

Case Number:	CM14-0136492		
Date Assigned:	09/03/2014	Date of Injury:	07/31/2000
Decision Date:	11/03/2014	UR Denial Date:	07/30/2014
Priority:	Standard	Application Received:	08/25/2014

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 Internal Medicine 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 an injured worker with the diagnoses of chronic low back pain, spondylolisthesis, radiculopathy, myofascial pain spasm, cervicalgia due to spondylosis with radiculopathy, hypertension, anemia history, gastroesophageal reflux disease, and right shoulder pain tendinitis. Date of injury was 07-31-2000. Pain management reevaluation report dated 7/15/2014 documented subjective complaints of low back, leg, neck and shoulder and arm pain. At this point her low back pain is the worst area. She continues to use a cane for ambulation. Her back and neck pain is constant. Shoulder pain is intermittent. Nucynta ER and Nucynta IR are helping control her pain level. The medications are helping her to function. Magnetic resonance imaging (MRI) of lumbar spine showed less of intervertebral disc height and disc desiccation changes are seen at the L4-5 and L5-S1 levels with straightening of the normal lumbar spine lordosis. No prevertebral soft tissue abnormality was noted. Grade 1 anterolisthesis seen at the L4-5 level measuring 3 mm. No spondylolysis. The rest of the levels demonstrate normal alignment. At the L5-S1 level, annular concentric and broad-based 3 mm disc protrusion is seen, flattening and abutting the anterior portion of the thecal sac with mild bilateral lateral spinal and neural foraminal stenosis. There is no extrusion or sequestration of the disc material. At the L4-5 level, annular concentric and broad-based 4mm disc protrusion is seen, flattening and abutting the anterior portion of the thecal sac with mild bilateral facet arthropathy changes. No central spinal stenosis, but there is mild to moderate bilateral lateral spinal and neural foraminal stenosis demonstrated. An MRI of the cervical spine showed minimal to mild central canal stenosis and minimal to mild left neural foraminal stenosis is seen at C5-6 secondary to a 4.0 mm left paracentral broad-based disc protrusion. Straightening of the normal lordotic curvature, this may be related to patient positioning and/or muscle spasms. Medications included Celebrex, Flector patch, Lyrica, Nucynta 50 mg twice a day as needed for pain, Nucynta ER 100 mg every twelve

hours as needed for pain, Subsys Fentanyl sublingual spray. On physical examination, the patient had neck and back pain. No new neurological deficits noted on exam. Diagnoses included chronic low back pain, spondylolisthesis, radiculopathy, myofascial pain spasm, cervicgia due to spondylosis with radiculopathy, hypertension, anemia history, GERD gastroesophageal reflux disease, and right shoulder pain tendinitis. Urine drug screen dated 11/19/13 was consistent. Treatment plan included Flector patches daily, Nucynta IR 50 mg twice a day as needed, and Nucynta ER 100 mg twice a day as needed.

IMR ISSUES, DECISIONS AND RATIONALES

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

Flector patches #30: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Topical Analgesics; NSAIDs (non-steroidal anti-inflammatory drugs Page(s): 111-113; 67-73.

Decision rationale: The MTUS Chronic Pain Medical Treatment Guidelines state that topical analgesics are largely experimental in use with few randomized controlled trials to determine efficacy or safety. There is little to no research to support the use of many of these agents. The efficacy in clinical trials of topical NSAIDs has been inconsistent and most studies are small and of short duration. Topical NSAIDs have been shown in meta-analysis to be either not superior to placebo after two weeks, or with a diminishing effect after two weeks. For osteoarthritis of the knee, topical NSAID effect appeared to diminish over time. There are no long-term studies of their effectiveness or safety for chronic musculoskeletal pain. There is little evidence to utilize topical NSAIDs for treatment of osteoarthritis of the spine, hip or shoulder. Topical NSAIDs are not recommended for neuropathic pain as there is no evidence to support use. All non-steroidal anti-inflammatory drugs (NSAIDs) have the U.S. Boxed Warning for associated risk of adverse cardiovascular events, including myocardial infarction, stroke, and new onset or worsening of pre-existing hypertension. NSAIDs can cause ulcers and bleeding in the stomach and intestines at any time during treatment (FDA Medication Guide). Use of NSAIDs may compromise renal function. FDA medication guide recommends lab monitoring of a CBC and chemistry profile (including liver and renal function tests). Routine blood pressure monitoring is recommended. It is generally recommended that the lowest effective dose be used for all NSAIDs for the shortest duration of time. Medical records document that the patient has a history of hypertension. The MTUS guidelines warn against the use of NSAIDs in patients with hypertension. The medical records document the long-term use of NSAIDs, which is not recommended by MTUS guidelines. Medical records do not document recent laboratory test results, which are recommended by MTUS for the use of NSAIDs. Medical records document that the patient has been prescribed Celebrex which is a NSAID. Flector patch is also an NSAID and would be redundant. Medical records and MTUS guidelines do not support the use of Flector Patch. Therefore, the request for Flector patches #30 is not medically necessary.

Nucynta IR 50mg #60: Overturned

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): 74-96.

Decision rationale: The MTUS Chronic Pain Medical Treatment Guidelines present the strategy for maintenance for long-term users of opioids. "Do not attempt to lower the dose if it is working." Supplemental doses of break-through medication may be required for incidental pain, end-of dose pain, and pain that occurs with predictable situations. The standard increase in dose is 25 to 50% for mild pain and 50 to 100% for severe pain. Actual maximum safe dose will be patient-specific and dependent on current and previous opioid exposure, as well as on whether the patient is using such medications chronically. When using single-agent opioid preparations, the dose should be slowly escalated until adequate pain relief is seen or side effects preclude further escalation. Medical records document stable use of opioid medications with regular office visits. The medical records document objective evidence of significant pathology. Urine drug test was consistent. Analgesia and activities of daily living have benefited. The patient reported benefits from opioid medications with improvement of function and pain management. Medical records support the maintenance of the patient's pain medication regimen. Medical records support the maintenance of the Nucynta IR 50 mg prescription. Therefore, the request for Nucynta IR 50mg #60 is medically necessary.

Nucynta ER 100mg #60: Overturned

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): 74-96.

Decision rationale: The MTUS Chronic Pain Medical Treatment Guidelines present the strategy for maintenance for long-term users of opioids. "Do not attempt to lower the dose if it is working." Supplemental doses of break-through medication may be required for incidental pain, end-of dose pain, and pain that occurs with predictable situations. The standard increase in dose is 25 to 50% for mild pain and 50 to 100% for severe pain. Actual maximum safe dose will be patient-specific and dependent on current and previous opioid exposure, as well as on whether the patient is using such medications chronically. When using single-agent opioid preparations, the dose should be slowly escalated until adequate pain relief is seen or side effects preclude further escalation. Medical records document stable use of opioid medications with regular office visits. The medical records document objective evidence of significant pathology. Urine drug test was consistent. Analgesia and activities of daily living have benefited. The patient reported benefits from opioid medications with improvement of function and pain management. Medical records support the maintenance of the patient's pain medication regimen. Medical records support the maintenance of the Nucynta ER 100 mg prescription. Therefore, the request for Nucynta ER 100 mg #60 is medically necessary.

