

AccuReview

An Independent Review Organization

569 TM West Parkway

West, TX 76691

Phone (254) 640-1738

Fax (888) 492-8305

Notice of Independent Review Decision

[Date notice sent to all parties]: June 3, 2014

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:

Refill x 3 Intrathecal Morphine Pump 62370 76942 J3490

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

This physician is Board Certified Anesthesiologist with over 12 years of experience.

REVIEW OUTCOME:

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

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.

INFORMATION PROVIDED TO THE IRO FOR REVIEW:

PATIENT CLINICAL HISTORY [SUMMARY]:

The claimant is a female who sustained an injury on xx/xx/xx. She was ambulatory on scene and reported no LOC. Initial complaints were headache, neck and right hip pain. The claimant has a PMH of minor MVA with neck injury in xxxx causing a slipped disk C4-5.

Xx/xx/xx: Emergency Room Visit. Chief complaint: headache, neck and right hip pain. PE: Neck: tender to palpation of right occipital to right shoulder. Chest: mild tenderness posteriorly to palpation. Ext: tender left leg with swelling and ecchymosis. Neuro: decreased sensation to right 4th and 5th fingers. Dx: acute cervical strain. Discharge instructions: Rest, PT, heat/ice, Flexeril and Vicodin as directed, follow-up as needed.

Xx/xx/xx: Hip 2 View X-Ray. Impression: negative without evidence for acute osseous injury nor significant arthritic changes.

Xx/xx/xx: Cervical Spine Complete X-Ray. Impression: no acute osseous injury seen. Mild lower cervical spondylosis.

07-01-96: Encounter Note dictated by PTA. Chief complaint: cervical strain. Objective: Pain constant pressure at base of neck that radiates into bilateral upper trapezius, headache, constant stinging/tightness of right forearm radiating to digits 1-3, pain 8/10. Cervical ROM: flexion-23 degrees, extension-40 degrees, RSB-27 degrees, LSB-27 degrees.

09-12-96: MRI Spine Cervical w/o Contrast. Impression: Findings compatible with a small disc herniation to the right at the C5-6 level, impinging on the nerve root.

10-23-96: Operative Report. Pre-operative Diagnosis: Cervicalgia. Post-operative Diagnosis: Same.

12-09-96: Operative Report. Pre-operative Diagnosis: Cervicalgia, Radiculitis, right upper extremity. Post-operative Diagnosis: Same.

03-05-97: Operative Report. Pre-operative Diagnosis: C4-5 instability; C5-6 herniated nucleus pulposus with C6 radiculopathy on the right. Post-operative Diagnosis: Same.

03-05-97: Operative Report. Pre-operative Diagnosis: C4-5 instability; Right C6 radiculopathy with disk at the C5-6 level. Post-operative Diagnosis: C4-5 and C5-6 anterior discectomy; anterior interbody fusion utilizing iliac crest bone graft C4-C6, with anterior instrumentation.

03-05-97: Pathology Report. Diagnosis: Intervetebral disc, C4-5 and C5-6: consistent with herniated nucleus pulposus.

03-05-97: Cross-table Lateral Cervical Spine, Three Views. Impression: interbody fusion as described, status post anterior fusion of C4-5 and C5-6.

10-03-97: MRI of the Lumbar Spine. Impression: 1. L5-S1: 3 mm posterocentral subligamentous disc herniation which minimally indents the central surface of the thecal sac. It does not appear to impinge upon the S1 nerve roots. 2. Multiple sacral meningeal cysts are noted at the S3 level and measure up to 15 mm in diameter. There is scalloping of the sacral canal. Generally such cysts are asymptomatic, but correlation for possible sacral radiculopathy may be indicated. 3. The lumbar spine above the L5 level appears pristine.

04-20-99: Operative Report dictated. Pre-operative Diagnosis: Cervical radiculopathy. Post-operative Diagnosis: same.

07-09-99: Cervical Spine, Four Views. Impression: 1. Slightly narrowed C6-7 disk space. 2. Post operative changes of fusion with metallic plate and screws inserted from C4 through C6.

