MAXIMUS Federal Services

Case Number:	CM14-0095731		
Date Assigned:	09/10/2014	Date of Injury:	10/07/2002
Decision Date:	11/20/2014	UR Denial Date:	05/30/2014
Priority:	Standard	Application Received:	06/23/2014

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 District of Columbia and Virginia. 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:

This is a year 60 old patient who sustained injury on Oct 7 2002 . He had issues with chronic pain syndrome, lumbar intervertebral disc degeneration, and lumbar post laminectomy syndrome. He was seen by the physician on Sept 25 and Nov 12 2013 for ongoing pain and was prescribed oxycodone and MS contin. The physician saw the patient on Jan 16 2014 and was given oxycodone and MS contin to treat ongoing pain. The physician saw the patient on May 20 2014 and was given oxycodone and MS contin to treat ongoing pain. An intrathecal pump was requested as an alternate to opiate administration.

IMR ISSUES, DECISIONS AND RATIONALES

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

Implantation of tunneled intrathecal or epidural catheter: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines (IDDSs) Page(s): 41,51, 52.

Decision rationale: Per guidelines listed, the patient has not met criteria for this device. It is unclear what the goals of care would be for this device. Per MTUS, Implantable drug-delivery systems (IDDSs): Recommended only as an end-stage treatment alternative for selected patients

for specific conditions indicated below, after failure of at least 6 months of less invasive methods, and following a successful temporary trial. Results of studies of opioids for musculoskeletal conditions (as opposed to cancer pain) generally recommend short use of opioids for severe cases, not to exceed 2 weeks, and do not support chronic use (for which a pump would be used), although IDDSs may be appropriate in selected cases of chronic, severe low back pain or failed back syndrome. This treatment should only be used relatively late in the treatment continuum, when there is little hope for effective management of chronic intractable pain from other therapies. (Angel, 1998) (Kumar, 2002) (Hassenbusch, 2004) (Boswell, 2005) F or most patients, it should be used as part of a program to facilitate restoration of function and return to activity, and not just for pain reduction. The specific criteria in these cases include the failure of at least 6 months of other conservative treatment modalities, intractable pain secondary to a disease state with objective documentation of pathology, further surgical intervention is not indicated, psychological evaluation unequivocally states that the pain is not psychological in origin, and a temporary trial has been successful prior to permanent implantation as defined by a 50% reduction in pain. (Tutak, 1996) (Yoshida, 1996) (BlueCross, 2005) (United Health Care, 2005) See also Opioids. In a study of IDDS in 136 patients with low back pain, after one year 87% of the patients described their quality of life as fair to excellent, and 87% said they would repeat the implant procedure. However, complication rates (i.e., infection, dislodging, and cerebrospinal fluid leak) are likely to rise with time in these procedures and more longitudinal outcome studies need to be conducted. (Deer, 2004) In one survey involving 429 patients with nonmalignant pain treated with intrathecal therapy, physician reports of global pain relief scores were excellent in 52.4% of patients, good in 42.9%, and poor in 4.8%. In another study of 120 patients, the mean pain intensity score had fallen from 93.6 to 30.5 six months after initiation of therapy. In both studies, patients reported significant improvement in activities of daily living, quality of life measures, and satisfaction with the therapy. Constipation, urinary retention, nausea, vomiting, and pruritus are typical early adverse effects of intrathecal morphine and are readily managed symptomatically. Other potential adverse effects include amenorrhea, loss of libido, edema, respiratory depression, and technical issues with the intrathecal system. (Winkelmuller, 1996) (Paice, 1997) One study in patients suffering from chronic low back pain caused by failed back syndrome found a 27% improvement after 5 years for patients in the intrathecal drug therapy group, compared with a 12% improvement in the control group. (Kumar, 2002) Supporting empirical evidence is significantly supplemented and enhanced when combined with the individually based observational evidence gained through an individual trial prior to implant. This individually based observational evidence should be used to demonstrate effectiveness and to determine appropriate subsequent treatment. Generally, use of implantable pumps is FDA approved and indicated for chronic intractable pain. Treatment conditions may include FBSS, CRPS, Arachnoiditis, Diffuse Cancer Pain, Osteoporosis, and Axial Somatic Pain. As we have gained more experience with this therapy, it has become apparent that even intrathecal opiates, when administered in the long term, can be associated with problems such as tolerance, hyperalgesia, and other side effects. Consequently, long-term efficacy has not beenconvincingly proven. However, it is important to note that there is a distinction between "tolerance" and "addiction", and the levels of drugs administered intrathecally should be significantly below what might be needed orally in their absence. (Osenbach, 2001) (BlueCross BlueShield, 2005) See also Intrathecal drug delivery systems, medications.

