

The DYLL REVIEW

We take the worry out of Peer Reviews

25 Highland Park Village #100-177 Dallas TX 75205
Phone: 888-950-4333 Fax: 888-9504-4443

Notice of Independent Review Decision

August 24, 2015

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:

Medical Necessity: Intrathecal Pain Pump Medication Refill, Fentanyl, Bupivacaine (PNR-Baclofen)

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

The physician performing this review is Board Certified, American Board of Physical Medicine & Rehabilitation. The physician is certified in pain management. The physician has a private practice of. The physician is a member of the Texas Medical Association and the Houston Physical Medicine and Rehabilitation Society. The physician is licensed in Texas and Michigan and has been in practice for over 25 years.

REVIEW OUTCOME:

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

- Upheld (Agree)
- Overturned (Disagree)
- Partially Overturned (Agree in part/Disagree in part)

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

Upon Independent Review the physician finds that the previous adverse determination should be ~ Overturned

PATIENT CLINICAL HISTORY [SUMMARY]:

This man had injured his back in. He apparently underwent back surgery in 1996 and 2001. He had failed back/post laminectomy syndrome diagnoses. A pump was implanted, it looks like, in 2003. He had back pain going to both lower extremities. The records describe refills of his medications with Fentanyl and Bupivacaine on a regular schedule, listed as 66 day intervals. I am a bit confused

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if the last refill was done on 3/25/15 of 4/3/15. There was a note suggesting 6/24/14 was to be the refill date. I suspect that was a typo error. He was due for refills. Prior reviewers denied the medication on grounds that there were no diagnostic studies provided and no documentation that he needs the medications or they were helpful. First, there is no need to order new diagnostic studies unless there is some change in status. I suspect any studies ordered without such a change would likely be denied. The comments about lack of improvement documentation are flaws with the EHR. I cannot say this with absolute certainty that this is true, but may EHR are fill in the template. If there is no template for the benefit from the pump, then the question would not be answered. On this point, we rely on the undated letter of appeal from Mr himself. He noted he had been in health care at one point and was familiar with the terminology.

He wrote that "The greatest functional improvement in physical and psychosocial functioning was made initially when the original pump was implanted in 2-5-2003. ...Current proof of the sustained functional improvement and psychosocial functioning obtained by initial implant is best demonstrated by the uninterrupted employment of patient with excellent attendance. Other doctors since have periodically attempted reductions in pump medicationsWith the reduction was an increase in back spasm and pain in lower back and bilaterally in legs...increased oral quantity of Norco ...(and baclofen) to cover increase in symptoms..."

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

The issue is the ongoing need for the pump, as well as the need for the specific medications. This is a late treatment where other treatment options have failed. It has worked for him.

He notes it allowed him to return to work. He worsened clinically and functional ability when the pump was stopped. He documents this in his appeal. Other doctors attempted this and these records are not necessarily available. So I see no reason to punish him when he documents his subjective and objective improvement in function and that this is not in the records available.

Therefore, I feel the need for the refills is medically justified

From the ODG:

Implantable drug-delivery systems (IDDSs)	Recommended only as an end-stage treatment alternative for selected patients for specific conditions indicated in the blue criteria below, after failure of at least 6 months of less invasive methods, and following a successful temporary trial. There is insufficient evidence to recommend the use of implantable drug-delivery systems (IDDS) for the treatment of chronic pain. There are no high quality studies on this topic that document that this therapy is safe and effective. Further, significant complications and adverse events have been documented and the data identifies a substantial risk to patients... This treatment may be considered relatively late in the treatment continuum, when there is little hope
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for effective management of chronic intractable pain from other therapies. ...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. ...

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 opioids, when administered in the long term, can be associated with problems such as tolerance and other side effects. Consequently, long-term efficacy has not been convincingly 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. ...Follow product instructions and dosing recommendations. Failure to comply with all implanted infusion pump product instructions can lead to technical errors or improper use and result in additional surgical procedures, a return of underlying symptoms, or a clinically significant drug underdose or fatal drug overdose....**

Indications for Implantable drug-delivery systems:

Implantable infusion pumps are considered medically necessary when used to deliver drugs for the treatment of:...

Permanently implanted intrathecal (intraspinal) infusion pumps for the administration of opioids or non-opioid analgesics, in the treatment of chronic intractable pain, are considered medically necessary when:...

