

Case Number:	CM13-0013765		
Date Assigned:	12/11/2013	Date of Injury:	09/18/1998
Decision Date:	08/12/2014	UR Denial Date:	08/06/2013
Priority:	Standard	Application Received:	08/20/2013

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 Massachusetts. 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 66-year-old female who presents with complaints in the low back bilateral and into the buttocks with tingling numbness and sharp shooting pain down both legs the level of the feet in and L5 distribution. Further workup indicated L4 / L5 disc protrusion with bilateral L5 neural impingement and compression. The pain is described as constant with exacerbations and unrelenting despite conservative measures. The pain is further described as a burning pain aggravated by walking and activity. Her diagnoses include is lumbosacral pain, lumbosacral neuritis / radiculitis, displacement of lumbar intervertebral disc without myelopathy and lumbago. She has undergoing a course of physical therapy, epidural steroid injection, and medication management. A request for diclofenac ER 100mg twice daily, gabapentin 600mg (2) tabs each evening, omeprazole 20mg twice per day, Theramine 101.5mg, 1-2 tablets every 4 hours and Terocin topical lotion was requested and denied.

IMR ISSUES, DECISIONS AND RATIONALES

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

Retrospective (DOS: 7/9/2013) Diclofenac Sodium ER (100mg - 1 tablet twice daily, #120):
Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs (non-steroidal anti-inflammatory drugs).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs (non-steroidal anti-inflammatory drugs) Page(s): 67.

Decision rationale: According to the Chronic Pain Medical Treatment Guidelines, NSAIDs are recommended at the lowest dose for the shortest period in patients with moderate to severe pain. Acetaminophen may be considered for initial therapy for patients with mild to moderate pain, and in particular, for those with gastrointestinal, cardiovascular or renovascular risk factors. NSAIDs appear to be superior to acetaminophen, particularly for patients with moderate to severe pain. There is no evidence to recommend one drug in this class over another based on efficacy. There should be documentation of pain relief and improvement in function as well as documentation of side effects incurred with use. According to the records provided, there is no assessment of pain relief or documentation of the medication dosing, response or side effects. Therefore, the request is not medical necessary.

Retrospective (DOS: 7/9/3012) Gabapentin (600mg - 2 tablets by mouth every night, #120): Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Antiepilepsy drugs (AEDs).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Antiepilepsy drugs (AEDs) Page(s): 17.

Decision rationale: According to the Chronic Pain Medical Treatment Guidelines, anti-epilepsy drugs (AEDs) are also referred to as anti-convulsants and are recommended for neuropathic pain (pain due to nerve damage). 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 (RCTs) for the use of this class of medication for neuropathic pain have been directed at postherpetic neuralgia and painful polyneuropathy (with diabetic polyneuropathy being the most common example). There are few RCTs directed at central pain and none for painful radiculopathy. Further, guidelines state that after initiation of treatment there should be documentation of pain relief and improvement in function as well as documentation of side effects incurred with use. According to the records provided, there is no assessment of pain relief or documentation of the medication dosing, response or side effects. Therefore, the request is not medical necessary.

Retrospective (DOS: 7/9/2013) Omeprazole (20mg - 1 tablet twice daily, #120): Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms & cardiovascular risk.

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

Decision rationale: According to the Chronic Pain Medical Treatment Guidelines, clinicians should weight the indications for NSAIDs against both GI and cardiovascular risk factors.

Determine if the patient is at risk for gastrointestinal events: (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). Recent studies tend to show that H. Pylori does not act synergistically with NSAIDs to develop gastroduodenal lesions. Patients with no risk factor and no cardiovascular disease; non-selective NSAIDs are okay to use. 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 (200 g four times daily) 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 cardio protection) and a PPI. If cardiovascular risk is greater than GI risk, the suggestion is naproxen plus low-dose aspirin plus a PPI. According to the records provided, there is no assessment or documentation of the medication dosing, response or side effects or indications for use. Therefore, the request is not medical necessary.

Retrospective(DOS: 7/9/13) Theramine (101.5mg - 1-2 tablet s every 4 hours, #360): Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation ODG-TWC Pain Procedure Summary.

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: According to the Official Disability guidelines, Theramine is not recommended. Theramine is a medical food from Physician Therapeutics, Los Angeles, CA, 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. There is no high quality peer-reviewed literature that suggests that GABA is indicated. There is no known medical need for choline supplementation. This medication is not indicated in current references for pain or inflammation. There is no indication for the use of this product. Until there are higher quality studies of the ingredients in Theramine, it remains not recommended. Therefore, the request is not medical necessary.

