

Case Number:	CM15-0140395		
Date Assigned:	08/04/2015	Date of Injury:	10/22/2010
Decision Date:	10/02/2015	UR Denial Date:	07/08/2015
Priority:	Standard	Application Received:	07/20/2015

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 51-year-old female injured worker suffered an industrial injury on 10-22-2010. The diagnoses included cervical and lumbar radiculopathy, lumbar disc protrusion, bilateral carpal tunnel syndrome and bilateral knee chondromalacia. The treatment included medications. On 4-20-2015, the treating provider reported constant neck pain radiating to the left upper extremity with numbness and tingling rated 9 out of 10. There was constant low back pain radiating to the bilateral lower extremities with numbness and tingling rated 9 out of 10. There was constant bilateral wrist pain with numbness, tingling rated 6 out of 10, and constant knee pain rated 8 out of 10. On exam, the cervical spine had reduced range of motion with tenderness and spasms. The lumbar spine had reduced range of motion with tenderness and spasms along with an impaired gait. The injured worker had not returned to work. The requested treatments included Omeprazole, Cyclobenzaprine, Norco, Terocin, (Flurbiprofen 20%, Lidocaine 5%, Amitriptyline 5%), Gabacyclotram, Genicin, Somnicin, Theramine, Sentra PM and Sentra AM.

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAID, GI symptoms Page(s): 68-71. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain Chapter--Proton pump inhibitors (PPIs).

Decision rationale: As per the ODG guidelines, Prilosec is a proton pump inhibitor. The CA MTUS guidelines indicate that proton pump inhibitors are recommended in those patients who are at risk for gastrointestinal events and no cardiovascular disease. The gastrointestinal event risk factors include: age over 65 years, history of peptic ulcer, GI (gastrointestinal) bleeding or perforation, concurrent use of ASA (aspirin), corticosteroids, and/or an anticoagulant, or high dose or multiple oral NSAID (non-steroidal anti-inflammatory drug) use. This injured worker is 51 years old. There is no evidence documented that she is at risk of gastrointestinal events, and there is no evidence of a history of peptic ulcer, gastrointestinal bleeding or perforation, concurrent use of aspirin, corticosteroids, anticoagulants, or high dose or multiple oral NSAID use. 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. This request is not medically necessary.

Cyclobenzaprine 10mg #45: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Muscle relaxants for pain.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines muscle relaxants Page(s): 63-65.

Decision rationale: MTUS Chronic Pain Medical Treatment Guidelines recommended oral muscle relaxants for a short course 2 to 3 weeks for acute neck and back conditions or for acute exacerbations and any repeated use should be contingent on evidence of specific prior benefit. Efficacy diminished overtime and prolonged use may lead to dependence. The preference is for non-sedating muscle relaxants. There are also indications for post-operative use. The documentation provided did not include evidence of an acute condition or an acute exacerbation. In this case, there is no compelling evidence presented by the treating provider that indicates in this injured worker, continuing this medication has been effective in maintaining any measurable objective evidence of functional improvement. The Requested Treatment: Cyclobenzaprine 10mg is not medically necessary.

Norco 10/325mg #120: Upheld

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

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

Decision rationale: MTUS discourages long-term usage unless there is evidence of "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." The documentation needs to contain assessments of analgesia, activities of daily living, adverse effects and aberrant drug taking behavior. "Functional improvement" is evidenced by a clinically significant improvement in activities of daily living or a reduction in work restrictions as measured during the history and physical exam, performed and documented as part of the evaluation and management and a reduction in the dependency on continued medical treatment. The documentation provided included pain levels but no evidence of a comprehensive pain assessment and evaluation with medication efficacy, no risk assessment for aberrant drug use and no evidence of functional improvement. Based on the currently available information and per review of guidelines, the medical necessity for Norco has not been established. The requested treatment is not medically necessary. Of note, discontinuation should include a taper to avoid withdrawal symptoms.

Terocin 120ml: 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 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 Terocin. Medical necessity for the requested topical medication has not been established. The requested treatment Terocin is not medically necessary.

Flurbiprofen 20%, Lidocaine 5%, Amitriptyline 5% 180gm: 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 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 the requested treatment: Compound Flurbiprofen 20%, Lidocaine 5%, Amitriptyline 5%. One of the ingredients in this compound is Flurbiprofen. It 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) Medical necessity for the requested topical compound medication has not been established. The requested treatment is not medically necessary.

Gabaclosetam 180gm: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Compounded topical analgesics Page(s): 111-113.

Decision rationale: MTUS Chronic Pain Medical Treatment Guidelines for Compounded topical analgesics stated that any compound product that contains at least 1 drug (or drug class) that is not recommended, is not recommended. The documentation provided indicated the preparation contained Gabapentin. The drug class of AED (antiepileptic drugs) has not been FDA approved for use in a topical preparation. Therefore, Gabaclosetam was not medically necessary. 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 Gabaclosetam. One of the ingredients of Gabaclosetam 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.

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. In addition, 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.

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 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.

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.

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. Official Disability Guidelines (ODG) do 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 neither mention any rationale, nor any documentation of deficiency. Request does not specify frequency. Based on the currently available information and per review of guidelines, the medical necessity for Theramine has not been established. The requested treatment is not medically necessary.

#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.

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. 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. Request does not specify frequency. Based on the currently available information and per review of guidelines, the medical necessity for Sentra has not been established. The requested treatment is not medically necessary.

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.

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: MTUS guidelines do not address this, therefore Official Disability Guidelines (ODG) and alternate resources were reviewed. 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. Request does not specify frequency. Based on the currently available information and per review of guidelines, the medical necessity for Sentra AM has not been established. The requested treatment is not medically necessary.