

Case Number:	CM14-0077244		
Date Assigned:	08/06/2014	Date of Injury:	02/16/2006
Decision Date:	09/11/2014	UR Denial Date:	05/02/2014
Priority:	Standard	Application Received:	05/27/2014

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 Physical Medicine & Rehabilitation, has a subspecialty in Interventional Spine 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 patient is a 57-year-old female with a date of injury of 02/16/2006. The listed diagnoses per [REDACTED] are: Lumbar radiculopathy, Chronic pain syndrome, Chronic pain related insomnia, Myofascial syndrome, Neuropathic pain, Chronic pain-related depression, Prescription narcotic dependence, Chronic pain-related sexual dysfunction. According to progress report 02/26/2014 by [REDACTED], the patient presents with severe low back pain radiating to the buttocks and legs. The patient is particularly having numbness and tingling in the lower part of her legs below the calves and to her feet. She also complains of weakness and instability. Treater states the patient is depressed and stressed. The patient's pain score is 8-9/10 currently with medications and without pain medications, score is 8/10. UDS from 12/30/2013 was inconsistent and showed negative for mirtazapine. Examination revealed the patient has severe point tenderness over the midline over the L4 and L5 spinous processes. There is diffuse tenderness over the superior aspect of the sacral hiatus. The patient has multiple trigger points and hypersensitivity over the entire lumbar paraspinal musculature. Treater is requesting authorization for urine drug screen to assess medication compliance and identify possible drug diversion, MRI of the lumbar spine, Topamax 50 mg #60 for neuropathic pain, fentanyl patch 10 mcg 1 topically every 72 hours, Trepadone #120 twice a day for inflammation, GABAdone 2 at bedtime for insomnia, Teramine 1 every 6 hours for neuropathic pain, one Toradol injection for acute pain, and one vitamin B12 injection for myofascial pain and nerve health. Utilization review denied the request on 05/02/2014.

IMR ISSUES, DECISIONS AND RATIONALES

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

Urine Drug Screen: Overturned

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Misuse of opioids, Cautionary red flags for patients that may potentially abuse opioids. Decision based on Non-MTUS Citation <http://sso.state.mi.us> - University of Michigan Health System Guidelines for Clinical Care: Managing Chronic Non-terminal Pain, including Prescribing Controlled Substances (May 2009), pg 10, 32, 33.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Drug testing Page(s): 43. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) ODG guidelines have the following regarding Urine Drug Screen:Criteria for Use of Urine Drug Testing.

Decision rationale: This patient presents with complaints of severe low back pain radiating to the buttocks and legs. The patient reports numbness and tingling in the lower part of her legs below the calves into the feet. The patient also reports being depressed and feeling distressed. The patient's medication regimen includes Topamax 50 mg, fentanyl patch 100 mcg, Trepadone, Percocet 10/325 mg, GABAdone, and Teramine. The treater is requesting a urine drug screen. While MTUS Guidelines do not specifically address how frequent UDS should be obtained or various risks of opiate users, ODG Guidelines provide clear recommendation. ODG recommends once-yearly urine drug testing following initial screening with the first 6 months for management of chronic opiate use in low-risk patients. In this case, the medical file provided for review indicates the patient had a UDS on 12/30/2013 which revealed negative for mirtazapine, which was a prescribed medication. The treater is requesting a repeat UDS. This patient has not had a UDS in 2014. ODG recommends once a year screening. Therefore, recommendation is for approval.

MRI of the Lumbar Spine: Upheld

Claims Administrator guideline: Decision based on MTUS ACOEM Chapter 12 Low Back Complaints Page(s): 303. Decision based on Non-MTUS Citation Official Disability Guidelines, Low Back - Lumbar & Thoracic (Acute & Chronic).

MAXIMUS guideline: Decision based on MTUS ACOEM Chapter 12 Low Back Complaints Page(s): 303. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) ODG-TWC guidelines (http://www.odg-twc.com/odgtwc/low_back.htm#Protocols).

Decision rationale: This patient presents with complaints of severe low back pain radiating to the buttocks and legs. The patient reports numbness and tingling in the lower part of her legs below the calves into the feet. The patient also reports being depressed and feeling distressed. The treater is requesting a repeat MRI of the lumbar spine. He states the patient is exhibiting new neurological findings and is having difficulties walking at this point. He believes the patient needs "a new lumbar MRI to help rule in or rule out new pathology." The medical file provided for review indicates the patient had an MRI of the lumbar spine on 01/29/2014, which revealed

L2-L3 and L3-L4 facet hypertrophy and moderate to marked bilateral foraminal impingement and moderate central canal thecal sac and cord compression. At the level of L3-L4, there is minimal disk desiccation and a 1.3-mm minimal posterior disk bulge. For special diagnostics, ACOEM Guidelines page 303 states "unequivocal objective findings that identify specific nerve compromise on the neurological examination is sufficient evidence to warrant imaging in patients who do not respond well to treatment and who would consider surgery as an option. When the neurologic examination is less clear, however, further physiologic evidence of nerve dysfunction should be obtained before ordering an imaging study." In this case, the treater would like an updated MRI for increased. However, there are no new injuries, no significant changes in examination, no bowel/bladder symptoms, no new location of symptoms requiring additional investigation. Recommendation is for denial.

