MAXIMUS Federal Services

Case Number:	CM14-0141084		
Date Assigned:	10/15/2014	Date of Injury:	01/30/2014
Decision Date:	11/18/2014	UR Denial Date:	08/20/2014
Priority:	Standard	Application Received:	09/02/2014

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. The expert reviewer is Board Certified in Anesthesiology, has a subspecialty in Pain Medicine and is licensed to practice in California. 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/services. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

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 37 year old male with date of injury 1/30/14 with related low back pain. Per progress report dated 7/7/14, the injured worker reported low back pain rated 6/10 extending to the right hand #3 digit with associated numbness. Per physical exam of the lumbar spine, range of motion was limited; tenderness was noted over the paraspinals, straight leg raise test was positive on the left. Treatment to date has included physical therapy, chiropractic manipulation, and medication management. The date of UR decision was 8/20/14.

IMR ISSUES, DECISIONS AND RATIONALES

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

Retrospective request for Sentra PM #60 (prescribed 4/7/14): 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 Chapter

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), Medical Foods

Decision rationale: The MTUS is silent on the topic of medical food. With regard to chronic pain, the Official Disability Guidelines say this about Sentra PM: "Sentra PM is a medical food from [redacted], intended for use in management of

sleep disorders associated with depression that is a proprietary blend of choline bitartrate, glutamate, and 5-hydroxytryptophan." The Official Disability Guidelines states that medical foods are not considered medically necessary except in those cases in which the patient has a medical disorder, disease or condition for which there are distinctive nutritional requirements. The records submitted for review do not include evidence that the injured worker has any distinctive nutritional requirements, nor have they addressed the injured worker's sleep hygiene. The request is not medically necessary.

Retrospective request for Sentra AM, #60 (prescribed 4/7/14): 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 Chapter

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), Medical Foods

Decision rationale: The MTUS is silent on the topic of medical food. With regard to chronic pain, the ODG guidelines say this about medical foods: medical foods are not considered medically necessary except in those cases in which the patient has a medical disorder, disease or condition for which there are distinctive nutritional requirements. The records submitted for review do not include evidence that the injured worker has any distinctive nutritional requirements. The request is not medically necessary.

Retrospective request for Tramadol ER #60 (prescribed 4/7/14): Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Tramadol and Opioids for chronic pain.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 76, 78, 93.

Decision rationale: Per MTUS Chronic Pain Medical Treatment Guidelines page 76 regarding therapeutic trial of opioids, questions to ask prior to starting therapy include "(a) Are there reasonable alternatives to treatment, and have these been tried? (b) Is the patient likely to improve? (c) Is there likelihood of abuse or an adverse outcome?"The documentation submitted for review does not indicate that the injured worker was refractory to first-line oral analgesics including NSAIDs and adjuvants prior to the initiation of opiate therapy. The request is not medically necessary.

Retrospective request for Omeprazole #60 (prescribed 4/7/14): Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms & cardiovascular risk. Decision based on Non-MTUS Citation Official Disability Guidelines, Pain Chapter

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms & cardiovascular risk Page(s): 68.

Decision rationale: In the treatment of dyspepsia secondary to NSAID therapy, the MTUS recommends stopping the NSAID, switching to a different NSAID, or considering the use of an H2-receptor antagonist or a PPI. The MTUS Chronic Pain Medical Treatment Guidelines recommend the use of proton pump inhibitors in conjunction with NSAIDs in situations in which the patient is at risk for gastrointestinal events including: (1) age > 65 years; (2) history of peptic ulcer, GI bleeding or perforation; (3) concurrent use of ASA, corticosteroids, and/or an anticoagulant; or (4) high dose/multiple NSAID (e.g., NSAID + low-dose ASA). Chronic Pain Medical Treatment Guidelines further specify: "Recommendations: Patients with no risk factor and no cardiovascular disease: Non-selective NSAIDs OK (e.g, ibuprofen, naproxen, etc.) Patients at intermediate risk for gastrointestinal events and no cardiovascular disease:(1) A non-selective NSAID with either a PPI (Proton Pump Inhibitor, for example, 20 mg omeprazole daily) or Misoprostol or (2) a Cox-2 selective agent. Long-term PPI use (> 1 year) has been shown to increase the risk of hip fracture (adjusted odds ratio 1.44). Patients at high risk for gastrointestinal events with no cardiovascular disease: A Cox-2 selective agent plus a PPI if absolutely necessary. Patients at high risk of gastrointestinal events with cardiovascular disease: If GI risk is high the suggestion is for a low-dose Cox-2 plus low dose Aspirin (for cardioprotection) and a PPI. If cardiovascular risk is greater than GI risk the suggestion is Naproxyn plus low-dose aspirin plus a PPI. (Laine, 2006) (Scholmerich, 2006) (Nielsen, 2006) (Chan, 2004) (Gold, 2007) (Laine, 2007)"As there is no documentation of peptic ulcer, GI bleeding or perforation, or cardiovascular disease in the records available for my review, the injured worker's risk for gastrointestinal events is low, as such, medical necessity cannot be affirmed. This request is not medically necessary.

