body part to be treated. Physical therapy was non-certified due to absent body part to be treated, intended duration, and frequency of sessions. TENS unit was denied because of no report concerning functional benefit from electrical stimulation under the supervision of a licensed physical therapist. Patient is in a non-operative state, hence, hot/cold unit was likewise denied.

IMR ISSUES, DECISIONS AND RATIONALES

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

KETOPROFEN 20% 120 GMS QTY 1: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines July 18, 2009, Topical Analgesics Page(s): 111-113. Decision based on Non-MTUS Citation Official Disability Guidelines, (ODG) - Treatment in Worker's Comp 2012, on the Web (www.odgtreatment.com) work loss data institute(www.worklossdata.com), (updated 10/14/12): Topical Analgesics Compounded.

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

Decision rationale: As stated on page 111, of the California MTUS Chronic Pain Medical Treatment Guidelines, Ketoprofen is not recommended for topical use, as there is a high incidence of photo contact dermatitis. Topical analgesics are largely experimental in use with few randomized controlled trials to determine safety or efficacy. In this case, patient has been on ketoprofen since November 2013. However, there is no documentation concerning pain relief and functional improvement derived from its use. Moreover, there is no evidence of intolerance to oral medications necessitating its use. There is likewise no discussion concerning need for multiple topical medications in this case. Therefore, the request for Ketoprofen 20% 120 gms QTY 1 is not medically necessary.

CYCLOPHENE 5% 120 GMS QTY 1: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines July 18, 2009, Topical Analgesics Page(s): 111-113. Decision based on Non-MTUS Citation Official Disability Guidelines, (ODG) - Treatment in Worker's Comp 2012, on the Web (www.odgtreatment.com) work loss data institute(www.worklossdata.com), (updated 10/14/12): Topical Analgesics Compounded.

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

Decision rationale: As stated on page 113 of the California MTUS Chronic Pain Medical Treatment Guidelines, use of Cyclobenzaprine as a topical muscle relaxant is not recommended. There is no evidence for use of any other muscle relaxant as a topical product. In this case, patient has been on Cyclophene since November 2013. However, there is no documentation concerning pain relief and functional improvement derived from its use. Moreover, there is no evidence of intolerance to oral medications necessitating its use. There is likewise no discussion concerning need for multiple topical medications in this case. Guidelines do not recommend cyclobenzaprine in a topical formulation. Therefore, the request for Cyclophene 5% 120 gms QTY 1 is not medically necessary.

SYNAPRYN 10 MG 500 ML QTY 1: 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) - Treatment in Worker's Comp 2012, on the Web (www.odgtreatment.com) work loss data institute(www.worklossdata.com), (updated 10/14/12): Medications, Compounded.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation US Food and Drug Administration, Synapryn (http://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?id=20039).

Decision rationale: The CA MTUS does not address this topic. Per the Strength of Evidence hierarchy established by the California Department of Industrial Relations, Division of Workers' Compensation, FDA was used instead. It states that Synapryn contains tramadol hydrochloride 10 mg/mL, in oral suspension with glucosamine. This drug has not been found by FDA to be safe and effective, and is not approved by the FDA. In this case, patient has been prescribed Synapyrn since November 2013. However, there is no clear rationale identifying why a first-line pain medication is not used, or why a compound/oral suspension is needed for this patient. There is no discussion concerning the need for variance from the guidelines. Therefore, the request for Synapryn 10 mg 500 ml, QTY 1 is not medically necessary.

TABRADOL 1 MG 250 ML QTY 1: 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) - Treatment in Worker's Comp 2012, on the Web (www.odgtreatment.com) work loss data institute(www.worklossdata.com), (updated 10/14/12): Medications, Compounded.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Cyclobenzaprine; Topical Analgesic Page(s): 41; 111.

Decision rationale: Page 111 of CA MTUS Chronic Pain Medical Treatment Guidelines states that any compounded product that contains at least one drug (drug class) that is not recommended is not recommended. Tabradol contains cyclobenzaprine. Page 41 of the CA MTUS states that cyclobenzaprine is more effective than placebo in the management of back pain; however, the addition of this drug to other agents is not recommended. There is no indication or evidence that a suspension formulation would be more superior to a tablet formulation. In this case, patient has been on Tabradol since November 2013. However, there is no documentation concerning pain relief and functional improvement derived from its use. Moreover, there is no compelling rationale for preferring a suspension, rather than a tablet formulation in this case. There is no discussion concerning need for variance from the guidelines. Therefore the request for Tabradol 1mg/mL oral suspension 250mL is not medically necessary.

DEPRIZINE 15 MG 250 ML QTY 1: 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) - Treatment in Worker's Comp 2012, on the Web (www.odgtreatment.com) work loss data institute(www.worklossdata.com), (updated 10/14/12): Medications, Compounded.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Deprizine http://www.drugs.com/pro/deprizine.html.

