

| | | | |
|-----------------------|--------------|------------------------------|------------|
| Case Number: | CM15-0066556 | | |
| Date Assigned: | 04/14/2015 | Date of Injury: | 09/11/2009 |
| Decision Date: | 05/18/2015 | UR Denial Date: | 03/26/2015 |
| Priority: | Standard | Application Received: | 04/08/2015 |

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: 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:

This 40-year-old female sustained an industrial injury on 9/11/09. She subsequently reported shoulder pain. Diagnoses include radial styloid tenosynovitis and shoulder impingement syndrome. Treatments to date have included x-rays, MRIs, physical therapy, surgery and prescription pain medications. The injured worker continues to experience right shoulder pain. A request for Lidocaine/Hyaluronic patch 6%/2% cream #120 and Flurbiprofen/Capsaicin patch 10%/0.25% cream #120 medications was made by the treating physician.

IMR ISSUES, DECISIONS AND RATIONALES

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

Lidocaine/Hyaluronic patch 6%/2% cream #120: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111-113.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3970829/>.

Decision rationale: 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)" The CA MTUS, ODG, National Guidelines Clearinghouse, and ACOEM provide no evidence-based recommendations regarding the topical application of hyaluronic acid. 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 hyaluronic acid 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. Per The Journal of Clinical and Aesthetic Dermatology: "The new nano-hyaluronic acid clearly demonstrated a significant benefit in decreasing the depth of wrinkles (up to 40%), and skin hydration (up to 96%) and skin firmness and elasticity were significantly enhanced (up to 55%) at the end of eight weeks." 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 anti-depressants 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. As topical hyaluronic acid is not recommended, the request is not medically necessary.

Flurbiprofen/Capsaicin patch 10%/0.25% cream #120: 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): 60, 111-113.

Decision rationale: Per MTUS with regard to Flurbiprofen (p112): "These medications may be useful for chronic musculoskeletal pain, but there are no long-term studies of their effectiveness or safety. (Mason, 2004) Indications: Osteoarthritis and tendinitis, in particular, that of the knee and elbow or other joints that are amenable to topical treatment: Recommended for short-term use (4-12 weeks). There is little evidence to utilize topical NSAIDs for treatment of osteoarthritis of the spine, hip or shoulder." Topical flurbiprofen is not indicated for the injured worker's shoulder pain. Capsaicin may have an indication for chronic lower back 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." The documentation submitted for review does not note neuropathic pain. Capsaicin is not indicated. 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. The MTUS Chronic Pain Medical Treatment Guidelines state that topical medications are: "Largely experimental in use with few randomized controlled trials to determine efficacy or safety. Primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. (Namaka, 2004) These agents are applied locally to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. (Colombo, 2006) Many agents are compounded as monotherapy or in combination for pain control (including NSAIDs, opioids, capsaicin, local anesthetics, antidepressants, glutamate receptor antagonists, α -adrenergic receptor agonist, adenosine, cannabinoids, cholinergic receptor agonists, agonists, prostanoids, bradykinin, adenosine triphosphate, biogenic amines, and nerve growth factor). (Argoff, 2006) 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." As neither of the compounded agents is recommended, the request is not medically necessary.