Topamax 50mg #60: Overturned

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Anti-epilepsy drugs (AEDs), Topiramate (Topamax).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topamax; Antiepilepsy drugs Page(s): 21; 16-17.

Decision rationale: This patient presents with complaints of severe low back pain radiating to the buttocks and legs. The patient reports numbness and tingling in the lower part of her legs below the calves into the feet. The patient also reports being depressed and feeling distressed. According to MTUS Guidelines page 21, "Topiramate (Topamax) has been shown to have variable efficacy, with failure to demonstrate efficacy in neuropathic pain of "central" etiology. It is still considered for use for neuropathic pain when other anticonvulsants have failed." MTUS Guidelines page 16 and 17 regarding antiepileptic drugs for chronic pain also states "that there is a lack of expert consensus on the treatment of neuropathic pain in general due to heterogeneous etiologies, symptoms, physical signs, and mechanisms. Most randomized controlled trials for the use of this class of medication for neuropathic pain had been directed at postherpetic neuralgia and painful polyneuropathy." In this case, progress reports note neuropathic pain in lower extremities. MTUS Guidelines support antiepileptic medications for the use of neuropathic pain. The requested Topamax is medically necessary and recommendation is for approval.

Fentanyl Patch 100mcg: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Duragesic (fentanyl transdermal system); Long-Term Users of Opioids; Opioids, criteria for use; Opioid hyperalgesia; Weaning of Medications.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Duragesic (fentanyl transdermal system); Topical Analgesics Page(s): 44; 111.

Decision rationale: This patient presents with complaints of severe low back pain radiating to the buttocks and legs. The patient reports numbness and tingling in the lower part of her legs

below the calves into the feet. The patient also reports being depressed and feeling distressed. The MTUS Guidelines page 44 states Duragesic (fentanyl transdermal system) is not recommended as a first line therapy. Duragesic is a trade name of fentanyl transdermal therapeutic system which releases fentanyl, a potent opioid, slowly to the skin. Progress reports from 01/29/2013 through 02/26/2014 were reviewed. The treater does not discuss any specific functional improvements. Functional measures include significant changes in ADL's or improvement in work status. Although the treater does use a pain scale to assess pain level, the treater does not specifically correlate the decreased pain level with the use of these patches. Finally, no outcome measures are documented as required by MTUS. Recommendation is for denial.

Trepadone #120: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Medical Foods, Trepadone.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) ODG guidelines under pain chapter: Theramine; Gabadone; Medical Foods.

Decision rationale: This patient presents with complaints of severe low back pain radiating to the buttocks and legs. The patient reports numbness and tingling in the lower part of her legs below the calves into the feet. The patient also reports being depressed and feeling distressed. ODG has the following under its pain section, "Trepadone is a medical food from [REDACTED], [REDACTED], that is a proprietary blend of L-arginine, L-glutamine, choline bitartrate, L-serine and gammaaminobutyric acid [GABA]. It is intended for use in the management of joint disorders associated with pain and inflammation. Regarding Medical Food, ODG states that it is to be used when there is a specific deficit requiring supplement. In this case, there is no evidence that the patient has deficits of L-arginine, L-glutamate, choline bitartrate, etc., contained in Trepadone. Recommendation is for denial.

Gabadone - Unspecified dosage and quantity: 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 (Chronic): Updated 04/10/14 - Medical food, GABAdone.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) ODG guidelines under pain chapter: Theramine; Gabadone; Medical Foods.

Decision rationale: This patient presents with complaints of severe low back pain radiating to the buttocks and legs. The patient reports numbness and tingling in the lower part of her legs below the calves into the feet. The patient also reports being depressed and feeling distressed. The ACOEM and MTUS do not discuss Gabadone. ODG has the following under its pain section, "Not recommended. GABAdone is a medical food from [REDACTED], [REDACTED], [REDACTED]."

