

Case Number:	CM14-0203519		
Date Assigned:	12/16/2014	Date of Injury:	03/12/2010
Decision Date:	02/06/2015	UR Denial Date:	11/11/2014
Priority:	Standard	Application Received:	12/05/2014

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 Internal Medicine, has a subspecialty in Rheumatology, Allergy & Immunology and is licensed to practice in Texas. 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:

This is a 58 year old female with a date of injury of 03/12/10 where she slipped and fell down two stairs. She is being treated for neck sprain/strain, shoulder sprain/strain, elbow/forearm sprain, wrist sprain, lumbago, myalgia, pain in shoulder joint, L4L5 degenerative disc disease, right elbow medial epicondylitis, C3-C4 protrusion, right shoulder bursitis and tendinosis, biceps tenosynovitis, right scapholunate dislocation, hand arthritis, right carpal tunnel syndrome. Subjective complaints during her most recent exam on 12/8/14 included continued right sided stiffness with increasing of activity and improved with medications and neck, pain in neck, right sided upper extremity, shoulder and back pain. Objective findings include limited ROM in right leg, cervical spine and lumbar spine. An electrodiagnostic study in 2012 which suggested bilateral carpal tunnel syndrome. MRI on 5/1/13 of the cervical spine shows C3-C4 central focal disc protrusion abutting the thecal sac. MRI 8/30/13 of the lumbar spine shows mild to moderate spinal stenosis and moderate bilateral foraminal narrowing greater on the left, impingement on bilateral exiting nerve root and descending right L4 nerve root. Previous treatments have included physical therapy, shockwave therapy, biofeedback, medications (Naprosyn, omeprazole, cyclobenzaprine), right shoulder arthroscopic procedure and carpal tunnel release. Previous Utilization Review on 11/11/14 was non-certify for Diclofenac 20%, Dextro/Tram/Amitrip, Flurb/Lido/Amitrip, Gaba/Cyclo/Tram, Flurb/Tram/Cyclo, Menthoderm as the MTUS recommends against most compounded pain medications with a few notable exceptions.

IMR ISSUES, DECISIONS AND RATIONALES

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

Retrospective Diclofenac 20%: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 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 recommend usage of topical analgesics as an option, but also further details "primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed." The medical documents do not indicate failure of antidepressants or anticonvulsants. 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." MTUS specifically states for Voltaren Gel 1% (diclofenac) that it "indicated for relief of osteoarthritis pain in joints that lend themselves to topical treatment (ankle, elbow, foot, hand, knee, and wrist). It has not been evaluated for treatment of the spine, hip or shoulder." Medical records do not indicate that the patient is being treated for osteoarthritis pain in the joints. Additionally, the records fail to indicate where the treatment area is or what the indication is making. The request for Diclofenac 20% is not medically necessary.

Dextro/Tram/Amitrip: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 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 recommend usage of topical analgesics as an option, but also further details "primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed." The medical documents do not indicate failure of antidepressants or anticonvulsants. 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." Since tramadol is not recommended topically, the request for Dextro/Tram/Amitrip is not medically necessary. MTUS states that the only FDA- approved NSAID medication for topical use includes diclofenac, which is indicated for relief of osteoarthritis pain in joints. Tramadol would not be indicated for topical use in this case. MTUS and ODG do not specifically make a recommendation on topical Amitriptyline, but does cite (Lynch ME, Clark AJ, Sawynok J, Sullivan MJ Topical 2% amitriptyline and 1% ketamine in neuropathic pain syndromes: a randomized, double-blind, placebo-controlled trial. Anesthesiology. 2005;103:140-6) and find that "this randomized, placebo-controlled trial

examining topical 2% amitriptyline, 1% ketamine, and a combination in the treatment of neuropathic pain revealed no difference between groups."

