

Case Number:	CM14-0105162		
Date Assigned:	08/06/2014	Date of Injury:	12/02/2008
Decision Date:	02/28/2015	UR Denial Date:	06/10/2014
Priority:	Standard	Application Received:	07/08/2014

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. 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/Service. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

The Expert Reviewer has the following credentials:
State(s) of Licensure: Colorado
Certification(s)/Specialty: Family Practice

CLINICAL CASE SUMMARY

The expert reviewer developed the following clinical case summary based on a review of the case file, including all medical records:

49 year old male with date of injury 12/2/2008 continues care with the treating physician. His primary complaints are neck pain, headaches, and upper back pain. Patient rates pain 6/10 with or without pain medication though function and sleep noted to be improved when taking medications. The treating physician requests continuing prescriptions for Mobic, Tramadol and Tramadol ER, Gabapentin, Norco, Klonopin, and Prozac.

IMR ISSUES, DECISIONS AND RATIONALES

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

Mobic 7.5 mg #60: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs (non-steroidal anti-inflammatory drugs Page(s): 67-68,70.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Pain Interventions and Treatments Page(s): 22 AND 68.

Decision rationale: Per the MTUS Guidelines, non-steroidal anti-inflammatory drugs are recommended as second line agents for pain, after trial of Acetaminophen, (particularly for those

patients at risk for gastrointestinal events, cardiac events, and renal disease), to be taken at the lowest effective dose for shortest period of time. Non-steroidal anti-inflammatory drugs may be first line for moderate to severe pain, based on available evidence, though studies cannot consistently confirm that non-steroidal anti-inflammatory drugs are superior to Acetaminophen. There is no evidence that any of the non-steroidal anti-inflammatory drugs are effective long term for pain relief or functional improvement. There is no consistent evidence that non-steroidal anti-inflammatory drugs are useful for long term management of neuropathic pain. For the patient of concern, there is no documentation more recent than May 2014. The documentation that is available does not specify why patient takes the Mobic, for headaches or neck pain or upper back pain. The records do indicate some issues with radicular pain, but unclear if Mobic is used for that. Mobic has been used for more than 3 months based on the records supplied, and pain ratings are 6/10 with or without medications. As there is no clear documentation of what is being treated and no evidence to support non-steroidal anti-inflammatory drug use long term, the Mobic is not medically indicated.

Prozac 20 mg #30: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Antidepressants for chronic pain Page(s): Pages 13-14.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Pain Intervention and Treatments Page(s): 13-16.

Decision rationale: Per the MTUS Guidelines, antidepressants can be considered first line treatment for neuropathic pain and possible option for treatment for non-neuropathic pain. Tricyclic antidepressants are the recommended first option for treatment of pain with antidepressant and should be used unless ineffective or not tolerated/contraindicated. Pain relief with antidepressants may occur within a few days to 1 week, though any antidepressant effect would take longer to occur. As with other treatments for pain, efficacy should be assessed regularly when using antidepressants. The following aspects associated with pain relief should be addressed: Pain reduction, Improvement in function, Changes in need for other pain medications, Sleep quality and quantity, Psychiatric evaluation, Side effects, especially those that may affect job performance, Long term efficacy of anti-depressants in treatment of pain is not known, and antidepressants in combination with other medications for pain have no quality evidence to support use. For the patient of concern, there is no documentation more recent than May 2014. The records supplied for the patient of concern do not indicate that patient has tried and failed a course of Tricyclic antidepressants. Furthermore, no documentation is supplied that addresses each issue above as it relates to the antidepressant therapy. It is also unclear in the record if the patient is taking the Prozac only for pain, or also for psychiatric diagnosis. As there is no documentation of objective assessment of the efficacy of Prozac for pain or psychiatric condition, the Prozac is not medically indicated. Antidepressants, including Prozac, should not be abruptly discontinued.

Tramadol HCL 50 mg #30: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 79- 80.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Pain Interventions and Treatments Page(s): 79-80, 85, 88-89 AND 93.

