

Case Number:	CM14-0037410		
Date Assigned:	06/25/2014	Date of Injury:	05/08/2003
Decision Date:	07/23/2014	UR Denial Date:	03/10/2014
Priority:	Standard	Application Received:	03/28/2014

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 Family Practice 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 claimant is a 69-year-old female who sustained a work injury on 5/8/03 resulting in a right wrist fracture, lumbar strain with disk herniations and post-traumatic headaches. The claimant had been on Tramadol since at least October 2013 and up until 5/23/14 for chronic pain. A progress note on 2/7/14 indicated the claimant had 6/10 pain in the morning and goes to 1-2/10 during the day. Exam findings include limited range of motion of the lumbar spine, paraspinal spasms and a positive straight leg raise. The treating physician continued Tramadol ER 150mg twice a day along with topical Amitramadol DM (Amitriptyline 4%/Tramadol 20%/Dextromethorphan 10%) transderm 240g, and topical Gabapentin 6%.Ketoprofen 20%, Lidocaine HCL 6.15%, Transderm 240gm Cream. A follow-up appointment in 5/23/14 indicated 7/10 pain in the low back with similar physical findings. Norco was provided in addition to the Tramadol.

IMR ISSUES, DECISIONS AND RATIONALES

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

Tramadol ER 150mg #60 with 2 refills: 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): 93-94.

Decision rationale: Opioid analgesics and Tramadol have been suggested as a second-line treatment (alone or in combination with first-line drugs). A recent consensus guideline stated that opioids could be considered first-line therapy for the following circumstances: (1) prompt pain relief while titrating a first-line drug; (2) treatment of episodic exacerbations of severe pain; [&] (3) treatment of neuropathic cancer pain. Tramadol is a synthetic opioid affecting the central nervous system. The immediate release formulation is recommended at a dose of 50 to 100mg by mouth (PO) every 4 to 6 hours (not to exceed 400mg/day). This dose is recommended after titrating patients up from 100mg/day, with dosing being increased every 3 days as tolerated. For patients in need of immediate pain relief, which outweighs the risk of non-tolerability the initial starting dose, may be 50mg to 100mg every 4 to 6 hours (max 400mg/day). Ultram ER: Patient currently not on immediate release tramadol should be started at a dose of 100mg once daily. The dose should be titrated upwards by 100mg increments if needed (Max dose 300mg/day). Patients currently on immediate release tramadol calculate the 24-hour dose of IR and initiate a total daily dose of ER rounded to the next lowest 100mg increment (Max dose 300mg/day). Treatment of chronic lumbar root pain: A limitation of current studies is that there are virtually no repeated dose analgesic trials for neuropathy secondary to lumbar radiculopathy. A recent study that addressed this problem found that chronic lumbar radicular pain did not respond to either a tricyclic antidepressant or opioid in doses that have been effective for painful diabetic neuropathy or postherpetic neuralgia. Morphine was the least effective treatment (reducing leg and back pain by 1-7% compared to placebo). Sample size and dropout rate was a limitation. (Khoromi, 2007). Not recommended as a first-line therapy for osteoarthritis. Short-term use: recommended on a trial basis for short-term use after there has been evidence of failure of first-line non-pharmacologic, medication options (such as acetaminophen or NSAIDs), and when there is evidence of moderate to severe pain. Also recommended for a trial if there is evidence of contraindications for use of first-line medications. Weak opioids should be considered at initiation of treatment with this class of drugs (such as Tramadol, Tramadol/acetaminophen, hydrocodone and codeine), and stronger opioids are only recommended for treatment of severe pain under exceptional circumstances (oxycodone, hydromorphone, fentanyl, morphine sulfate). Benefits of opioids are limited by frequent side effects (including nausea, constipation, dizziness, somnolence and vomiting). (Stitik, 2006) (Avouac, 2007) (Zhang, 2008). In this case, Tramadol had been used for over 7 months without improvement in pain. It has not been proven superior to first line agents such as NSAIDs. In addition, one opioid is not found to be superior to another. Combining Tramadol with Norco is not recommended. The continued use of Tramadol is not medically necessary.

Amitramadol DM (Amitriptyline 4%/Tramadol 20%/ Dextromethorphan 10%) transderm 240gm: 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: According to the MTUS guidelines, topical analgesics are recommended as an option as indicated below. 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. (Namaka, 2004) 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. (Colombo, 2006) Many agents are compounded as monotherapy or in combination for pain control (including NSAIDs, opioids, capsaicin, local anesthetics, antidepressants, glutamate receptor antagonists, -adrenergic receptor agonist, adenosine, cannabinoids, cholinergic receptor agonists, agonists, prostanoids, bradykinin, adenosine triphosphate, biogenic amines, and nerve growth factor). (Argoff, 2006) 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. [Note: Topical analgesics work locally underneath the skin where they are applied. These do not include transdermal analgesics that are systemic agents entering the body through a transdermal means. See Duragesic (fentanyl transdermal system).] As noted above, there is little to no evidence that topical antidepressants provide benefit. Amitriptyline is an antidepressant and therefore its topical formulation is not medically necessary.

Gabapentin 6%.Ketoprofen 20%, Lidocaine HCL 6.15%, Transderm 240gm Cream:
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: According to the MTUS guidelines, topical analgesics are recommended as an option as indicated below. 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. (Namaka, 2004) 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. (Colombo, 2006) Many agents are compounded as monotherapy or in combination for pain control (including NSAIDs, opioids, capsaicin, local anesthetics, antidepressants, glutamate receptor antagonists, -adrenergic receptor agonist, adenosine, cannabinoids, cholinergic receptor agonists, agonists, prostanoids, bradykinin, adenosine triphosphate, biogenic amines, and nerve growth factor). (Argoff, 2006) 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. [Note: Topical analgesics work locally underneath the skin where they are applied. These do not include transdermal analgesics that are systemic agents entering the body through a transdermal means. See Duragesic (fentanyl transdermal system).] However, Gabapentin is not recommended. There is no peer-reviewed

literature to support use. Since the product contains Gabapentin and Gabapentin is not recommended in topical form, the Gabapentin 6%.Ketoprofen 20%, Lidocaine HCL 6.15%, Transderm 240gm Cream is not medically necessary.