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| Case Number: | CM14-0043691 | | |
| Date Assigned: | 07/02/2014 | Date of Injury: | 05/29/2005 |
| Decision Date: | 08/21/2014 | UR Denial Date: | 03/21/2014 |
| Priority: | Standard | Application Received: | 04/10/2014 |

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 and 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 05/29/2005. This is a request for medication refill by [REDACTED]. The medical file provided for review does not include any progress reports from the requesting physician. There are multiple AME reports. The most recent AME report from 03/12/2014 by [REDACTED], states the patient has chronic low back and left ankle pain. The patient also has complaints of depression and insomnia. The patient states that the most troublesome pain is her left ankle. The pain is constant. The patient reported taking two opioid pain medications for left ankle, Opana ER 30 mg twice a day and Norco 10 mg x6 per day. She also sees [REDACTED] on a monthly basis for pain management. He has prescribed Opana and Norco. She currently gets chiropractic adjustments and physical therapy. It was noted the patient was also taking Neurontin 800 mg x3 a day. This is a request for Norco 10/325 mg #180, Prilosec 20 mg #30, Xanax 0.5 mg #90, and Opana ER 20 mg #90. These requests were denied by utilization review on 03/21/2014.

IMR ISSUES, DECISIONS AND RATIONALES

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

Norco 10/325 mg #180: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 91.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines on Long-term Opioid use, Opioids, long-term assessment CRITERIA FOR USE OF OPIOIDS Long-term Users of Opioids (6-months or more) 1) Re-assess (a) Has the diagnosis changed? (b) What other medications is the patient taking? Are they effective, producing side effects? (c) What treatments have been attempted since the use of opioids? Have they been effective? For how long? (d) Document pain and functional improvement and compare to baseline. Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function, or improved quality of life. Information from family members or other caregivers should be considered in determining the patient's response to treatment. Pain should be assessed at each visit, and functioning should be measured at 6-month intervals using a numerical scale or validated instrument. (e) Document adverse effects: constipation, nausea, vomiting, headache, dyspepsia, pruritis, dizziness, fatigue, dry mouth, sweating, hyperalgesia, sexual dysfunction, and sedation. (f) Does the patient appear to need a psychological consultation? Issues to examine would include motivation, attitude about pain/work, return-to-work, social life including interpersonal and work-related relationships. (g) Is there indication for a screening instrument for abuse/addiction. See Substance Abuse Screening. 2) Strategy for maintenance (a) Do not attempt to lower the dose if it is working (b) Supplemental doses of break-through medication may be required for incidental pain, end-of dose pain, and pain that occurs with predictable situations. This can be determined by information that the patient provides from a pain diary or evaluation of additional need for supplemental medication. (c) The standard increase in dose is 25 to 50% for mild pain and 50 to 100% for severe pain (Wisconsin) 3) Visit Frequency (a) There is no set visit frequency. This should be adjusted to the patient's need for evaluation of adverse effects, pain status, and appropriate use of medication, with recommended duration between visits from 1 to 6 months. (Washington, 2002) (Colorado, 2002) (Ontario, 2000) (VA/DoD, 2003) (Maddox-AAPM/APS, 1997) (Wisconsin, 2004) (Warfield, 2004) Outcomes measures: It is now suggested that rather than simply focus on pain severity, improvements in a wide range of outcomes should be evaluated, including measures of functioning, appropriate medication use, and side effects. Measures of pain assessment that allow for evaluation of the efficacy of opioids and whether their use should be maintained include the following: current pain; the least reported pain over the period since last assessment; average pain; intensity of pain after taking the opioid; how long it takes for pain relief; and how long pain relief lasts. (Nicholas, 2006) (Ballantyne, 2006) A recent epidemiologic study found that opioid treatment for chronic non-malignant pain did not seem to fulfill any of key outcome goals including pain relief, improved quality of life, and/or improved functional capacity. (Eriksen, 2006) Page 78 of MTUS require Pain Assessment that require current pain; the least reported pain over the period since last assessment; average pain; intensity of pain after taking the opioid; how long it takes for pain relief; and how long pain relief lasts. Furthermore, The 4 A's for ongoing monitoring are required that include analgesia, ADL's, adverse side effects and aberrant drug-seeking behavior.

