

Case Number:	CM15-0015127		
Date Assigned:	02/03/2015	Date of Injury:	07/23/2010
Decision Date:	04/01/2015	UR Denial Date:	01/02/2015
Priority:	Standard	Application Received:	01/27/2015

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: California, District of Columbia, Maryland
 Certification(s)/Specialty: Anesthesiology, Pain Management

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 63-year-old female, who sustained an industrial injury on 7/23/2010. She has reported left knee pain. The diagnoses have included internal derangement of the left knee, status post arthroscopy with persistent symptomatology. Treatment to date has included Non- Steroidal Anti-Inflammatory Drugs (NSAIDs); knee brace, status post left arthroscopy, steroid injection to knee, and sodium hyaluronate injection to left knee x 5. Currently, the Injured Worker complains of left knee pain associated with swelling, popping and clicking. On 11/24/14, physical examination significant for mild tenderness, positive McMurray's sign medially, no edema was noted. Plan of care included future sodium hyaluronate injection, continuation of Mirtazapine for insomnia, and Vicodin for pain. On 1/2/2015 Utilization Review non-certified Mirtazapine 15mg #30, Nalfon 400mg #60, Protonix 20mg #60, Lidopro Lotion 4oz, Terocin Patches #20 and one injection to the left knee, noting the documentation failed to support medical necessity. The MTUS Guidelines were cited. On 1/27/2015, the injured worker submitted an application for IMR for review of Mirtazapine 15mg #30, Nalfon 400mg #60, Protonix 20mg #60, Lidopro Lotion 4oz, Terocin Patches #20 and one injection to the left knee.

IMR ISSUES, DECISIONS AND RATIONALES

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

Mirtazapine 15 mg, thirty count: Overturned

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Antidepressants Page(s): P13.

Decision rationale: Above referenced MTUS citation notes antidepressants are "Recommended as a first line option for neuropathic pain, and as a possibility for non-neuropathic pain." ODG supports mirtazapine for insomnia, which this patient has. The UR physician related that mirtazapine is not supported for mild depression, but they did not cite the guidelines, which support this assertion. The request is medically necessary.

Nalfon 400 mg, sixty count: Overturned

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Osteoarthritis Page(s): p11.

Decision rationale: Current guidelines note that evidence is limited to make an initial recommendation with acetaminophen, and that NSAIDs may be more efficacious for treatment. In terms of treatment of the hand, it should be noted that there are no placebo trials of efficacy and recommendations have been extrapolated from other joints. The selection of acetaminophen as a first-line treatment appears to be made primarily based on side effect profile in osteoarthritis guidelines. The most recent Cochrane review on this subject suggests that non-steroidal anti-inflammatory drugs (NSAIDs) are more efficacious for osteoarthritis in terms of pain reduction, global assessments and improvement of functional status. With regard to the use of Fenoprofen, MTUS notes it is approved for treatment of OA. I disagree with the UR physician's assertion that the guidelines do not recommend long-term use of NSAIDs, as the MTUS does not state this expressly in all cases. Also, this is being used second line as the Injured Worker failed naproxen. The request is medically necessary.

Protonix 20 mg, sixty count: Overturned

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms & cardiovascular risk Page(s): p68.

Decision rationale: In the treatment of dyspepsia secondary to NSAID therapy, the MTUS recommends stopping the NSAID, switching to a different NSAID, or considering the use of an H2-receptor antagonist or a PPI. The MTUS Chronic Pain Medical Treatment Guidelines recommend the use of proton pump inhibitors in conjunction with NSAIDs in situations in which the patient is at risk for gastrointestinal events including: (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). CPMTG guidelines further specify: "Recommendations: Patients with no risk factor and no cardiovascular disease: Non-selective NSAIDs OK (e.g., ibuprofen, naproxen, etc.) 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 (200g 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). Patients at high risk for gastrointestinal events with no cardiovascular disease: A Cox-2 selective agent plus a PPI if absolutely necessary. Patients at high risk of gastrointestinal events with cardiovascular disease: If GI risk is high the suggestion is for a low-dose Cox-2 plus low dose Aspirin (for cardioprotection) and a PPI. If cardiovascular risk is greater than GI risk the suggestion is naproxen plus low-dose aspirin plus a PPI. (Laine, 2006) (Scholmerich, 2006) (Nielsen, 2006) (Chan, 2004) (Gold, 2007) (Laine, 2007)"The UR physician denied Protonix citing that the NSAID for which Protonix was needed (to treat dyspepsia) was not medically necessary. However, since the determination was that it was medically necessary, and there is documentation that the patient had dyspepsia, it is medically necessary.