Retrospective (DOS: 7/9/13) Terocin Lotion Pain Relief (#240): 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. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain-Chronic, Topical Analgesics.

Decision rationale: According to the Chronic Pain Medical Treatment Guidelines and the Official Disability Guidelines, topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. They are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. These agents are applied locally to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. 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. The use of these compounded agents requires knowledge of the specific analgesic effect of each agent and how it will be useful for the specific therapeutic goal required. According to the records provided, there is no assessment of pain relief or documentation of the medication dosing, response or side effects. Therefore, the request is not medical necessary.

Diclofenac Sodium ER (100mg - 1 tablet twice daily, #120): Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs (non-steroidal anti-inflammatory drugs).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDS Page(s): 67.

Decision rationale: According to the Chronic Pain Medical Treatment Guidelines, NSAIDS are recommended at the lowest dose for the shortest period in patients with moderate to severe pain. Acetaminophen may be considered for initial therapy for patients with mild to moderate pain, and in particular, for those with gastrointestinal, cardiovascular or renovascular risk factors. NSAIDs appear to be superior to acetaminophen, particularly for patients with moderate to severe pain. There is no evidence to recommend one drug in this class over another based on efficacy. There should be documentation of pain relief and improvement in function as well as documentation of side effects incurred with use. According to the records provided, there is no assessment of pain relief or documentation of the medication dosing, response or side effects. Therefore, the request is not medical necessary.

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Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Antiepilepsy drugs (AEDs).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Antiepilepsy drugs (AEDs) Page(s): 17.

Decision rationale: According to the Chronic Pain Medical Treatment Guidelines, anti-epilepsy drugs (AEDs) are also referred to as anti-convulsants and are recommended for neuropathic pain (pain due to nerve damage). 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 (RCTs) for the use of this class of medication for neuropathic pain have been directed at postherpetic neuralgia and painful polyneuropathy (with diabetic

polyneuropathy being the most common example). There are few RCTs directed at central pain and none for painful radiculopathy. Further, guidelines state that after initiation of treatment there should be documentation of pain relief and improvement in function as well as documentation of side effects incurred with use. According to the records provided, there is no assessment of pain relief or documentation of the medication dosing, response or side effects. Therefore, the request is not medical necessary.

Omeprazole (20mg - 1 tablet twice daily, #120): Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms & cardiovascular risk.

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

Decision rationale: According to the Chronic Pain Medical Treatment Guidelines, clinicians should weight the indications for NSAIDs against both GI and cardiovascular risk factors. Determine if the patient is at risk for gastrointestinal events: (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). Recent studies tend to show that H. Pylori does not act synergistically with NSAIDS to develop gastroduodenal lesions. Patients with no risk factor and no cardiovascular disease; non-selective NSAIDs are okay to use. 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 (200 g four times daily) 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 cardio protection) and a PPI. If cardiovascular risk is greater than GI risk, the suggestion is naproxen plus low-dose aspirin plus a PPI. According to the records provided, there is no assessment or documentation of the medication dosing, response or side effects or indications for use. Therefore, the request is not medical necessary.

Theramine (101.5mg - 1-2 tablet s every 4 hours, #360): Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation ODG-TWC Pain Procedure Summary.

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: According to the Official Disability guidelines, Theramine is not recommended. Theramine is a medical food from Physician Therapeutics, Los Angeles, CA, 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. There is no high quality peer-reviewed literature that suggests that GABA is indicated. There is no known medical need for choline supplementation. This medication is not indicated in current references for pain or inflammation. There is no indication for the use of this product. Until there are higher quality studies of the ingredients in Theramine, it remains not recommended. Therefore, the request is not medical necessary.

Terocin Lotion Pain Relief (#240): 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. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain-Chronic Topical Analgesics.

Decision rationale: According to the Chronic Pain Medical Treatment Guidelines and the Official Disability Guidelines, topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. They are primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. These agents are applied locally to painful areas with advantages that include lack of systemic side effects, absence of drug interactions, and no need to titrate. 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. The use of these compounded agents requires knowledge of the specific analgesic effect of each agent and how it will be useful for the specific therapeutic goal required. According to the records provided, there is no assessment of pain relief or documentation of the medication dosing, response or side effects. Therefore, the request is not medical necessary.