

Case Number:	CM15-0079013		
Date Assigned:	05/05/2015	Date of Injury:	12/17/2010
Decision Date:	09/08/2015	UR Denial Date:	03/26/2015
Priority:	Standard	Application Received:	04/24/2015

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: New York

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 52-year-old female who sustained an industrial injury on 12/17/10. Initial complaints and diagnoses are not available. Treatments to date include medications and right shoulder surgery. Diagnostic studies include MRIs, x-rays, stress test, Sudoscan, and cardiorespiratory diagnostic testing. Current complaints include headaches, and neck, mid back and low back pain. Current diagnoses include headaches, cervical and lumbar radiculitis, cervical and lumbar disc protrusion, thoracic sprain/strain, lumbar spinal stenosis, left shoulder tendinitis, left shoulder osteoarthritis, left hip and calf internal derangement, and depression. In a progress note dated 12/23/14, the treating provider reports the plan of care as aquatic therapy, neurology consultation, psychological evaluation, home exercise program, and medications including Ambien and Naproxen. The requested treatment include Omeprazole, Terocin patches, menthoderm, Theramine, Sentra AM, Sentra Pm, Terocin, Flurbi cream, Gabacyclotram, Genicin, Calpxo cream, Gabadone, and Somnicin.

IMR ISSUES, DECISIONS AND RATIONALES

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

Omeprazole 20mg #60: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain Chapter.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Proton pump inhibitors (PPIs) Page(s): 68-69. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter Proton pump inhibitors (PPIs).

Decision rationale: According to CA MTUS (2009), proton pump inhibitors, such as Omeprazole recommended for patients at risk for gastrointestinal events or taking NSAIDs with documented GI distress symptoms. There is no documentation indicating the patient has any GI symptoms or GI risk factors. Risk factors include, age >65, history of peptic ulcer disease, GI bleeding, concurrent use of aspirin, corticosteroids, and/or anticoagulants or high-dose/multiple NSAIDs. In this injured worker, there is no documentation of any reported GI complaints. Based on the available information provided for review, the medical necessity for Omeprazole has not been established.

Terocin Patch #20: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 56-57. Decision based on Non-MTUS Citation <http://dailymed.nlm.nih.gov/dailymed/lookup.cfm?setid=100ceb76-8ebe-437b-a8de-37cc76ece9bb>; Official Disability Guidelines (ODG) Pain Chapter.

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

Decision rationale: According to the California MTUS Guidelines, topical analgesics are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. These agents are applied topically to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. Many agents are compounded as monotherapy or in combination for pain control including, for example, NSAIDs, opioids, capsaicin, local anesthetics or antidepressants. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. In this case there is no documentation provided necessitating Terocin. This medication contains methyl salicylate, capsaicin, menthol, and lidocaine. MTUS states that capsaicin is recommended only as an option in patients who have not responded or are intolerant to other treatments. There is no documentation of intolerance to other previous medications. The treating provider's notes are not clear about using both liquid and patch. Medical necessity for the requested topical medication has not been established. The requested treatment Terocin patch is not medically necessary.

Menthoderm Gel 120ml: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Drugs.com.

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

Decision rationale: According to the California MTUS Guidelines (2009), topical analgesics

are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. These agents are applied topically to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. Many agents are compounded as monotherapy or in combination for pain control including, for example, NSAIDs, opioids, capsaicin, muscle relaxants, local anesthetics or antidepressants. Methoderm contains methyl salicylate/menthol. Guidelines indicate that any compounded product that contains at least one non-recommended drug (or drug class) is not recommended for use. Menthol is a compound from peppermint oil. Its use in isolation to treat chronic pain is not supported by evidence based treatment guidelines. Records do not indicate that injured worker is not able to use oral medications. There is no documentation in the submitted Medical Records that the injured worker has failed a trial of antidepressants and anticonvulsants. In this injured worker, the medical necessity for the requested topical cream has not been established. Therefore, as per guidelines stated above, the requested topical cream is not medically necessary.

Calypxo Cream 113gm: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Drugs.com.

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

Decision rationale: According to the California MTUS Guidelines (2009), topical analgesics are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. These agents are applied topically to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. Many agents are compounded as monotherapy or in combination for pain control including, for example, NSAIDs, opioids, capsaicin, muscle relaxants, local anesthetics or antidepressants. Guidelines indicate that any compounded product that contains at least one non-recommended drug (or drug class) is not recommended for use. Based on the currently available medical information for review, there is no documentation about the composition, of this cream and why this particular cream is requested, the medical necessity for this cream has not been established.

Theramine #90: 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) Chronic Pain Chapter Medical Food Theramine.

Decision rationale: ODG- state that dietary supplements/ vitamins are intended for specific dietary management of disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation. ODG state that medical food is not recommended. Medical food is a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for specific dietary management of disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation. Official Disability Guidelines (ODG) does not recommend Theramine 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%). The entries for 5-hydroxytryptophan, choline bitartrate, L-arginine, histidine, L-glutamine, L-serine and GABA are given and all indicate there is no role for these supplements as treatment for chronic pain. Review of medical records mention neither any rationale, nor any documentation of deficiency. Therefore, the request is not medically appropriate.

Sentra AM #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 (ODG).

