

Case Number:	CM14-0001962		
Date Assigned:	01/24/2014	Date of Injury:	01/09/2013
Decision Date:	12/31/2014	UR Denial Date:	12/30/2013
Priority:	Standard	Application Received:	01/06/2014

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 Neurology, has a subspecialty in Pain Medicine, and is licensed to practice in Florida. 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:

10/15/13 note reports pain in the lumbar spine since MVA. 8/30/13 EMG is reported to show L5 radiculopathy. MRI of cervical spine 9/9/13 reported multilevel spondylosis. MRI of lumbar spine reported 5 mm disc bulge at L3-4, 4 mm bulge at L4-5, and bulge at L5-S1. Insured had PT. There is intermittent neck and back pain. Examination notes normal strength and sensation.

IMR ISSUES, DECISIONS AND RATIONALES

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

Terocin 240ml (Capsaicin 0.25%, Methyl Salicylate 25%, Menthol 10%, Lidocaine 2.5%):
Upheld

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

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

Decision rationale: The medical records reports ongoing pain in the lumbar and cervical region but do not indicate specific failure of first line agents. There is no indication of a neuropathic pain condition for which a topical agent is FDA approved for use. ODG supports topical compounded creams are largely experimental in use with few randomized controlled trials to determine efficacy or safety. Primarily recommended for neuropathic pain when trials of

antidepressants and anticonvulsants have failed. (Namaka, 2004) These agents are applied locally to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. (Colombo, 2006) Many agents are compounded as monotherapy or in combination for pain control (including NSAIDs, opioids, capsaicin, local anesthetics, antidepressants, glutamate receptor antagonists, adrenergic receptor agonist, adenosine, cannabinoids, cholinergic receptor agonists, γ agonists, prostanoids, bradykinin, adenosine triphosphate, biogenic amines, and nerve growth factor). (Argoff, 2006) There is little to no research to support the use of many of these agents. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. As the medical records do not support the presence of a neuropathic pain condition, the records do not support the use of the compounded cream for treatment of the insured. Therefore the request is not medically necessary.

Genicin #90: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation ODG, Pain Chapter, Medical Foods.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) pain, medical foods.

Decision rationale: The medical records report neck and back pain and do not document the presence of a nutritional deficit. ODG supports the medical food class is a food which is formulated to be consumed or administered internally under the supervision of a physician which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements based on recognized scientific principles are established by medical evaluation. As the medical records do not support the presence of a nutritional deficit, the medical records do not support the medical necessity of Genicin. Therefore the request is not medically necessary.

Somnicin #30: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation ODG, Pain Chapter, Medical Foods.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) -pain medical foods.

Decision rationale: The medical records report neck and back pain and do not document the presence of a nutritional deficit. ODG supports the medical food class is a food which is formulated to be consumed or administered internally under the supervision of a physician which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements based on recognized scientific principles are established by medical evaluation. As the medical records do not support the presence of a nutritional deficit, the

medical records do not support the medical necessity of Somnicin. Therefore the request is not medically necessary.

Tramadol 150mg #60 For Head, Neck, and Back: 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) -pain, opioids.

Decision rationale: ODG guidelines support opioids with: Ongoing review and documentation of pain relief, functional status, appropriate medication use, and side effects. Pain assessment should include: current pain; the least reported pain over the period since last assessment; average pain; intensity of pain after taking the opioid; how long it takes for pain relief; and how long pain relief lasts. Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function, or improved quality of life. Information from family members or other caregivers should be considered in determining the patient's response to treatment. The 4 A's for Ongoing Monitoring: Four domains have been proposed as most relevant for ongoing monitoring of chronic pain patients on opioids: pain relief, side effects, physical and psychosocial functioning, and the occurrence of any potentially aberrant (or nonadherent) drug-related behaviors. The medical records report chronic pain but does not document ongoing opioid risk mitigation tool use in support of chronic therapy congruent with ODG guidelines. As such chronic opioids are not supported. The request is not medically necessary.

Flurbi (NAP) Cream-La 180 Grams -Flurbiprofen 20, Lidocaine 5%/Amitriptyline 4%: Upheld

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

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) -topicals, page 111.

Decision rationale: The medical records reports ongoing pain in the lumbar and cervical region but do not indicate specific failure of first line agents. There is no indication of a neuropathic pain condition for which a topical agent is FDA approved for use. ODG supports topical compounded creams are largely experimental in use with few randomized controlled trials to determine efficacy or safety. Primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. (Namaka, 2004) These agents are applied locally to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. (Colombo, 2006) Many agents are compounded as monotherapy or in combination for pain control (including NSAIDs, opioids, capsaicin, local anesthetics, antidepressants, glutamate receptor antagonists, a-adrenergic receptor agonist,

adenosine, cannabinoids, cholinergic receptor agonists, γ -agonists, prostanoids, bradykinin, adenosine triphosphate, biogenic amines, and nerve growth factor). (Argoff, 2006) There is little to no research to support the use of many of these agents. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. As the medical records do not support the presence of a neuropathic pain condition, the records do not support the use of the compounded cream for treatment of the insured. Therefore the request is not medically necessary.

Gabacyclotram Cream 180 Grams (Gabapentin 10%/Cyclobenzaprine 6%/Tramadol 10%): Upheld

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

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) -topicals page 111.

Decision rationale: The medical records reports ongoing pain in the lumbar and cervical region but do not indicate specific failure of first line agents. There is no indication of a neuropathic pain condition for which a topical agent is FDA approved for use. ODG supports topical compounded creams are largely experimental in use with few randomized controlled trials to determine efficacy or safety. Primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. (Namaka, 2004) These agents are applied locally to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. (Colombo, 2006) Many agents are compounded as monotherapy or in combination for pain control (including NSAIDs, opioids, capsaicin, local anesthetics, antidepressants, glutamate receptor antagonists, α -adrenergic receptor agonist, adenosine, cannabinoids, cholinergic receptor agonists, γ -agonists, prostanoids, bradykinin, adenosine triphosphate, biogenic amines, and nerve growth factor). (Argoff, 2006) There is little to no research to support the use of many of these agents. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. As the medical records do not support the presence of a neuropathic pain condition, the records do not support the use of the compounded cream for treatment of the insured. Therefore the request is not medically necessary.