Retrospective request for Cyclobenzaprine #60 (prescribed 4/7/14): Overturned

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Cyclobenzaprine (Flexeril) and Muscle relaxants (for pain).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Muscle Relaxants Page(s): 63-64.

Decision rationale: With regard to muscle relaxants, the MTUS Chronic Pain Medical Treatment Guidelines states: "Recommend non-sedating muscle relaxants with caution as a second-line option for short-term treatment of acute exacerbations in patients with chronic low back pain. (Chou, 2007) (Mens, 2005) (Van Tulder, 1998) (van Tulder, 2003) (van Tulder, 2006) (Schnitzer, 2004) (See, 2008) Muscle relaxants may be effective in reducing pain and muscle tension, and increasing mobility. However, in most low back pain cases, they show no benefit beyond NSAIDs in pain and overall improvement." Regarding Cyclobenzaprine: "Recommended for a short course of therapy. Limited, mixed-evidence does not allow for a recommendation for chronic use. Cyclobenzaprine is a skeletal muscle relaxant and a central nervous system depressant with similar effects to tricyclic antidepressants (e.g. Amitriptyline). Cyclobenzaprine is more effective than placebo in the management of back pain, although the effect is modest and comes at the price of adverse effects." Per progress report dated 3/26/14, the injured worker

complained of lumbar spine pain rated 8/10 in intensity. The documentation submitted for review did not state that Cyclobenzaprine was in use prior to this prescription. I respectfully disagree with the UR physician's assertion that medical necessity cannot be affirmed without knowing whether the medication was in use beforehand. The request is medically necessary.

Retrospective Theramine #90 (prescribed 4/7/14): 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 Chapter

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: The MTUS is silent on the topic of medical food. With regard to the treatment of chronic pain, the Official Disability Guidelines says this about Theramine: "Not recommended. Theramine is a medical food from [redacted], that is a proprietary blend of gamma-aminobutyric acid [GABA] and choline bitartrate, L-arginine, and L-serine. It is intended for use in themanagement of pain syndromes that include acute pain, chronic pain, fibromyalgia, neuropathic pain, and inflammatory pain. See Medical food, Gamma-aminobutyric acid (GABA), where it says, "There is no high quality peer-reviewed literature that suggests that GABA is indicated"; Choline, where it says, "There is no known medical need for choline supplementation"; L-Arginine, where it says, "This medication is not indicated in current references for pain or inflammation"; & L-Serine, where it says, "There is no indication for the use of this product." Theramine is not recommended by the Official Disability Guidelines and thus the request is not medically necessary.

Retrospective Urinalysis for toxicology (DOS 4/7/14): Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids, Criteria for use. Decision based on Non-MTUS Citation Official Disability Guidelines, Pain Chapter, Urine Drug Testing (UDT)

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 87.

Decision rationale: MTUS Chronic Pain guidelines recommend random drug screening for patients to avoid the misuse of opioids, particularly for those at high risk of abuse. Upon review of the submitted medical records, the injured worker is not a high risk for abuse. Per MTUS Chronic Pain Medical Treatment Guidelines page 87, "Indicators and predictors of possible misuse of controlled substances and/or addiction: 1) Adverse consequences: (a) Decreased functioning, (b) Observed intoxication, (c) Negative affective state2) Impaired control over medication use: (a) Failure to bring in unused medications, (b) Dose escalation without approval of the prescribing doctor, (c) Requests for early prescription refills, (d) Reports of lost or stolen prescriptions, (e) Unscheduled clinic appointments in "distress", (f) Frequent visits to the ED, (g) Family reports of overuse of intoxication3) Craving and preoccupation: (a) Non-compliance with

