

<b>Case Number:</b>	CM14-0162074		
<b>Date Assigned:</b>	10/07/2014	<b>Date of Injury:</b>	10/16/2013
<b>Decision Date:</b>	12/24/2014	<b>UR Denial Date:</b>	09/08/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	10/02/2014

### 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. The expert reviewer is Board Certified in Emergency Medicine and is licensed to practice in California. 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/services. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

### CLINICAL CASE SUMMARY

The expert reviewer developed the following clinical case summary based on a review of the case file, including all medical records:

Patient with reported date of injury on 10/18/2013. Mechanism of injury is claimed to be due to a losing balance and injuring R ankle with fall. Patient has a diagnosis of ligamentous injury of ankle on R ankle and degenerative arthritis of L ankle. Medical reports reviewed. Last report available until 8/12/14. Patient complaints of R ankle pain which is worsened with walking. Objective exam reveals tenderness to lateral ligaments, anterior ankle, base of 5th metatarsal, peroneal tendon and bottom of heel on L ankle. No recent medication list was provided. Last list from 6/27/14 reports Lisinopril, aspirin, metformin and Tylenol. An MRI of the R ankle was reportedly showed some arthritic changes but no official reports were provided. Independent Medical Review is for Flurbiprofen/Lansoprazole 100mg/10mg #90 with 3refills, Tramadol/Acetaminophen/Ondansetron 50/250/2mg #90 with 3refills and Flurbiprofen/Lidocaine 20%/5% #180g with 3refills. Prior UR on 9/8/14 recommended modification to no refills and time to transition to non-compounded products and non-certified the topical cream.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Flurbiprofen/Lansoprazole 100mg/10mg #90 with 3 refills:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms and cardiovascular risks Page(s): 68-69.

**Decision rationale:** This is a non-FDA approved compounded product. Lansoprazole is a proton-pump inhibitor used for dyspepsia from NSAID use or gastritis/peptic ulcer disease. As per MTUS guidelines, PPIs may be used in patients with high risk for gastric bleeds or problems or signs of dyspepsia. There is no documented to support either. There is no recent documentation of improvement or length of use of plan. Lansoprazole is not medically necessary. As per MTUS Chronic pain guidelines, NSAIDs are useful of osteoarthritis related pain. Due to side effects and risks of adverse reactions, MTUS recommends as low dose and short course as possible. It is not recommended in patients at risk for cardiovascular disease due to increased incidence of heart attacks. The number of tablets and refills is inappropriate and does not meet MTUS guidelines for appropriate monitoring. MTUS guidelines recommend FDA approved products only. There is no rationale for compounding 2 completely different medications together. Compounding medications together with no justification or rationale is medically inappropriate and dangerous. This compounded Flurbiprofen/Lansoprazole product is not medically necessary.

**Tramadol/Acetaminophen/Ondansetron 50/250/2mg #90 with 3 refills:** Upheld

**Claims Administrator guideline:** The Claims Administrator did not cite any medical evidence for its decision.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 76-78. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain(Chronic), Antiemetics(for opioid nausea)

**Decision rationale:** This is a non-FDA approved compounded product. This contains Acetaminophen and Tramadol, an opioid-like medication. As per MTUS Chronic pain guidelines, documentation requires appropriate documentation of analgesia, activity of daily living, adverse events and aberrant behavior. Documentation does not meet the appropriate documentation of criteria. There is no proper documentation of improvement in pain, objective improvement in activity of daily living or monitoring or side effects. There is no documentation of proper plan for initiation of opioids or proper documentation of pain. Tramadol/Acetaminophen is not medically necessary. Ondansetron is an anti-nausea medication. As per Official Disability Guide (ODG), anti emetics should only be used for short term nausea associated with opioids. Long term use is not recommended. Documentation provided by treating physicians does not document why this was prescribed. There is no documentation of nausea. The number of tablets prescribed does not meet criteria for short term use. Ondansetron is not medically necessary. MTUS guidelines recommend FDA approved products only. There is no rationale for compounding completely different medications together. Compounding medications together with no justification or rationale is medically inappropriate and dangerous. This compounded Tramadol/Acetaminophen/Ondansetron product is not medically necessary.

**Flurbiprofen/Lidocaine 20%/5% cream 180gm with 3 refills:** Upheld

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

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

**Decision rationale:** As per MTUS guidelines "Any compound product that contains a drug or drug class that is not recommended is not recommended." 1) Flurbiprofen: Shown to be superior to placebo. It should not be used long term. It may be useful. Patient appears to be on this medication chronically. While there is subjective report of improvement, provider has not appropriately documented close monitoring for potential side effects of chronic topical NSAID use or appropriate monitoring or pain such as a pain scale. Flurbiprofen is not FDA approved for topical application. There is no justification by the provider as to why the patient requires a non-FDA approved compounded NSAID when there are multiple other approved products including over the counter medications on the market. Flurbiprofen is not medically necessary. 2) Lidocaine: Topical lidocaine is recommended for post-herpetic neuralgia only although it may be considered as off-label use as a second line agent for peripheral neuropathic pain. It may be considered for peripheral neuropathic pain only after a trial of 1st line agent. There is no documentation of an attempt of trial with a 1st line agent and there is no documentation on where the cream is to be used. It is therefore not recommended. Both components of this compounded medication are not medically necessary therefore the entire compounded product is not medically necessary.