

Health Decisions, Inc.

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Notice of Independent Review Decision

[Date notice sent to all parties]: July 20, 2013

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:

Outpatient L3-S1 hardware removal at Health Center for Diagnostics and Surgery

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

This physician is a Board Certified Neurosurgeon with over 16 years of experience.

REVIEW OUTCOME:

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

Overturned (Disagree)

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:

02-07-13: Pump Refill Visit

02-12-13: C2 Medication Consult

03-12-13: C2 Medication Consult

03-26-13: Office Visit

04-09-13: Procedure Note

04-23-13: Office Visit

05-13-13: UR performed

06-03-13: Note

06-17-13: UR performed

PATIENT CLINICAL HISTORY [SUMMARY]:

The claimant is a male who was injured on xx/xx/xx when construction dirt collapsed. He underwent a 360 fusion from L3/4 to L5/S1 in 2000. Following surgery he continued with pain and underwent placement of a spinal cord stimulator. Due to continued pain, he then underwent placement of a morphine pump which provided relief and allowed him to stop taking his Oxycodone for

breakthrough pain. However, according to the records, in 2012 he began having discomfort in his lower back that progressively worsened. It was reported that over the last 6 months, he had lost 60 pounds secondary to not being able to eat because his teeth were breaking and falling out as a result of being on the morphine for so long. Since the lost of all the weight, his back pain severely worsened and he could feel a nodule on his left lower back.

February 7, 2013, performed a refill of Synchroned infusion pump.

March 12, 2013, evaluated the claimant and reported the claimant was having severe pain in the left hip at the surgery site where there were hard knots that he described as burning painful sites. looked and felt hardware was malfunctioning and recommended referring back for evaluation.

March 26, 2013, re-evaluated the claimant for left sided lower back pain that had progressively worsened over the past year. He noted difficulty walking, going up/down stairs, leaning against anything and is awakened from sleep because of burning in his lower back. He returned to taking Oxycodone 2-3 times a day to help with the burning in his lower back. On physical examination gait was antalgic to the right. Paravertebral muscles were tender on the left. Straight leg raises were normal bilaterally with no issues. Upon inspection of the lumbar spine there is evidence of a nodule on the left side near the L5/S1 level, it was significantly tender to palpation and appeared to be hardware right below the skin. Lower extremities strength was symmetrically present in all lower extremity muscle groups. DTRS were present at Hypo. X-ray performed in the office revealed good placement of hardware from L3-S1, hips appeared to be within normal limits and there were some mild degenerative changes of bilateral SI joints. On lateral view there were well healed fusions from L3-S1 with bony ingrowth in all cages. There was no haloing or lucency of any of the screws and no subsidence of any of the cages. There was no instability at the level above his fusion. Plan: She had a lengthy discussion reassuring him that the hardware was not loose, but because of his rapid weight loss he was now feeling his hardware and it was rubbing against skin which was causing pain. He was cautioned against any further weight loss because it could cause the hardware to abrade his skin and encouraged him to get some pigskin to put over the area to at least cushion the area for when he sits, leans or sleeps.

April 9, 2013, Procedure Note, Postoperative Diagnosis: 1. Lumbar spondylosis. 2. Failed back syndrome with chronic polyradiculopathy. 3. Painful hardware, L5-S1 lumbar spine. 4. Lumbar radiculitis. 5. Lumbago. 6. Chronic pain syndrome. 7. Intractable back pain. Procedure: Hardware injection at the L5-S1 spine, under C-arm fluoroscopy.

April 23, 2013, re-evaluated the claimant and reported the claimant had about 6 hours total of complete relief of his pain and was able to sit against a hardback chair without experiencing discomfort and lie down without very much discomfort. However, the pain did return after approximately 6 hours. On examination of the lumbar spine there was evidence of a nodule on the left side near the L5/S1 level

that was significantly tender to palpation and appeared to be the patient's hardware right below his skin. Assessment: Painful hardware on the left at L5-S1 with a well-healed fusion from L3-S1 with positive response to hardware injection for approximately 6 hours. Plan: Recommended hardware removal.

