

Case Number:	CM14-0133557		
Date Assigned:	09/12/2014	Date of Injury:	07/20/2007
Decision Date:	10/10/2014	UR Denial Date:	08/13/2014
Priority:	Standard	Application Received:	08/21/2014

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 Anesthesiology, has a subspecialty in Pain Management and is licensed to practice in Tennessee. 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 51 year old female with a 7/20/07 injury date. The mechanism of injury was not provided. In an orthopedic AME on 2/19/13, signs and symptoms are consistent with complex regional pain syndrome and include discoloration of the nails, hypersensitivity, coldness of the fingers, shininess of the skin, and altered skin color. In a follow-up on 7/24/14, the patient reports blistering and hair loss in the upper limbs and symptoms in the legs, with burning and severe pain. The patient is taking Gralise and Motrin, which are starting to be ineffective. Objective findings include pain, hair loss, allodynia in the lower limbs, a right elbow ulcer, and blistering in the right medial arm. The treatment plan at that time is for lumbar sympathetic block and medications. In a follow-up on 8/7/14, the provider recommends an Intrathecal Prialt Trial at L1-L3 levels, 2 mcg under fluoroscopy. Diagnostic impression: CRPS--upper and lower extremities. Treatment to date: medications. A UR decision on 8/12/14 denied the request for L2-3 Intrathecal Prialt Trial on the basis that there is limited evidence of failure from a full course of conservative care including sympathetic blocks and maximum dosage of current medications. There is also no evidence of psychological clearance prior to considering this procedure. The request for Zohydro ER was denied on the basis that there is no documentation of pain scores, opioid compliance guidelines, or documentation that trials of "Y" drugs in this class have failed.

IMR ISSUES, DECISIONS AND RATIONALES

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

L2-3 Space Intrathecal Prialt Trial 2mcg: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines 9792.24.2. Page(s): 52-53. Decision based on Non-MTUS Citation Other Medical Treatment Guideline or Medical Evidence: FDA (Prialt).

Decision rationale: CA MTUS states that Implantable Drug-Delivery Systems (IDDS) may be indicated following 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. CA MTUS and ODG do not address Prialt. The FDA states that Prialt (ziconotide) solution, intrathecal infusion is indicated for the management of severe chronic pain in adult patients for whom intrathecal therapy is warranted, and who are intolerant of or refractory to other treatment, such as systemic analgesics, adjunctive therapies, or intrathecal morphine. In the present case, there is limited evidence of a full course of prior conservative treatment including physical therapy and sympathetic blocks. In addition, it does not appear that the patient has had psychological clearance prior to consideration of implanting an intrathecal device. The medical necessity is not apparent in the fairly limited available documentation. Therefore, the request for the L2-3 Space Intrathecal Prialt Trial 2mcg, is not medically necessary.

Zohydro ER 10mg #30: Upheld

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

MAXIMUS guideline: Decision based on MTUS Chronic Pain Treatment Guidelines 9792.24.2 opiates Page(s): 78-81. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG): Pain Chapter--Zohydro.

Decision rationale: CA MTUS Chronic Pain Medical Treatment Guidelines do not support ongoing opioid treatment unless prescriptions are from a single practitioner and are taken as directed; are prescribed at the lowest possible dose; and unless there is ongoing review and documentation of pain relief, functional status, appropriate medication use, and side effects. However, given the 2007 date of injury, the duration of opiate use to date is not clear. There is no discussion regarding non-opiate means of pain control, or endpoints of treatment. The records do not clearly reflect continued analgesia, continued functional benefit, a lack of adverse side effects, or aberrant behavior. Although opiates may be appropriate, additional information would be necessary, as CA MTUS Chronic Pain Medical Treatment Guidelines require clear and concise documentation for ongoing management. Non-certification here does not imply abrupt cessation for a patient who may be at risk for withdrawal symptoms. Should the missing criteria necessary to support the medical necessity of this request remain unavailable, discontinuance should include a tapering prior to discontinuing to avoid withdrawal symptoms. ODG states that Zohydro is not recommended. Zohydro ER (Zogenix Inc) is the first single-entity extended-

release (ER) formulation of hydrocodone approved by the FDA. Zohydro does not have abuse-deterrent technology. According to the FDA, Zohydro ER should be reserved for use in patients for whom alternative treatment options are ineffective. FDA's Drug Advisory Committee of independent experts voted 11 to 2 to recommended against approval of Zohydro for the treatment of moderate to severe chronic pain because of the potential for abuse of this drug. Zohydro is not recommended as a first line drug in ODG. Therefore, the request for Zohydro ER 10mg #30, is not medically necessary.