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| <b>Case Number:</b>   | CM15-0113538 |                              |            |
| <b>Date Assigned:</b> | 06/19/2015   | <b>Date of Injury:</b>       | 07/03/2004 |
| <b>Decision Date:</b> | 09/23/2015   | <b>UR Denial Date:</b>       | 05/21/2015 |
| <b>Priority:</b>      | Standard     | <b>Application Received:</b> | 06/12/2015 |

### 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: California

Certification(s)/Specialty: Physical Medicine & Rehabilitation

### 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 54 year old male, who sustained an industrial injury on 7/3/04. The injured worker has complaints of neck pain that radiates down right upper extremity bilateral upper extremities and is aggravated by activity and walking. The injured worker has complaints of low back pain that radiates down the bilateral lower extremities right greater than left and is accompanied by tingling frequently in the bilateral lower extremities to the level of the foot and muscle weakness frequently in the bilateral lower extremities and is aggravated by activity, standing and walking. The doc noted that the injured worker reports gastroesophageal reflux disease related to medications associated with gastrointestinal upset. The cervical examination revealed tenderness noted upon palpation at the bilateral paravertebral C4-7 area and range of motion of the cervical spine was slightly limited due to pain and pain was significantly increased with flexion and extension. Lumbar examination revealed spasm noted L4-S1 (sacroiliac) and tenderness noted upon palpation in the bilateral paravertebral area L3-S1 (sacroiliac) and range of motion was moderately limited secondary to pain. The diagnoses have included cervical radiculopathy; status post cervical spinal fusion; lumbar radiculopathy; status post fusion, lumbar spine; gastritis and gastroesophageal reflux disease. Treatment to date has included magnetic resonance imaging (MRI) of the lumbar spine dated 6/26/14 showed multilevel degenerative changes of the lumbar spine, foraminal narrowing appears most notable on the right at L3-4 with a right far lateral disc protrusion which abuts the inferior exiting right L3 nerve root, correlate for right L3 radicular symptoms; injections; omeprazole; robaxin; naloxone and morphine. The request was for omeprazole DR 20mg (for gastroesophageal reflux disease) #60; robaxin 750mg

#90; naloxone HCL 0.4mg (Evzio) pre filled syringe x 2; naloxone dispense #1 emergency kit; morphine ER 30mg #90 and morphine IR 15mg #60.

### **IMR ISSUES, DECISIONS AND RATIONALES**

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

**Omeprazole DR 20mg (for GERD) #60:** Overturned

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms & cardiovascular risk Page(s): 68.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines NSAIDs, GI symptoms, and cardiovascular risks Page(s): 60-69.

**Decision rationale:** The patient was injured on 07/03/04 and presents with neck pain and low back pain. The request is for OMEPRAZOLE DR 20 MG (FOR GERD) #60. The RFA is dated 05/13/15 and the patient is not currently working. The patient has been taking this medication as early as 11/24/14. MTUS Guidelines, NSAIDs, page 60 and 69 state that Omeprazole is recommended with precaution for patients at risk for gastrointestinal events: 1. Age 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. MTUS page 69 states, NSAIDs, GI symptoms, and cardiovascular risks: Treatment of dyspepsia secondary to NSAID therapy: Stop the NSAID, switch to a different NSAID, or consider H2 receptor antagonist or a PPI. The patient is diagnosed with cervical radiculopathy, status post cervical spinal fusion, lumbar spine radiculopathy, status post fusion of lumbar spine, gastritis, and gastroesophageal reflux disease. The 04/27/15 report states that the patient reports GERD related, medication associated gastrointestinal upset. As of 04/27/15, the patient is taking Gabapentin, MS Contin, MS IR, Robaxin, and Naloxone. Given that the patient is diagnosed with gastritis and GERD, the requested Omeprazole appears reasonable. Use of PPIs is indicated for GERD and other stomach issues, as this patient is diagnosed with. Therefore, the request IS medically necessary.

**Robaxin 750mg #90:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Muscle relaxants (for pain) Page(s): 63.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines muscle relaxants (for pain) Page(s): 63-66.

