



Case Number:	CM15-0163014		
Date Assigned:	09/14/2015	Date of Injury:	07/07/2014
Decision Date:	10/19/2015	UR Denial Date:	08/10/2015
Priority:	Standard	Application Received:	08/19/2015

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: Tennessee, Florida, Ohio
 Certification(s)/Specialty: Surgery, Surgical Critical Care

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 45 year old male, who sustained an industrial injury on 7-7-2014. Medical records indicate the worker is undergoing treatment for lumbar disc displacement with myelopathy and sciatica. A progress note dated 4-28-2015, reported the injured worker complained low back pain rated 7 out of 10 and difficulty with activities of daily living. Physical examination showed lumbar tenderness and spasm. A recent progress note dated 5-18-2015, reported the injured worker complained of lumbar pain that radiated down the hips and legs. Physical examination revealed lumbar spasm and tenderness in the paraspinal muscles. Kemp's test, straight leg test and Yeoman's test was positive bilaterally and Braggard's test was positive on the right. Treatment to date has included magnetic resonance imaging, acupuncture, pain management consultation and medication management. The physician is requesting Genicin (Glucosamine Sodium 500mg) #90, Somnicin (Melatonin 2mg SHTP 50mg - L tryptophan 100mg - Pyridoxine 10mg - Magnesium 50mg) #30, Flurbi NAP cream 180g #1, Gabacyclotram 180gms #1, Terocin 120ml #1, Theramine #180, Trepadone #120, Internal medicine consultation, [REDACTED] narcotic test, Cardio-resp testing of autonomic system; vasomotor adrenergic innervation, Rhythm electrocardiogram, Diagnostic testing to rule out RPA, SDB, OSA, CSR, Pulmonary stress test; complex to include CO2 production, O2 uptake and electroc, Sleep study; unattended, simultaneous recording of heart rate, oxygen saturation, resp airflow, Noninvasive ear or pulse oximetry for oxygen saturation by continuous overnight saturation and Testing of autonomic nervous system function; vasomotor adrenergic innervation (sympathetic adrenergic. On 8-10-2015, the Utilization Review noncertified Genicin (Glucosamine Sodium

500mg) #90, Somnicin (Melatonin 2mg SHTP 50mg - L tryptophan 100mg - Pyridoxine 10mg - Magnesium 50mg) #30, Flurbi NAP cream 180g #1, Gabacyclotram 180gms #1, Terocin 120ml #1, Theramine #180, Trepadone #120, Internal medicine consultation, [REDACTED] narcotic test, Cardio-resp testing of autonomic system; vasomotor adrenergic innervation, Rhythm electrocardiogram, Diagnostic testing to rule out RPA, SDB, OSA, CSR, Pulmonary stress test; complex to include CO2 production, O2 uptake and electroc, Sleep study; unattended, simultaneous recording of heart rate, oxygen saturation, resp airflow, Noninvasive ear or pulse oximetry for oxygen saturation by continuous overnight saturation and Testing of autonomic nervous system function; vasomotor adrenergic innervation (sympathetic adrenergic).

IMR ISSUES, DECISIONS AND RATIONALES

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

Genicin (Glucosamine Sodium 500mg) #90: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Glucosamine (and Chondroitin Sulfate).

Decision rationale: There is not sufficient clinical information provided to justify the medical necessity of this medication for this patient. Per the California MTUS Guidelines, Glucosamine is recommended as an option in patients with moderate arthritis pain, especially for knee osteoarthritis. This patient has been documented to have lower back pain caused by an industrial accident. He has not been documented to have osteoarthritis of the knee. Thus, per MTUS guidelines, the medication is not indicated. Therefore, medical necessity for glucosamine sodium prescription has not been established.

Somnicin (Melatonin 2mg SHTP 50mg - L tryptophan 100mg - Pyridoxine 10mg - Magnesium 50mg) #30: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines, Pain (Chronic).

