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| Case Number: | CM15-0013530 | | |
| Date Assigned: | 02/02/2015 | Date of Injury: | 11/19/2003 |
| Decision Date: | 03/19/2015 | UR Denial Date: | 12/24/2014 |
| Priority: | Standard | Application Received: | 01/23/2015 |

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: North Carolina
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:

This 58 year old male sustained an industrial injury on 11/19/03. He subsequently reports chronic low back pain. The injured worker underwent spinal surgery in 2004. The injured worker's condition is currently being maintained with prescription medications. The UR decision dated 12/24/14 partially-certified 1 Prescription of Opana IR 5MG #60 WITH 1 REFILL, Modified to 1 Prescription of Opana IR 5MG #45 with 0 Refills and 1 Prescription of Exalgo 12MG #30 with 1 Refill, modified to 1 Prescription of Exalgo 12MG #30 with 0 Refills. The decision to modify the above medications was based on CA MTUS guidelines. The UR decision dated 12/24/14 non-certified 1 Basic Metabolic Panel and 1 Hepatic Function Panel. The denial of the 1 Basic Metabolic Panel and 1 Hepatic Function Panel were based on non-MTUS, ODG guidelines.

IMR ISSUES, DECISIONS AND RATIONALES

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

Opana IR 5 mg #60 with 1 refill: Upheld

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

Decision rationale: The California chronic pain medical treatment guidelines section on opioids states for ongoing management: On-Going Management. Actions Should Include:(a) Prescriptions from a single practitioner taken as directed, and all prescriptions from a single pharmacy.(b) The lowest possible dose should be prescribed to improve pain and function.(c) Office: Ongoing review and documentation of pain relief, functional status, appropriate medication use, and side effects. Pain assessment 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. 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. The 4 A's for Ongoing Monitoring: Four domains have been proposed as most relevant for ongoing monitoring of chronic pain patients on opioids: pain relief, side effects, physical and psychosocial functioning, and the occurrence of any potentially aberrant (or non-adherent) drug-related behaviors. These domains have been summarized as the "4 A's" (analgesia, activities of daily living, adverse side effects, and aberrant drug taking behaviors). 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)(d) Home: To aid in pain and functioning assessment, the patient should be requested to keep a pain diary that includes entries such as pain triggers, and incidence of end-of-dose pain. It should be emphasized that using this diary will help in tailoring the opioid dose. This should not be a requirement for pain management.(e) Use of drug screening or inpatient treatment with issues of abuse, addiction, or poor pain control.(f) Documentation of misuse of medications (doctor-shopping, uncontrolled drug escalation, drug diversion).(g) Continuing review of overall situation with regard to nonopioid means of pain control.(h) Consideration of a consultation with a multidisciplinary pain clinic if doses of opioids are required beyond what is usually required for the condition or pain does not improve on opioids in 3 months. Consider a psych consult if there is evidence of depression, anxiety or irritability. Consider an addiction medicine consult if there is evidence of substance misuse. When to Continue Opioids(a) If the patient has returned to work(b) If the patient has improved functioning and pain(Washington, 2002) (Colorado, 2002) (Ontario, 2000) (VA/DoD, 2003) (Maddox-AAPM/APS, 1997) (Wisconsin, 2004) (Warfield, 2004)- Chronic back pain: Appears to be efficacious but limited for short-term pain relief, and long term efficacy is unclear (16 weeks), but also appears limited. Failure to respond to a time limited course of opioids has led to the suggestion of reassessment and consideration of alternative therapy. There is no evidence to recommend one opioid over another. In patients taking opioids for back pain, the prevalence of lifetime substance use disorders has ranged from 36% to 56% (a statistic limited by poor study design). Limited information indicated that up to one-fourth of patients who receive opioids exhibit aberrant medication-taking behavior. (Martell-Annals, 2007) (Chou, 2007)The long-term use of this medication class is not recommended per the California MTUS unless there documented evidence of benefit with measurable outcome measures and improvement in function. The most recent progress reports do not mention the patient's work status. There is no included objective improvement in pain such as VAS scores. There is no mention of objective functional improvement. The patient is noted to need family assistance with activity. For these reasons the criteria set forth above of ongoing and continued used of opioids have not been met. Therefore the request is not certified.

