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| Case Number: | CM14-0212389 | | |
| Date Assigned: | 01/02/2015 | Date of Injury: | 01/07/2004 |
| Decision Date: | 02/23/2015 | UR Denial Date: | 12/06/2014 |
| Priority: | Standard | Application Received: | 12/18/2014 |

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. 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: Florida

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:

The patient is a 50-year-old male who sustained a work related injury on 1/7/2004. He has a diagnosis of chronic back pain secondary to lumbosacral degenerative disc disease. He had an intrathecal drug delivery system placed in 2008, and he has been following up routinely for pump refills and maintenance since. His current delivery system's battery is running out of life, and therefore replacement has been requested. An initial request was declined. An appeal was subsequently requested on 12/5/2014. A utilization review physician has again non-certified the request citing as his rationale that based on the recommendations of the guidelines (he cites MTUS) the intrathecal pain pump is not medically warranted. He also makes note that the patient is still taking many of the same medications that he was taking prior to placement of the pain pump. An independent medical review was requested to determine the medical necessity of this request.

IMR ISSUES, DECISIONS AND RATIONALES

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

1 Referral for consult and replacement of pain pump: Overturned

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Indications for Implantable Drug Delivery Systems Page(s): 53-54.

Decision rationale: MTUS guidelines regarding placement of intrathecal pain pumps have been thoroughly reviewed, and there is nothing in these guidelines that prohibits this patient from having his pain pump exchanged. The portion of the guideline that addresses this issue has been copied below for perusal. These guidelines are more aimed at giving guidance on deciding who should receive a first time implantable drug delivery system. They do not address who should receive subsequent replacement pumps. There is documentation provided that his pain pump has been beneficial in reducing pain and improving function. There is also documentation that he is still taking oral opiates. Nonetheless, the MTUS guidelines do not state that continued use of oral opiates is a reason to discontinue a patient's intrathecal drug delivery device. Therefore, this request for consultation and replacement of his pain pump is considered medically necessary.

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);
- Metastatic colorectal cancer where metastases are limited to the liver (intrahepatic artery injection of chemotherapeutic agents);
- Head/neck cancers (intra-arterial injection of chemotherapeutic agents);
- 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: 1. Documentation, in the medical record, of the failure of 6 months of other conservative treatment modalities (pharmacologic, surgical, psychologic 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. The request for 1 Referral for consult and replacement of pain pump is medically necessary.