May 13, 2013, performed a UR. Rationale for Denial: There is a discrepancy in the request for removal of hardware at L4-5 rather than L5-S1 or L3-S1. In light of this discrepancy between the request and the clinical notes, the requested service is denied at least until clarified.

June 17, 2013, performed a UR. Rationale for Denial: The previous non-certification for only hardware removal at L4-L5 on May 8, 2013, was due to the discrepancy of removal of hardware at L4-5 rather than at L5-S1 or L3 to S1. The claimant was noted to have undergone hardware injection on the left with symptomatic improvement on April 9, 2013. The previous non-certification is supported. Additional records were not provided for review. The location of the prior request for hardware removal at L4-L5 would have been incorrect. The current hardware placed is not fully described. The claimant had solid fusion from L3 to S1, but only had localized tenderness to the left at L5-S1 and had undergone a localized hardware injection at this level that did objectify painful hardware as symptoms improved after the injection and by clinical examination it was state there was a palpable screw underneath the skin to the left at L5-S1. This was the only localized area of tenderness. Imaging does not fully objectify the type of hardware under the skin which was not described by the clinician, but noted on physical examination to likely be a screw. The necessity of removing all hardware between L3 to S1 was not medically necessary, as there is only a focal point of irritation on the left at L5-S1, and hardware removal would only be necessary at L3 to S1 if the symptomatic portion of the hardware was in a large construct. The guidelines indicate routine removal would not be accepted except in cases of persistent pain after ruling out other causes of pain, such as infection or non-union. There should be a diagnostic hardware injection block prior to consideration of removal of hardware. The claimant has a focal area of pain to the left at L5-S1 and had undergone a recent hardware injection block, which was unsuccessful and by physical examination and was felt to be a screw head underneath the skin, which was tender by palpation. The pain has been persistent and if there is a focal local removal of hardware would be medically supported, but hardware removal from L3 to S1 would only be necessary if the hardware located in the left low back at L5-S1 is part of a larger construct.

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

The previous adverse determinations are overturned. The claimant has painful hardware localized to the left L5/S1 area by hardware block. His radiographs do not show any infection, hardware loosening, or nonunion of his fusion from L3 to S1. He has likely pedicle screws from L3 to S1 and this usually is a cross linked construct that will warrant removal of all the claimant's implanted posterior hardware. It would be impractical to only remove part of the hardware if any part of it needs to come out, especially if the claimant is at risk for losing more weight.

His fusion is solid so his hardware has served its purpose. The hardware removal carries risk but this claimant already has maximal management now with resumption of oral narcotics in the presence of a Spinal Cord Stimulator and Pain Pump. This is not a routine case or hardware removal request. The ODG guidelines support hardware removal in cases such as this with relief from a block and doesn't specify the duration of relief needed. Therefore, the request for Outpatient L3-S1 hardware removal at Health Center for Diagnostics and Surgery is found to be medically necessary.

PER ODG:

Hardware implant removal (fixation)	Not recommend the routine removal of hardware implanted for fixation, except in the case of broken hardware or persistent pain, after ruling out other causes of pain such as infection and nonunion. Not recommended solely to protect against allergy, carcinogenesis, or metal detection. Although hardware removal is commonly done, it should not be considered a routine procedure. The decision to remove hardware has significant economic implications, including the costs of the procedure as well as possible work time lost for postoperative recovery, and implant removal may be challenging and lead to complications, such as neurovascular injury, refracture, or recurrence of deformity. The routine removal of orthopaedic fixation devices after healing remains an issue of debate, but implant removal in symptomatic patients is rated to be moderately effective. Many surgeons refuse a routine implant removal policy, and do not believe in clinically significant adverse effects of retained metal implants. For more information and references, see the Ankle Chapter .
Hardware injection (block)	Recommended only for diagnostic evaluation of failed back surgery syndrome. This injection procedure is performed on patients who have undergone a fusion with hardware to determine if continued pain is caused by the hardware. If the steroid/anesthetic medication can eliminate the pain by reducing the swelling and inflammation near the hardware, the surgeon may decide to remove the patient's hardware. (Guyer, 2006)

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)**