

<b>Case Number:</b>	CM15-0044333		
<b>Date Assigned:</b>	03/16/2015	<b>Date of Injury:</b>	09/12/2014
<b>Decision Date:</b>	04/13/2015	<b>UR Denial Date:</b>	02/24/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	03/09/2015

### 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: Iowa, Illinois, Hawaii

Certification(s)/Specialty: Preventive Medicine, Occupational Medicine, Public Health & General Preventive 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:

This is a 53 year old patient with date of injury of 09/12/2014. Medical records indicate the patient is undergoing treatment for ankle pain. Subjective complaints include right ankle pain, rated 8/10, right ankle swelling and weakness, difficulty sleeping due to pain. Objective findings could not be reviewed, as the handwritten note was difficult to read. Treatment has consisted of MRI, chiropractic treatment, acupuncture, sleep study, Trepadone and compound creams. The utilization review determination was rendered on 02/24/2015 recommending non-certification of Flurbiprofen, Capsaicin, Camphor 10/.025 Percent/2 Percent/1 Percent 120 Gram, Ketoprofen/Cyclobenzaprine/Lidocaine 10 Percent/3 Percent/5 Percent 120 Gram and Trepadone #90.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Flurbiprofen, Capsaicin, Camphor 10/.025 Percent/2 Percent/1 Percent 120 Gram: Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics, Capsaicin Page(s): 111-113, 28. 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 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 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." 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. As such, the request for Flurbiprofen, Capsaicin, Camphor 10/.025 Percent/2 Percent/1 Percent 120 Gram is not medically necessary.

**Ketoprofen/Cyclobenzaprine/Lidocaine 10 Percent/3 Percent/5 Percent 120 Gram:** Upheld

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

**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 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 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. As such, the request for Ketoprofen/Cyclobenzaprine/Lidocaine 10 Percent/3 Percent/5 Percent 120 Gram is not medically necessary.

**Trepadone #90:** Upheld

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

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic), Treadone and Medical Food.

**Decision rationale:** MTUS is silent concerning Treadone. ODG states that a medical food is "a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation." ODG comments on Treadone directly, "Treadone" is a medical food from [REDACTED], that is a proprietary blend of L-arginine, L-glutamine, choline bitartrate, L-serine and gammaaminobutyric acid [GABA]. It is intended for use in the management of joint disorders associated with pain and inflammation. See Medical food, L-Arginine, Glutamic Acid, Choline, L-Serine, and Gamma-aminobutyric acid (GABA)." ODG states, "Gamma-aminobutyric acid (GABA): This supplement is indicated for epilepsy, spasticity and tardive dyskinesia." Medical records do not indicate that this medication would be used to treat epilepsy, spasticity and tardive dyskinesia. ODG states, "L-Serine: There is no indication in Micromedex, Clinical Pharmacology, or AltMedDex for the use of this supplement." This component is not indicated. ODG states, "L-Arginine: This supplement is not indicated in current references for pain or" inflammation. It is indicated to detoxify urine. Other indications include in use for angina, atherosclerosis, coronary artery disease, hypertension, migraines, obesity, and metabolic syndrome." Medical records do not indicate that this medication would be utilized for urine detoxification or for treatment off the other indicated reasons. The medical records do not indicate the specific dietary disease or condition for which there is a distinctive nutritional requirement that the medication would be used for. Additionally, there are several components of this medication that are not recommended per guidelines. As such, the request for Treadone #90 is not medically necessary.