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| <b>Case Number:</b>   | CM13-0053606 |                              |            |
| <b>Date Assigned:</b> | 01/22/2014   | <b>Date of Injury:</b>       | 09/01/2007 |
| <b>Decision Date:</b> | 06/06/2014   | <b>UR Denial Date:</b>       | 10/22/2013 |
| <b>Priority:</b>      | Standard     | <b>Application Received:</b> | 11/18/2013 |

### 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 Anesthesiology, has a subspecialty in Pain Management 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:

The patient is an employee of the [REDACTED] and has submitted a claim for sensorineural hearing loss associated with an industrial injury date of September 1, 2007. Utilization review from October 22, 2013 denied the retrospective requests for compound medications which included compounded amitriptyline, dextromethorphan, tramadol, diclofenac, and flurbiprofen due to little to no evidence of clinical efficacy as well as a retrorequest for diclofenac due to no specific number dispensed. Treatments to date has included chiropractic treatment, hearing aids, and medications. The medical records from 2013 were reviewed showing the patient complaining of problems with loss of hearing and tinnitus. The patient has been using hearing aids but does not help with the tinnitus. On examination, there was noted impacted cerumen in the right ear with decreased hearing in the high frequencies. There was also decreased hearing in the high frequencies for the left ear. The hearing loss is noted to be a result from exposure to excessive noise intermittently during work and inadequate hearing protection. Medications prescribed since the industrial accident was not clearly listed.

### IMR ISSUES, DECISIONS AND RATIONALES

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

**COMPOUND CREAM: AMTRIPTYLINE - DEXTROMETHORPHAN - TRAMADOL - PENCREAM, DISPENSED ON SEPTEMBER 23, 2013: Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines 2009 Page(s): 111-113.

**Decision rationale:** As stated on pages 111-113 of the California MTUS Chronic Pain Medical Treatment Guidelines, any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Topical analgesics are largely experimental in use with few randomized controlled trials to determine safety or efficacy. The California MTUS does not support antidepressants, Dextromethorphan, and opioids for topical application. In this case, the patient has been prescribed this medication since 2012. However, there was no documentation concerning the outcome of the medication. In addition, the guidelines do not support compounded medications that have unsupported components. There is no discussion the need for variance from the guidelines. Therefore, the request for Compound Cream: Amitriptyline - Dextromethorphan - Tramadol - Pen cream, dispensed on September 23, 2013 is not medically necessary.

**COMPOUND CREAM: AMTRYPTYLINE - DEXTROMETHORPHAN - TRAMADOL - ULTRADERM, DISPENSED ON FEBRUARY 1, 2012: Upheld**

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

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

**Decision rationale:** As stated on pages 111-113 of the California MTUS Chronic Pain Medical Treatment Guidelines, any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Topical analgesics are largely experimental in use with few randomized controlled trials to determine safety or efficacy. The California MTUS does not support antidepressants, Dextromethorphan, and opioids for topical application. In this case, the patient has been prescribed this medication since 2012. However, there was no documentation concerning the outcome of the medication. In addition, the guidelines do not support compounded medications that have unsupported components. There is no discussion the need for variance from the guidelines. Therefore, the request for Compound Cream: Amitriptyline - Dextromethorphan - Tramadol - Ultraderm, dispensed on February 1, 2012 is not medically necessary.

**COMPOUND: DICLOFENAC - FLURBIPROFEN - ULTRADERM, DISPENSED FEBRUARY 1, 2012: Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines 2009 Page(s): 111-113.

**Decision rationale:** As stated on pages 111-113 of the California MTUS Chronic Pain Medical Treatment Guidelines, any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Topical analgesics are largely experimental in use with few randomized controlled trials to determine safety or efficacy. The California MTUS only supports specific NSAID topical which does not include diclofenac and Flurbiprofen. In this case, the patient has been prescribed this medication since 2012. However, there was no documentation concerning the outcome of the medication. In addition, the guidelines do not support compounded medications that have unsupported components. There is no discussion the need for variance from the guidelines. Therefore, the request for Compound: Diclofenac - Flurbiprofen - Ultraderm, dispensed on February 1, 2012 is not medically necessary.

**COMPOUND: AMTRIPTYLINE - DEXTROMETHORPHAN - TRAMADOL - ULTRAD, DISPENSED FEBRUARY 1, 2012: Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines 2009 Page(s): 111-113.

**Decision rationale:** As stated on pages 111-113 of the California MTUS Chronic Pain Medical Treatment Guidelines, any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Topical analgesics are largely experimental in use with few randomized controlled trials to determine safety or efficacy. The California MTUS does not support antidepressants, Dextromethorphan, and opioids for topical application. In this case, the patient has been prescribed this medication since 2012. However, there was no documentation concerning the outcome of the medication. In addition, the guidelines do not support compounded medications that have unsupported components. There is no discussion the need for variance from the guidelines. Therefore, the request for Compound: Amitryptiline - Dextromethorphan - Tramadol - Ultraderm, dispensed on February 1, 2012 is not medically necessary.

**COMPOUND: DICLOFENAC - FLURBIPROFEN - ULTRADERM, DISPENSED MARCH 28, 2012: Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines 2009 Page(s): 111-113.

**Decision rationale:** As stated on pages 111-113 of the California MTUS Chronic Pain Medical Treatment Guidelines, any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. Topical analgesics are largely experimental in use with few randomized controlled trials to determine safety or efficacy. The California MTUS only supports specific NSAID topical which does not include diclofenac and Flurbiprofen. In

this case, the patient has been prescribed this medication since 2012. However, there was no documentation concerning the outcome of the medication. In addition, the guidelines do not support compounded medications that have unsupported components. There is no discussion the need for variance from the guidelines. Therefore, the request for Compound: Diclofenac - Flurbiprofen - Ultraderm, dispensed on March 28, 2012 is not medically necessary.

**DICLOFENAC SODIUM ER 100 MG, DISPENSED ON JUNE 6, 2012: Upheld**

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

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 67-68.

**Decision rationale:** As stated on pages 67-68 of the California MTUS Chronic Pain Medical Treatment Guidelines, NSAIDs are useful in treating breakthrough and mixed pain conditions such as neuropathic pain, osteoarthritis, and back pain; there is no evidence for long-term effectiveness for pain and function. In this case, the patient has been taking NSAIDs since 2012. However, the outcome from the use of this medication was not clearly documented such as improvements in activities of daily living. In addition, the request does not specify frequency and duration. Therefore, the request for diclofenac sodium is not medically necessary.