

<b>Case Number:</b>	CM15-0027580		
<b>Date Assigned:</b>	02/19/2015	<b>Date of Injury:</b>	10/25/2011
<b>Decision Date:</b>	04/08/2015	<b>UR Denial Date:</b>	01/17/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	02/12/2015

### 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: New York  
Certification(s)/Specialty: Emergency 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 injured worker is a 53 year-old female who has reported neck and low back pain after a lifting injury on October 25, 2011. The diagnoses have included cervical spine and lumbar spine discopathy. Diagnostic studies have included an magnetic resonance study of the cervical and lumbar spine and electromyography studies. Treatment to date has included medications, TENS, physical therapy, aquatic therapy, epidural steroid injections, and LINT. The treating physician has seen the injured worker periodically since January 2012. He has dispensed amitriptyline-tramadol-dextromethorphan, flurbiprofen-diclofenac, Cidaflex, and Medrox on prior occasions. None of his reports describe the patient-specific indications and results of use for any of the medications that he prescribes/dispenses. Work status has remained as "temporarily totally disabled." An amphetamine positive urine drug screen in 2012 was not addressed. As of January 2015 the injured worker continued to report neck and low back pain, work status remained as "temporarily totally disabled," and the medications now under Independent Medical Review were dispensed. There was no discussion of the patient-specific indications and results for any of these medications. On January 17, 2015, Utilization Review non-certified Cidaflex, App Trim, Amitrip/Dextro/Tram, Diclo/Flurb, and Medrox. The MTUS and ODG guidelines were cited in support of the decision.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Cidaflex:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 50, 105, 111-113. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Chronic Pain, Medical food and Salicylate topicals.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Glucosamine Page(s): 50.

**Decision rationale:** The treating physician is dispensing glucosamine sulfate/chondroitin without clear indications. The MTUS recommends glucosamine for arthritis (primarily of the knee), and the glucosamine should be of a specific type defined in the MTUS. The injured worker does not have a clearly defined arthritis condition. There is no evidence of benefit from taking this supplement. The form of glucosamine used in this case is not the proper form recommended in the MTUS, as the MTUS describes a specific chemical form on which medical evidence is based and the treating physician has not discussed the nature of the ingredients. Other forms lack scientific credibility. Cidaflex appears to contain glucosamine hydrochloride, a form not recommended in the MTUS. Chondroitin is not indicated per the MTUS. Cidaflex is not medically necessary based on the MTUS.

**AppTrim:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 50, 105, 111-113. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Chronic Pain, Medical food and Salicylate topicals.

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain section, Medical food and Other Medical Treatment Guidelines Other Medical Treatment Guideline or Medical Evidence: FDA Definition of medical foods: Defined in section 5(b) of the Orphan Drug Act (21 U.s.c.360ee (b) (3)).

**Decision rationale:** There are no physician reports which provided specific medical evidence in support of amino acid supplements for the treatment of this patient. Medical foods, per the FDA definition, are for treatment of specific dietary conditions and deficiencies. No medical reports have established any specific dietary deficiencies. The MTUS does not address "medical food." The Official Disability Guidelines have several recommendations and indications (such as liver deficiency, achlorhydria), per the citation above. This injured worker does not meet any of the indications in the Official Disability Guidelines, and the treating physician has not identified any specific indications for the ingredients in Apptrim. This medical food is not medically necessary based on the lack of any indications in this injured worker and the recommendations of the guidelines and the FDA.

**Amitrip/Dextro/Tram:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 50, 105, 111-113. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Chronic Pain, Medical food and Salicylate topicals.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Medications for chronic pain, Topical Medications Page(s): 60, 111-113. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain chapter, topical analgesics.

**Decision rationale:** No physician reports discuss the specific indications and medical evidence in support of the topical medications prescribed in this case. The ingredients appear to include amitriptyline-tramadol-dextromethorphan. The treating physician has not discussed the ingredients of this topical agent and the specific indications for this injured worker. Per the MTUS page 60, medications are to be given individually, one at a time, with assessment of specific benefit for each medication. Provision of multiple medications simultaneously is not recommended. In addition to any other reason for lack of medical necessity for these topical agents, they are not medically necessary on this basis at minimum. The MTUS states that any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. The MTUS does not address topical compounded antidepressants, opioids, or cough suppressants. The Official Disability Guidelines state that "Custom compounding and dispensing of combinations of medicines that have never been studied is not recommended, as there is no evidence to support their use and there is potential for harm." The ingredients in this compound meet the criteria for this recommendation, as they have not been adequately studied, are novel, and are experimental. Absent credible medical evidence supplied by the treating physician, this compounded agent is not medically necessary due to lack of medical evidence, its experimental nature, and the possible toxicity of an untested compound.

**Diclo/Flurb:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 50, 105, 111-113. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Chronic Pain, Medical food and Salicylate topicals.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Medications for chronic pain, Topical Medications Page(s): 60, 111-113. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain chapter, Topical analgesics.

**Decision rationale:** No physician reports discuss the specific indications and medical evidence in support of the topical medications prescribed in this case. The ingredients appear to include flurbiprofen-diclofenac. The treating physician has not discussed the ingredients of this topical agent and the specific indications for this injured worker. Per the MTUS page 60, medications are to be given individually, one at a time, with assessment of specific benefit for each medication. Provision of multiple medications simultaneously is not recommended. In addition to any other reason for lack of medical necessity for these topical agents, they are not medically necessary on this basis at minimum. The Official Disability Guidelines state that "Custom compounding and dispensing of combinations of medicines that have never been studied is not recommended, as there is no evidence to support their use and there is potential for harm." The

compounded topical agent in this case is not supported by good medical evidence and is not medically necessary based on this Official Disability Guidelines recommendation. The MTUS states that any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Per the MTUS, topical NSAIDs for short term pain relief may be indicated for pain in the extremities caused by osteoarthritis or tendonitis. There is no good evidence supporting topical NSAIDs for shoulder or axial pain, as has occurred in this case. Note that topical flurbiprofen is not FDA approved, and is therefore experimental and cannot be presumed as safe and efficacious. Non-FDA approved medications are not medically necessary. Two topical NSAIDs were dispensed simultaneously (diclofenac and flurbiprofen) which is duplicative and unnecessary, as well as possibly toxic. Topical diclofenac is readily available in FDA-approved forms, making a topical compounded form unnecessary and experimental. Topical flurbiprofen-diclofenac is not medically necessary based on the MTUS, lack of medical evidence, lack of FDA approval, and inappropriate prescribing.

**Medrox:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 50, 105, 111-113. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Chronic Pain, Medical food and Salicylate topicals.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Medications, Medications for chronic pain Page(s): 112, 60.

**Decision rationale:** No reports from the treating physician address the medical necessity for Medrox or discuss the specific components and their respective indications for this injured worker. Medrox is Capsaicin/Menthol/Methyl Salicylate; this combination of medications is not recommended in the MTUS. The MTUS does not recommend 0.0375% capsaicin, as medical evidence is lacking. When indicated, capsaicin is for injured workers who have not responded to other treatments. Capsaicin was dispensed before the injured worker had failed adequate trials of other customary treatment. The MTUS page 60 does not recommend initiating multiple medications simultaneously, as this makes determination of benefit and side effects impossible. In this case, Medrox contains multiple medications (one of which is not recommended), and the MTUS does not support this kind of prescribing. Medrox is not medically necessary based on the MTUS.