07-19-99: MRI Cervical Spine w/wo Contrast. Impression: 1. Postoperative changes of fusion of C4 through C6 vertebral bodies. No significant spinal canal involvement by scar tissue. 2. No herniated disk, intrinsic cord pathology, extrinsic cord, or significant nerve root compression detected at any levels.

08-12-99: Operative Report. Pre-operative Diagnosis: 1. Cervicalgia. 2. Cervical radiculopathy. Post-operative Diagnosis: same.

05-09-00: Operative Report. Pre-operative Diagnosis: 1. Cervicalgia. 2. Cervical radiculopathy. Post-operative Diagnosis: same.

05-16-00: Operative Report. Pre-operative Diagnosis: 1. Cervicalgia. 2. Cervical radiculopathy. Post-operative Diagnosis: same.

05-23-00: Operative Report. Pre-operative Diagnosis: 1. Cervicalgia. 2. Cervical radiculopathy. Post-operative Diagnosis: same.

11-16-00: Operative Report. Pre-operative Diagnosis: 1. Lumbar facet arthropathy. 2. Sacroiliac arthropathy. Post-operative Diagnosis: same.

12-12-00: Operative Report. Pre-operative Diagnosis: Cervical radicular pain. Post-operative Diagnosis: same.

12-19-00: Operative Report. Pre-operative Diagnosis: 1. Cervicalgia. 2. Cervical radiculopathy. Post-operative Diagnosis: same.

01-04-01: Operative Report. Pre-operative Diagnosis: 1. Cervicalgia. 2. Cervical radiculopathy. Post-operative Diagnosis: same.

07-13-01: Operative Report. Pre-operative Diagnosis: 1. Cervicalgia. 2. Cervical radiculopathy. Post-operative Diagnosis: same.

08-07-01: Operative Report. Pre-operative Diagnosis: 1. Cervicalgia. 2. Cervical radiculopathy. Post-operative Diagnosis: same.

08-14-01: Operative Report, Pre-operative Diagnosis: 1. Cervicalgia. 2. Cervical radiculopathy. Post-operative Diagnosis: same.

08-22-02: Operative Report. Pre-operative Diagnosis: 1. Cervicalgia. 2. Cervical radiculopathy. Post-operative Diagnosis: same.

09-03-02: Operative Report. Pre-operative Diagnosis: 1. Cervicalgia with cervical radicular pain. Post-operative Diagnosis: same.

09-10-02: Operative Report. Pre-operative Diagnosis: 1. Cervicalgia with cervical radicular pain. Post-operative Diagnosis: same.

09-24-02: Operative Report. Pre-operative Diagnosis: 1. Lumbar facet arthropathy. 2. Sacroiliac arthropathy. Post-operative Diagnosis: same.

02-11-03: Operative Report. Pre-operative Diagnosis: Cervicalgia. Post-operative Diagnosis: same.

05-13-03: Operative Report. Pre-operative Diagnosis: Low back pain. Post-operative Diagnosis: same.

05-20-03: Operative Report. Pre-operative Diagnosis: Lumbar radicular pain. Post-operative Diagnosis: same.

09-02-03: Operative Report. Pre-operative Diagnosis: Cervicalgia. Post-operative Diagnosis: same.

09-09-03: Operative Report. Pre-operative Diagnosis: Cervicalgia. Post-operative Diagnosis: same.

09-16-03: Operative Report. Pre-operative Diagnosis: Cervicalgia. Post-operative Diagnosis: same.

02-17-04: Operative Report. Pre-operative Diagnosis: Cervicalgia, low back pain. Post-operative Diagnosis: same. Procedure: Morphine pump trial.

04-15-04: Operative Report. Pre-operative Diagnosis: Cervicalgia, low back pain. Post-operative Diagnosis: same. Procedure: Morphine pump implant, analysis, reprogramming and refilling of morphine pump.