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 Medical Food, Sentra AM.

Decision rationale: ODG state that dietary supplements/ vitamins are intended for specific dietary management of disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation. ODG state that medical food is not recommended. Medical food is a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for specific dietary management of disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation. Sentra is a medical food that contains choline barbitrate and glutamate, acetyl-l-choline, coco powder, grape seed extract, hawthorn berry and ginkgo biloba. There is no role for these supplements as treatment for chronic pain. Review of medical records mention neither any rationale, nor any documentation of deficiency. Therefore, the request is not medically appropriate.

Sentra PM #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 (ODG).

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 Medical Food, Sentra PM.

Decision rationale: ODG state that dietary supplements/ vitamins are intended for specific dietary management of disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation. ODG state that medical food is not recommended. Medical food is a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for specific dietary management of disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation. Sentra is a medical food that contains choline barbitrate and glutamate, acetyl-l-choline, coco powder, grape seed extract, hawthorn berry and ginkgo biloba. There is no role for these supplements as treatment for chronic pain. Review of medical records mention neither any rationale, nor any documentation of deficiency. Therefore, the request is not medically appropriate.

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 (ODG).

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 Medical Food.

Decision rationale: ODG state that dietary supplements/ vitamins are intended for specific dietary management of disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation. ODG state that medical food is not recommended. Medical food is a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for specific dietary management of disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation. Based on the currently available medical information for review, there is no documentation about the composition, of this medical food and why this particular medical food is requested; the medical necessity for Gabadone has not been established.

Terocin 120ml- capsaicin, methyl salicylate, menthol, lidocaine: Upheld

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

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

Decision rationale: According to the California MTUS Guidelines, topical analgesics are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. These agents are applied topically to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. Many agents are compounded as monotherapy or in combination for pain control including, for example, NSAIDs, opioids, capsaicin, local anesthetics or antidepressants. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. In this case, there is no documentation provided necessitating Terocin. This medication contains methyl salicylate, capsaicin, menthol, and lidocaine. MTUS states that capsaicin is recommended only as an option in patients who have not responded or are intolerant to other treatments. There is no documentation of intolerance to other previous medications. The treating provider's notes are not clear about using both liquid and patch. Medical necessity for the requested topical medication has not been established. The requested treatment Terocin patch is not medically necessary.

Flurbi Cream-LA 180gm - flurbiprofen, lidocaine, amitriptyline: Upheld

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

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

Decision rationale: According to the California MTUS Guidelines (2009), topical analgesics are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. These agents are applied topically to painful areas with advantages

that include lack of systemic side effects, absence of drug interactions, and no need to titrate. Many agents are compounded as monotherapy or in combination for pain control including, for example, NSAIDs, opioids, capsaicin, muscle relaxants, local anesthetics or antidepressants. Guidelines indicate that any compounded product that contains at least one non-recommended drug (or drug class) is not recommended for use. Flurbiprofen is used as a topical NSAID. It has been shown in a meta-analysis to be superior to placebo during the first two weeks of treatment for osteoarthritis but either, not afterward, or with diminishing effect over another two-week period. There are no clinical studies to support the safety or effectiveness of Flurbiprofen in a topical delivery system (excluding ophthalmic). In this injured worker, the medical necessity for the requested topical cream has not been established. Therefore, as per guidelines stated above, the requested topical cream is not medically necessary.

Gabacyclotram 180mg - gabapentin, cyclobenzaprine, tramadol: Upheld

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

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

Decision rationale: According to the California MTUS Guidelines, topical analgesics are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. These agents are applied topically to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. Many agents are compounded as monotherapy or in combination for pain control including, for example, NSAIDs, opioids, capsaicin, local anesthetics or antidepressants. Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. In this case there is no documentation provided necessitating requested treatment: Compound gabapentin, cyclobenzaprine, tramadol. One of the ingredients is gabapentin. MTUS states that gabapentin is not recommended topically. There is no peer-reviewed literature to support use. Medical necessity for the requested topical medication has not been established. The requested treatment is not medically necessary.

Genicin #90: Upheld

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

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter - Chondroitin/Glucosamine.

Decision rationale: As per ODG Criteria it is recommended as an option (glucosamine sulfate only) 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). For all herbals and dietary supplements, there may be concerns for potential interactions with prescription and over-the-counter medications and lack of manufacturing quality controls. In this case, within the submitted documentation it is not clear how long injured worker has

been using Genicin and what is the functional improvement. Also, there is no mention of frequency and dosage. Based on the currently available information, the medical necessity for Genicin has not been established. The requested treatment 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 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) Chronic Pain Chapter Medical Food, Somnicin.

Decision rationale: ODG- state that dietary supplements/ vitamins are intended for specific dietary management of disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation. ODG further states that medical food is not recommended. Somnicin contains certain ingredients, among them are Melatonin, 5-HTP, L-tryptopan, Vitamin B6 and Magnesium. Review of medical records mention neither any rationale, nor any documentation of deficiency. In this case, within the submitted documentation it is not clear how long injured worker has been using Somnicin and what is the functional improvement. Based on the currently available information and guidelines, the medical necessity for Somnicin has not been established. The requested treatment is not medically necessary.

