

Case Number:	CM14-0157440		
Date Assigned:	09/30/2014	Date of Injury:	06/27/2012
Decision Date:	11/05/2014	UR Denial Date:	09/02/2014
Priority:	Standard	Application Received:	09/25/2014

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 Florida. 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 41-year-old male who reported an injury on 06/27/2012. The mechanism of injury was due to a fall. The injured worker's diagnoses included lumbar radiculopathy, lumbar discopathy, lumbago, and sciatica, the injured worker's past treatments included physical therapy and medications. The injured worker's surgical history included a spinal surgery performed on 08/22/2014. The injured worker's diagnostic testing included an MRI of the lumbar spine, performed on 12/20/2013, which was noted to reveal disc desiccation at L3-4 with minimal bilateral neural foraminal narrowing. At L4-5, there was an annular tear in the posterior disc slightly right paracentrally, and AP disc protrusion with resultant mild to moderate spinal canal stenosis encroachment upon the descending left and right L5 nerve roots. On 08/13/2014, the injured worker complained of constant low back pain, radiating into the left lower extremity with numbness and tingling. He rated the pain 7/10 on a pain scale. Upon physical examination, he was noted to have decreased range of motion to the lumbar area with flexion limited at 30 degrees, extension at 10 degrees, and right and left lateral flexion at 10 degrees. The injured worker's medications included naproxen sodium 550 mg, omeprazole 20 mg, ondansetron 8 mg, cyclobenzaprine 7.5 mg, hydrocodone/acetaminophen .5/325 mg, tramadol ER 150 mg, sumatriptan succinate tablets 25 mg, levofloxacin 750 mg, quazepam 15 mg, Terocin patch, and Methoderm gel. The request was for Methoderm gel, Xolindo 2% cream, Gabadone #60, Theramine #90, Sentra AM #60, Sentra PM #60, Trepadone #120, Terocin patch #120, Terocin patch #20, Toradol 60 mg, and Theramine #90. The rationale for the request was not provided. The Request for Authorization form was not submitted for review.

IMR ISSUES, DECISIONS AND RATIONALES

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

RETRO: Mentoderm Gel #120 DOS 6/11/2014: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation ODG; Topical Analgesics

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines TOPICAL ANALGESICS Page(s): 111.

Decision rationale: The request for retro: Mentoderm Gel #120 DOS 6/11/2014 is not medically necessary. The California MTUS Guidelines state that topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. Primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. Many agents are compounded as monotherapy or in combination for pain control. 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. The documentation did not provide sufficient evidence of the efficacy of the medication. The documentation did not provide evidence of significant objective functional improvement or documented objective decrease in pain. The rationale for the use of this medication was not clearly provided. There was no evidence of failure with the already prescribed oral anti-inflammatory medication. In the absence of documentation with sufficient evidence of the efficacy of the medication to include significant objective functional improvement, documented objective decrease in pain, and a clear rationale for this medication in addition to previously prescribed oral anti-inflammatory medication, the request is not supported. Additionally, as the request was written, there was no frequency provided. Therefore, the request is not medically necessary.

RETRO: Xolindo 2% cream DOS 06/11/2014: 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): 111-112.

Decision rationale: The request for retro: Xolindo 2% cream DOS 06/11/2014 is not medically necessary. The California MTUS Guidelines state that topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. Primarily recommended for neuropathic pain when trials of antidepressants and anticonvulsants have failed. Many agents are compounded as monotherapy or in combination for pain control. 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. Xolindo 2% cream has an active ingredient of lidocaine. Lidocaine has been indicated for localized peripheral pain after there has been evidence of a trial of first line therapy. Topical lidocaine, in the formulation of the dermal patch Lidoderm, has been designated for orphan status by the FDA for neuropathic pain. No other commercially approved topical formulations of lidocaine (whether creams, lotions, or gels) are indicated for neuropathic pain. Further research is needed to recommend this treatment for chronic neuropathic pain disorders, other than post-herpetic neuralgia. In 02/2007, the FDA notified consumers and healthcare professionals of the potential hazards of the use of topical lidocaine. The documentation does not indicate a rationale for the use of Xolindo cream. The patient did not report the efficacy of the medication since prescribed. In the absence of documentation with sufficient evidence of a clear rationale for the use of the medication, documented evidence of post-herpetic neuralgia, and efficacy of the medication, the request is not supported. Additionally, as the request was written, there was no frequency provided. Therefore, the request is not medically necessary.

RETRO: Gabadone #60 DOS 06/11/2014: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation ODG; regarding medical foods

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Gabadone; Pain, Medical foods.