11-30-04: Cervical Myelogram and Post Myelographic CT Examination. Cervical Myelogram findings: 1. Mild to moderate ventral extradural impression upon the thecal sac is demonstrated at C6-7 level. 2. Mature osseous and fully incorporated C4-5 and C5-6 anterior interbody fusions with instrumentation are demonstrated. 3. There is no significant underfilling of the cervical nerve root sleeves. 4. Cervical cord is of normal configuration and caliber throughout the cervical spine. CT scan lumbar spine postmyelogram: 1. Mild osseous central canal stenosis at C6-7 level secondary to posterior spondylosis and broad-based posterior annular bulge, indenting the thecal sac approximately 2-3 mm without cervical cord compression or distortion. 2. Minimal ventral impression upon the left C7 sleeve by the C6-7 disc osteophyte complex without significant compressive effect upon the emanating left C7 nerve. 3. Mature osseous and fully incorporated C4-5 and C5-6 anterior interbody fusions with instrumentation, with widely patent central canal, ventral outlets and neural foramina at both postoperative levels. 4. No evidence of accelerated spondylosis or cervical disc herniation above the fusion level.

03-14-06: Operative Report. Pre-operative Diagnosis: Cervicalgia, low back pain. Post-operative Diagnosis: same.

04-27-06: Operative Report. Preoperative Diagnosis: Revision of morphine pump. Postoperative Diagnosis: same.

03-27-07: Operative Report. Pre-operative Diagnosis: Cervicalgia, lower back pain, worsening pain. Post-operative Diagnosis: same.

08-13-09: CT Scan L-spine w/o Contrast. Impression: 1. Intrathecal morphine pump noted entering the spinal canal to the left of the midline at the level of L2-3 with the tip of the catheter located in the right side of the spinal canal at T12. No granuloma appreciated around the tip of the catheter. However, I believe MRI study is more sensitive for ruling out granuloma. Degenerative disc disease at L2-3, L4-5 and L5-S1 levels described above. 3. No lumbar side herniation detected.

05-30-13: Operative Report. Pre-operative Diagnosis: 1. Intrathecal pump battery depletion, in need of replacement. 2. Cervical post laminectomy syndrome. 3. Posttraumatic chronic severe low back pain. Post-operative Diagnosis: same.

11-28-13: Office Visit. Current medications: Lorcet 10/650, Venlafexine HCL, Neurontin. Claimant is currently on sufentanil at 37.5 ug per day. She continues to report benefit with her intrathecal and oral medication for control of her chronic pain. She is not experiencing any adverse effects from the combination of her medications. She is seen today for refill and reevaluation with no new complaint. Objective: C5-T1 intact in both upper extremities, L1-S2 intact in both lower extremities. Assessment: Cervicalgia/cervical radiculitis/headache. Plan: Refill intrathecal pain pump with sufentanil 50 ug/cc.

02-18-14: Office Visit. Current medications: Vicodin HP 10/300 mg, Venlafexine HCL 37.35 mg. Subjective: Refill of intrathecal pain pump, currently on sufentanil 37.5 ug intrathecally for control of her chronic cervical and lumbar pain. She continued to report benefit at her current rate of delivery and did state that the Vicodin has continued to aid in breakthrough pain. No adverse effects are reported from combination of medications. Objective: C5-T1 intact in both upper extremities, L1-S2 intact in both lower extremities. Assessment: Cervicalgia/cervical radiculitis/headache. Plan: Refill intrathecal pain pump with sufentanil 50 ug/cc.

04-20-14: UR. Reason for denial: The clinical information submitted for review fails to meet the evidence-based guidelines for the requested service. The mechanism of injury is not provided in the medical records. The claimant's medication regimen includes Vicodin HP oral 10/300 mg 1 tablet 4 times a day, venlafaxine HCL 37.5 mg 1 tablet twice a day, and sufentanil at 37.5 per day via intrathecal pain pump. Surgical history information is not provided in the medical records. There is no diagnostic studies information provided in the medical