Decision rationale: Tramadol is a synthetic opioid that exerts its effect on the central nervous system. The MTUS Guidelines establish criteria for use of opioids, including long term use (6 months or more). When managing patients using long term opioids, the following should be addressed: Re-assess the diagnosis and review previous treatments and whether or not they were helpful. When re-assessing, pain levels and improvement in function should be documented. Pain levels should be documented every visit. Function should be evaluated every 6 months using a validated clinical assessment tool. Adverse effects, including hyperalgesia, should also be addressed each visit. Patient's motivation and attitudes about pain / work / interpersonal relationships can be examined to determine if patient requires psychological evaluation as well. Aberrant / addictive behavior should be addressed if present. Do not decrease dose if effective. Medication for breakthrough pain may be helpful in limiting overall medication. Follow up evaluations are recommended every 1-6 months. To summarize the above, the 4A's of Drug Monitoring (analgesia, activities of daily living, adverse side effects, and aberrant drug-taking Behaviors) have been established. The monitoring of these outcomes over time should affect therapeutic decisions and provide a framework for documentation of the clinical use of these controlled drugs. (Passik, 2000) Several circumstances need to be considered when determining to discontinue opioids: 1) Verify patient has not had failure to improve because of inappropriate dosing or under-dosing of opioids 2) Consider possible reasons for immediate discontinuation including diversion, prescription forgery, illicit drug use, suicide attempt, arrest related to opioids, and aggressive or threatening behavior in clinic. Weaning from the medication over 30 day period, under direct medical supervision, is recommended unless a reason for immediate discontinuation exists. If a medication contract is in place, some physicians will allow one infraction without immediate discontinuation, but the contract and clinic policy should be reviewed with patient and consequences of further violations made clear to patient. 3) Consider discontinuation if there has been no improvement in overall function, or a decrease in function. 4) Patient has evidence of unacceptable side effects. 5) Patient's pain has resolved. 6) Patient exhibits "serious non-adherence" or misuse. Per the Guidelines, Chelminski defines "serious substance misuse" as meeting any of the following criteria: (a) cocaine or amphetamines on urine toxicology screen (positive cannabinoid was not considered serious substance abuse); (b) procurement of opioids from more than one provider on a regular basis; (c) diversion of opioids; (d) urine toxicology screen negative for prescribed drugs on at least two occasions (an indicator of possible diversion); & (e) urine toxicology screen positive on at least two occasions for opioids not routinely prescribed. (Chelminski, 2005) 7) Patient requests discontinuing opioids. 8) Consider verifying that patient is in consultation with physician specializing in addiction to consider detoxification if patient continues to violate the medication contract or shows other signs of abuse / addiction. 9) Document the basis for decision to discontinue opioids. Likewise, when making the decision to continue opioids long term, consider the following: Has patient returned to work. Has patient had improved function and decreased pain with the opioids. For the patient of concern, there is no documentation more recent than May 2014. At the May 2014 clinic visit, it is specifically documented that patient's pain is the same, 6/10, with or without

medications. The records refer to monitoring of medications with Patient activity reports and urine drug screens, but these are not supplied in the records for review. No clear reason is specified in the records for use of the combination of Tramadol, Tramadol ER, and Norco. Without more current and complete documentation indicating opioid therapy is effective and appropriately monitored, the Tramadol is not approved as medically necessary.

Gabapentin 300 mg #60: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Anti-epilepsy Drugs Page(s): 16-18.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Pain Interventions and Treatments Page(s): 16-19.

Decision rationale: Per the guidelines, Gabapentin, an anti-epileptic drug, is recommended for treatment of neuropathic pain, as is the class of anti-epilepsy drugs (AED's). These drugs have been most studied for treatment of post herpetic neuralgia and diabetic neuropathy. Because neuropathic pain is often multifactorial with variable symptoms and physical findings, there is a lack of agreement among experts on the best treatment. There is also a lack of quality evidence for any specific treatment for neuropathic pain with most randomized control trials addressing the above mentioned post-herpetic neuralgia and other polyneuropathies, and few randomized control trials for central pain, none for treatment of radicular pain. As there is a lack of good evidence / expert agreement, per the guidelines, the choice of a specific agent for treatment of neuropathic pain and the decision to continue treatment with a specific anti-epileptic drug are generally determined by efficacy of the medication and any adverse reactions experienced. When using anti-epileptic drugs for treatment of neuropathic pain, the guidelines define a "good" response to the use of AEDs...as a 50% reduction in pain and a "moderate" response as a 30% reduction. It has been reported that a 30% reduction in pain is clinically important to patients and a lack of response of this magnitude may be the "trigger" for the following: (1) a switch to a different first-line agent (2) combination therapy if treatment with a single drug agent fails. (Eisenberg, 2007) (Jensen, 2006) Per the guidelines, patient pain levels and functional improvement while taking medications should be documented at follow up appointments. Gabapentin specifically has good evidence to support its use, first-line, in neuropathic pain. (Backonja, 2002) (ICSI, 2007) (Knotkova, 2007) (Eisenberg, 2007) (Attal, 2006) It is FDA-approved for use in post-herpetic neuralgia. In addition to use in neuropathic pain, Gabapentin has evidence to support its use in spinal stenosis, fibromyalgia, spinal cord injury, and some evidence to support its use in post-operative pain to decrease anxiety and need for opioids. For the patient of concern the most recent records available are dated May 2014. Per the records, there is no documentation that patient has had a "good" or "moderate" response to the Gabapentin. The records do not include evidence that the patient has had objective quantifiable documentation of functional improvement with the Gabapentin. Furthermore, it is not clear from the records that patient has neuropathic pain, although radicular pain is indicated in diagnoses. As patient has not achieved recommended level of pain relief and functional improvement with Gabapentin, and as the diagnosis for which patient is taking Gabapentin is not clearly defined, the Gabapentin is therefore not medically necessary.

