MAXIMUS Federal Services

Case Number:	CM15-0109518		
Date Assigned:	06/16/2015	Date of Injury:	11/05/2014
Decision Date:	08/21/2015	UR Denial Date:	05/27/2015
Priority:	Standard	Application Received:	06/08/2015

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: Maryland, Texas, Virginia
Certification(s)/Specialty: Internal Medicine, Allergy and Immunology, Rheumatology

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 34-year-old male, who sustained an industrial injury on 11/05/2014, while working in a poultry shop, as a result of cumulative trauma. The injured worker was diagnosed as having rotator cuff syndrome, ankle sprain/strain, elbow sprain/strain, right shoulder sprain/strain, wrist sprain/strain, hand sprain/strain, anxiety/depression, insomnia, dizziness, carpal tunnel syndrome, and tendon tear, shoulder and ankle. Treatment to date has included diagnostics, physiotherapy, extracorporeal shockwave therapy right shoulder, and medications. Currently, the injured worker complains of bilateral shoulder pain, rated 6/10, lumbar spine pain, rated 7/10, right wrist pain, rated 6/10, and bilateral foot pain, rated 7/10. This was documented as unchanged since his last visit. He had 6 physiotherapy sessions with minimal relief. He also reported that he experienced dizziness and insomnia and was documented as having notable anxiety and stress. Physical exam noted decreased range of motion of the shoulders and reflex testing of the upper and lower extremities was completed, with no abnormal changes were recorded. Imaging reports were referenced (ankles, shoulders, wrists). Gastrointestinal complaints were not noted. The treatment plan included shockwave therapy treatment, Naproxen, Prilosec, and topical compound analgesic cream (Flurbiprofen 20%, Baclofen 2%, Dexamethasone 2%, Menthol 2%, Camphor 2%, Capsaicin 0.0375%, Hyaluronic acid 0.20%). The progress notes referenced topical compound creams, Naproxen, and Prilosec since at least 2/2015.

IMR ISSUES, DECISIONS AND RATIONALES

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

Shockwave therapy x 4 sessions: 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) Shoulder and Knee, ESWT and Other Medical Treatment Guidelines PubMed ESWT.

Decision rationale: MTUS does not specifically refer to Electric Shockwave therapy. The ODG guidelines were consulted for ESWT treatment of the shoulder and only recommended Shoulder ESWT when: 1) Patients whose pain from calcifying tendinitis of the shoulder has remained despite six months of standard treatment. 2) At least three conservative treatments have been performed prior to use of ESWT. These would include: a. Rest, b. Ice, c. NSAIDs, d. Orthotics, e. Physical Therapy, e. Injections (Cortisone). Medical records do not detail what conservative therapy was tried and does not provide any detail regarding the physical therapy of the shoulder and its outcome. Medical documents do not provide sufficient details of failed conservative therapy for the shoulder. As such, the request for Shockwave Therapy x 4 sessions is not medically necessary.

FCL (Flurbiprofen 20%, Baclofen 2%, Dexamethanoe 2%, Menthol 2%, Camphor 2%, Capsaicin 0.0375%, Hyaluronic acid 0.20%) in 180 grams: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Boswellia Serrata Resin, Capsaicin, Topical Analgesics Page(s): 25, 28, 111-113.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-113. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Compound creams.

Decision rationale: MTUS and ODG recommends usage of topical analgesics as an option, but also further details primarily recommended for neuropathic pain when trials of antidepressants and anti-convulsants have failed. The medical documents do not indicate failure of antidepressants or anti-convulsants. MTUS states, "There is little to no research to support the use of many of these agents. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended."FLURBIPROFEN (NOT RECOMMENDED) MTUS states that the only FDA- approved NSAID medication for topical use includes diclofenac, which is indicated for relief of osteoarthritis pain in joints. Flurbiprofen would not be indicated for topical use in this case. BACLOFEN (NOT RECOMMENDED) MTUS states that topical Baclofen is not recommended. MENTHOLODG only comments on menthol in the context of cryotherapy for acute pain, but does state "Topical OTC pain relievers that contain menthol, methyl salicylate, or capsaicin, may in rare instances cause serious burns, a new alert from the FDA warns."CAPSAICIN (RECOMMENDED AFTER FAILURE OF 1ST LINE) Chronic Pain Medical Treatment Guidelines Capsaicin page(s) 28. MTUS recommends topical capsaicin only as an option in patients who have not responded or are intolerant to other treatments. There is no indication that the patient has failed oral medication or is intolerant to other treatments. Additionally, ODG states "Topical OTC pain relievers that contain menthol, methyl salicylate, or capsaicin, may in rare instances cause serious burns, a new alert from the FDA warns." In this case, there are multiple medications in this compound that are not