Refills: IDDSs dispense drugs according to instructions programmed by the clinician to deliver a specific amount of drug per day or to deliver varying regimens based on flexible programmingoptions, and the pump may need to be refilled at regular intervals. The time

between refills will vary based on pump reservoir size, drug concentration, dose, and flow rate. A programming session, which may occur along with or independent of a refill session, allows the clinician to adjust the patient's prescription as well as record or recall important information about the prescription. (Hassenbusch, 2004) Indications for Implantable drug-delivery systems:

Implantable infusion pumps are considered medically necessary when used to deliver drugs for the treatment of: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);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 opiatesor 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 t he 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 m onths 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 psychologic 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 mprovementand associated reduction in oral pain medication use. A temporary trial ofintrathecal (intraspinal) infusion pumps is considered medically necessary only when criteria 1-5 above are met.

For CPRS, Pain management: (a) Pharmacological: antidepressants (particularly amitriptyline);anticonvulsants (particularly gabapentin); steroids; NSAIDS; opioids; calcitonin; bisphosphonates; α1 adrenoceptor antagonists (terazosin or phenoxybenzamine). The latter class of drugs has been helpful in SMP. Clonidine has been given transdermally and epidurally. (See CRPS, medications.) Bisphosphonates have some literature support in the presence of osteopenia. (Rho, 2002) (b) Minimally invasive: depends on degree of SMP, stage of rehabilitation (passive or active movement), and response to blocks. (See CRPS, sympathetic blocks.) Responders to sympathetic blocks (3 to 6 blocks with

concomitant PT) may be all that is required. For non-responders somatic block or epidural infusion may be required to optimize analgesia for PT. (c) More invasive: After failure of progression or partial relief, consider tunneled epidural catheters for prolonged sympathetic or somatic blocks or neurostimulation with SCS in CRPS-I and II. S ee CRPS, spinal cord stimulators. A lso consider peripheral nerve stimulation in CRPS-II and intrathecal drug delivery in patients with dystonia, failed neurostimulation, long-standing disease, multi-limb involvement and requirement of palliative care. (d) Surgical: Sympathectomy is not generally recommended, but has been considered in patients that respond to sympathetic blocks. Pre-procedure the patient should have outcomes assessed with radiofrequency and neurolytic procedures. (See CRPS, sympathectomy.) M otor Cortex Stimulation has been considered.

Oxycodone 30mg #180: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Opioids Page(s): 74,95,78.

Decision rationale: With the documentation provided, there is no clear indication for why patient would need long term opiates. The patient did not demonstrate a functional benefit from receiving the opiate during the period in which he was receiving it.Oxycodone is a potentially addictive opioid analgesic medication, and it is a Schedule II controlled substance. See Opioids.Pure-agonists: include natural and synthetic opioids such as morphine sulfate (MS Contin), hydromorphone (Dilaudid), oxymorphone (Numorphan), levorphanol (Levo-Dromoran), codeine (Tylenol w/Codeine 3), hydrocodone (Vicodin), oxycodone OxyContin), methadone (Dolophine HCl), and fentanyl (Duragesic). This group of opioids does not have a ceiling effect for their analgesic efficacy nor do they antagonize (reverse) the effects of otherpure opioids. (Baumann, 2002) Morphine is the most widely used type of opioid analgesic forthe treatment of moderate to severe pain due to its availability, the range of doses offered, and its low cost.Regarding on-Going Management. Actions Should include:(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 opi oids: pain relief, side effects, physical and psychosocial functioning, and the occurrence of any potentially aberrant (or nonadherent) 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 for documentation of the clinical use of these controlled drugs. (Passik, 2000).