Klonopin 0.5 mg #90: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Benzodiazepines Page(s): 24. Decision based on Non-MTUS Citation Official Disability Guidelines, Treatment in Worker's Compensation, Work Loss Data Institute, 12th edition, 2014, Pain (Chronic) Chapter(03/26/2014), Benzodiazepines

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Pain Interventions and Treatments Page(s): 24.

Decision rationale: Benzodiazepines are not recommended for long term use. Per the guidelines, benzodiazepines can be used short term, no more than 4 weeks, in chronic pain, and in other indications including sedative/hypnotic, anxiolytic, anti-epileptic, and muscle relaxation. Chronic benzodiazepine use is rarely indicated, and can make symptoms worse over time. Tolerance to the anxiolytic and sedative properties of benzodiazepines develops within first few months of use. Per the records supplied, the patient has been taking Klonopin for several months at current dose. It is unclear in the records if patient has been taking it strictly for psychiatric condition(s), or for multiple reasons, including chronic pain. It is unclear in the records exactly how the Klonopin helps the patient. Regardless, as it is not recommended for long term use for any condition that patient has documented, the request for Klonopin is not medically necessary.

Tramadol ER 200 mg: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 79-80.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Pain Interventions and Treatments Page(s): 79-80, 85, 88-89 AND 93.

Decision rationale: Tramadol is a synthetic opioid that exerts its effect on the central nervous system. The MTUS Guidelines establish criteria for use of opioids, including long term use (6 months or more). When managing patients using long term opioids, the following should be addressed: Re-assess the diagnosis and review previous treatments and whether or not they were helpful. When re-assessing, pain levels and improvement in function should be documented. Pain levels should be documented every visit. Function should be evaluated every 6 months using a validated clinical assessment tool. Adverse effects, including hyperalgesia, should also be addressed each visit. Patient's motivation and attitudes about pain / work / interpersonal relationships can be examined to determine if patient requires psychological evaluation as well. Aberrant / addictive behavior should be addressed if present. Do not decrease dose if effective. Medication for breakthrough pain may be helpful in limiting overall medication. Follow up evaluations are recommended every 1-6 months. To summarize the above, the 4A's of Drug Monitoring (analgesia, activities of daily living, adverse side effects, and aberrant drug-taking Behaviors) have been established. The monitoring of these outcomes over time should affect therapeutic decisions and provide a framework for documentation of the clinical use of these controlled drugs. (Passik, 2000) Several circumstances need to be considered when determining to discontinue opioids: 1) Verify patient has not had failure to improve because of inappropriate

dosing or under-dosing of opioids²) Consider possible reasons for immediate discontinuation including diversion, prescription forgery, illicit drug use, suicide attempt, arrest related to opioids, and aggressive or threatening behavior in clinic. Weaning from the medication over 30 day period, under direct medical supervision, is recommended unless a reason for immediate discontinuation exists. If a medication contract is in place, some physicians will allow one infraction without immediate discontinuation, but the contract and clinic policy should be reviewed with patient and consequences of further violations made clear to patient.³) Consider discontinuation if there has been no improvement in overall function, or a decrease in function.⁴) Patient has evidence of unacceptable side effects.⁵) Patient's pain has resolved.⁶) Patient exhibits "serious non-adherence" or misuse. Per the Guidelines, Chelminski defines "serious substance misuse" as meeting any of the following criteria:(a) cocaine or amphetamines on urine toxicology screen (positive cannabinoid was not considered serious substance abuse); (b) procurement of opioids from more than one provider on a regular basis; (c) diversion of opioids; (d) urine toxicology screen negative for prescribed drugs on at least two occasions (an indicator of possible diversion); & (e) urine toxicology screen positive on at least two occasions for opioids not routinely prescribed. (Chelminski, 2005)⁷) Patient requests discontinuing opioids.⁸) Consider verifying that patient is in consultation with physician specializing in addiction to consider detoxification if patient continues to violate the medication contract or shows other signs of abuse / addiction. 9) Document the basis for decision to discontinue opioids. Likewise, when making the decision to continue opioids long term, consider the following: Has patient returned to work. Has patient had improved function and decreased pain with the opioids. The rationale for Tramadol ER is the same as that for Tramaol and Norco. For the patient of concern, there is no documentation more recent than May 2014. At the May 2014 clinic visit, it is specifically documented that patient's pain is the same, 6/10, with or without medications. The records refer to monitoring of medications with Patient activity reports and urine drug screens, but these are not supplied in the records for review. No clear reason is specified in the records for use of the combination of Tramadol, Tramadol ER, and Norco. Without more current and complete documentation indicating opioid therapy is effective and appropriately monitored, the Tramadol ER is not approved as medically necessary.

