

Case Number:	CM15-0136945		
Date Assigned:	07/24/2015	Date of Injury:	10/21/2012
Decision Date:	09/18/2015	UR Denial Date:	06/10/2015
Priority:	Standard	Application Received:	07/14/2015

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: Indiana

Certification(s)/Specialty: Preventive Medicine, Occupational 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 29 year old male who sustained an industrial injury on 10/21/12. Progress report dated 3/31/15 reports continued complaints of constant mid and low back pain radiating to the lower extremities with numbness and tingling rated 8/10. He also has complaints of constant bilateral knee pain rated 5/10 on the right and 7/10 on the left with associated weakness and giving way. Right ankle pain is constant and is rated 8/10. Diagnoses include: lumbar spine disc protrusion, lumbar spinal stenosis, lumbar radiculopathy, chondromalacia patella right knee, status post right ankle surgery, stress and anxiety. Plan of care includes: request psychological evaluation, prescription given for cyclobenzaprine hydrochloride 7.5 mg #60, terocin 240 ml apply 3-4 times per day, flurbi cream-LA 180 gm apply 2-3 times per day as needed, gabacyclotram 180 mg apply 2-3 times per day as needed, genicin #90, and somnicin #30 and continue home exercise program. Work status: remain temporarily totally disabled until 5/4/15. Follow up in 4-6 weeks.

IMR ISSUES, DECISIONS AND RATIONALES

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

Somnicin #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 (ODG).

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 Food.

Decision rationale: One of the components of Somnicin is 5-hydroxytryptophan, which ODG considers to be medical food. ODG states "Not recommended for chronic pain. 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. FDA defines a medical food as "a food which is formulated to be consumed or administered enterally under the supervision of a physician and 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." There are no quality studies demonstrating the benefit of medical foods in the treatment of chronic pain." Furthermore, "5-hydroxytryptophan: This supplement has been found to be possibly effective in treatment of anxiety disorders, fibromyalgia, obesity and sleep disorders. It has been found to be effective for depression. In alternative medicine it has been used for depression, anxiety, insomnia, obesity, aggressive behavior, eating disorders, fibromyalgia, chronic headaches and various pain disorders. It should be used with caution in individuals using SSRI antidepressants. This product has been linked to a contaminant that causes a condition called eosinophilia-myalgia syndrome." This is clearly a case of chronic pain leading to insomnia, which the ODG guidelines do not recommend medical food for. Therefore, the request is not medically necessary.

Cyclobenzaprine Hydrochloride 7.5mg #60: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 63.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines cyclobenzaprine, anti-spasmodics Page(s): 41-66. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Cyclobenzaprine (Flexeril®).

Decision rationale: MTUS Chronic Pain Medical Treatment states for Cyclobenzaprine, "Recommended as an option, using a short course of therapy. . . The effect is greatest in the first 4 days of treatment, suggesting that shorter courses may be better. (Browning, 2001) Treatment should be brief." The medical documents indicate that patient is far in excess of the initial treatment window and period. Additionally, MTUS outlines that "Relief of pain with the use of medications is generally temporary, and measures of the lasting benefit from this modality should include evaluating the effect of pain relief in relationship to improvements in function and increased activity. Before prescribing any medication for pain the following should occur: (1) determine the aim of use of the medication; (2) determine the potential benefits and adverse effects; (3) determine the patient's preference. Only one medication should be given at a time, and interventions that are active and passive should remain unchanged at the time of the medication change. A trial should be given for each individual medication. Analgesic

medications should show effects within 1 to 3 days, and the analgesic effect of antidepressants should occur within 1 week. A record of pain and function with the medication should be recorded. (Mens, 2005)" Uptodate "flexeril" also recommends "Do not use longer than 2-3 weeks". Medical documents do not fully detail the components outlined in the guidelines above and do not establish the need for long term/chronic usage of cyclobenzaprine. ODG states regarding cyclobenzaprine, "Recommended as an option, using a short course of therapy . . . The addition of cyclobenzaprine to other agents is not recommended." Several other pain medications are being requested, along with cyclobenzaprine, which ODG recommends against. As such, the request is not medically necessary.

Gabapentin 10% Cyclobenzaprine 6% Tramadol 10% 180gm: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical analgesics Page(s): 111-113. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Compound creams.

Decision rationale: MTUS and ODG recommends usage of topical analgesics as an option, but also further details "primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed." The medical documents do not indicate failure of antidepressants or anticonvulsants. MTUS states, "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." MTUS states that topical Gabapentin is "Not recommended." And further clarifies, "anti-epilepsy drugs: There is no evidence for use of any other anti-epilepsy drug as a topical product." Therefore, the request is not medically necessary.

Genicin 500mg #90: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 50.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Glucosamine Page(s): 50. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Glucosamine.

Decision rationale: Genicin is a brand named version of glucosamine. MTUS and ODG state, "Recommended as an option given its low risk, in patients with moderate arthritis pain, especially for knee osteoarthritis. Studies have demonstrated a highly significant efficacy for crystalline glucosamine sulphate (GS) on all outcomes, including joint space narrowing, pain, mobility, safety, and response to treatment, but similar studies are lacking for glucosamine hydrochloride (GH) . . . Compelling evidence exists that GS may reduce the progression of knee osteoarthritis. Results obtained with GS may not be extrapolated to other salts (hydrochloride) or formulations (OTC or food supplements) in which no warranty exists about content, pharmacokinetics and pharmacodynamics of the tablets." Medical records do indicate the patient

undergoing treatment for unspecified osteoarthritis, but does not specify the location(s) of the osteoarthritis and does not provide collaborating exam findings or other diagnostic information to support such a diagnosis. As such, the request is not medically necessary.

Terocin Lotion: Capsaicin 0.025% Methyl Salicylate 25% Menthol 10% Lidocaine 120ml:
Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Capsaicin; topical analgesics Page(s): 28, 111-113. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) compound creams.

Decision rationale: MTUS and ODG recommends usage of topical analgesics as an option, but also further details "primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed." The medical documents do not indicate failure of antidepressants or anticonvulsants. MTUS states, "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." MTUS recommends topical capsaicin "only as an option in patients who have not responded or are intolerant to other treatments." There is no indication that the patient has failed oral medication or is intolerant to other treatments. Additionally, ODG states "Topical OTC pain relievers that contain menthol, methyl salicylate, or capsaicin, may in rare instances cause serious burns, a new alert from the FDA warns." Therefore, the request is not medically necessary.