other treatment modalities, (b) Failure to keep appointments, (c) No interest in rehabilitation, only in symptom control, (d) No relief of pain or improved function with opioid therapy, (e) Overwhelming focus on opiate issues.4) Adverse behavior: (a) Selling prescription drugs, (b) Forging prescriptions, (c) Stealing drugs, (d) Using prescription drugs is ways other than prescribed (such as injecting oral formulations), (e) Concurrent use of alcohol or other illicit drugs (as detected on urine screens), (f) Obtaining prescription drugs from non-medical sources"At the time of the request, the injured worker was not yet on opiate therapy, nor was it medically necessary. As such, the request for urinalysis is not medically necessary.

Retrospective Flurbiprofen/Capsaicin/Menthol/Camphor (prescribed 4/7/14): 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): 60, 111-112.

Decision rationale: Capsaicin may have an indication for chronic lower back pain in this context. Per MTUS page 112 "Indications: There are positive randomized studies with Capsaicin cream in patients with osteoarthritis, fibromyalgia, and chronic non-specific back pain, but it should be considered experimental in very high doses. Although topical capsaicin has moderate to poor efficacy, it may be particularly useful (alone or in conjunction with other modalities) in patients whose pain has not been controlled successfully with conventional therapy." Per MTUS with regard to Flurbiprofen (page 112), "(Biswal, 2006) These medications may be useful for chronic musculoskeletal pain, but there are no long-term studies of their effectiveness or safety. Indications: Osteoarthritis and tendinitis, in particular, that of the knee and elbow or other joints that are amenable to topical treatment: Recommended 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." The documentation contains no evidence of osteoarthritis or tendinitis. Flurbiprofen is not indicated. Regarding the use of multiple medications, MTUS page 60 states "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) The recent AHRQ review of comparative effectiveness and safety of analgesics for osteoarthritis concluded that each of the analgesics was associated with a unique set of benefits and risks, and no currently available analgesic was identified as offering a clear overall advantage compared with the others." Therefore, it would be optimal to trial each medication individually. The California MTUS, Official Disability Guidelines, National Guidelines Clearinghouse, and ACOEM provide no evidence-based recommendations regarding the topical application of menthol or camphor. It is the opinion of this IMR reviewer that a lack of endorsement, a lack of mention, inherently implies a lack of recommendation, or a status equivalent to "not recommended". Since several components are not medically indicated, then the overall product is not indicated per MTUS as outlined below. Note the statement on page 111: Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. The request is not medically necessary.

Retrospective request for Ketoprofen/Cyclobenzaprine/Lidocaine 120gram (prescribed 4/7/14): 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): 60, 111-113.

Decision rationale: With regard to topical Ketoprofen, the MTUS Chronic Pain Medical Treatment Guidelines states "This agent is not currently FDA approved for a topical application. It has an extremely high incidence of photo contact dermatitis. (Diaz, 2006) (Hindsen, 2006)". Per MTUS Chronic Pain Medical Treatment Guidelines page 113, "There is no evidence for use of any other muscle relaxant as a topical product. [apart from Baclofen, which is also not recommended]" Cyclobenzaprine is not indicated. With regard to Lidocaine MTUS page 112 states "Further research is needed to recommend this treatment for chronic neuropathic pain disorders and other than post-herpetic neuralgia" and "Non-neuropathic pain: Not recommended. There is only one trial that tested 4% Lidocaine for treatment of chronic muscle pain. The results showed there was no superiority over placebo. (Scudds, 1995)". The injured worker has not been diagnosed with post-herpetic neuralgia. Lidocaine is not indicated. Regarding the use of multiple medications, MTUS page 60 states "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) The recent AHRQ review of comparative effectiveness and safety of analgesics for osteoarthritis concluded that each of the analgesics was associated with a unique set of benefits and risks, and no currently available analgesic was identified as offering a clear overall advantage compared with the others." Therefore, it would be optimal to trial each medication individually. Note the statement on page 111: Any compounded product that contains at least one drug (or drug class) that is not recommended is not recommended. As none of the agents in this compound are recommended, the request is not medically necessary.