Norco 10/325 mg #60: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 79-80.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Pain Interventions and Treatments Page(s): 79-80, 85, 88-89 AND 91.

Decision rationale: The Guidelines establish criteria for use of opioids, including long term use (6 months or more). When managing patients using long term opioids, the following should be addressed: Re-assess the diagnosis and review previous treatments and whether or not they were helpful. When re-assessing, pain levels and improvement in function should be documented. Pain levels should be documented every visit. Function should be evaluated every 6 months using a validated tool. Adverse effects, including hyperalgesia, should also be addressed each visit. Patient's motivation and attitudes about pain / work / interpersonal relationships can be examined to determine if patient requires psychological evaluation as well. Aberrant / addictive

behavior should be addressed if present. Do not decrease dose if effective. Medication for breakthrough pain may be helpful in limiting overall medication. Follow up evaluations are recommended every 1-6 months. To summarize the above, the 4A's of Drug Monitoring (analgesia, activities of daily living, adverse side effects, and aberrant drug-taking Behaviors) have been established. The monitoring of these outcomes over time should affect therapeutic decisions and provide a framework for documentation of the clinical use of these controlled drugs. (Passik, 2000) Several circumstances need to be considered when determining to discontinue opioids: 1) Verify patient has not had failure to improve because of inappropriate dosing or under-dosing of opioids 2) Consider possible reasons for immediate discontinuation including diversion, prescription forgery, illicit drug use, suicide attempt, arrest related to opioids, and aggressive or threatening behavior in clinic. Weaning from the medication over 30 day period, under direct medical supervision, is recommended unless a reason for immediate discontinuation exists. If a medication contract is in place, some physicians will allow one infraction without immediate discontinuation, but the contract and clinic policy should be reviewed with patient and consequences of further violations made clear to patient. 3) Consider discontinuation if there has been no improvement in overall function, or a decrease in function. 4) Patient has evidence of unacceptable side effects. 5) Patient's pain has resolved. 6) Patient exhibits "serious non-adherence." Per the Guidelines, Chelminski defines "serious substance misuse" or non-adherence as meeting any of the following criteria: (a) cocaine or amphetamines on urine toxicology screen (positive cannabinoid was not considered serious substance abuse); (b) procurement of opioids from more than one provider on a regular basis; (c) diversion of opioids; (d) urine toxicology screen negative for prescribed drugs on at least two occasions (an indicator of possible diversion); & (e) urine toxicology screen positive on at least two occasions for opioids not routinely prescribed. (Chelminski, 2005) 7) Patient requests discontinuing opioids. 8) Consider verifying that patient is in consultation with physician specializing in addiction to consider detoxification if patient continues to violate the medication contract or shows other signs of abuse / addiction. 9) Document the basis for decision to discontinue opioids. Likewise, when making the decision to continue opioids long term, consider the following: Has patient returned to work. Has patient had improved function and decreased pain with the opioids. The rationale for Norco is the same as that for Tramadol and Tramadol ER. For the patient of concern, there is no documentation more recent than May 2014. At the May 2014 clinic visit, it is specifically documented that patient's pain is the same, 6/10, with or without medications. The records refer to monitoring of medications with Patient activity reports and urine drug screens, but these are not supplied in the records for review. No clear reason is specified in the records for use of the combination of Tramadol, Tramadol ER, and Norco. Without more current and complete documentation indicating opioid therapy is effective and appropriately monitored, the Norco is not approved as medically necessary.