Decision rationale: The request for retro: Gabadone #60 DOS 06/11/2014 is not medically necessary. The Official Disability Guidelines do not recommend Gabadone. 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. It is not recommended for chronic pain. Medical foods are not recommended for treatment of chronic pain as they have not been shown to produce meaningful benefits or improvements in functional outcomes. The documentation did not provide sufficient evidence for the rationale for the Gabadone. The injured worker did report pain, however, the guidelines do not recommend medical food for the use of chronic pain. In the absence of documentation with sufficient evidence for a clear rationale for the use of the medication, and a complete and thorough pain assessment to include the least reported pain over the period since last assessment, intensity of pain after taking medication, and how long pain relief lasts, the request is not supported. Additionally, the guidelines do not recommend Gabadone. Furthermore, as the request is written, there is no frequency provided. Therefore, the request is not medically necessary.

RETRO: Theramine #90 DOS 06/11/2014: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation ODG; regarding medical foods

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

Decision rationale: The request for retro: Theramine #90 DOS 06/11/2014 is not medically necessary. The Official Disability Guidelines state that Theramine is not recommended for the treatment of chronic pain. It is intended for use in the management of pain syndrome that include acute pain, chronic pain, fibromyalgia, neuropathic pain, and inflammatory pain. Until there are higher quality studies of the ingredients in Theramine, it remains not recommended. The injured worker was noted to have a pain that he rated a 7/10 on a pain scale; however, there was not a complete and thorough pain evaluation documented to include the least reported pain over the period since last assessment, intensity of pain after taking medication, and how long pain relief lasts. Additionally, the guidelines do not recommend Theramine. Furthermore, as the request was written, there was no frequency provided. Therefore, the request is not medically necessary.

RETRO: Sentra AM #60 DOS 06/11/2014: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Medical food.

Decision rationale: The request for retro: Sentra AM #60 DOS 06/11/2014 is not medically necessary. The Official Disability Guidelines do not recommend medical food for chronic pain. Medical foods are not recommended for treatment of chronic pain as they have not been shown to produce meaningful benefits or improvements in functional outcomes. There are no quality studies the benefit of medical foods in the treatment of chronic pain. Choline is a precursor of acetylcholine. There is no known medical need for choline supplementation except for the case of choline long term parenteral nutrition, or for individuals with choline deficiency secondary to liver deficiency. There is inconclusive evidence that this product is indicated for an endurance aide, memory, seizures, and transient ischemic attacks. Side effects of high dose choline include hypotension, acute GI distress, and cholinergic side effects such as sweating and diarrhea. The documentation did not provide sufficient evidence of a rationale for the use of this medication. The injured worker was not documented with long term parenteral nutrition or choline deficiency secondary to liver deficiency. In the absence of documentation with sufficient evidence of long term parenteral nutrition, choline deficiency secondary to liver deficiency, or a clear rationale for the use of the medication, the request is not supported. Additionally, as the request was written, there was no frequency provided. Therefore, the request is not medically necessary.

RETRO: Sentra PM #60 DOS 06/11/2014: Upheld

Claims Administrator guideline: The Claims Administrator did not cite any medical evidence for its decision.

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Pain, Medical food.

Decision rationale: The request for retro: Sentra PM #60 DOS 06/11/2014 is not medically necessary. The Official Disability Guidelines do not recommend medical food for chronic pain. Medical foods are not recommended for treatment of chronic pain as they have not been shown to produce meaningful benefits or improvements in functional outcomes. There are no quality studies the benefit of medical foods in the treatment of chronic pain. Choline is a precursor of acetylcholine. There is no known medical need for choline supplementation except for the case of choline long term parenteral nutrition, or for individuals with choline deficiency secondary to liver deficiency. There is inconclusive evidence that this product is indicated for an endurance aide, memory, seizures, and transient ischemic attacks. Side effects of high dose choline include hypotension, acute GI distress, and cholinergic side effects such as sweating and diarrhea. The documentation did not provide sufficient evidence of a rationale for the use of this medication. The injured worker was not documented with long term parenteral nutrition or choline deficiency secondary to liver deficiency. In the absence of documentation with sufficient evidence of long term parenteral nutrition, choline deficiency secondary to liver deficiency, or a clear rationale for the use of the medication, the request is not supported. Additionally, as the request was written, there was no frequency provided. Therefore, the request is not medically necessary.