records. Other therapies include activity modification, medication management, and intrathecal pain pump placement. The claimant is female who reported injury on xx/xx/xx. A review of the medical records reveals the claimant's diagnosis is cervicalgia ICD9 code 723.1. The clinical note dated 04/03/14 reports the claimant was being seen for follow-up and refill of her intrathecal pain pump. She is currently receiving sufentanil at 37.5 per day. The claimant continued to report benefit at her current rate of delivery. She is not reporting any adverse effect from combination of the intrathecal and oral medication. Objective findings upon examination revealed C5 to T1 nerve dermatomes intact in bilateral upper extremities, and L1 to S2 remained intact to bilateral lower extremities. The requested service is for a Refill x 3 Intrathecal Morphine Pump 62370 (refill), 76942 (ultrasound guidance) and J3490 (unclassified drugs, which is the sufentanil). The ODG guidelines state that intrathecal drug delivery system medications that are recommended are generally morphine as the initial medication. It is stated that other opioids including Fentanyl and sufentanil have been used for intrathecal chronic pain malignant pain, but they are non-FDA approved, and have little research associated with their use. The clinical documentation states that the claimant is currently using the sufentanil at a daily dose of 37.5. Per ODG guidelines, the requested medication is not FDA approved. As there is no peer reviewed criteria for the use of the medication, the medical necessity cannot be determined at this time. Therefore, the request for Refill x 3 Intrathecal Morphine Pump 62370 76942 J3490 is non-certified. While the requested medication does not meet medical necessity based on information presented it is expected that the ordering provider will follow recommended medication guidelines for safe discontinuation.

04-23-14: Office Visit. Current medications: Vicodin HP 10/300 mg, Venlafaxine HCL 37.5 mg. The claimant presented for refill of intrathecal pain pump, currently on sufentanil at 37.5 ug per day. She continued to report benefit with the control of her pain with her intrathecal and oral medication and not reporting any adverse effects from her current therapy. She continued to be compliant on her last urinalysis. Objective: C5-T1 intact in both upper extremities, L1-S2 in both lower extremities. Assessment: chronic cervicalgia/cervical radiculitis/headache, chronic low back pain. Plan: Refill of intrathecal pain pump. Telemetry unit was used to determine reservoir volume which was 4 ml, aspiration with 4 ml obtained and sufentanil 50 ug per cc was used to refill the pain pump; 19 cc place in pump with 1 cc discarded. Claimant scheduled to follow-up for the next refill.

05-07-14: UR. Reason for denial: The claimant is a female who is s/p a cervical fusion at C4-5 and C5-6 in the late xxxx. She reported continued cervical pain and had a CT myelogram done on 11/20/11 with reported findings of a mild osseous central canal stenosis at C6-7 with minimal ventral impression on the left C7 sleeve by the disc osteophyte complex and mature and fully incorporated C4-5 and C5-6 anterior interbody fusions. She is s/p placement of an IDDS, and has periodic Intrathecal Morphine Pump refills. She currently received 37.5 mf Sufentanil per day. She has reported continued benefit at the current medication delivery rate without adverse effects of intrathecal medication, demonstrated compliance with last urinalysis, benefit ROM, and mobility, and has been able to

decrease oral pain medication. This is a non-certification of an appeal of three intrathecal morphine pump refills. The previous non-certification on 04/18/14, was due to the current use of sufentanil, the medication requested not being FDA approved, and lack of peer-reviewed criteria for the use of the medication. The previous non-certification is supported. Additional records were not provided for review. This medication is not approved by FDA for an intrathecal drug system. There are no peer-reviewed criteria for the use of this medication. The request for an appeal of three intrathecal morphine pump refills is not certified.

05-13-14: UR. Reason for denial: The request for an intrathecal morphine pump refill (62370 and 76942) and sufentanil J3490 is not warranted at this time. In reference to the UDS (80101), per the documentation provided in the medical records, it is stated on the clinical note dated 04/02/14 that the claimant had been compliant with her medication regimen as per the previous UDS. Per the ODG guidelines, it is stated that quantitative urine drug testing is not recommended verifying compliance without evidence of necessity. Also, the request should have documentation as to why in evidence of necessity. The frequency of urine drug testing should be based on documented evidence of risk stratification, including the use of a testing instrument. It is also noted that there is no documentation of any aberrant behavior or signs that would suggest that the claimant is not compliant with her current regimen at this time. Therefore, the request for a UDS (80101) is not warranted at this time. As the requested intrathecal morphine pump refill medication sufentanil is not recommended per the ODG guidelines, and as there are no documented signs of the claimant is at risk of any aberrant behavior or is non-compliant with her medication regimen; the request for an intrathecal morphine pump refill (62370) and (76942, sufentanil (J3490) and a UDS (80101) is non-certified.