Flurb/Lido/Amitrip: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 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 recommend usage of topical analgesics as an option, but also further details "primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed." The medical documents do not indicate failure of antidepressants or anticonvulsants. 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." Given that Flurbiprofen is not recommended and the patient is not being treated for neuropathic pain (indication for Lidocaine) and topical amitriptyline is not effective, the request for Flurb/Lido/Amitrip is not medically necessary. 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. ODG also states that topical lidocaine is appropriate in usage as patch under certain criteria, but that "no other commercially approved topical formulations of lidocaine (whether creams, lotions or gels) are indicated for neuropathic pain." MTUS states regarding lidocaine, "Neuropathic pain Recommended for localized peripheral pain after there has been evidence of a trial of first-line therapy (tri-cyclic or SNRI anti-depressants or an AED such as gabapentin or Lyrica)." MTUS indicates lidocaine "Non-neuropathic pain: Not recommended." The medical records do not indicate failure of first-line therapy for neuropathic pain and lidocaine is also not indicated for non-neuropathic pain. ODG states regarding lidocaine topical patch, "This is not a first-line treatment and is only FDA approved for post-herpetic neuralgia". Medical documents do not indicate the patient as having post-herpetic neuralgia. MTUS and ODG do not specifically make a recommendation on topical Amitriptyline, but does cite (Lynch ME, Clark AJ, Sawynok J, Sullivan MJ Topical 2% amitriptyline and 1% ketamine in neuropathic pain syndromes: a randomized, double-blind, placebo-controlled trial. Anesthesiology. 2005;103:140-6) and find that "this randomized, placebo-controlled trial examining topical 2% amitriptyline, 1% ketamine, and a combination in the treatment of neuropathic pain revealed no difference between groups."

Gaba/Cyclo/Tram: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 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 recommend usage of topical analgesics as an option, but also further details "primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed." The medical documents do not indicate failure of antidepressants or anticonvulsants. 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." All three medications in this compounded topical agent are not recommended by MTUS guidelines making the request for Gaba/Cyclo/Tram not medically necessary. MTUS states that topical Gabapentin is "Not recommended." And further clarifies, "antiepilepsy drugs: There is no evidence for use of any other antiepilepsy drug as a topical product." MTUS states regarding topical muscle relaxants, "Other muscle relaxants: There is no evidence for use of any other muscle relaxant as a topical product." Topical cyclobenzaprine is not indicated for this usage, per MTUS. MTUS states that the only FDA- approved NSAID medication for topical use includes diclofenac, which is indicated for relief of osteoarthritis pain in joints. Tramadol would not be indicated for topical use in this case.

Flurb/Tram/Cyclo: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 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 recommend usage of topical analgesics as an option, but also further details "primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed." The medical documents do not indicate failure of antidepressants or anticonvulsants. 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." All three medications in this compounded topical agent are not recommended by MTUS guidelines making the request for Flurb/Tram/Cyclo not medically necessary. 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. MTUS states that the only FDA- approved NSAID medication for topical use includes diclofenac, which is indicated for relief of osteoarthritis pain in joints. Tramadol would not be indicated for topical use in this case. MTUS states regarding topical muscle relaxants, "Other muscle relaxants: There is no evidence for use of any other muscle relaxant as a topical product." Topical cyclobenzaprine is not indicated for this usage, per MTUS.

Mentherm: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 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 recommend usage of topical analgesics as an option, but also further details "primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed." The medical documents do not indicate failure of antidepressants or anticonvulsants. 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." Methoderm/Thera-Gesic is the brand name version of a topical analgesic containing methyl salicylate and menthol. ODG recommends usage of topical analgesics as an option, but also further details "primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed." The medical documents do not indicate failure of antidepressants or anticonvulsants. 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." MTUS states regarding topical Salicylate, "Recommended. Topical salicylate (e.g., Ben-Gay, methyl salicylate) is significantly better than placebo in chronic pain. (Mason-BMJ, 2004) See also Topical analgesics; & Topical analgesics, compounded." ODG 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." In this case, the treating physician does not document the failure of first line treatments. As such, the request for methoderm is not medically necessary.