

<b>Case Number:</b>	CM14-0185630		
<b>Date Assigned:</b>	11/13/2014	<b>Date of Injury:</b>	04/08/2013
<b>Decision Date:</b>	12/19/2014	<b>UR Denial Date:</b>	10/29/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	11/07/2014

### 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 Family 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:

This is a 46-year old female patient who sustained an injury on 4/08/2013. She sustained the injury due to slipped on oil on the floor. The diagnoses include right knee pain flare up, history of sprain/strain injury, status post Brostrom procedure with arthroscopy of the right ankle with ongoing pain and instability. Per the doctor's note dated 10/09/14, patient had complaints of right knee pain as well as right ankle pain. Physical examination revealed right knee-very painful patellar compression, peripatellar swelling, exquisite tenderness over the infrapatellar tendon with swelling and tenderness over the medial condyle; right ankle-tenderness over the lateral malleolus, painful inversion and crepitus in the ankle joint upon circumduction. The medication list includes Zorvolex and Norco. She has undergone right ankle Brostrom procedure on 10/23/13. She has had right knee MRI which revealed myxoid degeneration of the posterior horn and medial meniscus with infra patellar tendinitis; right ankle MRI dated 7/31/14 which revealed anterior talofibular ligament tear and postoperative changes. She has had injections to the right ankle and right knee. She has had physical therapy visits for this injury.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Zorvolex 35mg #90:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs (non-steroidal anti-inflammatory drugs).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Anti-inflammatory medications Page(s): 22. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG); Chapter:Pain (updated 11/21/14) Zorvolex (diclofenac)

**Decision rationale:** According to CA MTUS chronic pain medical treatment guidelines. Anti-inflammatories are the traditional first line of treatment, to reduce pain so activity and functional restoration can resume, but long-term use may not be warranted. Patient had chronic right knee and right ankle pain. Therefore use of NSAID is medically appropriate and necessary. However per the cited guidelines Zorvolex is "Not recommended except as a second-line option, because diclofenac products are not recommended as first-line choices due to potential increased adverse effects. See Diclofenac. While diclofenac has potent anti-inflammatory and analgesic properties, research has linked this drug to sometimes serious adverse outcomes, including cardiovascular thrombotic events, myocardial infarction, stroke, gastrointestinal ulcers, gastrointestinal bleeding, and renal events (such as acute renal failure). (FDA, 2014) This new formulation of diclofenac does not present any apparent advantages versus other medications of the class. Zorvolex is pure acid versus salt in other formulations, resulting in faster dissolution using SoluMatrix Fine Particle Technology. However, it has the same side effect profile while more expensive than other NSAIDs that are available as generics. It is an expensive, brand name only, second-line medication with little to no place in the treatment of workers compensation injuries. (FDA, 2013). Therefore per the cited guidelines there is no additional advantage of Zorvolex compared to other generic NSAIDs. Response to other NSAID like naproxen is not specified in the records provided. The Zorvolex 35mg #90 is not medically necessary.

**Norco 5/325mg #60:** Upheld

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

**MAXIMUS guideline:** The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Chapter: Pain (updated 11/21/14) Opioids, criteria for use

**Decision rationale:** According to the cited guidelines, "A therapeutic trial of opioids should not be employed until the patient has failed a trial of non-opioid analgesics. Before initiating therapy, the patient should set goals, and the continued use of opioids should be contingent on meeting these goals. The records provided do not specify that that patient has set goals regarding the use of opioid analgesic. The treatment failure with non-opioid analgesics is not specified in the records provided. Other criteria for ongoing management of opioids are: "The lowest possible dose should be prescribed to improve pain and function. Continuing review of overall situation with regard to nonopioid means of pain control. Ongoing review and documentation of pain relief, functional status, appropriate medication use, and side effects. Consider the use of a urine drug screen to assess for the use or the presence of illegal drugs. The records provided do not provide a documentation of response in regards to pain control and functional improvement to opioid analgesic for this patient. The continued review of overall situation with regard to non-opioid means of pain control is not documented in the records provided. As recommended by the cited guidelines a documentation of pain relief, functional status, appropriate medication use, and

side effects should be maintained for ongoing management of opioid analgesic, these are not specified in the records provided. A recent urine drug screen report is also not specified in the records provided. This patient did not meet criteria for ongoing continued use of opioids analgesic. Norco 5/325mg #60 is not medically necessary.