MAXIMUS Federal Services

Case Number:	CM15-0145156		
Date Assigned:	08/06/2015	Date of Injury:	03/06/2014
Decision Date:	09/18/2015	UR Denial Date:	07/20/2015
Priority:	Standard	Application Received:	07/27/2015

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: New York
Certification(s)/Specialty: Anesthesiology

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 31 year old male, who sustained an industrial injury on 03-06-2014. The injured worker is currently temporarily totally disabled. The injured worker is currently diagnosed as having left shoulder sprain/strain, left shoulder subcortical cyst, left shoulder bursitis, lumbar spine sprain/strain, lumbar spine disc displacement, lumbar spine degenerative disc disease, lumbar grade I retrolisthesis, Schmori's node at T12 down to L3, Tarlov's cyst at S2 level, and lumbar radiculopathy. Treatment and diagnostics to date has included a lumbar spine MRI and use of medications. A lumbar spine MRI dated 05-21-2014 which showed straightening of the lumbar lordotic curvature which may reflect an element of myospasms, disc desiccation and annular tear at L5-S1, degenerative retrolisthesis of L5 over S1, and posterior disc herniation together with the retrolisthesis of L5 and bilateral facet degenerative change to L5-S1. Left shoulder MRI dated 06-30-2015 showed mild supraspinatus tendinosis and flat acromion.In a progress note dated 07-13-2015, the injured worker reported burning left shoulder pain rated 4 out of 10 on the pain scale and burning low back pain also rate 4 out of 10 on the pain scale. Objective findings included tenderness to palpation at the trapezius and levator scapula muscles with trigger points noted, decreased left shoulder range of motion, tenderness to lumbar paraspinal muscles, and decreased lumbar spine range of motion. The treating physician reported requesting authorization for Amitriptyline-Gabapentin-Bupivacaine-Hyaluronic Acid cream, Flurbiprofen-Baclofen-Dexamethasone-Hyaluronic Acid cream, Pain Management specialist consultation, shockwave therapy treatments for the left shoulder, shockwave therapy treatments

for the lumbar spine, platelet rich plasma therapy for the left shoulder, and platelet rich plasma therapy for the lumbar spine.

IMR ISSUES, DECISIONS AND RATIONALES

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

HNPC1 (Amitriptyline HCL (hydrochloride) 10%, Gabapentin 10%, Bupivacaine HCL 5%, Hyaluronic Acid .2% in cream base) 240gm: 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.

Decision rationale: According to the California MTUS Guidelines (2009), topical analgesics are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. These agents are applied topically to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. Many agents are compounded as monotherapy or in combination for pain control (for example including, NSAIDs, opioids, capsaicin, muscle relaxants, local anesthetics and/or antidepressants). Guidelines indicate that any compounded product that contains at least 1 non-recommended drug (or drug class) is not recommended for use. In this case, the topical analgesic compound contains: Amitriptyline 10%/Gabapentin 10%, Bupivacaine HCL 5%, Hyaluronic Acid 0.2% in a cream base. Gabapentin is not recommended as a topical agent per CA MTUS Guidelines. There is no peer-reviewed literature to support its use. Medical necessity for the requested topical analgesic has not been established. The request for the compounded topical analgesic cream is not medically necessary.

HMPC2 (Flurbiprofen 20%, Baclofen 10%, Dexamethasone Nico .2%, Hyaluronic Acid .2% in cream base), 240gm: 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.

Decision rationale: According to the California MTUS Guidelines (2009), topical analgesics are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. These agents are applied topically to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. Many agents are compounded as monotherapy or in combination for pain control including, for example, NSAIDs, opioids, capsaicin, muscle relaxants, local anesthetics or antidepressants. Guidelines indicate that any compounded product that contains at least 1 non-recommended drug (or drug class) is not recommended for use. In this case, the topical analgesic compounded medication

contains: Flurbiprofen 20%, Baclofen 10%, Dexamethasone Nico 0.2%, and Hyaluronic Acid 0.2%. There are no clinical studies to support the safety or effectiveness of Flurbiprofen in a topical delivery system (excluding ophthalmic). Baclofen is not recommended. There is no peer-reviewed literature to support the use of topical baclofen. Medical necessity for the requested topical compounded medication has not been established. The requested topical analgesic cream is not medically necessary.

Consultation with pain management specialist: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Epidural steroid injections (ESIs), Criteria for the use of Epidural steroid injections.

MAXIMUS guideline: Decision based on MTUS ACOEM Chapter 5 Cornerstones of Disability Prevention and Management, Chronic Pain Treatment Guidelines ESIs Page(s): 46.

Decision rationale: According to the CA MTUS/ACOEM, a consultation is indicated to aid in the diagnosis, prognosis, and therapeutic management, determination of medical stability, and permanent residual loss and/or, the injured worker's fitness to return to work. In this case, the requested Pain Management consultation is for the evaluation of possible lumbar epidural steroid injections (ESIs). There is no evidence of radiculopathy. Guidelines do not support ESIs without documentation of radiculopathy through exam and imaging studies. There is also no documentation that diagnostic and therapeutic management has been exhausted within the present treating provider's scope of practice. Medical necessity for the requested service has not been established. The requested service is not medically necessary.