Lidopro lotion, 4 ounces: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Section.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topicals Page(s): 25, 60, 105, 111-113.

Decision rationale: LidoPro is capsaicin, lidocaine, menthol, methyl salicylate Capsaicin may have an indication for OA pain in this context. Per MTUS p 112 "Indications: There are positive randomized studies with capsaicin cream in patients with osteoarthritis, fibromyalgia, and chronic non-specific back pain, but it should be considered experimental in very high doses. Although topical capsaicin has moderate to poor efficacy, it may be particularly useful (alone or in conjunction with other modalities) in patients whose pain has not been controlled successfully with conventional therapy." Methyl salicylate may have an indication for chronic pain in this context. Per MTUS p105, "Recommended. Topical salicylate (e.g., Ben-Gay, methyl salicylate) is significantly better than placebo in chronic pain. (Mason-BMJ, 2004)." However, the other ingredients in LidoPro are not indicated. The preponderance of evidence indicates that overall, this medication is not medically necessary. Regarding topical lidocaine, MTUS states (p112) "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). Non-neuropathic pain: Not recommended. There is only one trial that tested 4% lidocaine for treatment of chronic muscle pain. The results showed there was no superiority over placebo. (Scudds, 1995). " LidoPro topical lotion contains menthol. The CA MTUS, ODG, National Guidelines Clearinghouse, and ACOEM provide no evidence-based recommendations regarding the topical application of menthol. It is the opinion of this IMR reviewer that a lack of endorsement, a lack of mention, inherently implies a lack of recommendation, or a status equivalent to "not recommended". Since menthol is not medically indicated, then the overall

product is not indicated per MTUS as outlined below. Note the statement on page 111: Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Regarding the use of multiple medications, MTUS p60 states "Only one medication should be given at a time, and interventions that are active and passive should remain unchanged at the time of the medication change. A trial should be given for each individual medication. Analgesic medications should show effects within 1 to 3 days, and the analgesic effect of antidepressants should occur within 1 week. A record of pain and function with the medication should be recorded. (Mens, 2005) The recent AHRQ review of comparative effectiveness and safety of analgesics for osteoarthritis concluded that each of the analgesics was associated with a unique set of benefits and risks, and no currently available analgesic was identified as offering a clear overall advantage compared with the others." Therefore, it would be optimal to trial each medication individually.

Terocin Patches, twenty count: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topicals Page(s): 25, 60, 105, 111-113.

Decision rationale: Terocin is capsaicin, lidocaine, menthol, methyl salicylate, and boswellia serrata. Capsaicin may have an indication for OA pain in this context. Per MTUS p 112 "Indications: There are positive randomized studies with capsaicin cream in patients with osteoarthritis, fibromyalgia, and chronic non-specific back pain, but it should be considered experimental in very high doses. Although topical capsaicin has moderate to poor efficacy, it may be particularly useful (alone or in conjunction with other modalities) in patients whose pain has not been controlled successfully with conventional therapy." Methyl salicylate may have an indication for chronic pain in this context. Per MTUS p105, "Recommended. Topical salicylate (e.g., Ben-Gay, methyl salicylate) is significantly better than placebo in chronic pain. (Mason-BMJ, 2004)." However, the other ingredients in Terocin are not indicated. The preponderance of evidence indicates that overall, this medication is not medically necessary. Regarding topical lidocaine, MTUS states (p112) "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). Non-neuropathic pain: Not recommended. There is only one trial that tested 4% lidocaine for treatment of chronic muscle pain. The results showed there was no superiority over placebo. (Scudds, 1995)." Per MTUS p25 Boswellia Serrata Resin is not recommended for chronic pain. Terocin topical lotion contains menthol. The CA MTUS, ODG, National Guidelines Clearinghouse, and ACOEM provide no evidence-based recommendations regarding the topical application of menthol. It is the opinion of this IMR reviewer that a lack of endorsement, a lack of mention, inherently implies a lack of recommendation, or a status equivalent to "not recommended". Since menthol is not medically indicated, then the overall product is not indicated per MTUS as outlined below. Note the statement on page 111: Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Regarding the use of multiple medications, MTUS p60 states "Only one medication should be given at a time, and interventions that are active and passive should remain

