

<b>Case Number:</b>	CM15-0219699		
<b>Date Assigned:</b>	11/12/2015	<b>Date of Injury:</b>	06/15/1997
<b>Decision Date:</b>	12/31/2015	<b>UR Denial Date:</b>	11/05/2015
<b>Priority:</b>	Standard	<b>Application Received:</b>	11/09/2015

### 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: California

Certification(s)/Specialty: Physical Medicine & Rehabilitation

### 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 61 year old male, who sustained an industrial injury on 6-15-97. The injured worker is diagnosed with right shoulder impingement syndrome and post right distal clavicle excision. He is not working and is on Social Security Disability. A note dated 9-18-15 reveals the injured worker presented with complaints of intermittent right shoulder pain. The note also states he does not engage in household chores due to pain. A physical examination dated 10-21-15 revealed tenderness to the right rotator cuff and biceps tendon. There is some tenderness along the posterior shoulder joint with weakness to resisted function. Treatment to date has included TENS unit, heat and cold wrap, activity modification and a right acromioclavicular joint resection. The injured worker's medication regimen includes; Nalfon, AcipHex, Ultracet (all 10-2015), Voltaren, Diclofenac, Celebrex, Protonix and Tramadol ER were discontinued due to insurance denial. Diagnostic studies include right shoulder MRI revealed degenerative changes along the shoulder and bicipital tendinitis, per physician note dated 8-19-15 and right shoulder x-ray. A request for authorization dated 10-21-15 for Nalfon 400 mg #60, AcipHex 20 mg #30 and Ultracet 37.5 mg #60 is denied, per Utilization Review letter dated 11-5-15.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**Nalfon 400mg, QTY: 60.00:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): NSAIDs (non-steroidal anti-inflammatory drugs).

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Anti-inflammatory medications, Medications for chronic pain.

**Decision rationale:** Based on the 9/18/15 progress report provided by the treating physician, this patient presents with intermittent right shoulder pain. The treater has asked for nalfon 400MG, QTY 60.00 on 10/21/15. The patient's diagnosis per request for authorization dated 10/21/15 is impingement syndrome of right shoulder. The patient would prefer to avoid surgery and injections at this time per 9/18/15 report. The patient prefers taking Voltaren once a month for inflammation over Naproxen, Nalfon, or Celebrex per 9/18/15 report. The patient is s/p AC joint resection on right shoulder with subsequent 6 months of disability in 2009 per review of reports. The patient is currently doing little chores around the house and avoiding overhead activities, and not lifting over 10 pounds with the right arm per 10/21/15 report. The patient is currently not working and is on social security disability per 10/21/15 report. MTUS, Anti-inflammatory medications section pg. 22: 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. A comprehensive review of clinical trials on the efficacy and safety of drugs for the treatment of low back pain concludes that available evidence supports the effectiveness of non-selective non-steroidal anti-inflammatory drugs (NSAIDs) in chronic LBP and of antidepressants in chronic LBP. MTUS, Medications for Chronic Pain, pg. 60: Recommended as indicated below. Relief of pain with the use of medications is generally temporary, and measures of the lasting benefit from this modality should include evaluating the effect of pain relief in relationship to improvements in function and increased activity. Review of the reports does not show any evidence of prior use of Nalfon. Utilization review letter dated 11/5/15 denies the request due to lack of documentation of efficacy. The 9/18/15 report states that He prefers [Voltaren] over the Naproxen, Nalfon, and/or Celebrex. However, the patient is taking another NSAID (Voltaren) since 6/11/15 report, and is taking it as of 9/18/15 report. Regarding medications for chronic pain, MTUS pg. 60 states treater must determine the aim of use, potential benefits, adverse effects, and patient's preference. In this case, the treater does not explain why Nalfon is being prescribed when the patient has explicitly stated his preference for Voltaren over Nalfon, and appears to be currently taking Voltaren. Therefore, the request is not medically necessary.

**AcipHex 20mg, QTY: 30.00:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): NSAIDs, GI symptoms & cardiovascular risk.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): NSAIDs, GI symptoms & cardiovascular risk.