RETRO: Trepadone #120 DOS 06/11/2014: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation ODG; regarding medical foods

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

Decision rationale: The request for retro: Trepadone #120 DOS 06/11/2014 is not medically necessary. The Official Disability Guidelines do not recommend Trepadone for the treatment of chronic pain. It is intended for use in the management of joint disorders associated with pain and inflammation. Trepadone is a medical food that is a proprietary blend of L arginine, L glutamine choline bitartrate, L serine, and Gaba. The guidelines state that there is no indication for the use of the supplement L serine. L arginine is not indicated in current references for pain or inflammation. It is indicated to detoxify urine. Gaba is indicated for epilepsy, spasticity, and tardive dyskinesia. There is no high quality peer reviewed literature that suggests that Gaba is indicated for treatment of insomnia. Documentation did not provide sufficient evidence of a clear rationale for the use of the medication. Guidelines do not indicate this medication for chronic pain. In the absence of evidence based peer reviewed literature that suggests that Trepadone is indicated for chronic pain, and a clear and thorough rationale for the use of the medication, the request is not supported. Additionally, as the request was written, there was no frequency provided. Therefore, the request is not medically necessary.

Terocin patch #20 (Capsacin 0.025%, Menthyl Salicylate 25%, Menthol 10%, Lidocaine 2.5%) DOS 06/11/2014: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines TOPICAL ANALGESICS Page(s): 98-99.

Decision rationale: The request for Terocin patch #20 (capsacin 0.025%, menthyl salicylate 25%, Menthol 10%, Lidocaine 2.5%) DOS 06/11/2014 is not medically necessary. The California MTUS Guidelines state that 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. Many agents are compounded as monotherapy or in combination for pain control, however, 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, therefore, 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. Lidocaine may be recommended for localized peripheral pain after there has been evidence of a trial of first line therapy. Topical lidocaine, in the formulation of the dermal patch, Lidoderm, has been designated for orphan status by the FDA for neuropathic pain. No other commercially approved topical formulations of lidocaine are indicated for neuropathic pain. Further research is needed to recommend this treatment for chronic neuropathic pain disorders, other than post-herpetic neuralgia. In 02/20007, the FDA notified consumers and healthcare professionals of the potential hazards of the use of topical lidocaine. Capsaicin may be recommended only as an option in patients who have not responded or are intolerant to other treatments. The injured worker complained of pain, and rated it a 7/10 on a pain scale. However, the documentation did not provide a thorough pain assessment to include the least reported pain over the period since last assessment, intensity of pain after taking medication, and how long pain relief lasts. The documentation did not indicate an intolerance or failed response to other treatments. In the absence of documentation with evidence of a complete and thorough pain evaluation, documented evidence of post-herpetic neuralgia, and documented evidence of an intolerance or failed response to other treatments, the request is not supported. Additionally, as the request was written, there was no frequency provided. Therefore, the request is not medically necessary.

RETRO: Theramine #90 DOS 06/11/2014: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation ODG; regarding medical foods

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

Decision rationale: The request for retro: Theramine #90 DOS 06/11/2014 is not medically necessary. The Official Disability Guidelines state that Theramine is not recommended for the treatment of chronic pain. It is intended for use in the management of pain syndrome that

include acute pain, chronic pain, fibromyalgia, neuropathic pain, and inflammatory pain. Until there are higher quality studies of the ingredients in Theramine, it remains not recommended. The injured worker was noted to have a pain that he rated a 7/10 on a pain scale, however, there was not a complete and thorough pain evaluation documented to include the least reported pain over the period since last assessment, intensity of pain after taking medication, and how long pain relief lasts. Additionally, the guidelines do not recommend Theramine. Furthermore, as the request was written, there was no frequency provided. Therefore, the request is not medically necessary.

RETRO: Toradol 60mg DOS 06/11/2014: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Ketorolac (Toradol, generic available)

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDS Page(s): 68-72.

Decision rationale: The request for retro: Toradol 60mg DOS 06/11/2014 is not medically necessary. The California MTUS Guidelines state that NSAIDs may be recommended as an option for short term symptomatic relief of chronic low back pain. There is inconsistent evidence for the use of these medications to treat long term neuropathic pain. Toradol is not indicated for minor or chronic painful conditions. The documentation indicates that the patient has a condition of chronic low back pain, which Toradol is not indicated for. The documentation did not provide evidence of a complete and thorough pain evaluation to include a current quantified pain, intensity of pain after taking medication, how long the pain relief lasts, and the least reported pain over the period since the last assessment. In the absence of a complete pain evaluation and consistent evidence for the use of this medication for chronic pain, the request is not supported. Additionally, as the request was written, there was no frequency provided. As such, the request is not medically necessary.