

Case Number:	CM14-0051206		
Date Assigned:	07/07/2014	Date of Injury:	01/13/2010
Decision Date:	11/05/2014	UR Denial Date:	04/10/2014
Priority:	Standard	Application Received:	04/18/2014

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 Neurology, has a subspecialty in Neuromuscular Medicine and is licensed to practice in New Jersey. 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 man who sustained a work-related injury on January 15, 2010. Subsequently he developed chronic low back pain. The pain was described as throbbing, shooting stabbing and aching pain. The patient has minimal ability to function and his pain was rated as severe. His physical examination demonstrated the lumbar tenderness with reduced range of motion and difficulty with ambulating. The patient was diagnosed with the status post L4-L5 and L5-S1 fusion, left lower extremity radiculitis and facet disease. The patient was treated with Norco, Cymbalta, Percocet and fentanyl. There is no documentation of the efficacy of these drugs. The provider requested authorization to intrathecal opioid administration.

IMR ISSUES, DECISIONS AND RATIONALES

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

1 Trial Of Intrathecal Opiates with 4 to 5 Hours Postprocedure Recovery Room Monitoring: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines, Pain (Chronic)

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Implantable drug-delivery systems Page(s): 53.

Decision rationale: According to MTUS guidelines, < Indications for Implantable drug-delivery systems: Implantable infusion pumps are considered medically necessary when used to deliver drugs for the treatment of: o Primary liver cancer (intrahepatic artery injection of chemotherapeutic agents);o Metastatic colorectal cancer where metastases are limited to the liver (intrahepatic artery injection of chemotherapeutic agents);o Head/neck cancers (intra-arterial injection of chemotherapeutic agents);o Severe, refractory spasticity of cerebral or spinal cord origin in patients who are unresponsive to or cannot tolerate oral baclofen (Lioresal) therapy (intrathecal injection of baclofen) Permanently implanted intrathecal (intraspinal) infusion pumps for the administration of opiates or non-opiate analgesics, in the treatment of chronic intractable pain, are considered medically necessary when: Used for the treatment of malignant (cancerous) pain and all of the following criteria are met: 1. Strong opioids or other analgesics in adequate doses, with fixed schedule (not PRN) dosing, have failed to relieve pain or intolerable side effects to systemic opioids or other analgesics have developed; and 2. Life expectancy is greater than 3 months (less invasive techniques such as external infusion pumps provide comparable pain relief in the short term and are consistent with standard of care); and 3. Tumor encroachment on the thecal sac has been ruled out by appropriate testing; and 4. No contraindications to implantation exist such as sepsis or coagulopathy; and 5. A temporary trial of spinal (epidural or intrathecal) opiates has been successful prior to permanent implantation as defined by a 50% reduction in pain. A temporary trial of intrathecal (intraspinal) infusion pumps is considered medically necessary only when criteria 1-4 above are met.- Used for the treatment of non-malignant (non-cancerous) pain with a duration of greater than 6 months and all of the following criteria are met: Documentation, in the medical record, of the failure of 6 months of other conservative treatment modalities (pharmacologic, surgical, psychological or physical), if appropriate and not contraindicated; and 2. Intractable pain secondary to a disease state with objective documentation of pathology in the medical record; and 3. Further surgical intervention or other treatment is not indicated or likely to be effective; and 4. Psychological evaluation has been obtained and evaluation states that the pain is not primarily psychological in origin and that benefit would occur with implantation despite any psychiatric comorbidity; 5. No contraindications to implantation exist such as sepsis or coagulopathy; and 6. A temporary trial of spinal (epidural or intrathecal) opiates has been successful prior to permanent implantation as defined by at least a 50% to 70% reduction in pain and documentation in the medical record of functional improvement and associated reduction in oral pain medication use. A temporary trial of intrathecal (intraspinal) infusion pumps is considered medically necessary only when criteria 1-5 above are met>. There is no documentation that the patient is suffering from pain related to cancer. There is no documentation of failure of 6 months of conservative treatments. There is no documentation of psychological evaluation. Therefore, the 1 Trial Of Intrathecal Opiates with 4 to 5 Hours Postprocedure Recovery Room Monitoring is not medically necessary.

15 Fentanyl patches 75 MCG with 1 refill: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids, criteria for use; Fentanyl.

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 75-81.

Decision rationale: According to MTUS guidelines, long acting opioids are highly potent form of opiate analgesic. Establishing a treatment plan, looking for alternatives to treatment, assessing the efficacy of the drug, using the lowest possible dose and considering multiple disciplinary approach if high dose is needed or if the pain does not improve after 3 months of treatment. Fentanyl is indicated for the management of moderate to severe chronic pain that requires continuous around the clock Opioid therapy and that is resistant to alternative therapies. There is no documentation in the patient records supporting the efficacy of Fentanyl or other Opioids. Based on the above, 15 Fentanyl patches 75 MCG with 1 refill is not medically necessary.

180 Oxycontin 5mg with 1 refill: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines. Decision based on Non-MTUS Citation Official Disability Guidelines, Pain (Chronic)

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 75-81.

Decision rationale: According to MTUS guidelines, Oxycodone as well as other short acting opioids are indicated for intermittent or breakthrough pain (page 75). It can be used in acute post operative pain. It is not recommended for chronic pain of longterm use as prescribed in this case. In addition and according to MTUS guidelines, ongoing use of opioids should follow specific rules: <(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>Based on the patient chart, there is no clear rationale behind the use of 2 opioids. Additionally, there is no clear documentation of pain and functional improvement with Oxycontin. There is no documentation of pain or functional improvement from previous use of Oxycodone. There is no documentation of breakthrough pain. Therefore, the prescription of 180 Oxycontin 5mg with 1 refill is not medically necessary at this time.

180 Norco 10/325mg with 1 refill: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines. Decision based on Non-MTUS Citation Official Disability Guidelines, Pain (Chronic)

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Criteria for use of opioids Page(s): 76-79.

Decision rationale: According to MTUS guidelines, Norco (Hydrocodone/Acetaminophen) is a synthetic opioid indicated for the pain management but not recommended as a first line oral analgesic. In addition and according to MTUS guidelines, ongoing use of opioids should follow specific rules:<(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. 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>According to the patient file, there is no objective documentation of pain and functional improvement to justify continuous use of Norco. Norco was used without documentation of functional improvement or evidence of return to work or improvement of activity of daily living. Therefore, the prescription of 180 Norco 10/325mg with 1 refill is not medically necessary.

60 Cymbalta 60mg with 1 refill: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Cymbalta (duloxetine). Decision based on Non-MTUS Citation Official Disability Guidelines, Pain (Chronic)

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines SPECIFIC ANTIDEPRESSANTS Page(s): 15-16.

Decision rationale: Cymbalta is FDA approved for diabetic neuropathy. It is also used off label for neuropathic pain and radiculopathy. There is no high quality evidence to support its use for lumbar radiculopathy. There is no clear evidence that the patient have diabetic neuropathy. A prolonged use of cymbalta in this patient cannot be warranted without continuous monitoring of its efficacy, the drug was used off label. Therefore, the request of 60 Cymbalta 60mg with 1 refill is not medically necessary.