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| Case Number: | CM14-0183789 | | |
| Date Assigned: | 11/10/2014 | Date of Injury: | 08/31/2004 |
| Decision Date: | 12/15/2014 | UR Denial Date: | 10/13/2014 |
| Priority: | Standard | Application Received: | 11/04/2014 |

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 determinatio

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 44-year-old man who sustained a work related injury on March 31, 2004. Subsequently, he developed chronic low back pain. On March 25, 2011, the patient underwent a disc replacement surgery. Other treatments have included: physical therapy, SCS (failed), activity modification, lumbar ESI, and medication. The patient underwent a trial of intrathecal opioid, Dilaudid, on July 22, 2013. The pain was greatly improved, but he had side effects of diaphoresis and pruritus. According to a progress report dated October 7, 2014, the patient reported ongoing significant low back pain and throbbing and aching pain in the right leg with tingling and numbness radiating to his right foot. The pain follows a line, anterior lateral thigh and leg to the top of the right foot. He described the pain as electrical and pounding. The patient failed a spinal cord stimulator trial. Examination of the lumbar spine revealed no tenderness of the spinous process, the transverse process, the sacral promontory, the sacrum, or the coccyx. Bony palpation of the right hip. No tenderness of the iliac crest, the PSIS, the sciatic notch, the SI joint, or the greater trochanter. Soft tissue palpation on the right: no tenderness of the gluteus maximus, the gluteus medius, the sciatic nerve, or the piriformis and tenderness of the paraspinal region at L4 and the iliolumbar region. Soft tissue palpation on the left: no tenderness of the gluteus maximus, the gluteus medius, the sciatic nerve, or the piriformis and tenderness of the paraspinal region at L4. Active range of motion: flexion normal, extension normal, lateral flexion normal rotation normal, and pain with motion. L5 Motor strength on the left: ankle dorsiflexion tibialis anterior 4/5 and great toe extension extensor hallucis longus 4/5. S1 motor strength on the left: plantar flexion gastrocnemius 4/5. Valsalva's tested negative. Ankle reflex right diminished. Ankle reflex left normal. Sensation on the right: decreased sensation on the lateral leg and dorsum of the foot and decreased sensation on the sole of the foot and the posterior leg. Seated straight leg raising test was positive. The patient was diagnosed with lumbar sprain,

inflammatory neuropathy, and degeneration of intervertebral disc, lumbar post-laminectomy syndrome, disorder of trunk, displacement of lumbar intervertebral disc without myelopathy, and disorder of back. The provider requested authorization for Trial of intrathecal opiates using prialt.

IMR ISSUES, DECISIONS AND RATIONALES

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

Trial of intrathecal opiates using prialt: Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 55.

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; and 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 has a formal psychiatric evaluation for possible susceptibility for Prilat. The latter may cause psychosis. Therefore, the Trial of intrathecal opiates using prialt is not medically necessary.