██████████, that is a proprietary blend of Choline Bitartrate, Glutamic Acid, 5-Hydroxytryptophan, and GABA. It is intended to meet the nutritional requirements for inducing sleep, promoting restorative sleep and reducing snoring in patients who are experiencing anxiety related to sleep disorders." ODG states that for ingredient choline, "There is no known medical need for choline supplementation." For Glutamic Acid, "This supplement is used for treatment of hypochlohydria and achlorhydria. Treatment indications include those for impaired intestinal permeability, short bowel syndrome, cancer and critical illnesses. It is generally used for digestive disorders in complementary medicine." For 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." While some of the ingredients may be indicated, choline is not. Furthermore, medical foods in general are not recommended per ODG unless there is a specific deficit for supplemented ingredient. Recommendation is for denial.

Theramine - Unspecified dosage and quantity:

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines, Pain (Chronic): Updated 04/10/14 - Medical Food, Theramine.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) ODG guidelines under pain chapter:Theramine; Gabadone; Medical Foods.

Decision rationale: This patient presents with complaints of severe low back pain radiating to the buttocks and legs. The patient reports numbness and tingling in the lower part of her legs below the calves into the feet. The patient also reports being depressed and feeling distressed. The ACOEM and MTUS guidelines do not discuss theramine, a medical food. ODG guidelines under pain chapter, has the following regarding Theramine, "Not recommended. Theramine is a medical food from ██████████, ██████████, that is a proprietary blend of gamma-aminobutyric acid [GABA] and choline bitartrate, L-arginine, and L-serine. It is intended for use in the management of pain syndromes that include acute pain, chronic pain, fibromyalgia, neuropathic pain, and inflammatory pain." Theramine is not supported by ODG. Recommendation is for denial.

One (1) Toradol 60mg injection: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, specific drug list & adverse effects: Ketorolac (Toradol, generic available).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Ketorolac (Toradol, generic available): 10 mg. [Boxed Warning]: This medication is not indicated for minor or chronic painful conditions Page(s): 72. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) ODG guidelines on Toradol for Shoulder subacromial injection.Recommended as an option to corticosteroid injections, with up to three subacromial injections. Avoid use of an oral NSAID at the same time as the injections. Injection of the

NSAID ketorolac shows superiority over corticosteroid injections in the treatment of shoulder pain. The mean improvement in the assessment score for the ketorolac group was 7.15 compared with just 2.13 in the steroid group, and the ketorolac group showed an increase in forward flexion strength and improved patient satisfaction over the steroid group, and only the ketorolac group had a sustained response. Two other advantages of NSAID injections are limited tissue atrophy or cartilage damage, and the injections may not be as limited in frequency. Ketorolac injections have an extremely strong anti-inflammatory effect, but they may also have side effects. They can cause bleeding, and patients cannot take oral NSAIDs while they're receiving injections or if they have kidney damage. (Min, 2011) Other Medical Treatment Guideline or Medical Evidence: Academic Emergency Medicine, Vol 5, 118-122, "Intramuscular ketorolac vs oral ibuprofen in emergency department patients with acute pain" study demonstrated that there is no difference between the two and both provided comparable levels of analgesia in emergency patients presenting with moderate to severe pain.

Decision rationale: This patient presents with complaints of severe low back pain radiating to the buttocks and legs. The patient reports numbness and tingling in the lower part of her legs below the calves into the feet. The patient also reports being depressed and feeling distressed. The MTUS Guidelines page 70 under NSAIDs, specific drug list and adverse effects states, "recommended with cautions below: Disease-state warnings for all NSAIDs, all NSAIDs have US boxed warnings for associated risk of adverse cardiovascular events including MI, stroke, and new onset or worsening of pre-existing hypertension. Boxed warning for ketorolac 10 mg states that medication is not indicated for minor or chronic painful conditions." Furthermore, the Academic Emergency Medicine volume V page 118 to 122 states "intramuscular ketorolac versus oral ibuprofen in emergency room department patients with acute pain." Study demonstrated that there is no difference between the two and both provided comparable levels of analgesia in emergency patients presenting with moderate to severe pain. The requested Toradol injection is not medically necessary and recommendation is for denial.

One (1) Vitamin B12 Injection: 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 (Chronic): Vitamin B.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: AETNA Clinical Policy Bulletin:Vitamin B-12 Therapy.

Decision rationale: This patient presents with complaints of severe low back pain radiating to the buttocks and legs. The patient reports numbness and tingling in the lower part of her legs below the calves into the feet. The patient also reports being depressed and feeling distressed. The ACOEM, MTUS ODG guidelines do not discuss Vitamin injections. AETNA guidelines discuss Vitamin B-12 therapy for medical conditions and considers it for Anemia, GI disorders, Neuropathy due to malnutrition/alcoholism/pernicious anemia/posterolateral sclerosis. Aetna considers Vitamin B-12 injections experimental and investigational for all other indications.

Based on current evidence it does not appear that either Vitamin B12 are supported for chronic pain. Recommendation is for denial.