**Decision rationale:** Based on the 9/18/15 progress report provided by the treating physician, this patient presents with intermittent right shoulder pain. The treater has asked for aciphex 20MG, QTY 30.00 on 10/21/15. The patient's diagnosis per request for authorization dated 10/21/15 is impingement syndrome of right shoulder. The patient would prefer to avoid surgery and injections at this time per 9/18/15 report. The patient prefers taking Voltaren once a month for inflammation over Naproxen, Nalfon, or Celebrex per 9/18/15 report. The patient is s/p AC joint resection on right shoulder with subsequent 6 months of disability in 2009 per review of reports. The patient is currently doing little chores around the house and avoiding overhead activities, and not lifting over 10 pounds with the right arm per 10/21/15 report. The patient is currently not working and is on social security disability per 10/21/15 report. MTUS, NSAIDs, GI symptoms & cardiovascular risk Section page 69 states: Clinicians should weight the indications for NSAIDs against both GI and cardiovascular risk factors. Determine if the patient is at risk for gastrointestinal events: (1) age > 65 years; (2) history of peptic ulcer, GI bleeding or perforation; (3) concurrent use of ASA, corticosteroids, and/or an anticoagulant; or (4) high dose/multiple NSAID (e.g., NSAID + low-dose ASA). Treatment of dyspepsia secondary to NSAID therapy: Stop the NSAID, switch to a different NSAID, or consider H2-receptor antagonists or a PPI. Per progress report dated 10/21/15, the treater is requesting authorization for Aciphex. Review of the reports does not show any evidence of prior use of Aciphex. Utilization review letter dated 11/5/15 denies the request as the concurrently requested NSAID (Nalfon) is also not indicated. However, the patient was prescribed Protonix on 8/19/15 report. However, the treater has not documented the efficacy of Protonix per review of reports. Furthermore, even though the records indicate that the patient has been utilizing NSAIDs (Voltaren), the treater has not included GI assessment or complaints of GI upset, secondary to NSAID intake to substantiate such a medication. Without an appropriate GI assessment or evidence of dyspepsia secondary to NSAID utilization, this medication cannot be substantiated. Therefore, the request is not medically necessary.

**Ultracet 37.5mg, QTY: 60.00:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Opioids for chronic pain.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Medications for chronic pain, Opioids, criteria for use.

**Decision rationale:** Based on the 9/18/15 progress report provided by the treating physician, this patient presents with intermittent right shoulder pain. The treater has asked for ultracet 37.5MG, QTY 60.00 on 10/21/15. The patient's diagnosis per request for authorization dated 10/21/15 is impingement syndrome of right shoulder. The patient would prefer to avoid surgery and injections at this time per 9/18/15 report. The patient prefers taking Voltaren once a month for inflammation over Naproxen, Nalfon, or Celebrex per 9/18/15 report. The patient is s/p AC joint resection on right shoulder with subsequent 6 months of disability in 2009 per review of reports. The patient is currently doing little chores around the house and avoiding overhead activities, and not lifting over 10 pounds with the right arm per 10/21/15 report. The patient is currently not working and is on social security disability per 10/21/15 report. MTUS, Criteria for Use of

Opioids Section, pages 88 and 89 states that "pain should be assessed at each visit, and functioning should be measured at 6-month intervals using a numerical scale or validated instrument." MTUS, Criteria For Use Of Opioids Section, page 78 also requires documentation of the 4As (analgesia, ADLs, adverse side effects, and adverse behavior), as well as "pain assessment" or outcome measures that include current pain, average pain, least pain, intensity of pain after taking the opioid, time it takes for medication to work and duration of pain relief. MTUS, Criteria for Use of Opioids Section, page 77, states that "function should include social, physical, psychological, daily and work activities, and should be performed using a validated instrument or numerical rating scale." MTUS, Medications for Chronic Pain Section, page 60 states that "relief of pain with the use of medications is generally temporary, and measures of the lasting benefit from this modality should include evaluating the effect of pain relief in relationship to improvements in function and increased activity." The treater does not discuss this request in the reports provided. The patient was prescribed Ultracet on 8/19/15 report. It is not clear if the patient is still on opiate therapy as there is no discussion in the subsequent 10/21/15 report. Utilization review letter dated 11/5/15 modifies the request for Ultracet from 50 to 30 tablets due to lack of documentation of functional improvement. MTUS requires appropriate discussion of all the 4A's; however, in addressing the 4A's, the treater does not discuss how this medication significantly improves patient's activities of daily living. No validated instrument is used to show analgesia. There is no UDS, no CURES and no opioid contract provided. Given the lack of documentation as required by MTUS, the request does not meet the specifications given by the guidelines. Therefore, the request is not medically necessary.