• 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

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(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.

(9) For average hospital LOS if criteria are met, see [Hospital length of stay](#) (LOS). If treatment is determined to be medically necessary, as with all other treatment modalities, the efficacy and continued need for this intervention and refills should be periodically reassessed and documented.

Medications for IDDS if determined to be medically necessary:

First stage: Morphine is generally the initial IDDS medication. The maximum recommended dose for this drug is 15 mg/day with a concentration of 20 mg/mL. An alternative non-FDA approved medication is hydromorphone. The maximum recommended dose for this medication is 4 mg/day with a concentration of 10 mg/mL. Other opioids (including Fentanyl and Sufentanil) have been used for intrathecal chronic non-malignant pain but are non-FDA approved and have little research associated with their use. ([Wara-Wolleat, 2006](#)) ([Deer, 2007](#)) The previous 2003 Polyanalgesic conference recommended a maximum dose of intrathecal morphine at 15 mg/day with a maximum concentration of 30 mg/mL. They also recommended a maximum dose of hydromorphone of 10 mg/day with a concentration of 30 mg/mL. ([Hassenbusch, 2004](#)) The newer maximum concentrations were recommended, in part, to prevent granulomas.

Second stage: If side effects occur, an upper limit of dosing is reached, or neuropathic pain is present, clonidine is next recommended as an addition to an opioid (maximum recommended dose of 1 mg/day and a concentration of 2 mg/mL). Bupivacaine has also been recommended as an alternative to clonidine (maximum dose of 30 mg/day and a concentration of 40 mg/mL). Clonidine, which is FDA approved for intrathecal delivery, is thought to provide analgesic effect via a non-opioid mechanism. It has been found to offer only short-term relief when used as a single agent. ([Deer, 2007](#))

Third stage: The recommendation has been made to add both clonidine and bupivacaine. Baclofen has been used to treat intractable spasticity from brain injury, cerebral palsy, and spinal cord injury and has resulted in improvement in muscle tone and pain relief. ([Guillaume, 2005](#)) See also [Ziconotide](#) (Prialt®), which is recommended after documentation of a failure of a trial of intrathecal morphine or hydromorphone (Dilaudid).

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 programming options, 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

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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](#)) According to the FDA, the manufacturer's manuals should be consulted for specific instructions and precautions for initial filling, refilling and programming. ([FDA, 2010](#)) For most pumps, the maximum dose that can be delivered between refills is 1000mg. If refills are usually administered after 16 to 17 mL have been infused, and most pumps are 18-20mL, the minimum time between each visit is 42 days if the daily dose rate is 20 mg/day. Given that a refill visit presents a good opportunity for monitoring, this panel suggested that the concentration be adjusted to allow refill visits a minimum of every 4 to 6 weeks, and maximum of every 2-3 months. ([Bennett, 2000](#))

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

- ACOEM- AMERICAN COLLEGE OF OCCUPATIONAL & ENVIRONMENTAL MEDICINE UM KNOWLEDGEBASE
- AHCPR- AGENCY FOR HEALTHCARE RESEARCH & QUALITY GUIDELINES
- DWC- DIVISION OF WORKERS COMPENSATION POLICIES OR GUIDELINES
- EUROPEAN GUIDELINES FOR MANAGEMENT OF CHRONIC LOW BACK PAIN
- INTERQUAL CRITERIA
- MEDICAL JUDGEMENT, CLINICAL EXPERIENCE, AND EXPERTISE IN ACCORDANCE WITH ACCEPTED MEDICAL STANDARDS
- MERCY CENTER CONSENSUS CONFERENCE GUIDELINES
- MILLIMAN CARE GUIDELINES
- ODG- OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES
- PRESSLEY REED, THE MEDICAL DISABILITY ADVISOR
- TEXAS GUIDELINES FOR CHIROPRACTIC QUALITY ASSURANCE & PRACTICE PARAMETERS
- TEXAS TACADA GUIDELINES
- TMF SCREENING CRITERIA MANUAL
- PEER REVIEWED NATIONALLY ACCEPTED MEDICAL LITERATURE (PROVIDE A DESCRIPTION)
- OTHER EVIDENCE BASED, SCIENTIFICALLY VALID, OUTCOME FOCUSED GUIDELINES (PROVIDE A DESCRIPTION)