Decision rationale: The CA MTUS does not address this topic. Per the Strength of Evidence hierarchy established by the California Department of Industrial Relations, Division of Workers' Compensation, FDA was used instead. Deprizine is ranitidine with other proprietary ingredients in oral suspension. It is used to treat and prevent ulcers in the stomach and intestines. In this case, patient has been on deprizine since November 2013. However, there is no documentation regarding gastrointestinal symptoms in this patient. The medical necessity was not established. Therefore, the request for Deprizine 15mg 250 ml is not medically necessary.

DICOPANOL 5 MG 150 ML QTY 1: 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) - Treatment in Worker's Comp 2012, on the Web (www.odgtreatment.com) work loss data institute(www.worklossdata.com), (updated 10/14/12): Medications, Compounded.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation US Food and Drug Administration, Diphenhydramine.

Decision rationale: Dicopanol is a diphenhydramine hydrochloride 5 mg/mL oral suspension. The CA MTUS does not address this topic. Per the Strength of Evidence hierarchy established by the California Department of Industrial Relations, Division of Workers' Compensation, FDA Diphenhydramine was used instead. The FDA states that diphenhydramine is used to treat occasional sleeplessness and difficulty falling asleep. In this case, patient has been on this medication since November 2013. However, there was no discussion concerning sleep hygiene. No improvement was likewise reported with the use of Dicopanol. The medical necessity was not established. Therefore, the request for Dicopanol 5mg 150 ml is not medically necessary.

FANATREX 25 MG 420 ML QTY 1: 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) - Treatment in Worker's Comp 2012, on the Web (www.odgtreatment.com) work loss data institute(www.worklossdata.com), (updated 10/14/12): Medications, Compounded.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation US Food and Drug Administration, Fanatrex.

Decision rationale: US Food and Drug Administration stated that Fanatrex is gabapentin in a form of suspension. As stated on pages 16 - 17 of CA MTUS Chronic Pain Medical Treatment Guidelines, antidepressants, such as pregabalin and gabapentin, are recommended as a first line option for neuropathic pain, i.e., painful polyneuropathy. In this case, patient has been on Fanatrex since November 2013. However, there is no documentation concerning pain relief and functional improvement derived from its use. Moreover, there is no compelling rationale for preferring a suspension, rather than a tablet formulation in this case. There is no discussion concerning need for variance from the guidelines. Therefore the request for Fanatrex 25 mg 420 ml QTY 1 is not medically necessary.

X-RAY QTY 1: 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), Forearm, Wrist, and Hand, Radiography.

Decision rationale: The CA MTUS does not specifically address this topic. Per the Strength of Evidence hierarchy established by the California Department of Industrial Relations, Division of Workers Compensation, the Official Disability Guidelines (ODG) were used instead. ODG states that radiographic survey provides adequate diagnostic information for most patients with known or suspected trauma of the hand, wrist, or both. In this case, patient is status post partial amputation of the distal phalanx of right thumb on 6/6/13. Patient complained of residual pain corroborated by findings of tenderness, weakness, and dysesthesia. However, the present request failed to specify the body part to be tested. The request is incomplete; therefore, the request for X-ray QTY 1 is not medically necessary.

MRI (UNSPECIFIED BODY PART) QTY 1: Upheld

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

MAXIMUS guideline: Decision based on MTUS ACOEM Chapter 11 Forearm, Wrist, and Hand Complaints Page(s): 254.

Decision rationale: CA MTUS ACOEM Guidelines for hand/wrist MRI include normal radiographs and acute hand or wrist trauma or chronic wrist pain with a suspicion for a specific pathology. In this case, patient is status post partial amputation of the distal phalanx of right thumb on 6/6/13. Patient complained of residual pain corroborated by findings of tenderness, weakness, and dysesthesia. However, the present request failed to specify the body part to be tested. The request is incomplete; therefore, the request for MRI (Unspecified Body Part) QTY 1 is not medically necessary.

EMG (UNSPECIFIED BODY PART): Upheld

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

MAXIMUS guideline: Decision based on MTUS ACOEM Chapter 8 Neck and Upper Back Complaints.

Decision rationale: CA MTUS ACOEM Guidelines state that electromyography (EMG) studies may help identify subtle focal neurologic dysfunction in patients with neck or arm symptoms, or both, lasting more than three or four weeks. In this case, patient is status post partial amputation of the distal phalanx of right thumb on 6/6/13. Patient complained of residual pain corroborated by findings of tenderness, weakness, and dysesthesia. However, the present request failed to specify the body part to be tested. The request is incomplete; therefore, the request for EMG (Unspecified Body Part) is not medically necessary.

NCV (UNSPECIFIED BODY PART) QTY 1: Upheld

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

MAXIMUS guideline: Decision based on MTUS ACOEM Chapter 11 Forearm, Wrist, and Hand Complaints Page(s): 261-262. Decision based on Non-MTUS Citation Official Disability Guidelines, Neck and Upper Back, Nerve Conduction Studies.

