

<b>Case Number:</b>	CM14-0070145		
<b>Date Assigned:</b>	07/14/2014	<b>Date of Injury:</b>	05/24/2010
<b>Decision Date:</b>	10/01/2014	<b>UR Denial Date:</b>	04/24/2014
<b>Priority:</b>	Standard	<b>Application Received:</b>	05/15/2014

### 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 Anesthesiology, has a subspecialty in Pain Management and is licensed to practice in Tennessee. 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 a 67-year-old female who has submitted a claim for lumbosacral intervertebral disc degeneration associated with an industrial injury date of May 24, 2010. Medical records from 2013 to 2014 were reviewed. The patient complained of cervical spine pain rated 3/10, right shoulder pain rated 2/10, and lumbar spine pain rated 2/10. Physical examination showed decreased range of motion of the cervical and lumbar spine, and positive impingement sign on the right shoulder. He has previously used compounded medications such as flurbiprofen 20%/tramadol 20% in a Mediderm base as well as gabapentin 10%/ dextromethorphan 10%/amitriptyline 10% in a Mediderm base. However, the response to these medications was not documented. MRI of the cervical spine done on October 12, 2013 revealed nonspecific straightening of the normal cervical lordosis, and posterior annular tear in the intervertebral disc with accompanying 1-2mm posterior disc bulge without evidence of canal stenosis or neural foraminal narrowing at C6-C7. Lumbar spine MRI on October 12, 2013 demonstrated a 1 to 2mm posterior disc bulge without evidence of canal stenosis or neural foraminal narrowing at L2-L3; mild right foraminal narrowing and bilateral exiting nerve root compromise secondary to 1-2mm posterior disc bulge at L4-L5; and moderate to severe bilateral neural foraminal narrowing, mild canal stenosis, and bilateral exiting nerve root compromise secondary to grade 1 anterolisthesis, 2mm posterior disc bulge and facet hypertrophy. MRI of the right shoulder on December 7, 2013 showed lobular fluid collection adjacent to the posterior superior lip of the glenoid labrum, most likely representing synovial versus ganglion cyst, and acromioclavicular osteoarthritis. The diagnoses were cervical spine myofasciitis, cervical spine degenerative disc disease, right shoulder impingement syndrome, and lumbar spine degenerative disc disease. Treatment to date has included oral and topical analgesics and chiropractic therapy. Utilization review from April 24, 2014 denied the requests for flurbiprofen

20%/tramadol 20%/cyclobenzaprine 4% and gabapentin 10%/dextromethorphan 10%/amitriptyline 10%. The patient has not failed first line therapies, and documentation does not indicate if pain is neuropathic in nature.

### **IMR ISSUES, DECISIONS AND RATIONALES**

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

**Flurbiprofen 20%, Tramadol 20%, Cyclobenzaprine 4%, 210gm: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 111, 112, 113. Decision based on Non-MTUS Citation Official Disability Guidelines, Compound Drugs

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

**Decision rationale:** As stated on pages 111-113 of the CA MTUS Chronic Pain Medical Treatment Guidelines, topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy and safety. They are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. CA MTUS does not support the use of opioid medications in topical formulation. With regards to flurbiprofen, the only recommended topical NSAID formulation is diclofenac. Also, there is no evidence to support the use of topical cyclobenzaprine, and its addition to other agents is not recommended. The guideline states that any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. In this case, previous use of flurbiprofen 20%/tramadol 20% was noted as far back as November 2013. However, the medical records do not reflect continued analgesia and significant functional improvement derived from its use. Moreover, there was no documentation of trial and failure of antidepressants and anticonvulsants. There was also no evidence of failure of oral pain medications that warrant use of topical preparations. Furthermore, all the components of the requested compounded medication are not supported by the guideline for topical use. Any compounded product that contains at least one drug that is not recommended is not recommended. The medical necessity has not been established. There was no compelling rationale concerning the need for variance from the guideline. Therefore, the request for Flurbiprofen 20%, Tramadol 20%, Cyclobenzaprine 4%, 210gm is not medically necessary.

**Gabapentin 10%, Dextromethorphan 10%, Amitriptyline 10, 210gm: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics Page(s): 13, 15, 111, 112, 113. Decision based on Non-MTUS Citation Official Disability Guidelines, Compound Drugs

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

**Decision rationale:** As stated on pages 111-113 of the CA MTUS Chronic Pain Medical Treatment Guidelines, topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy and safety. They are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. The use of gabapentin in a topical formulation is not supported, while dextromethorphan is not addressed in the guidelines. Regarding the amitriptyline component, guidelines recommend its use with ketamine for treatment of chemotherapy-induced peripheral neuropathy. In addition, guideline states that any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. In this case, previous use of this compounded medication was noted as far back as November 2013. However, there was no evidence of continued analgesia and significant functional improvement with its use. Moreover, medical records did not show failure or intolerance to oral formulations and first-line agents. Gabapentin is not recommended for topical use. There was also no evidence of chemotherapy-induced peripheral neuropathy to warrant the use of topical amitriptyline. Any compounded product that contains at least one drug that is not recommended is not recommended. The compounded product contains gabapentin, dextromethorphan, and amitriptyline, which are not recommended for topical use. The medical necessity has not been established. Therefore, the request for Gabapentin 10%, Dextromethorphan 10%, Amitriptyline 10%, 210gm is not medically necessary.