

| | | | |
|-----------------------|--------------|------------------------------|------------|
| Case Number: | CM15-0028197 | | |
| Date Assigned: | 02/20/2015 | Date of Injury: | 08/23/2013 |
| Decision Date: | 04/07/2015 | UR Denial Date: | 01/15/2015 |
| Priority: | Standard | Application Received: | 02/13/2015 |

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: Pennsylvania

Certification(s)/Specialty: Internal Medicine

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 34 year old female who sustained an industrial injury reported on 8/23/2013. She has reported neck and low back pain. The diagnoses were noted to have included cervical spine sprain/strain, displacement cervical intervertebral disc, lumbar spine sprain/strain, lumbar radiculitis, displacement lumbar intervertebral disc, and myospasm. Diagnostic testing has included MRI of the cervical and lumbar spine on 11/4/14. Treatments to date have included consultations, diagnostic imaging studies, acupuncture, chiropractic therapy, and medications. The documentation includes notation of chiropractic treatment with 9 sessions in October to December 2014, and 10 sessions from April to July 2014. There was notation of three sessions of acupuncture in December 2014 and 10 sessions of acupuncture in April to July 2014. Examination on 1/6/15 showed muscle spasm in the cervical and lumbar areas and positive straight leg raising on the right. The work status classification for this injured worker was noted to be remaining off work/temporarily totally disabled. On 1/15/2015, Utilization Review (UR) non-certified, for medical necessity, the request, made on 1/8/2015, for Tramadol 150mg #60; Cyclobenzaprine 7.5mg #90, Flurbiprofen/Capsaicin/Camphor 10/0.025%/2%/1% 120gm, Ketoprofen 10%, Cyclobenzaprine 3%, lidocaine 5% 120gm, medical foods Theramine #90/sentra PM #60/sentra AM #60/gabapone #60, ortho shockwave to cervical spine, chiropractic physiotherapy 3 x 4, and acupuncture 1 x 4. The Medical Treatment Utilization Schedule, ODG, ACOEM, and peer review literature were cited by UR.

IMR ISSUES, DECISIONS AND RATIONALES

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

Tramadol 150mg # 60: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids. Decision based on Non-MTUS Citation Official Disability Guidelines.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines opioids Page(s): p. 74-96.

Decision rationale: There is no evidence that the treating physician is prescribing opioids according to the MTUS, which recommends prescribing according to function, with specific functional goals, return to work, random drug testing, and opioid contract. There should be a prior failure of non-opioid therapy. None of these aspects of prescribing are in evidence. There was no discussion of functional goals, work status was temporarily totally disabled, and there was no documentation of an opioid contract. A urine drug screen performed on 12/8/14 was positive for butalbital which was noted as inconsistent with prescribed medications; this finding was not addressed. Per the MTUS, opioids are minimally indicated, if at all, for chronic non-specific pain, osteoarthritis, "mechanical and compressive etiologies," and chronic back pain. The documentation shows that this injured worker has chronic back pain. The prescribing physician does not specifically address function with respect to prescribing opioids, and does not address the other recommendations in the MTUS. The MTUS states that a therapeutic trial of opioids should not be employed until the patient has failed a trial of non-opioid analgesics. Ongoing management should reflect four domains of monitoring, including analgesia, activities of daily living, adverse side effects, and aberrant drug-taking behaviors. Change in activities of daily living, discussion of adverse side effects, and screening for aberrant drug-taking behaviors were not documented. As currently prescribed, tramadol does not meet the criteria for long term opioids as elaborated in the MTUS and is therefore not medically necessary.

Cyclobenzaprine 7.5mg # 90: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Muscle Relaxants. Decision based on Non-MTUS Citation Official Disability Guidelines.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines cyclobenzaprine p. 41-42 muscle relaxants p. 63-66 Page(s): 41-42, 63-66.

Decision rationale: The MTUS for chronic pain does not recommend muscle relaxants for chronic pain. Non-sedating muscle relaxants are an option for short-term exacerbations of chronic low back pain. The muscle relaxant prescribed in this case is sedating. The injured worker has chronic pain with no evidence of prescribing for flare-ups. The quantity prescribed implies long term use, not for a short period of use for acute pain. Per the MTUS chronic pain medical treatment guidelines, cyclobenzaprine (Flexeril, fexmid) is a skeletal muscle relaxant and a central nervous system depressant. It is recommended as an option for a short course of therapy, with greatest effect in the first four days of treatment. Guidelines state that treatment should be brief. The addition of cyclobenzaprine to other agents is not recommended. Limited,

mixed evidence does not allow for a recommendation for chronic use. Due to the number requested consistent with a treatment duration in excess of what is recommended by the guidelines, and the prescription of other agents, the request for cyclobenzaprine is not medically necessary.