Decision rationale: CA MTUS ACOEM Guidelines state that appropriate electrodiagnostic studies may help differentiate between carpal tunnel syndrome and other conditions, such as cervical radiculopathy. These include nerve conduction studies, or in more difficult cases, electromyography may be helpful. Moreover, ODG states that NCS is not recommended to demonstrate radiculopathy if radiculopathy has already been clearly identified by EMG and obvious clinical signs, but is recommended if the EMG is not clearly consistent with radiculopathy. In this case, patient is status post partial amputation of the distal phalanx of right thumb on 6/6/13. Patient complained of residual pain corroborated by findings of tenderness, weakness, and dysesthesia. However, the present request failed to specify the body part to be tested. The request is incomplete; therefore, the request for NCV (Unspecified Body Part) is not medically necessary.

SHOCK WAVE QTY 1: Upheld

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

MAXIMUS guideline: Decision based on MTUS ACOEM Chapter 9 Shoulder Complaints Page(s): 203.

Decision rationale: According to page 203 of the ACOEM Practice Guidelines referenced by CA MTUS, physical modalities, such as ultrasound treatment, etc. are not supported by high-

quality medical studies but they may be useful in the initial conservative treatment of acute symptoms. Some medium quality evidence supports high-energy extracorporeal shock wave therapy for calcifying tendinitis of the shoulder. In this case, patient is status post partial amputation of the distal phalanx of right thumb on 6/6/13. Patient complained of residual pain corroborated by findings of tenderness, weakness, and dysesthesia. However, patient's symptom is chronic in nature, and the guidelines only recommend it for treatment during the acute phase. Furthermore, the request failed to specify the body part to be treated and the quantity of sessions being requested. Therefore, the request for Shock Wave is not medically necessary.

PHYSICAL THERAPY (UNSPECIFIED FERQUENCY AND DURATION) QTY 1: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Physical Medicine and Functional Improvement Measures Page(s): 48,98-99.

MAXIMUS guideline: Decision based on MTUS Postsurgical Treatment Guidelines Page(s): 20.

Decision rationale: CA MTUS Post-Surgical Treatment Guidelines recommend physical therapy for 14 visits over 3 months for status post amputation of thumb. In this case, patient is status post partial amputation of the distal phalanx of right thumb on 6/6/13. Patient complained of residual pain corroborated by findings of tenderness, weakness, and dysesthesia. Physical therapy is necessary for early recovery. However, the present request failed to specify the body part to be tested, and the number of sessions. The request is incomplete; therefore, the request for Physical Therapy (Unspecified Ferquency And Duration) QTY 1 is not medically necessary.

TENS UNIT QTY 1: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Transcutaneous Electrotherapy, Criteria for use of TENS Page(s): 114-121.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Transcutaneous Electrotherapy, TENS - Post-operative Pain Page(s): 116.

Decision rationale: Page 116 of CA MTUS Chronic Pain Medical Treatment Guidelines, recommends TENS as a treatment option for acute post-operative pain in the first 30 days post-surgery. Transcutaneous electrical nerve stimulation (TENS) appears to be most effective for mild to moderate thoracotomy pain. It has been shown to be of lesser effect, or not at all for other orthopedic surgical procedures. The proposed necessity of the unit should be documented upon request. Rental would be preferred over purchase during this 30-day period. In this case, patient is status post partial amputation of the distal phalanx of right thumb on 6/6/13. Patient complained of residual pain corroborated by findings of tenderness, weakness, and dysesthesia. However, patient is beyond the first 30 days of post-operative period, which is not recommended for the use of TENS as stated above. The medical records likewise failed to provide indication for its use. The request also failed to specify if the device is for rental or purchase. Therefore, the request for a TENS Unit QTY 1 is not medically necessary.

HOT/COLD UNIT QTY 1: 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) - Treatment in Worker's Comp 2012, on the Web (www.odgtreatment.com) work loss data institute(www.worklossdata.com), (updated 10/14/12): Cold/Heat Packs, Continuous-Flow Cryotherapy.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation AETNA Clinical Policy Bulletin, Hot or Ice Machine.

Decision rationale: CA MTUS and ODG do not specifically address hot/cold therapy unit. As stated on AETNA Clinical Policy Bulletin, the use of the Hot/Ice Machine and similar devices (e.g., the Hot/Ice Thermal Blanket, the TEC Thermoelectric Cooling System (an iceless cold compression device), the Vital Wear Cold/Hot Wrap, and the Vital Wrap) are experimental and investigational for reducing pain and swelling after surgery or injury. Studies in the published literature have been poorly designed and have failed to show that the Hot/Ice Machine offers any benefit over standard cryotherapy with ice bags/packs; and there are no studies evaluating its use as a heat source. In this case, patient is status post partial amputation of the distal phalanx of right thumb on 6/6/13. Patient complained of residual pain corroborated by findings of tenderness, weakness, and dysesthesia. However, there was no compelling rationale for hot / cold unit use despite it being experimental and investigational. Moreover, simple at-home applications can suffice for the delivery of hot and cold therapy. Therefore, the request for Hot/Cold Unit QTY 1 is not medically necessary.