**Decision rationale:** The patient was injured on 07/03/04 and presents with neck pain and low back pain. The request is for ROBAXIN 750 MG #90. The RFA is dated 05/13/15 and the patient is not currently working. The patient has been taking this medication as early as 02/16/15. MTUS Guidelines, Muscle Relaxants, pages 63-66 for muscle relaxants (for pain) states: Recommend non-sedating muscle relaxants with caution as a second-line option for short- term treatment of acute exacerbations in patients with chronic low back pain. MTUS Guidelines, Antispasmodics, pages 63-66, under antispasmodics for methocarbamol (Robaxin,

Relaxin, generic available) states: The mechanism of action is unknown, but appears to be related to central nervous system depressant effects with related sedative properties. The patient is diagnosed with cervical radiculopathy, status post cervical spinal fusion, lumbar spine radiculopathy, status post fusion of lumbar spine, gastritis, and gastroesophageal reflux disease. There is tenderness upon palpation at the bilateral paravertebral C4-7 area, a decreased cervical spine range of motion, spasm noted L4-S1 (sacroiliac), and tenderness noted upon palpation in the bilateral paravertebral area L3-S1 (sacroiliac) and range of motion was moderately limited secondary to pain. Robaxin has sedating properties, which does not appear to be in accordance with MTUS guidelines. Furthermore, MTUS recommends non-sedating muscle relaxants for a short period of time. In this case, the patient has been taking Robaxin since 02/16/15 which does not indicate short-term use of this medication. Therefore, the requested Robaxin IS NOT medically necessary.

**Naloxone HCL 0.4mg (Evzio) pre filled syringe x 2: Upheld**

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 75. Decision based on Non-MTUS Citation Official Disability Guidelines, Pain Chapter.

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

**Decision rationale:** The patient was injured on 07/03/04 and presents with neck pain and low back pain. The request is for NALAXONE HCL 0.4 mg (EVZIO) PRE FILLED SYRINGE x 2. The RFA is dated 05/13/15 and the patient is not currently working. The patient has been taking this medication as early as 04/27/15. ODG Guidelines, Pain Chapter, under Naloxone states, recommended in hospital-based and emergency department settings as currently indicated to address opioid overdose cases. Recommended on a case-by-case basis for outpatient, pre-hospital use, to treat opioid overdose for patients who are prescribed opioids for acute and chronic pain (malignant and non-malignant) due to documented pathology. (See Criteria Below) There is little evidence-based research to guide who should receive Naloxone in an outpatient medically prescribed setting. Guidance is partially dependent on risk factors for overdose. When used in these pre-hospital settings, the patient will still require emergency and perhaps long term care. Criteria includes: complete documentation of history including prior drug and alcohol use, evidence that education has been provided to the patient; evidence that the patient has been counseled about drug use; evidence that the patient has been given information about the risk of overdose, etc. The patient is diagnosed with cervical radiculopathy, status post cervical spinal fusion, lumbar spine radiculopathy, status post fusion of lumbar spine, gastritis, and gastroesophageal reflux disease. The 04/27/15 report states that the patient may use these syringes for suspected opioid overdose. Although the patient has been taking Morphine since 11/24/15, the treater does not provide documentation or discussion explaining why the patient is at risk for an opioid overdose, and if at risk, why opiate is being prescribed. There is currently no support for the use of Naloxone for outpatient setting. The request IS NOT medically necessary.

**Naloxone dispense #1 emergency kit:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 75. Decision based on Non-MTUS Citation Official Disability Guidelines, Pain Chapter.

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

**Decision rationale:** The patient was injured on 07/03/04 and presents with neck pain and low back pain. The request is for NALOXONE DISPENSE #1 EMERGENCY KIT. The RFA is dated 05/13/15 and the patient is not currently working. ODG Guidelines, Pain Chapter, under Naloxone states, recommended in hospital-based and emergency department settings as currently indicated to address opioid overdose cases. Recommended on a case-by-case basis for outpatient, pre-hospital use, to treat opioid overdose for patients who are prescribed opioids for acute and chronic pain (malignant and non-malignant) due to documented pathology. (See Criteria Below) There is little evidence-based research to guide who should receive Naloxone in an outpatient medically prescribed setting. Guidance is partially dependent on risk factors for overdose. When used in these pre-hospital settings, the patient will still require emergency and perhaps long term care. Criteria includes: complete documentation of history including prior drug and alcohol use, evidence that education has been provided to the patient; evidence that the patient has been counseled about drug use; evidence that the patient has been given information about the risk of overdose, etc. The patient is diagnosed with cervical radiculopathy, status post cervical spinal fusion, and lumbar spine radiculopathy, status post fusion of lumbar spine, gastritis, and gastroesophageal reflux disease. The 04/27/15 report states that the patient may use these syringes for suspected opioid overdose. Although the patient has been taking Morphine since 11/24/15, the treater does not provide documentation or discussion explaining why the patient is at risk for an opioid overdose, and if at risk, why opiate is being prescribed. If opiate overdose is a significant risk, the patient should be tapered off of opiates and perhaps placed on Suboxone or Butrans. There is no guidelines discussion for the use of Emergency Kit and the treater does not provide literature support either. Furthermore, the Emergency Kit is used by trained medical personnel in emergency departments and ambulances. Therefore, the request IS NOT medically necessary.

