

Case Number:	CM15-0204717		
Date Assigned:	10/21/2015	Date of Injury:	03/12/2001
Decision Date:	12/03/2015	UR Denial Date:	09/24/2015
Priority:	Standard	Application Received:	10/19/2015

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: Montana, Oregon, Idaho

Certification(s)/Specialty: Orthopedic Surgery

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 injured worker is a 42 year old female, who sustained an industrial injury on 3-12-2001. The injured worker was being treated for chronic regional pain syndrome (CPRS) of the left upper extremity and bilateral lower extremities, depression and insomnia due to chronic pain, and chronic pain syndrome. The injured worker (7-8-2015) reported unchanged chronic regional pain syndrome. The treating physician noted the injured worker's analgesia was stable and satisfactory. The injured worker (8-12-2015, 8-26-2015) reported unchanged chronic regional pain syndrome. The treating physician noted the injured worker's analgesia was stable and unsatisfactory. The medical records (7-8-2015) show the injured worker's functional status included sitting was okay, standing 30 minutes, walking 30 minutes, and she performs her basic activities of daily living. The injured worker reported waking up 3-4 times per night due to pain. The medical records (8-12-2015, 8-26-2015) show the injured worker's functional status included sitting was okay, standing 30 minutes, walking 30 minutes, and she performs her basic activities of daily living. Per the treating physician (8-26-2015 report) there were no aberrant behaviors noted and urine drug test and Controlled Substance Utilization Review and Evaluation System (CURES) report are consistent with current therapy and injured worker history. The injured worker reported waking up 4-5 times per night due to pain. The physical exam (7-8-2015) reveals the injured worker sat stiffly in a chair with her arm elevated on a pillow for comfort and a flat affect. The treating physician noted the injured worker stood for filling of the pump and the pump pocket is intact in the right lower quadrant without erythema, exudate, or induration. The physical exam (8-12-2015) reveals the injured worker sat stiffly in a chair with

her arm elevated on a pillow for comfort and a flat affect. The physical exam (8-26-2015) reveals a depressed and flattened affect, fatigues and uncomfortable appearance, and splinting of the left arm for comfort. The treating physician noted the injured worker stood for filling of the pump and the pump pocket is intact in the right lower quadrant without erythema, exudate, or induration. The urine drug screen (5-5-2015) stated there a negative result for Fentanyl and a positive result for Tapentadol. The urine drug screen (7-8-2015) stated there was a positive result for Norfentanyl Oxalate. Per the treating physician (6-12-2015 report), a urine drug test was negative for Fentanyl and positive for Tapentadol. Treatment has included short-acting and long- acting oral pain, intrathecal pain (Fentanyl and Bupivacaine), anti-epilepsy, antidepressant, antipsychotic, muscle relaxant, and non-steroidal anti-inflammatory. On 9-16-2015, the requested treatments included a Prialt pump trial for CPRS. On 9-24-2015, the original utilization review non-certified a request for a Prialt pump trial for (CPRS).

IMR ISSUES, DECISIONS AND RATIONALES

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

Prialt pump trial for CRPS: Overturned

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG), Pain, Implantable drug-delivery systems (IDDSs).

MAXIMUS guideline: Decision based on MTUS Chronic Pain Medical Treatment 2009, Section(s): Intrathecal drug delivery systems, medications.

Decision rationale: Recommended for use after there is evidence of a failure of a trial of intrathecal morphine or hydromorphone (Dilaudid), 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 intrathecally, 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, adjunctive therapies. This medication is meant to be an option for patients who are intolerant and/or refractory to intrathecal morphine. The advantage of the medication is that it is considered non-addictive. Current case reports have described many challenges in converting from morphine to Ziconotide, including inadequate analgesia, adverse medication effects, and opioid withdrawal symptoms. An option for treatment is combining Ziconotide with other currently available intrathecal medications, although this has not been studied in placebo-controlled trials. In this case the injured worker is a 42 year old female who sustained a work injury in 2001. She has been diagnosed with CRPS and has already had an intrathecal pain pump placed. The documentation supports that she has failed a trial of intrathecal opioids to control her pain. The guidelines do support a trial of the requested drug as 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, adjunctive therapies. The request meets the criteria set forth in the guidelines and is therefore medically necessary.