

Case Number:	CM15-0145165		
Date Assigned:	08/06/2015	Date of Injury:	07/21/1998
Decision Date:	09/22/2015	UR Denial Date:	07/14/2015
Priority:	Standard	Application Received:	07/27/2015

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

Certification(s)/Specialty: Preventive Medicine, Occupational Medicine

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 51-year-old male injured worker suffered an industrial injury on 7-21-1998. The diagnoses included lumbar fusion and lumbar radiculopathy. The treatment included medications and surgery. The diagnostics included lumbar magnetic resonance imaging, lumbar computerized tomography and electromyographic studies. On 6-22-2015, the treating provider reported persistent lower back pain and reported gastritis from medications. He reported persistent numbness to the legs with weakness. He reported the medications bring the pain down from 10 out of 10 to 6 out of 10. On exam, the lumbar spine had reduced range of motion with extreme weakness of both legs. It was not clear if the injured worker had returned to work. The requested treatments included Terocin Lotion, Miseflex-C and Narcosoft.

IMR ISSUES, DECISIONS AND RATIONALES

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

Terocin Lotion: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 111, 112-113.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Capsaicin Section, Salicylate Topicals Section, Topical Analgesics Section Page(s): 28, 105, 111-113.

Decision rationale: Per manufacturer's information, Terocin lotion is a combination topical analgesic with active ingredients that include capsaicin 0.025%, menthol 10%, methyl salicylate 25% and lidocaine 2.50%. Topical capsaicin is recommended by the MTUS Guidelines only as an option in patients who have not responded or are intolerant to other treatments. There are positive randomized studies with capsaicin cream in patients with osteoarthritis, fibromyalgia, and chronic non-specific back pain. Capsaicin is generally available as a 0.025% formulation as a treatment for osteoarthritis and a 0.075% formulation primarily studied for post-herpetic neuralgia, diabetic neuropathy and post-mastectomy pain. There are no studies of a 0.0375% formulation, and there is no current indication that this increase over a 0.025% formulation would provide any further efficacy. Salicylate topical is recommended by the MTUS Guidelines, as it is significantly better than placebo in chronic pain. Menthol is not addressed by the MTUS Guidelines, but it is often included in formulations of anesthetic agents. It induces tingling and cooling sensations when applied topically. Menthol induces analgesia through calcium channel-blocking actions, as well as binding to kappa-opioid receptors. Menthol is also an effective topical permeation enhancer for water-soluble drugs. There are reports of negative effects from high doses of menthol such as 40% preparations. Topical lidocaine is used primarily for neuropathic pain when trials of antidepressants and anticonvulsants have failed. The FDA for neuropathic pain has designated topical lidocaine, in the formulation of a dermal patch (Lidoderm) for orphan status. Lidoderm is also used off-label for diabetic neuropathy. No other commercially approved topical formulations of lidocaine (whether creams, lotions or gels) are indicated for neuropathic pain. Non-dermal patch formulations are generally indicated as local anesthetics and anti-pruritics. Topical analgesics are recommended by the MTUS Guidelines. Compounded topical analgesics that contain at least one drug or drug class that is not recommended is not recommended. Topical lidocaine in the formulation of a cream or lotion is not recommended, therefore Terocin is not recommended by the MTUS Guidelines. The request for Terocin Lotion is determined to not be medically necessary.

Miseflex-C: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain, and Medical Food.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter/Glucosamine (and Chondroitin Sulfate) Section and Other Medical Treatment Guidelines <https://enovachem.us.com/product/miseflex-c/>.

Decision rationale: Per manufacturer's information, Miseflex-C is a nutritional supplement consisting of a combination of calcium, magnesium, chondroitin, bromelain and a proprietary blend consisting of valerian, passiflora, and ginkgo biloba extract. Some studies have shown that the ingredients listed in Miseflex-C may help with muscle soreness and cramps. MTUS guidelines do not address the use of Miseflex-C. Per the ODG, glucosamine is recommended as an option (glucosamine sulfate only) given its low risk, in patients with moderate arthritis pain, especially for knee osteoarthritis. Studies have demonstrated a highly significant efficacy for crystalline glucosamine sulphate (GS) on all outcomes, including joint space narrowing, pain, mobility, safety, and response to treatment, but similar studies are lacking for glucosamine hydrochloride (GH). For all herbals and dietary supplements, there may be concerns for potential

interactions with prescription and over-the-counter medications and lack of manufacturing quality controls. In this case, the injured worker is not diagnosed with arthritic pain. There is no evidenced-based literature to support the use of Miseflex-C; therefore, the request for Miseflex-C is determined to not be medically necessary.

Narcosoft #30: 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), Opioid induced constipation.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids, Criteria for Use Section Page(s): 77. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter/Opioid Induced Constipation Treatment Section and Other Medical Treatment Guidelines <https://enovachem.com/product/narcosoft>.

Decision rationale: The MTUS guidelines and ODG do not address the use of Narcosoft for the treatment of opioid-induced constipation. The MTUS guidelines and the ODG do address the use of laxatives in general. Per manufacture information, Narcosoft is a Nutritional Supplement containing of a blend of soluble fibers and natural laxatives that may help to relieve symptoms of occasional constipation. The MTUS Guidelines recommends the prophylactic treatment of constipation when initiating opioid therapy. The ODG states that first line treatment for opioid induced constipation includes laxatives to help stimulate gastric motility, as well as other medications to help loosen hard stools, add bulk, and increase water content of the stool. The injured worker is noted be treated with opioid medications, and occasionally reports problems with constipation, therefore, the request for Narco Soft Capsules #60 3 refills is determined to be medically necessary.