recommended. As such, the request for FCL (Flurbiprofen 20%, Baclofen 2%, Dexamethasone 2%, Menthol 2%, Camphor 2%, Capsaicin 0.0375%, Hyaluronic acid 0.2%) is not medically necessary.

Naproxen 500mg #60: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms & cardiovascular risk Page(s): 67. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain Chapter, NSAIDs.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs (non-steroidal anti-inflammatory drugs) Page(s): 67-73. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic), Naproxen, NSAIDs (non-steroidal anti-inflammatory drugs).

Decision rationale: MTUS and ODG recommends usage of topical analgesics as an option, but also further details primarily recommended for neuropathic pain when trials of antidepressants and anti-convulsants have failed. The medical documents do not indicate failure of antidepressants or anti-convulsants. MTUS states, "There is little to no research to support the use of many of these agents. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended."FLURBIPROFEN (NOT RECOMMENDED) MTUS states that the only FDA- approved NSAID medication for topical use includes diclofenac, which is indicated for relief of osteoarthritis pain in joints. Flurbiprofen would not be indicated for topical use in this case. BACLOFEN (NOT RECOMMENDED) MTUS states that topical Baclofen is not recommended. MENTHOLODG only comments on menthol in the context of cryotherapy for acute pain, but does state "Topical OTC pain relievers that contain menthol, methyl salicylate, or capsaicin, may in rare instances cause serious burns, a new alert from the FDA warns."CAPSAICIN (RECOMMENDED AFTER FAILURE OF 1ST LINE). Chronic Pain Medical Treatment Guidelines Capsaicin page(s) 28. MTUS recommends topical capsaicin only as an option in patients who have not responded or are intolerant to other treatments. There is no indication that the patient has failed oral medication or is intolerant to other treatments. Additionally, ODG states "Topical OTC pain relievers that contain menthol, methyl salicylate, or capsaicin, may in rare instances cause serious burns, a new alert from the FDA warns." In this case, there are multiple medications in this compound that are not recommended. As such, the request for FCL (Flurbiprofen 20%, Baclofen 2%, Dexamethasone 2%, Menthol 2%, Camphor 2%, Capsaicin 0.0375%, Hyaluronic acid 0.2%) is not medically necessary.

Prilosec 20mg #30: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms & cardiovascular risk Page(s): 68.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms & cardiovascular risk Page(s): 68-69. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic), NSAIDs, GI symptoms cardiovascular risk.

Decision rationale: MTUS states "Determine if the patient is at risk for gastrointestinal events: (1) Age > 65 years; (2) History of peptic ulcer, GI bleeding or perforation; (3) Concurrent use of ASA, corticosteroids, and/or an anticoagulant; or (4) High dose/multiple NSAID (e.g., NSAID +

low-dose ASA)." And "Patients at intermediate risk for gastrointestinal events and no cardiovascular disease: (1) A non-selective NSAID with either a PPI (Proton Pump Inhibitor, for example, 20 mg omeprazole daily) or misoprostol (200 g four times daily) or (2) A Cox-2 selective agent. Long-term PPI use (> 1 year) has been shown to increase the risk of hip fracture (adjusted odds ratio 1.44)." The medical documents provided do not establish the patient has having documented GI bleeding/perforation/peptic ulcer or other GI risk factors as outlined in MTUS. Additionally, there is no evidence provided to indicate the patient suffers from dyspepsia because of the present medication regimen. The Naproxen is not medically necessary. As such, the request for Prilosec 20mg #60 is not medically necessary.