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

Decision rationale: There is not sufficient clinical information provided to justify the medical necessity of Somnicin for this patient. Somnicin contains melatonin. The California MTUS guidelines and the ACOEM Guidelines do not address the topic of melatonin. According to the Official Disability Guidelines (ODG), "Melatonin appears to reduce sleep onset latency to a greater extent in people with delayed sleep phase syndrome than in people with insomnia. Delayed sleep phase syndrome is characterized by late sleep onset and wake up time. It results in late wake up time, resulting in excessive daytime sleepiness, insomnia, and daytime functional

impairment. Melatonin is also used for treatment of rapid eye movement sleep behavior disorder. There is no evidence that Melatonin is effective in treating secondary sleep disorders accompanying sleep restriction, such as jet lag and shift work disorder. The literature reporting treatment of chronic insomnia disorder with Melatonin remains inconclusive." This patient has been documented to have insomnia from chronic pain. There is no evidence that Melatonin or its combination with other herbal supplements is effective for this indication. Therefore, medical necessity for Somnicin prescription has not been established.

Flurbi NAP cream 180g #1: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): NSAIDs (non-steroidal anti-inflammatory drugs), NSAIDs, GI symptoms & cardiovascular risk, NSAIDs, specific drug list & adverse effects.

Decision rationale: There is not sufficient clinical information provided to justify the medical necessity of this medication for this patient. Per the California MTUS guidelines, topical NSAIDs are only recommended for Osteoarthritis and tendinitis, in particular, that of the knee and elbow or other joints that are amenable to topical treatment. They should only be used for short-term use (4-12 weeks). There is little evidence to utilize topical NSAIDs for treatment of osteoarthritis of the spine, hip or shoulder. Use for neuropathic pain is not recommended as there is no evidence to support use. This patient has been documented to have chronic back pain secondary to his industrial accident. He has no evidence of osteoarthritis or tendinitis, particularly of the knee or elbow. Per MTUS, topical NSAID application is not warranted for this indication. Therefore, based on the submitted medical documentation, the request for NAP cream is not medically necessary.

Gabacyclotram 180gms #1: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): NSAIDs (non-steroidal anti-inflammatory drugs), NSAIDs, GI symptoms & cardiovascular risk.

Decision rationale: There is not sufficient clinical information provided to justify the medical necessity of this medication for this patient. Per the California MTUS Chronic Pain Guidelines, topical analgesics are largely experimental in use with few randomized control trials to determine efficacy or safety. They are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. Indications for topical non-steroidal anti-inflammatory drugs (NSAIDs) include osteoarthritis and tendinitis, that of the knee and elbow or other joints that are amenable to topical treatment. They are recommended for short-term use, including 4 to 12 weeks. The medical records submitted for review demonstrate that this patient

has chronic lower back pain caused by his industrial accident. There is no evidence that he has failed to respond to first-line treatment, prior to the request for a topical analgesic. Therefore, based on the submitted medical documentation, the request for Gabacyclotram is not medically necessary.

Terocin 120ml #1: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Lidoderm (lidocaine patch).

Decision rationale: There is not sufficient clinical information provided to justify the medical necessity of this medication for this patient. Per the California MTUS Chronic Pain guidelines, topical analgesics are recommended as an option and are largely experimental in use with few randomized control trials to determine efficacy or safety. They are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. Any compounded product that contains at least one drug or drug class that is not recommended is not recommended as a whole. Terocin cream is a combination of Methyl Salicylate, Capsaicin, Menthol, and Lidocaine. Topical Lidocaine, in the formulation of a dermal patch, has been designated for neuropathic pain by the FDA. No other commercially-approved topical formulation of Lidocaine is indicated for neuropathic pain. The clinical information submitted for review fails to provide evidence of a failure to respond to antidepressants or anticonvulsants prior to the request for an initiation of a topical analgesic. Hence the request for Terocin is not appropriate or indicated by MTUS guidelines. Therefore, based on the submitted medical documentation, the request for Terocin is not medically necessary.

Theramine #180: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines, Pain (Chronic).

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

Decision rationale: There is not sufficient clinical information provided to justify the medical necessity of this medication for this patient. The California MTUS guidelines and the ACOEM Guidelines do not address this topic. According to the Official Disability Guidelines (ODG), Theramine is: "Not recommended for the treatment of chronic pain. Theramine is a medical food that contains 5-hydroxytryptophan 95%, choline bitartrate, L-arginine, histidine, L-glutamine, L-serine, gamma-aminobutyric acid (GABA), whey protein concentrates, grape seed extract 85%, cinnamon, and cocoa (theobromine 6%)." This patient has chronic lower back pain secondary to an industrial accident. Per ODG, Theramine is specifically not indicated for the treatment of chronic pain. Therefore, based on the submitted medical documentation, the request for Theramine is not medically necessary.

Trepadone #120: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines, Pain (Chronic).

