

Case Number:	CM14-0174961		
Date Assigned:	10/28/2014	Date of Injury:	02/09/2011
Decision Date:	01/02/2015	UR Denial Date:	10/22/2014
Priority:	Standard	Application Received:	10/22/2014

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 Physical Medicine & Rehabilitation, has a subspecialty in Interventional Spine 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 a 41 year old female with an injury date of 02/09/11. The 10/14/14 progress report states that the patient presents with severe right upper extremity pain worse around the right elbow and forearm. Pain is worsening with increased stiffness at the elbow and small joints of the right hand. The right hand perspires more than the left and right hand nails grow faster and thinner. There is increased tremor /spasm/shaking in addition to hypersensitivity and allodynia. The patient cannot withstand the application of ointments due to pain and has minimal use of the right upper extremity. She also presents with headaches and GI symptoms. Examination reveals right upper extremity stiffness of the right hand wrist joints with right wrist decreased range of motion. The right hand also has decreased range of motion with hand grip 2/5. The right arm, forearm and hand are cold, the patient is protective of the right upper extremity and keeps the right elbow away from her side, and there is edema of the right upper extremity and right hand. The patient is unable to make a fist and there is mild atrophy of the muscles of the forearm. The patient's diagnoses include complex regional pain syndrome, type II, upper limb, mononeuritis of upper limb and mononeuritis multiplex; lesion of ulnar nerve and injury of ulnar nerve. Operative reports provided include on 04/23/14 Ketamine injections for CRPS, 10/04/13 T2 interlaminar ESI, 09/14/12 spinal cord stimulator trial, 03/09/12 cervical thoracic injection and 02/15/12 T2 ganglion block. The utilization review being challenged is dated 10/22/14. The rationale is that there is no documentation of intrathecal opioids prior to considering Ziconotide trial. Reports were provided from 03/09/12 to 10/14/14.

IMR ISSUES, DECISIONS AND RATIONALES

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

Trial Intrathecal Ziconotide (Prialt): Upheld

Claims Administrator guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Ziconotide (Prialt).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines Implantable drug-delivery systems (IDDSs) Page(s): 52-54. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) pain chapter under Ziconotide

Decision rationale: The patient presents with severe right upper extremity pain and stiffness with decreased range of motion as well as hypersensitivity headaches, GI issues, depression and sleep disturbance. MTUS page 53 Indications for Implantable drug-delivery systems: has the following in the pain section, which states, "Indications for implantable drug delivery system when it is used for the treatment of non-malignant pain with a duration of greater than six months and all of the following criteria are met:" Failure of conservative care, intractable pain due to objective pathology, no further surgical option, psychological evaluation shows non-psychogenic pain, no contraindication and a successful trial of spinal opiates prior to a permanent one. Regarding Prialt, ODG guidelines pain chapter under Ziconotide has the following: "Recommended for use after there is evidence of failure of a trial of intrathecal morphine or Hydromorphone (Dilaudid). Indicated for the management of severe chronic pain in patients for whom intrathecal therapy is warranted, and who are intolerant of or refractory to other treatment, such as systemic analgesics, adjunctive therapies or IT morphine, and only in individuals for whom the potential benefits outweigh the risks of serious neuropsychiatric adverse effects. The 2007 Polyanalgesic Consensus Conference Recommendations for the Management of Pain by Intrathecal Drug Delivery concluded that Ziconotide should be updated to a first-line intrathecal drug. Ziconotide (Prialt) is a synthetic calcium channel blocker that is delivered intrathecal, offering a non-opioid option for treatment of chronic pain, and possibly, spasticity associated with spinal cord trauma. It is FDA-approved for the management of severe chronic pain in patients for whom intrathecal therapy is warranted and who are intolerant of other treatments, such as systemic analgesics or adjunctive therapies. This medication is meant to be an option for patients who are intolerant and/or refractory to intrathecal morphine." "The 05/01/14 Pain management report by [REDACTED] states that the patient is 1 weeks post RFA right T3-T4 with initially good sympathetic blockade. The physician further states the patient has one of the most severe cases of hypersensitivity and allodynia due to nerve damage and has right ulnar nerve transposition. [REDACTED] further states, "We have tried spinal cord stimulation which did not greatly help." For the recent RFA the physician states, "I had to do upper thoracic epidural steroid injection. This is an extremely difficult case." The report further states procedures have been done extremely well without side effect but pain has not improved. The 07/21/14 report by [REDACTED] states there was excellent capture for the spinal cord stimulator trial with paresthesia covering the entire right upper extremity, but pain was not improved. These report further states, "The only remaining option from a Pain Management perspective is a trial of intrathecal Ziconotide (Prialt)." The reports show a regimen of pain medications, prior Ketamine injections (04/23/14), T2 interlaminar ESI (10/04/13), and 02/15/12 T2 ganglion block. The 07/23/12 psychiatric clearance for spinal cord stimulator trial is included. In this case, there is no

indication of a pump trial. While there is a psychological evaluation from 2012 for spinal cord stimulator, an updated one for IT pump is not provided. Furthermore, ODG guidelines do not support Prialt unless other medications including morphine has failed with IT pump. Recommendation is for denial.