

IMED, INC.

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[Date notice sent to all parties]:

03/28/2016

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE: refill of intrathecal pump with Dilaudid 15 mg containing Bupivacaine 30 mg, ultrasound guided synchomed pump refill

A DESCRIPTION OF THE QUALIFICATIONS FOR EACH PHYSICIAN OR OTHER HEALTH CARE PROVIDER WHO REVIEWED THE DECISION:

Board Certified Orthopedic Surgeon

REVIEW OUTCOME:

Upon independent review, the reviewer finds that the previous adverse determination/adverse determinations should be:

X Upheld (Agree)

Provide a description of the review outcome that clearly states whether medical necessity exists for each of the health care services in dispute.

PATIENT CLINICAL HISTORY [SUMMARY]:

This lady has chronic low back pain that has not improved with exercise, treatment, surgery or medications including intrathecal narcotics. ODG recommendations for intrathecal narcotics note that in non-malignant conditions, this method should be used for increase in function and return to normal activities. This lady has continued to use heavier doses of medications, and there is no evidence in the presented medical records that any effort has been made to reduce the dosage of either the intra-thecal or the oral medications.

In addition, objective testing has shown her to be depressed, with psychological involvement that worsens the pain.

ANALYSIS AND EXPLANATION OF THE DECISION INCLUDE CLINICAL BASIS, FINDINGS, AND CONCLUSIONS USED TO SUPPORT THE DECISION:

For 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 or other intervention is not indicated, there are no contraindications to a trial, psychological evaluation unequivocally states that the individual has realistic expectations and 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.

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 and documented by treating providers in the medical record:

- (1) Non-opioid oral medication regimens have been tried and have failed to relieve pain and improve function (see functional improvement); and
- (2) At least 6 months of other conservative treatment modalities (injection, surgical, psychologic or physical), have been ineffective in relieving pain and improving function; and
- (3) Intractable pain secondary to a disease state with objective documentation of pathology in the medical record (per symptoms, physical examination and diagnostic testing); and
- (4) Further surgical intervention or other treatment is not indicated or likely to be effective; and
- (5) Independent psychological evaluation has been obtained and evaluation states that the pain is not primarily psychologic in origin, the patient has realistic expectations and that benefit would occur with implantation despite any psychiatric comorbidity; and
- (6) No contraindications to implantation exist such as sepsis, spinal infection, anticoagulation or coagulopathy; and
- (7) There has been documented improvement in pain and function in response to oral opioid medications but intolerable adverse effects preclude their continued use; and
- (8) 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 1-7 above are met.

There are no indications that she has positive objective findings that correlate with the subjective complaints.

Therefore, the request is not approved based on the medical records including objective physical findings on her history of not meeting criteria established by ODG for the requested procedure.

IRO REVIEWER REPORT TEMPLATE -WC

A DESCRIPTION AND THE SOURCE OF THE SCREENING CRITERIA OR OTHER CLINICAL BASIS USED TO MAKE THE DECISION:

X ODG- OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES

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 and documented by treating providers in the medical record:

(1) Non-opioid oral medication regimens have been tried and have failed to relieve pain and improve function (see functional improvement); and

(2) At least 6 months of other conservative treatment modalities (injection, surgical, psychologic or physical), have been ineffective in relieving pain and improving function; and

(3) Intractable pain secondary to a disease state with objective documentation of pathology in the medical record (per symptoms, physical examination and diagnostic testing); and

(4) Further surgical intervention or other treatment is not indicated or likely to be effective; and

(5) Independent psychological evaluation has been obtained and evaluation states that the pain is not primarily psychologic in origin, the patient has realistic expectations and that benefit would occur with implantation despite any psychiatric comorbidity; and

(6) No contraindications to implantation exist such as sepsis, spinal infection, anticoagulation or coagulopathy; and

(7) There has been documented improvement in pain and function in response to oral opioid medications but intolerable adverse effects preclude their continued use; and

(8) 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 1-7 above are met.