Exalgo 12 mg #30 with 1 refill: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines opioids
Page(s): 76-84.

Decision rationale: The California chronic pain medical treatment guidelines section on opioids states for ongoing management: On-Going Management. Actions Should Include:(a) Prescriptions from a single practitioner taken as directed, and all prescriptions from a single pharmacy.(b) The lowest possible dose should be prescribed to improve pain and function.(c) Office: Ongoing review and documentation of pain relief, functional status, appropriate medication use, and side effects. Pain assessment 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. 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. The 4 A's for Ongoing Monitoring: Four domains have been proposed as most relevant for ongoing monitoring of chronic pain patients on opioids: pain relief, side effects, physical and psychosocial functioning, and the occurrence of any potentially aberrant (or nonadherent) drug-related behaviors. These domains have been summarized as the "4 A's" (analgesia, activities of daily living, adverse side effects, and aberrant drug taking behaviors). 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)(d) Home: To aid in pain and functioning assessment, the patient should be requested to keep a pain diary that includes entries such as pain triggers, and incidence of end-of-dose pain. It should be emphasized that using this diary will help in tailoring the opioid dose. This should not be a requirement for pain management.(e) Use of drug screening or inpatient treatment with issues of abuse, addiction, or poor pain control.(f) Documentation of misuse of medications (doctor-shopping, uncontrolled drug escalation, drug diversion).(g) Continuing review of overall situation with regard to nonopioid means of pain control.(h) Consideration of a consultation with a multidisciplinary pain clinic if doses of opioids are required beyond what is usually required for the condition or pain does not improve on opioids in 3 months. Consider a psych consult if there is evidence of depression, anxiety or irritability. Consider an addiction medicine consult if there is evidence of substance misuse. When to Continue Opioids(a) If the patient has returned to work(b) If the patient has improved functioning and pain(Washington, 2002) (Colorado, 2002) (Ontario, 2000) (VA/DoD, 2003) (Maddox-AAPM/APS, 1997) (Wisconsin, 2004) (Warfield, 2004)- Chronic back pain: Appears to be efficacious but limited for short-term pain relief, and long term efficacy is unclear (16 weeks), but also appears limited. Failure to respond to a time limited course of opioids has led to the suggestion of reassessment and consideration of alternative therapy. There is no evidence to recommend one opioid over another. In patients taking opioids for back pain, the prevalence of lifetime substance use disorders has ranged from 36% to 56% (a

statistic limited by poor study design). Limited information indicated that up to one-fourth of patients who receive opioids exhibit aberrant medication-taking behavior. (Martell-Annals, 2007) (Chou, 2007) The long-term use of this medication class is not recommended per the California MTUS unless there documented evidence of benefit with measurable outcome measures and improvement in function. The most recent progress reports do not mention the patient's work status. There is no included objective improvement in pain such as VAS scores. There is no mention of objective functional improvement. The patient is noted to need family assistance with activity. For these reasons the criteria set forth above of ongoing and continued used of opioids have not been met. Therefore the request is not certified.

One (1) basic metabolic panel: Overturned

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 Up-To-Date Medical Guidelines

Decision rationale: The California MTUS, ACOEM and the ODG do not specifically address the requested services. Per the Up to Date Guidelines, the following lab tests are indicated for specific conditions. Basic metabolic panels tests are indicated in the evaluation of potential kidney disorders and chronic medication side effects for medications that are processed through the kidney. This patient is on medications that are renally processed and therefore the request is warranted.

One (1) hepatic function panel: Overturned

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 Up-To-Date Medical Guidelines

Decision rationale: The California MTUS, ACOEM and the ODG do not specifically address the requested services. Per the Up to Date Guidelines, the following lab tests are indicated for specific conditions. Hepatic function tests are indicated in the evaluation of potential liver disorders and chronic medication side effects for medications that are processed through the liver. The patient is on medication that is processed through the liver and thus the request is certified.