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

The previous adverse determinations are upheld and agreed upon. The claimant is a female who is status post a cervical fusion at C4-5 and C5-6 in the late xxx. Claimant had placement of an IDDS, and has periodic Intrathecal Morphine Pump refills. Currently, sufentanil is not approved by FDA for an intrathecal drug system. There are no peer-reviewed criteria for the use of this medication. Per ODG, the requested refill of the intrathecal morphine pump with sufentanil is not recommended as the patient is compliant with medications and does not display any aberrant behavior to suggest a change in oral medication regimen. Therefore, the request for Refill x 3 Intrathecal Morphine Pump 62370 76942 J3490 is not certified.

Per ODG:

Implantable drug-delivery systems (IDDSs)	<p style="text-align: center;">Indications for Implantable drug-delivery systems:</p> <p><u>Implantable infusion pumps</u> are considered medically necessary when used to deliver drugs for the treatment of:</p> <ul style="list-style-type: none"> o Primary liver cancer (intrahepatic artery injection of chemotherapeutic agents); o Metastatic colorectal cancer where metastases are limited to the liver (intrahepatic artery injection of chemotherapeutic agents); o Head/neck cancers (intra-arterial injection of chemotherapeutic agents);
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	<p>o Severe, refractory spasticity of cerebral or spinal cord origin in patients who are unresponsive to or cannot tolerate oral baclofen (Lioresal®) therapy (intrathecal injection of baclofen)</p> <p><u>Permanently implanted intrathecal (intraspinal) infusion pumps</u> for the administration of opiates or non-opiate analgesics, in the treatment of chronic intractable pain, are considered medically necessary when:</p> <ul style="list-style-type: none"> • Used for the treatment of <u>malignant (cancerous) pain</u> and all of the following criteria are met: <ol style="list-style-type: none"> 1. Strong opioids or other analgesics in adequate doses, with fixed schedule (not PRN) dosing, have failed to relieve pain or intolerable side effects to systemic opioids or other analgesics have developed; and 2. Life expectancy is greater than 3 months (less invasive techniques such as external infusion pumps provide comparable pain relief in the short term and are consistent with standard of care); and 3. Tumor encroachment on the thecal sac has been ruled out by appropriate testing; and 4. No contraindications to implantation exist such as sepsis or coagulopathy; and 5. A temporary trial of spinal (epidural or intrathecal) opiates has been successful prior to permanent implantation as defined by a 50% reduction in pain. A <i>temporary</i> trial of intrathecal (intraspinal) infusion pumps is considered medically necessary only when criteria 1-4 above are met. • Used for the treatment of <u>non-malignant (non-cancerous) pain</u> with a duration of greater than 6 months and all of the following criteria are met: <ol style="list-style-type: none"> 1. Documentation, in the medical record, of the failure of 6 months of other conservative treatment modalities (pharmacologic, injection, surgical, psychologic or physical), if appropriate and not contraindicated; and 2. Intractable pain secondary to a disease state with objective documentation of pathology in the medical record (per symptoms, exam and diagnostic testing); and 3. Further surgical intervention or other treatment is not indicated or likely to be effective; and 4. 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 5. No contraindications to implantation exist such as sepsis, spinal infection, anticoagulation or coagulopathy; and 6. 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 <u>functional improvement</u> and associated reduction in oral pain medication use. A temporary trial of intrathecal (intraspinal) infusion pumps is considered medically necessary only when criteria 1-5 above are met. <p>For average hospital LOS if criteria are met, see Hospital length of stay (LOS).</p>
<p>Intrathecal drug delivery systems, medications</p>	<p>Recommended as indicated below.</p> <p><u>Recommended 1st stage:</u> 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. (Waara-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) It can be seen that there has been a substantial decrease in concentration (particularly for hydromorphone). The newer</p>

	<p>maximum concentrations were recommended, in part, to prevent granulomas.</p> <p><u>Recommended 2nd stage:</u> 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)</p> <p><u>Recommended 3rd stage:</u> 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). 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. This recommendation was published in a journal not yet accepted for inclusion in MEDLINE and the conference was sponsored by Elan Pharmaceuticals. (Deer, 2007)</p>
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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)**