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Chronic Pain, Medical Food.

Decision rationale: There is not sufficient clinical information provided to justify the medical necessity of Trepadone for this patient. Trepadone is a combination medical food product which includes ingredients such as GABA, 5-HTP, L-arginine, choline, cocoa, glucosamine, chondroitin, and many others and is used for the treatment of joint disorders. The California MTUS guidelines and the ACOEM Guidelines do not address this topic of Trepadone or its ingredients individually. The Occupational Disability Guidelines (ODG), however, states that medical food may be recommended in certain situations where there is a distinctive nutritional requirement. Choline, one of the ingredients in Trepadone is only recommended for long-term parenteral nutrition or for individuals with choline deficiency secondary to liver deficiency, and is not generally recommended yet for other indications. Choline as well as many of the other amino acids and other ingredients found in Trepadone are found in foods, which can be prescribed to patients as well, so there is no need for a specific product for most patients. This patient has a history of chronic back pain secondary to an industrial injury. The patient's medical records do not document any vitamin or nutritional deficiencies in the clinic notes/labwork submitted. Considering these products are generally not recommended for cases without nutritional deficiency, the use of Trepadone is not indicated. Therefore, based on the submitted medical documentation, the request for Trepadone is not medically necessary.

Internal medicine consult: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation ACOEM Practice Guidelines, Chapter 7: Independent Medical Examinations and Consultations, page 127.

MAXIMUS guideline: Decision based on MTUS General Approaches 2004, Section(s): Prevention, General Approach to Initial Assessment and Documentation.

Decision rationale: There is not sufficient clinical information provided to justify the medical necessity of the requested internal medicine consultation for this patient. The reason for consultation was stress related conditions. The California MTUS guidelines address the issue of consultants by stating: "If physiologic evidence indicates tissue insult or nerve impairment, consider a discussion with a consultant regarding next steps." The medical records indicate that this patient has chronic back pain secondary to an industrial accident. The patient's most recent clinic records do not indicate acute depression or signs/symptoms of severe stress. An acute change is also not documented from prior visits. Since there is not physiologic evidence of insult,

a consultation is not indicated. Therefore, based on the submitted medical documentation, the request for Internal Medicine consultation is not medically necessary.

██████ narcotic test: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines, Pain (Chronic).

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain (Chronic), Genetic testing for potential opioid abuse.

Decision rationale: There is not sufficient clinical information provided to justify the medical necessity of this test for this patient. The ██████ Narcotic Risk Test is a genetic narcotic risk profile that identifies patients at elevated risk for misuse of narcotics with an 80% positive predictive value. The California MTUS guidelines and the ACOEM Guidelines do not address this topic. Per the Occupational Disability Guidelines (ODG), genetic testing for potential opioid abuse is: "Not recommended. While there appears to be a strong genetic component to addictive behavior, current research is experimental in terms of testing for this. Studies are inconsistent, with inadequate statistics and large phenotype range." Therefore, based on the submitted medical documentation, the request for ██████ Narcotic Risk Test is not medically necessary.

Cardio-resp testing of autonomic system; vasomotor adrenergic innervation: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Chronic Pain, Autonomic nervous system function testing.

Decision rationale: There is not sufficient clinical information provided to justify the medical necessity of Autonomic nervous system function testing for this patient. The California MTUS guidelines and the ACOEM Guidelines do not address the topic of this test. Per the Official Disability Guidelines (ODG), Autonomic nervous system function testing is not generally recommended as a diagnostic test for chronic pain syndrome. This patient has been requested to receive this test for evaluation of his chronic back pain secondary to an industrial accident. Per ODG, the test is not indicated. Likewise, an autonomic test battery is not generally recommended as a diagnostic test chronic pain syndrome. Therefore, based on the submitted medical documentation, the request for cardio-respiratory testing of the autonomic system; vasomotor adrenergic innervation testing is not-medically necessary.

Rhythm ECG: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

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

Decision rationale: There is not sufficient clinical information provided to justify the medical necessity of an ECG for this patient. The California MTUS guidelines and the ACOEM Guidelines do not address this topic. The Occupational Disability Guidelines (ODG) states that "ECGs in patients without known risk factors for coronary disease, regardless of age, may not be necessary." This patient is young at 45 years of age. He has no documented signs of unstable angina on his most recent clinical encounter. His complaint of chronic back pain is related to an industrial injury. In this clinical situation, a screening ECG is not warranted. Therefore, based on the submitted medical documentation, the request for ECG testing is not medically necessary.