**Topical Agents: Flurbiprofen/Capsaicin/Camphor 10%/0.025%/2%/1% 120gm/
Ketoprofen 10%/ Cyclobenzaprine 3%/Lidocaine 5% 120gm: Upheld**

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines topical analgesics Page(s): 111-113. Decision based on Non-MTUS Citation Uptodate: camphor and menthol: drug information. In UpToDate, edited by Ted. W. Post, published by UpToDate in Waltham, MA, 2015.

Decision rationale: Per the MTUS, topical analgesics are recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. If any compounded product contains at least one drug or drug class that is not recommended, the compounded product is not recommended. Ketoprofen, a nonsteroidal anti-inflammatory agent (NSAID), is not currently FDA approved for topical application. It has a high incidence of photocontact dermatitis. Flurbiprofen is also a NSAID. The only FDA approved topical NSAID is voltaren gel (diclofenac). There is little evidence to utilize topical NSAIDS for treatment of osteoarthritis of the spine, hip, or shoulder, and topical NSAIDS are not recommended for neuropathic pain. Capsaicin has some indications, in the standard formulations readily available without custom compounding. The MTUS also states that capsaicin is only recommended when other treatments have failed. The treating physician did not discuss the failure of other, adequate trials of conventional treatments. The MTUS is silent with regards to camphor. It may be used for relief of dry, itchy skin. This agent carries warnings that it may cause serious burns. Cyclobenzaprine is a muscle relaxant. The MTUS notes that there is no evidence for use of muscle relaxants as topical products. Lidocaine is only FDA approved for treating post-herpetic neuralgia, and the dermal patch form (Lidoderm) is the only form indicated for neuropathic pain. No other commercially approved topical formulations of lidocaine (whether creams, lotions, or gels) are indicated for neuropathic pain. Due to multiple agents in each of the requested compound medications being non-recommended by the guidelines, these compounded topical medications are not medically necessary.

Ortho shockwave to Cervical spine: 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) low back chapter: shock wave therapy and Other Medical Treatment Guidelines Jeon JH et al. The effect of extracorporeal shock wave therapy on myofascial pain syndrome. In Ann Rehabil Med 2012 Oct;

36(5):665-74. Wang, Ching-Jen. Extracorporeal shockwave therapy in musculoskeletal disorders. In Journal of Orthopaedic Surgery and Research 2012, 7:11.

Decision rationale: The MTUS is silent with regards to shock wave therapy for the cervical spine. The ODG does not address shock wave therapy for the cervical spine. Per the ODG, low back chapter, shock wave therapy is not recommended. The available evidence does not support the effectiveness of ultrasound or shock wave for treating low back pain. A study of thirty patients with trapezius myofascial pain in trapezius muscle showed that extracorporeal shock wave therapy was as effective as trigger point injections and transcutaneous electrical nerve stimulation (TENS) for the purpose of pain relief and improving cervical range of motion. Some studies have shown positive effects from extracorporeal shockwave therapy (ESWT), but others have reported that ESWT is ineffective or less effective with the results comparable to the placebo effect. The FDA has approved specific shockwave devices for the treatment of plantar fasciitis and lateral epicondylitis. Other uses of ESWT have been studied off-label. As the use of shock wave therapy to the cervical spine is considered experimental and is not FDA approved, the request for Ortho shockwave to Cervical spine is not medically necessary.

Chiropractic Physiotherapy 3 x 4: Upheld

Claims Administrator guideline: Decision based on MTUS ACOEM Chapter 8 Neck and Upper Back Complaints Page(s): 173. Decision based on Non-MTUS Citation ACOEM Pain, Suffering, and the Restoration of Function Chapter, Page 114 Official Disability Guidelines- Neck and Upper Back Chapter.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines manual therapy and manipulation Page(s): p. 58-60.

