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IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:

Hardware removal

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

Orthopedic Physician

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.

PATIENT CLINICAL HISTORY [SUMMARY]:

The patient is a male who was apparently injured on the job where he was struck from behind with a large 16 or 18-inch gas pipe flexing in forward and injured his left lower extremity, ankle, back and chest.

On XX/XX/XX, the patient was evaluated for a work-related injury. He had an open ankle fracture. Computerized tomography (CT) scan of the chest and abdomen suggested a fracture at T12. He was wearing an ankle brace. X-rays suggested a Chance fracture through the body of T12 with both anterior and posterior bony disruption. It was quite unstable. The plan was to proceed with an MRI of the thoracic and lumbar region. The patient also apparently had severe congenital stenosis at the lumbar region. XX placed him on total bedrest and planned on surgery.

On XX/XX/XX, the patient underwent exploration of fracture internal stabilization with internal fixator

from T11 to L1. The postoperative diagnoses were burst fracture at T12 with posterior ligamentous disruption and facet disruption.

On XX/XX/XX, XX evaluated the patient for a postoperative follow-up visit. He was doing well and continued to wear the lumbosacral orthosis (LSO) brace and was participating with physical therapy (PT) at home. The incision appeared well approximated and healing without evidence of acute infection. The patient was kept off work for a minimum of three months. Pain management was continued.

On XX/XX/XX, XX evaluated the patient who stated he was doing well and had no significant back pain. He continued to wear a brace on his left leg. He stated he wanted to return to work soon. He was mostly nonweightbearing on his left lower extremity. Examination revealed he was strong and able to stand with minimal weightbearing to the left foot with good strength. He was advised to follow-up regarding return to work. He reported having some light duty that he could perform if allowed.

On XX/XX/XX, XX planned to wean the patient out of his brace and start him on an exercise program.

On XX/XX/XX, the patient underwent a PT evaluation at XX and was recommended to undergo PT sessions twice a week for four weeks. From XX/XX/XX, to XX/XX/XX, the patient underwent PT sessions. Modalities included therapeutic exercises, therapeutic activities, neuromuscular re-education, patient/family education, ultrasound, hot/cold packs, massage, transcutaneous electrical nerve stimulation (TENS), neuromuscular electrical stimulation (NMES), and interferential current (IFC).

On XX/XX/XX, the patient was evaluated. He reported doing pretty well except for some low back pain. He had been released to light duty with restrictions. He reported mechanical back pain with ambulation that improved with sitting. Examination was notable for tenderness and mild muscle spasms at the L5-S1 level. A Medrol Dosepak was prescribed. XX recommended core strengthening exercises.

On XX/XX/XX, XX evaluated the patient who reported the Medrol Dosepak had helped his low back pain some but he had ongoing low back pain with ambulation. He had returned to work with some lifting limitations. He was recommended to continue strengthening exercises. He was returned to full duty.

On XX/XX/XX, XX evaluated the patient and assessed the pain was due to internal orthopedic prosthetic devices, implants and grafts and recommended removing the hardware after obtaining a CT.

On XX/XX/XX, the patient underwent a CT of the lumbar spine. The study revealed progression of the T12 loss of height with healing of a fracture, mild visualized portion of the thoracic and lumbar

spondylosis with spinal canal stenosis, multiple disc bulges and L4-L5 disc herniation.

On XX/XX/XX, the patient was evaluated. His CT scan was reviewed and showed good fusion. XX planned to remove the hardware.

On XX/XX/XX, XX denied the request for hardware removal. The decision was given with the following rationale: *“XX DOB XX/XX/XX, XX DO1 XX/XX/XX Injury: Struck by pipe. Treatment history: status post posterior spinal fusion T11-L1 XX/XX/XX. Request: Hardware removal. Per ODG spinal hardware removal 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, per documents submitted there is a vague complaint of "some discomfort" without qualitative or quantitative description. No indication of how "some discomfort" affects activity, function or quality of life. No documentation of physical exam findings or provocative testing indicating painful hardware. No physical exam documented at all at the time decision was made to remove hardware on XX/XX/XX. No diagnostic injection performed to confirm painful hardware and no documentation that infection ruled out.”*

On XX/XX/XX, XX appealed on behalf of the patient.

On XX/XX/XX, per reconsideration review letter, the denial was upheld. The following rationale was provided: *“The proposed treatment consisting of Hardware Removal, Spine is not appropriate and/or medically necessary for this diagnosis and clinical findings. The guidelines do not recommend routine hardware removal in cases where hardware is asymptomatic and there is no evidence of infection. In this case, CT studies did not identify any complications of the claimant’s hardware in the thoracolumbar region. The most recent evaluation did not include any specific objective findings regarding symptomatic hardware. There was also no recent diagnostic hardware blocks performed indicating symptomatic hardware. As the clinical records provided for review do not meet guideline recommendations regarding the proposed service, this reviewer would not recommend certification for the request.”*

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

Hardware removal from the lumbar spine would not be considered medically necessary and appropriate based upon the Official Disability Guidelines. This claimant is status post a previous T11 through L1 instrumented spinal fusion. This was performed in XX/XX/XX. There are office notes provided that document complaints of back pain off and on. There were no complaints of back pain at the XX/XX/XX office visit. At the XX/XX/XX office visit, there were complaints of back pain. This claimant was evaluated in XX/XX/XX and XX opined that this was due to an internal orthopedic prosthetic device, and he recommended removal of the hardware after obtaining a CT scan. The CT scan was obtained and demonstrated a healed fracture and good hardware placement without loosening. At the XX/XX/XX office visit, XX reviewed the CT scan and did not perform an examination. He again opined that the back pain

was due to internal orthopedic hardware. No diagnostic injection has been performed. If one looks toward the Official Disability Guidelines, hardware injections are recommended to determine if continued pain is caused by the hardware. Hardware removal is not recommended except in cases of broken hardware or persistent pain after ruling out other causes of pain such as infection or nonunion. As this claimant has not undergone an infection workup or diagnostic hardware injection, and based upon the Official Disability Guidelines, removal of hardware from the lumbar spine cannot be certified.

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

ODG- OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES

Official Disability Guidelines® (21st annual edition) 2016

Low Back (updated 04/25/16)

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)

Official Disability Guidelines® (21st annual edition) 2016

Ankle & Foot (updated 03/01/16)

Hardware implant removal (fracture fixation)

Not recommend the routine removal of hardware implanted for fracture 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. Current literature does not support the routine removal of implants to protect against allergy, carcinogenesis, or metal detection. (Busam, 2006) Despite advances in metallurgy, fatigue failure of hardware is common when a fracture fails to heal. Revision procedures can be difficult, usually requiring removal of intact or broken hardware. (Hak, 2008) Following fracture healing, improvement in pain relief and function can be expected after removal of hardware in patients with persistent pain in the region of implanted hardware, after ruling out other causes of pain such as infection and nonunion. (Minkowitz, 2007)

The routine removal of orthopaedic fixation devices after fracture 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. Given the frequency of the procedure in orthopaedic departments worldwide, there is an urgent need for a large randomized trial to determine the efficacy and effectiveness of implant removal with regard to patient-centered outcomes. (Hanson, 2008)