**Morphine ER 30mg #90:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 78.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Medications for chronic pain CRITERIA FOR USE OF OPIOIDS Page(s): 60, 61, 76-78, 88, 89.

**Decision rationale:** The patient was injured on 07/03/04 and presents with neck pain and low back pain. The request is for MORPHINE ER 30 MG #90. The RFA is dated 05/13/15 and the patient is not currently working. The patient has been taking this medication as early as 11/24/14.

There are three treatment reports provided from 11/24/14, 02/16/15, and 04/27/15. MTUS Guidelines pages 88 and 89 under Criteria For Use of Opioids (Long-Term Users of Opioids): "Pain should be assessed at each visit, and functioning should be measured at 6-month intervals using a numerical scale or validated instrument." MTUS page 78 under Criteria For Use of Opioids - Therapeutic Trial of Opioids, also requires documentation of the 4As, analgesia, ADLs, adverse side effects, and adverse behavior, as well as "pain assessment" or outcome measures that include current pain, average pain, least pain, intensity of pain after taking the opioid, time it takes for medication to work and duration of pain relief. MTUS Guidelines, under Opioids For Chronic Pain, pages 80 and 81 state the following regarding chronic low 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. Long-term use of opiates may be indicated for nociceptive pain as it is recommended as the standard of care for treatment of moderate or severe nociceptive pain (defined as pain that is presumed to be maintained by continual injury with the most common example being pain secondary to cancer). However, this patient does not present with pain that is "presumed to be maintained by continual injury." The 02/16/15 report states that the patient rates his pain as a 7/10 with medications and a 9/10 without medications. The 04/27/15 report states that the patient rates his pain as an 8/10 with medications and a 1/10 with medications. A CURES report was obtained Nov 24, 2014 and reviewed with the patient. There were no inconsistencies noted. The patient had a urine drug screen on 11/24/14 and was consistent with his prescribed medications. Although the treater discusses pain scales, not all of the 4 A's are addressed as required by MTUS Guidelines. There are no examples of ADLs which demonstrate medication efficacy nor are there any discussions on side effects or aberrant behavior the patient may have. No validated instruments are used either and no outcome measures are provided as required by MTUS Guidelines. The treating physician does not provide adequate documentation that is required by MTUS Guidelines for continued opiate use. The request IS NOT medically necessary.

**Morphine IR 15mg #60:** Upheld

**Claims Administrator guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 78.

**MAXIMUS guideline:** Decision based on MTUS Chronic Pain Treatment Guidelines Medications for chronic pain CRITERIA FOR USE OF OPIOIDS Page(s): 60, 61, 76-78, 88, 89.

**Decision rationale:** The patient was injured on 07/03/04 and presents with neck pain and low back pain. The request is for MORPHINE IR 15 MG #60. The RFA is dated 05/13/15 and the patient is not currently working. The patient has been taking this medication as early as 11/24/14. There are three treatment reports provided from 11/24/14, 02/16/15, and 04/27/15. MTUS Guidelines pages 88 and 89 under Criteria for Use of Opioids (Long-Term Users of Opioids): "Pain should be assessed at each visit, and functioning should be measured at 6-month intervals using a numerical scale or validated instrument." MTUS page 78 under Criteria For Use of Opioids - Therapeutic Trial of Opioids, also requires documentation of the 4As, analgesia, ADLs, adverse side effects, and adverse behavior, as well as "pain assessment" or outcome measures that include current pain, average pain, least pain, intensity of pain after taking the opioid, time it takes for medication to work and duration of pain relief. MTUS

Guidelines, under Opioids For Chronic Pain, pages 80 and 81 state the following regarding chronic low 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. Long-term use of opiates may be indicated for nociceptive pain as it is recommended as the standard of care for treatment of moderate or severe nociceptive pain (defined as pain that is presumed to be maintained by continual injury with the most common example being pain secondary to cancer). However, this patient does not present with pain that is "presumed to be maintained by continual injury." The 02/16/15 report states that the patient rates his pain as a 7/10 with medications and a 9/10 without medications. The 04/27/15 report states that the patient rates his pain as an 8/10 with medications and a 1/10 with medications. A CURES report was obtained Nov 24, 2014 and reviewed with the patient. There were no inconsistencies noted. The patient had a urine drug screen on 11/24/14 and was consistent with his prescribed medications. Although the treater discusses pain scales, not all of the 4 A's are addressed as required by MTUS Guidelines. There are no examples of ADLs which demonstrate medication efficacy nor are there any discussions on side effects or aberrant behavior the patient may have. No validated instruments are used either and no outcome measures are provided as required by MTUS Guidelines. The treating physician does not provide adequate documentation that is required by MTUS Guidelines for continued opiate use. The request IS NOT medically necessary.