Decision rationale: This patient presents with chronic low back and left ankle pain. This is a request for refill of Norco 10/325 mg #180 by [REDACTED]. The medical file provided for review does not include any progress reports from the requesting physician. AME report from 03/12/2014 indicates the patient is seeing [REDACTED] on a monthly basis for medication management in which he is prescribing these medications. Page 78 of MTUS requires Pain Assessment that should include, current pain; the least reported pain over the period since last assessment; average pain; intensity of pain after taking the opioid; how long it takes for pain relief; and how long pain relief lasts. Furthermore, The 4 A's for ongoing monitoring are required that include analgesia, activities of daily living, adverse side effects and aberrant drug-seeking behavior. MTUS requires outcome measures, pain assessment and documentation of functional improvement for continued opioid use. In this case, these required items are provided in the medical file. Norco 10/325mg is not medically necessary.

Prilosec 20 mg #30: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Page(s): 68.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms & cardiovascular risk Recommend with precautions as indicated below. 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. Recommendations Patients with no risk factor and no cardiovascular disease: Non-selective NSAIDs OK (e.g, ibuprofen, naproxen, etc.) 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 cardioprotection) and a PPI. If cardiovascular risk is greater than GI risk the suggestion is naproxyn plus low-dose aspirin plus a PPI. (Laine, 2006) (Scholmerich, 2006) (Nielsen, 2006) (Chan, 2004) (Gold, 2007) (Laine, 2007) Cardiovascular disease: A non-pharmacological choice should be the first option in patients with cardiac risk factors. It is then suggested that acetaminophen or aspirin be used for short-term needs. An opioid also remains a short-term alternative for analgesia. Major risk factors (recent MI, or coronary artery surgery, including recent stent placement): If NSAID therapy is necessary, the suggested treatment is naproxyn plus low-dose aspirin plus a PPI. Mild to moderate risk factors: If long-term or high-dose therapy is required, full-dose naproxen (500 mg twice a day) appears to be the preferred choice of NSAID. If naproxyn is ineffective, the suggested treatment is (1) the addition of aspirin to naproxyn plus a PPI, or (2) a low-dose Cox-2 plus ASA. Cardiovascular risk does appear to extend to all non-aspirin NSAIDs, with the highest risk found for the Cox-2 agents. (Johnsen, 2005) (Lanas, 2006) (Antman, 2007) (Laine, 2007) Use with Aspirin for cardio-protective effect: In terms of GI protective effect: The GI protective effect of Cox-2 agents is diminished in patients taking low-dose aspirin and a PPI may be required for those patients with GI risk factors. (Laine, 2007) In terms of the actual cardioprotective effect of aspirin: Traditional NSAIDs (both ibuprofen and naproxen) appear to attenuate the antiplatelet effect of enteric-coated aspirin and should be taken 30 minutes after ASA or 8 hours before. (Antman, 2007) Cox-2 NSAIDs and diclofenac (a traditional NSAID) do not decrease anti-platelet effect. (Laine, 2007) Use of NSAIDs and SSRIs: The concurrent use of SSRIs and NSAIDs is associated with moderate excess relative risk of serious upper GI events when compared to NSAIDs alone. This risk was higher for non-selective NSAIDs when compared to Cox-2 selective agents (adjusted odds ratio of 1.77 and 1.33, respectively). (Helin-Salmivaara, 2007) Treatment of dyspepsia secondary to NSAID therapy: Stop the NSAID, switch to a different NSAID, or consider H2-receptor antagonists or a PPI.

Decision rationale: This patient presents with chronic low back and left ankle pain. The request is for Prilosec 20 mg #30. The MTUS Guidelines page 68 and 69 state, Clinicians should weight the indications for NSAIDs against both GI and cardiovascular risk factors. MTUS recommends

determining risk for GI events before prescribing prophylactic PPI or omeprazole. GI risk factors include: (1) Age is greater than 65, (2) History of peptic ulcer disease and GI bleeding or perforation, (3) Concurrent use of ASA or corticosteroid and/or anticoagulant, (4) High dose/multiple NSAID. The medical file includes no progress reports. AME reports do not provide discussion of gastric irritation, peptic ulcer history, or concurrent use of ASA, etc. The treating physician does not mention why the patient is being prescribed omeprazole and it is unclear if the patient is taking NSAID as the treating physician does not provide a list of current medication. Routine prophylactic use of PPI without documentation of gastric issues is not supported by the guidelines without GI-risk assessment. Prilosec is found to be not medically necessary.