Decision rationale: Per the MTUS for Chronic Pain, the purpose of manual medicine is functional improvement, progression in a therapeutic exercise program, and return to productive activities (including work). Per the MTUS for Chronic Pain, a trial of 6 visits of manual therapy and manipulation may be provided over 2 weeks, with any further manual therapy contingent upon functional improvement. For the low back, if there is objective functional improvement, a total of up to 18 visits are recommended. Per the MTUS, chiropractic manipulation is not recommended for the "Ankle & Foot, Carpal tunnel syndrome, Forearm, Wrist, & Hand, Knee." The specific body part to be treated was not specified. The injured worker has received 19 sessions of chiropractic treatment from April to July and October to December 2014. There was no documentation of functional improvement as a result of the chiropractic treatment already received. The injured worker remains temporarily totally disabled, and there was no documentation of improvement in activities of daily living, or decrease in medication use or frequency of office visits. Given that the focus of manipulative therapy is functional improvement, "temporarily totally disabled" is not an appropriate starting point for therapy, and does not represent a sufficient emphasis on restoring function. Due to the lack of functional improvement as a result of chiropractic treatment already received, the request for chiropractic physiotherapy 3 x 4 is not medically necessary.

Acupuncture 1 x 4 shoulder: Upheld

Claims Administrator guideline: Decision based on MTUS ACOEM Chapter 9 Shoulder Complaints Page(s): 204. Decision based on Non-MTUS Citation Official Disability Guidelines, Shoulder Chapter.

MAXIMUS guideline: Decision based on MTUS Acupuncture Treatment Guidelines.

Decision rationale: Per the MTUS, acupuncture is used as an option when pain medication is reduced or not tolerated; it may be used as an adjunct to physical rehabilitation and/or surgical intervention to hasten functional recovery. The MTUS recommends an initial trial of 3-6 visits of acupuncture. Frequency of treatment of 1-3 times per week with an optimum duration of 1-2 months is specified by the MTUS. Medical necessity for any further acupuncture is considered in light of functional improvement. Acupuncture treatments may be extended if functional improvement is documented. This injured worker has already had 13 prior sessions of acupuncture from April to July and December 2014. There is no evidence of a specific physical rehabilitation program (or surgical intervention). There was no discussion by the treating physician regarding a decrease or intolerance to pain medication. The prolonged temporarily totally disabled work status is evidence of lack of a treatment program focused on functional recovery. There was no documentation of functional improvement as a result of the prior acupuncture treatments. Due to lack of indication and lack of functional improvement as a result of the prior acupuncture treatments, the request for acupuncture is not medically necessary.

Medical Foods: Theramine #90, Sentra PM # 60, Sentra AM # 60, Gabadone # 60: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines- 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) chronic pain chapter: insomnia treatment, Sentra PM, medical food, gabadone, theramine.

Decision rationale: The ODG states that medical food is not recommended for the treatment of chronic pain. Sentra PM is a medical food from intended for use in management of sleep disorders associated with depression. It is a proprietary blend of choline bitartrate, glutamate, and 5-hydroxytryptophan, hawthorn berry, cocoa, ginkgo biloba, and acetyl L-carnitine. The MTUS does not address the use of hypnotics other than benzodiazepines. The ODG specifies that pharmacologic agents for the treatment of insomnia should only be used after careful evaluation of potential causes of sleep disturbance. No physician reports discuss insomnia or describe the specific criteria for a sleep disorder. Treatment of a sleep disorder, including prescribing hypnotics, should not be initiated without a careful diagnosis. There is no evidence of that in this case. Per the ODG, Sentra PM is not recommended. Sentra AM is a medical food intended for use in the management of chronic and generalized fatigue, fibromyalgia, post-traumatic stress syndrome (PTSD), neurotoxicity-induced fatigue syndrome, and cognitive impairment involving arousal, alertness, and memory. The ODG states that medical foods are not recommended for treatment of chronic pain as they have not been shown to produce meaningful benefits or improvements in functional outcomes. Gabadone is a medical food that is a proprietary blend of

choline bitartrate, glutamic acid, 5-hydroxytryptophan, GABA, grape seed extract, griffonia extract, whey protein, valerian extract, ginkgo biloba and cocoa. It is intended to meet the nutritional requirements for sleep disorders and sleep disorders associated with insomnia. The ODG specifies that pharmacologic agents for the treatment of insomnia should only be used after careful evaluation of potential causes of sleep disturbance. As noted, the documentation does not discuss insomnia or evaluation of sleep disorder. Per the ODG, Gabadone is not recommended for sleep disorders based on limited available research. Theramine is medical food intended for use in the management of chronic pain syndromes which 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%). Per the ODG, theramine is not recommended for the treatment of chronic pain. As none of the medical foods requested are recommended, the request for Medical Foods: Theramine #90, Sentra PM # 60, Sentra AM # 60, Gabadone # 60 is not medically necessary.