

<b>Case Number:</b>	CM14-0052053		
<b>Date Assigned:</b>	07/07/2014	<b>Date of Injury:</b>	06/11/1985
<b>Decision Date:</b>	09/03/2014	<b>UR Denial Date:</b>	03/24/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	04/21/2014

### 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 61 year old patient who reported an industrial injury on 6/11/1985, over 29 years ago, to the lower back attributed to the performance of his customary job tasks. The patient has been treated conservatively for chronic mechanical back pain. The patient has been prescribed Opana ER; Zolpidem; Gabapentin; Bisacodyl; Colace; Voltaren topical gel 1% prescribed since 10/14/13. The objective findings on examination included tenderness in the posterior superior iliac spine; SLR was mildly positive bilaterally; diminished sensation in the L4 and L5 on the left lower extremity; reflexes to plus bilaterally; muscle strength including EHL was 5/5. The diagnosis was status post lumbar spine fusion and chronic low back pain. The patient was prescribed topical Voltaren gel 1%; Diclofenac 50 mg #60; Colace 100 mg #60; and a second Voltaren gel 1% unspecified amount.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Voltaren Gel 1 percent #100:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Steps to take before a Therapeutic Trial of Opioids, Topical Analgesics Page(s): 77, 112.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids, topical analgesics, NSAIDs pages 22, 67-68 71 Page(s): 22, 67-68 71, 74-97; 111-113. Decision

based on Non-MTUS Citation American College of Occupational and Environmental Medicine (ACOEM), 2ndEdition, (2004) Chapter 6 pages 114-16.

**Decision rationale:** The topical NSAID, Voltaren gel, is not medically necessary in addition to prescribed oral NSAIDs. The patient has been prescribed topical Voltaren gel in addition to oral Diclofenac. The patient has received topical NSAID gels since 10/2013 exceeding the time period recommended by evidence based guidelines. There is no demonstrated medical necessity for both an oral NSAID and a topical NSAID. There is no provided subjective or objective evidence that the patient has failed or not responded to other conventional and recommended forms of treatment for relief of the effects of the industrial injury. The patient has used the prescribed topical gel for a prolonged period of time exceeding the recommendations of evidence based guidelines. There is no documented functional improvement by the provider attributed to the topical NSAID. The use of topical NSAIDS is documented to have efficacy for only 2-4 weeks subsequent to injury and thereafter is not demonstrated to be as effective as oral NSAIDs. The patient is not demonstrated to have any GI issue at all with NSAIDS. The patient was prescribed an oral and topical NSAID concurrently. The use of the topical creams/gels does not provide the appropriate therapeutic serum levels of medications due to the inaccurate dosing performed by rubbing variable amounts of creams on areas that are not precise. The volume applied and the times per day that the creams are applied are variable and do not provide consistent serum levels consistent with effective treatment. There is no medical necessity for the addition of creams to the oral medications in the same drug classes. There is no demonstrated evidence that the topicals are more effective than generic oral medications. The prolonged use of topical Voltaren gel 1% 100 g not supported by the applicable evidence based guidelines. The continued use of topical NSAIDs for the current clinical conditions is not otherwise warranted or demonstrated to be medically necessary.

**Diclofenac Sodium 50 mg #60:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Nonselective NSAIDs Page(s): 112. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs Page(s): 22, 67-88 71. Decision based on Non-MTUS Citation American College of Occupational and Environmental Medicine (ACOEM), 2ndEdition, (2004) Chapter 6 pages 114-16Official Disability Guidelines (ODG) Pain Chapter NSAIDs.

**Decision rationale:** The use of Diclofenac(Voltaren) 100 mg is consistent with the currently accepted guidelines and the general practice of medicine for musculoskeletal strains and injuries; however there is no evidence of functional improvement or benefit from this NSAID. There is no evidence that OTC NSAIDs would not be appropriate for similar use for this patient. The prescription of Diclofenac is not supported with appropriate objective evidence as opposed to the NSAIDs available OTC. The prescription of Diclofenac XL is directed to pain and inflammation associated with reported chronic pain. There is no provided evidence that the available OTC NSAIDs were ineffective for the treatment of inflammation. There is no demonstrated medical necessity for the prescribed Diclofenac 50 mg.

**Voltarem Gel 1 percent: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Nonselective NSAIDs, Topical Analgesics Page(s): 71, 112.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs Page(s): 22, 67-68, 71. Decision based on Non-MTUS Citation American College of Occupational and Environmental Medicine (ACOEM), 2nd Edition, (2004) Chapter 6 pages 114-16 Official Disability Guidelines (ODG) Pain chapter NSAIDs.

**Decision rationale:** The topical NSAID, Voltaren gel, is not medically necessary in addition to prescribed oral NSAIDs. The patient has been prescribed topical Voltaren gel in addition to oral Diclofenac. The patient has received topical NSAID gels since 10/2013 exceeding the time period recommended by evidence based guidelines. There is no demonstrated medical necessity for both an oral NSAID and a topical NSAID. There is no provided subjective or objective evidence that the patient has failed or not responded to other conventional and recommended forms of treatment for relief of the effects of the industrial injury. There is no documented functional improvement by the provider attributed to the topical NSAID. The use of topical NSAIDs is documented to have efficacy for only 2-4 weeks subsequent to injury and thereafter is not demonstrated to be as effective as oral NSAIDs. There is less ability to control serum levels and dosing with the topicals. The patient is not demonstrated to have any GI issue at all with NSAIDs. The patient was prescribed an oral and topical NSAID concurrently. The use of the topical creams/gels does not provide the appropriate therapeutic serum levels of medications due to the inaccurate dosing performed by rubbing variable amounts of creams on areas that are not precise. The volume applied and the times per day that the creams are applied are variable and do not provide consistent serum levels consistent with effective treatment. There is no medical necessity for the addition of creams to the oral medications in the same drug classes. There is no demonstrated evidence that the topicals are more effective than generic oral medications. The prolonged use of topical Voltaren gel 1% unspecified quantity not supported by the applicable evidence based guidelines. The continued use of topical NSAIDs for the current clinical conditions is not otherwise warranted or demonstrated to be medically necessary.

**Colace Sodium 100 mg #60: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Steps to take before a Therapeutic Trials of Opioids Page(s): 77.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 80-82. Decision based on Non-MTUS Citation American College of Occupational and Environmental Medicine (ACOEM), 2nd Edition, (2004) Chapter 6 pages 114-16 Official Disability Guidelines (ODG) Pain chapter opioids.

**Decision rationale:** The prescription of Colace 100 mg bid is medically necessary only if the patient has constipation as a side effect of the prescribed opioid medications. The patient is not demonstrated to have constipation as a side effect of opioids prescribed for mechanical back pain

s/p fusion. The patient is prescribed a stool softener. There is no discussion that the patient was counseled as to diet or activity in regards to the fact she has constipation. The use of Colace, Docusate Sodium, was provided prior to any evaluation of the symptoms or conservative treatment with diet and exercise. The use of Colace is demonstrated to be medically necessary with the "as needed" (PRN) use of Hydrocodone and is not medically necessary for the treatment of the reported chronic back pain. The provider identified Opana ER that may lead to constipation for which Colace was prescribed; however it was prescribed as a first line treatment instead of the recommended conservative treatment with fiber and diet prior to prescriptions. There was no documented functional improvement to the prescribed Colace.