Shockwave therapy for the left shoulder, #3 treatments: Upheld

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

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Medscape Internal Medicine 2014.

Decision rationale: Extracorporeal shock wave therapy (ESWT) is a noninvasive treatment proposed to treat refractory tendonopathies such as, plantar fasciitis or calcifying tendinitis of the shoulder. It has also been introduced as an alternative to surgery for patients that have not responded to other conservative therapies. ESWT is a noninvasive treatment that involves delivery of low or high energy shock waves via a device to a specific site within the body. These pressure waves travel through fluid and soft tissue; their effects occur at sites where there is a change in impedance, such as the bone/soft tissue interface. Low-energy shock wave treatments are generally given in one session and usually require some type of anesthesia. In this case, the patient did not have evidence of calcifying tendinitis affecting either shoulder, but has evidence of acromioclavicular joint arthrosis, which is a contraindication to ESWT. There is no support in evidence-based guidelines for the use of ESWT in the treatment of any shoulder complaints. Medical necessity of the requested ESWT for the left shoulder, have not been established. The requested ESWT therapies are not medically necessary.

Shockwave therapy for the lumbar spine, #6 treatments: 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), Low Back & Lumbar & Thoracic (Acute & Chronic).

MAXIMUS guideline: Decision based on MTUS ACOEM Chapter 12 Low Back Complaints. Decision based on Non-MTUS Citation Medscape Internal Medicine 2014.

Decision rationale: Extracorporeal shock wave therapy (ESWT) is a noninvasive treatment proposed to treat refractory tendonopathies such as, plantar fasciitis. It has also been introduced as an alternative to surgery for patients that have not responded to other conservative therapies. ESWT involves delivery of low or high energy shock waves via a device to a specific site within the body. These pressure waves travel through fluid and soft tissue; their effects occur at sites where there is a change in impedance, such as the bone/soft tissue interface. Low-energy shock wave treatments are generally given in one session and usually require some type of anesthesia. According to the ODG, ESWT is not recommended. The available evidence does not support the effectiveness of ultrasound or shock wave for treating low back pain. There are limited large- scale, long-term references showing the safety and efficacy of the requested treatment in this patient's clinical scenario. Medical necessity for the requested procedure has not been established. The requested service is not medically necessary.

One (1) course of PRP (platelet rich plasma) therapy for the left shoulder: 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), Shoulder (Acute & Chronic) - Platelet-rich plasma (PRP).

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) PRP (platelet rich plasma).

Decision rationale: According to the ODG, platelet rich plasma (PRP) is under study as a solo treatment. PRP is recommended as an option in conjunction with arthroscopic repair for large to massive rotator cuff tears. PRP has become popular among professional athletes because it promises to enhance performance, but there is no current science behind it. In a blinded, prospective, randomized trial of PRP v.s. placebo in patients undergoing surgery to repair a torn rotator cuff, there was no difference in pain relief or in function. The only difference was the time it took to do the repair; it was longer if PRP was placed in the joint. There were also no differences in residual defects on MRI. Platelets are known to release various growth factors that are associated with tissue regeneration/healing and angiogenesis, as well as a variety of chemicals (adenosine, serotonin, histamine, and calcium) that may be important in inhibiting inflammation and promoting angiogenesis. The exact mechanism of action in the context of PRP is still being investigated. A study of PRP injections in patients with early arthritis compared the effectiveness of PRP with that of low-molecular-weight hyaluronic acid and high-molecular-

weight hyaluronic acid injections, and concluded that PRP is promising for less severe, very early arthritis, in younger people under 50 years of age, but it is not promising for very severe osteoarthritis in older patients. There is no specific indication for PRP for the treatment of the patient's condition. Medical necessity for the requested treatment has not been established. The requested treatment is not medically necessary.

One (1) course of PRP (platelet rich plasma) therapy for the lumbar spine: 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), Low Back & Lumbar & Thoracic (Acute & Chronic) - Platelet-rich plasma (PRP).

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Low back pain, Platelet-rich plasma (PRP).

Decision rationale: According to the ODG, platelet rich plasma (PRP) is under study as a solo treatment. PRP is recommended as an option in conjunction with arthroscopic repair for large to massive rotator cuff tears. PRP has become popular among professional athletes because it promises to enhance performance, but there is no current science behind it. The results of PRP in spine surgery are limited and controversial. Adding PRP in posterior lumbar fusion did not lead to a substantial improvement when compared with autologous bone only. The expense of using PRP cannot be justified until statistical significance can be reached in a larger study. A study of platelet-rich plasma on anterior fusion in spinal injuries concluded that this is not a clear advancement in spinal fusion in terms of a clinical benefit. Medical necessity for the requested treatment has not been established. The requested treatment is not medically necessary.