unchanged at the time of the medication change. A trial should be given for each individual medication. Analgesic medications should show effects within 1 to 3 days, and the analgesic effect of antidepressants should occur within 1 week. A record of pain and function with the medication should be recorded. (Mens, 2005) The recent AHRQ review of comparative effectiveness and safety of analgesics for osteoarthritis concluded that each of the analgesics was associated with a unique set of benefits and risks, and no currently available analgesic was identified as offering a clear overall advantage compared with the others." Therefore, it would be optimal to trial each medication individually.

One injection to the left knee: Overturned

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Knee & Leg (Acute & Chronic) Chapter.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation ODG Knee & Leg, Hyaluronic Acid Injections.

Decision rationale: Review of the records indicates this request is for hyaluronic acid injection. The MTUS is silent on the use of hyaluronic acid injections. Per ODG TWC with regard to viscosupplementation, hyaluronic acid injections are "Recommended as a possible option for severe osteoarthritis for patients who have not responded adequately to recommended conservative treatments (exercise, NSAIDs or acetaminophen), to potentially delay total knee replacement, but in recent quality studies the magnitude of improvement appears modest at best. While osteoarthritis of the knee is a recommended indication, there is insufficient evidence for other conditions, including patellofemoral arthritis, chondromalacia patellae, osteochondritis dissecans, or patellofemoral syndrome (patellar knee pain)."Criteria for Hyaluronic acid injections: Patients experience significantly symptomatic osteoarthritis but have not responded adequately to recommended conservative non-pharmacologic (e.g., exercise) and pharmacologic treatments or are intolerant of these therapies (e.g., gastrointestinal problems related to anti-inflammatory medications), after at least 3 months; Documented symptomatic severe osteoarthritis of the knee, which may include the following: Bony enlargement; Bony tenderness; Crepitus (noisy, grating sound) on active motion; Less than 30 minutes of morning stiffness; No palpable warmth of synovium; Over 50 years of age; Pain interferes with functional activities (e.g., ambulation, prolonged standing) and not attributed to other forms of joint disease; Failure to adequately respond to aspiration and injection of intra-articular steroids; Generally performed without fluoroscopic or ultrasound guidance; Are not currently candidates for total knee replacement or who have failed previous knee surgery for their arthritis, unless younger patients wanting to delay total knee replacement. (Wen, 2000); Repeat series of injections: If documented significant improvement in symptoms for 6 months or more, and symptoms recur, may be reasonable to do another series. No maximum established by high quality scientific evidence; see Repeat series of injections above; Hyaluronic acid injections are not recommended for any other indications such as chondromalacia patellae, facet joint arthropathy, osteochondritis dissecans, or patellofemoral arthritis, patellofemoral syndrome (patellar knee pain), plantar nerve entrapment syndrome, or for use in joints other than the knee (e.g., ankle, carpo-metacarpal joint, elbow, hip, metatarso-phalangeal joint, shoulder, and temporomandibular joint) because the effectiveness of

hyaluronic acid injections for these indications has not been established. The documentation submitted for review indicates that the injured worker has previously received a series of hyaluronic acid injections to the left knee with documentation of over one year of relief. The Injured Worker wishes to hold off on knee replacement at this time. I disagree with the UR physician's assertion that the Injured Worker does not meet criteria simply because they are working full time with the use of Vicodin as a rationale that they should not receive an injection that was helpful for them before. As the guideline criteria calls for 6 months or more of pain relief for repeat injections, the request is medically necessary.