Diagnostic testing to rule out RPA, SDB, OSA, CSR: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

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

Decision rationale: There is not sufficient clinical information provided to justify the medical necessity of a sleep study for this patient. The California MTUS guidelines and the ACOEM Guidelines do not address this topic. According to the Official Disability Guidelines (ODG), a sleep study is: "Recommended after at least six months of an insomnia complaint (at least four nights a week), unresponsive to behavior intervention and sedative/sleep-promoting medications, and after psychiatric etiology has been excluded." Additionally, ODG states that sleep studies are: "Not recommended for the routine evaluation of transient insomnia, chronic insomnia, or insomnia associated with psychiatric disorders." Regarding this patient's case, there is no documentation of this patient's insomnia being unresponsive to behavioral intervention and sleep promoting medications. This patient's insomnia is felt to be secondary to his chronic back pain which is not an indication for polysomnography. Therefore, based on the submitted medical documentation, the request for diagnostic testing (Polysomnography) to rule out RPA, SDB, OSA, and CSR is not medically necessary.

Pulmonary stress test; complex to include CO2 production, O2 uptake and electroc: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines, Pulmonary.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pulmonary (Acute & Chronic), Pulmonary Function Testing.

Decision rationale: There is not sufficient clinical information provided to justify the medical necessity of complete pulmonary function testing for this patient. The California MTUS guidelines and the ACOEM Guidelines do not address the topic of pulmonary function testing. Per the Occupational Disability Guidelines (ODG), pulmonary function testing is recommended for the diagnosis and management of chronic lung diseases. Lastly, it is recommended in the pre-operative evaluation of individuals who may have some degree of pulmonary compromise and require pulmonary resection or in the pre-operative assessment of the pulmonary patient. This patient has a history of chronic back pain but has not been diagnosed with chronic lung disease. The complex (complete) pulmonary function test (PFT) adds tests of the lung volumes and the diffusing capacity for carbon monoxide (DLCO) to incentive spirometry testing. Testing is not indicated for screening purposes. Therefore, based on the submitted medical documentation, the request for complex pulmonary stress test is not-medically necessary.

Sleep study; unattended, simultaneous recording of heart rate, oxygen saturation, resp airflow: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines, Pain (Chronic).

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

Decision rationale: There is not sufficient clinical information provided to justify the medical necessity of a sleep study for this patient. The California MTUS guidelines and the ACOEM Guidelines do not address the topic of sleep studies. According to the Official Disability Guidelines (ODG), a sleep study is: "Recommended after at least six months of an insomnia complaint (at least four nights a week), unresponsive to behavior intervention and sedative/sleep-promoting medications, and after psychiatric etiology has been excluded." Additionally, ODG states that sleep studies are: "Not recommended for the routine evaluation of transient insomnia, chronic insomnia, or insomnia associated with psychiatric disorders." Regarding this patient's case, there is no documentation of this patient's insomnia being unresponsive to behavioral intervention and sleep promoting medications. Therefore based on the submitted medical documentation, the request for a sleep study, unattended with simultaneous recording of heart rate, oxygen saturation and resp airflow is not medically necessary.

Noninvasive ear or pulse oximetry for oxygen saturation by continuous overnight saturation: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Mental, Polysomnography, Pulmonary, Pulmonary Function Testing.

Decision rationale: There is not sufficient clinical information provided to justify the medical necessity of complete pulmonary function testing for this patient. The California MTUS guidelines and the ACOEM Guidelines do not address the topic of oximetry testing. The California MTUS guidelines and the ACOEM Guidelines do not address this topic. According to the Official Disability Guidelines (ODG), a sleep study is: "Recommended after at least six months of an insomnia complaint (at least four nights a week), unresponsive to behavior intervention and sedative/sleep-promoting medications, and after psychiatric etiology has been excluded." Additionally, ODG states that sleep studies are: "Not recommended for the routine evaluation of transient insomnia, chronic insomnia, or insomnia associated with psychiatric disorders." This patient has a history of chronic back pain but has not been diagnosed with chronic lung disease. Since this patient has not been authorized to receive polysomnography, overnight oximetry is also not indicated. Therefore, based on the submitted medical documentation, the request for noninvasive ear or pulse oximetry for oxygen saturation by continuous overnight saturation is not medically necessary.