

Case Number:	CM15-0105637		
Date Assigned:	06/10/2015	Date of Injury:	03/26/2014
Decision Date:	07/13/2015	UR Denial Date:	05/08/2015
Priority:	Standard	Application Received:	06/01/2015

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 53 year old female, who sustained an industrial injury on March 26, 2014. The mechanism of injury was a slip and fall. The injured worker sustained a right ankle injury. The injured worker has been treated for neck, back, shoulder and bilateral upper extremity complaints. The diagnoses have included right ankle fracture, lumbar spine sprain/strain, history of a left fifth toe fracture, cervical spine sprain/strain, right shoulder sprain/strain, bilateral elbow sprain/strain secondary to use of a cane, right elbow lateral epicondylitis, bilateral hip sprain/strain secondary to an antalgic gait and right hip trochanteric bursitis. Treatment to date has included medications, radiological studies, physical therapy and a right ankle open reduction and internal fixation. Current documentation dated January 28, 2015 notes that the injured worker reported multiple complaints including headaches and pain in the neck, lower back, right shoulder/arm, bilateral forearms/elbows, bilateral hips/thighs and right ankle/foot. Examination of the right ankle/foot revealed grade 2 tenderness to palpation which had decreased from the last visit and a restricted range of motion. The treating physician's plan of care included a request for retrospective Flurbuprofen/Lidocaine/Gabapentin/Cyclobenzaprine/Tramadol (date of service 2/9/15), retrospective Gabapentin Cyclobenzaprine/Tramadol (date of service 2/19/15), extracorporeal shockwave therapy for the right ankle # 4, Flurbuprofen/Lidocaine/Amitriptyline cream 180 gm in the morning, Gabacyclotram cream 180 mg in the evening and additional physical therapy to the right ankle # 12.

IMR ISSUES, DECISIONS AND RATIONALES

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

Retro: flurbiprofen/lidocaine/amitriptyline (DOS: 2/9/15): Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines topical analgesics Page(s): 111-113, 121-122.

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/compounded medication is a flurbiprofen/lidocaine/ amitriptyline cream. There are no clinical studies to support the safety or effectiveness of Flurbiprofen in a topical delivery system (excluding ophthalmic). There is no documentation of intolerance to other previous oral medications. The medical necessity of the requested compounded medication was not established. The requested topical analgesic compound was not medically necessary.

Retro: gabapentin/cyclobenzaprine/tramadol (DOS: 2/9/15): Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines topical analgesics Page(s): 111-113, 121-122.

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 requested compounded topical agent is Gabapentin, Cyclobenzaprine, Tramadol (GabaCycloTram) cream. Cyclobenzaprine is not FDA approved for use as a topical application. There is no evidence for the use of any muscle relaxant as a topical agent. In addition, Gabapentin and Tramadol are not FDA approved for a topical application. There is no peer-reviewed literature to support its use. Medical necessity for the requested compounded topical analgesic cream was not established. The request for the compounded topical analgesic agent was not medically necessary.

4 Extracorporeal Shockwave Therapy (ESWT) visits for the right ankle: Upheld

Claims Administrator guideline: Decision based on MTUS ACOEM Chapter 14 Ankle and Foot Complaints. Decision based on Non-MTUS Citation Official Disability Guidelines, Foot and Ankle.

MAXIMUS guideline: Decision based on MTUS ACOEM Chapter 14 Ankle and Foot Complaints Page(s): 371. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Ankle and Foot.

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 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. There is no indication that this patient suffers from either plantar fasciitis or chronic Achilles tendonitis. Medical necessity for the requested procedure has not been established. The requested service is not medically necessary.

Flubiprofen/lidocaine/amitriptyline cream 180gm in the morning: 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/compounded medication is a flubiprofen/lidocaine/ amitriptyline cream. There are no clinical studies to support the safety or effectiveness of Flurbiprofen in a topical delivery system (excluding ophthalmic). There is no documentation of intolerance to other previous oral medications. The medical necessity of the requested compounded medication has not been established. The requested topical analgesic compound is not medically necessary.

Gabaclyotram cream 180gm in the evening: 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 requested compounded topical agent is Gabapentin, Cyclobenzaprine, Tramadol (GabaCycloTram) cream. Cyclobenzaprine is not FDA approved for use as a topical application. There is no evidence for the use of any muscle relaxant as a topical agent. In addition, Gabapentin and Tramadol are not FDA approved for a topical application. There is no peer-reviewed literature to support its use. Medical necessity for the requested compounded topical analgesic cream has not been established. The request for the compounded topical analgesic agent is not medically necessary.

Additional 12 physical therapy visits for the right ankle: Upheld

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

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) Physical Therapy.

Decision rationale: According to the California MTUS Treatment guidelines, physical therapy (PT) is indicated for the treatment of musculoskeletal pain. Active therapy is based on the philosophy that therapeutic exercise and/or activity are beneficial for restoring flexibility, strength, endurance, function, range of motion, and can alleviate discomfort. Patients are instructed and expected to continue active therapies at home as an extension of the treatment process in order to maintain improvement levels. Per ODG, patients should be formally assessed after a "6-visit trial" to see progress made by patient. When the duration and/or number of visits have exceeded the guidelines, exceptional factors should be documented. Additional treatment would be assessed based on functional improvement and appropriate goals for additional treatment. In this case, there is reported widespread pain of the neck, lower back, right shoulder and arm, both elbows and forearms, both hips and thighs, and the right ankle and foot. According to the records, this patient has had 65 PT visits since her injury in 03/2014. There is no documentation indicating that she had a defined functional improvement in her condition. There is no specific indication for the additional 12 PT sessions for the right ankle, which exceed the MTUS and ODG guidelines. Medical necessity for the additional PT visits requested have not been established. The requested services are not medically necessary.