Xanax 0.5 mg #90: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Benzodiazepines Not recommended for long-term use because long-term efficacy is unproven and there is a risk of dependence. Most guidelines limit use to 4 weeks. Their range of action includes sedative/hypnotic, anxiolytic, anticonvulsant, and muscle relaxant. Chronic benzodiazepines are the treatment of choice in very few conditions. Tolerance to hypnotic effects develops rapidly. Tolerance to anxiolytic effects occurs within months and long-term use may actually increase anxiety. A more appropriate treatment for anxiety disorder is an antidepressant. Tolerance to anticonvulsant and muscle relaxant effects occurs within weeks. (Baillargeon, 2003) (Ashton, 2005) Page(s): 24.

Decision rationale: This patient presents with chronic low back and left ankle pain. The treating physician is requesting Xanax 0.5 mg #90. The MTUS Guidelines page 24 state Benzodiazepines are not recommended for long-term use because long-term efficacy is unproven and there is a risk of dependence. Most guidelines limit use to 4 weeks. The request is for Xanax #90. MTUS Guidelines are clear on long-term use of benzodiazepines. It recommends maximum use of 4 weeks due to unproven efficacy and risk of dependence. Xanax is not medically necessary.

Opana ER 20 mg #90: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines on Long-term Opioid use, Opioids, long-term assessment CRITERIA FOR USE OF OPIOIDS Long-term Users of Opioids (6-months or more) 1) Re-assess (a) Has the diagnosis changed? (b) What other medications is the patient taking? Are they effective, producing side effects? (c) What treatments have been attempted since the use of opioids? Have they been effective? For how long? (d) Document pain and functional improvement and compare to baseline. Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function, or improved quality of life. Information from family members or other caregivers should be considered in determining the patient's response to treatment. Pain should be assessed at each visit, and functioning should be measured at 6-month intervals using a numerical scale or validated instrument. (e) Document adverse effects: constipation, nausea, vomiting, headache, dyspepsia, pruritis, dizziness, fatigue, dry mouth, sweating, hyperalgesia, sexual dysfunction, and sedation. (f) Does the patient appear to need a psychological consultation? Issues to examine

would include motivation, attitude about pain/work, return-to-work, social life including interpersonal and work-related relationships. (g) Is there indication for a screening instrument for abuse/addiction. See Substance Abuse Screening. 2) Strategy for maintenance (a) Do not attempt to lower the dose if it is working (b) Supplemental doses of break-through medication may be required for incidental pain, end-of dose pain, and pain that occurs with predictable situations. This can be determined by information that the patient provides from a pain diary or evaluation of additional need for supplemental medication. (c) The standard increase in dose is 25 to 50% for mild pain and 50 to 100% for severe pain (Wisconsin) 3) Visit Frequency (a) There is no set visit frequency. This should be adjusted to the patient's need for evaluation of adverse effects, pain status, and appropriate use of medication, with recommended duration between visits from 1 to 6 months. (Washington, 2002) (Colorado, 2002) (Ontario, 2000) (VA/DoD, 2003) (Maddox-AAPM/APS, 1997) (Wisconsin, 2004) (Warfield, 2004) Outcomes measures: It is now suggested that rather than simply focus on pain severity, improvements in a wide range of outcomes should be evaluated, including measures of functioning, appropriate medication use, and side effects. Measures of pain assessment that allow for evaluation of the efficacy of opioids and whether their use should be maintained include the following: current pain; the least reported pain over the period since last assessment; average pain; intensity of pain after taking the opioid; how long it takes for pain relief; and how long pain relief lasts. (Nicholas, 2006) (Ballantyne, 2006) A recent epidemiologic study found that opioid treatment for chronic non-malignant pain did not seem to fulfill any of key outcome goals including pain relief, improved quality of life, and/or improved functional capacity. (Eriksen, 2006) Page 78 of MTUS require Pain Assessment that require current pain; the least reported pain over the period since last assessment; average pain; intensity of pain after taking the opioid; how long it takes for pain relief; and how long pain relief lasts. Furthermore, The 4 A's for ongoing monitoring are required that include analgesia, ADL's, adverse side effects and aberrant drug-seeking behavior.

Decision rationale: This patient presents with chronic low back and left ankle pain. The request is for Opana ER 20 mg #90. Page 78 of MTUS requires Pain Assessment that should include, current pain; the least reported pain over the period since last assessment; average pain; intensity of pain after taking the opioid; how long it takes for pain relief; and how long pain relief lasts. Furthermore, The 4 A's for ongoing monitoring are required that include analgesia, activities of daily living, adverse side effects and aberrant drug-seeking behavior. In this case, AME report indicates the treating physician provides these medications on a monthly basis. But there is no adequate documentation of this medication's efficacy in terms of pain assessment and functional changes as required by the MTUS. Opana ER is found to be not medically necessary.