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Notice of Independent Review Decision

Date: September 24, 2013

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:
Hardware removal with exploration and fusion, decompression, and possible revision fusion at the L5-S1 level with 3 day inpatient hospital stay

A DESCRIPTION OF THE QUALIFICATIONS FOR EACH PHYSICIAN OR OTHER HEALTH CARE PROVIDER WHO REVIEWED THE DECISION:
Diplomate American Board of Orthopaedic Surgery
Fellowship Trained in Spine Surgery

REVIEW OUTCOME:

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

☒ Upheld (Agree)

Medical documentation **does not support** the medical necessity of the health care services in dispute.

INFORMATION PROVIDED TO THE IRO FOR REVIEW:

- Office visits (08/20/09 – 06/19/13)
- Diagnostics (12/03/12 – 12/10/12)
- Utilization reviews (07/02/13, 07/31/13)
- Letter (07/24/13)

- Office visits (01/30/07 – 08/14/13)
- Procedure (03/02/07)
- PT evaluation (06/11/07 – 03/05/12)
- Diagnostics (05/28/09 – 12/10/12)
- Letter (07/24/13)

- Utilization reviews (07/02/13, 07/31/13)

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- Utilization reviews (07/02/13, 07/19/13, 07/31/13)

ODG criteria have been utilized for the denials.

PATIENT CLINICAL HISTORY [SUMMARY]:
The patient is a male who sustained an injury on xx/xx/xx.

2006: No records are available.

2007: On January 30, 2007 evaluated the patient for back and leg pain. The patient stated that the pain had originally started in xxxx. It occurred while he was at work when he slipped. The pain had progressively worsened since the original injury. The pain travelled from the low back area down into the bilateral lower extremities affecting right more than left. It affected the buttocks, thigh, calf and feet. He had spasms into the legs. He also had numbness and tingling into the legs. He had undergone laminectomy x2 without relief. He also underwent epidural steroid injections (ESIs) as well as nerve root blocks without improvement. He was presently taking approximately three to four Vicodin tablets per day for pain management. He had increased pain with sitting. Surgical history was positive for L5 to S1 bilateral laminectomy and right partial discectomy in 2000 and revision right L5-S1 laminectomy. The patient admitted that he was taking half a pack of tobacco per day. Examination of the lumbar spine showed decreased range of motion (ROM) with pain on motion, some spasm and positive straight leg raise (SLR) on the right with decreased sensation in the L5-S1 distribution on the right compared to left. X-rays and magnetic resonance imaging (MRI) scan showed disc herniation, degeneration and stenosis primarily at L5-S1 at the site of previous laminectomies. diagnosed L5-S1 residual herniation and stenosis with degenerative disc disease (DDD) and segmental instability. He recommended decompression and revision.

On March 2, 2007, performed L5-S1 revision laminectomy and decompression, discectomy and spinal fusion with Medtronic Engage segmental instrumentation, Discovery facet screw, allograft, Infuse bone morphogenic protein into Hollywood interbody fusion device.

From March 20, 2007, through July 10, 2007, noted that the patient was doing well. The patient's back was feeling better. He had been able to do most of the activities without problem. maintained the patient on brace and a walking program. He recommended starting some exercises.

On June 11, 2007, the patient underwent physical therapy (PT) evaluation at Rehabilitation. He was recommended starting therapy two to three times a week for four weeks.

2008: No records are available.

2009: On May 26, 2009 noted that the patient had some increasing back pain over the last few months radiating over the left buttock to the back of the thigh.

Examination showed decreased ROM with pain on motion of back and a positive SLR. diagnosed lumbar listhesis, disc herniation and stenosis and status post previous revision. He recommended obtaining an MRI of the lumbar spine.

On May 28, 2009, MRI of the lumbar spine showed: At L5-S1, status post L5 laminectomy. There were pedicle screws and interconnecting rods at L5-S1.

On June 9, 2009, noted that the patient still had significant pain which was worse with activities including bending or lifting. He recommended getting a myelogram to evaluate the more subtle stenosis in detail than the MRI.

On July 9, 2009, computerized tomography (CT) scan of the lumbar spine showed: (1) At T11-T12, there was 1-2 mm anterolisthesis of T11 on T12 with associated 1 mm broad-based posterior protrusion. There was a superimposed 4 or 5 mm right posterolateral protrusion. Right facet arthrosis and hypertrophy were present along with ossification of the right ligamentum flavum. There was right lateral recess stenosis, marked right foraminal narrowing and displacement of the emanating right T11 nerve root sleeve. (2) At L2-L3, 2-mm symmetric broad-based posterior fusion abutting the sac. There was mild bilateral foraminal narrowing but no displacement of the L3 nerve root sleeves. At L3-L4, there was a 2-mm symmetric broad-based posterior protrusion with a superimposed 5-mm broad-based far left posterolateral protrusion. There was mild bilateral facet arthrosis present. There was mild right and moderate left foraminal narrowing present. There was effacement of the emanating left L3 nerve root sleeve/dorsal root ganglion. (3) At L4-L5, a 2-mm broad-based posterior protrusion mildly indenting the sac. There was mild bilateral facet arthrosis. There was moderate bilateral foraminal narrowing present. However, there was no visible effect upon the L4 nerve root sleeves. The L5 nerve root sleeves filled normally. (4) At L5-S1, status post transdiscal interbody arthrodesis. There was continuous osseous bridging across a small portion of the disc space. Mild disc space narrowing was present. The right laminectomy and left laminectomy defect was present. There was a left transarticular screw at L5-S1 and transpedicular/transsacral screw with posterior instrumentation on the right. Right laminectomy and left laminectomy defects were present. Moderate-to-marked bilateral foraminal narrowing was present. There was a 5 or 6 mm bony right posterior protrusion which appeared to deviate and efface the right S1 nerve root sleeve. The S1 nerve root sleeves filled relatively normally.

On July 15, 2009, reviewed the CT-myelogram findings that confirmed solid fusion at L5-S1 with left-sided disc herniation at L3-L4 with some listhesis and stenosis at T11-T12 as well. He recommended activity modification and getting an impairment rating (IR) as those problems in his neck, back and shoulder had developed from original work-related injuries, to assess full extent of impact of those injuries.

On August 5, 2009, referred the patient to a pain management doctor, for injections. The patient was started on Lyrica as he seemed to have some component of fibromyalgia.

On August 20, 2009, performed transforaminal epidural steroid injection (ESI) at the right T11, left L3 and left L5 and right S1.

On September 30, s013, EMG/NVC of the lower extremities identified chronic S1 lumbar radiculopathy bilaterally more marked on the right and early distal axonal sensory polyneuropathy.

2010: On March 24, 2010, continued the patient on medications as well as Lyrica.

2011: From March 22, 2011, through July 6, 2011, evaluated the patient for back and neck pain. He reviewed the MRI findings of the cervical spine that showed significant disc herniation at C3-C4 on the left with some disc degenerative changes and mild-to-moderate stenosis at C5-C6 and C6-C7. recommended an injection on the left at C3-C4 both as a diagnostic and therapeutic.

On August 11, 2011, performed transforaminal ESI at left C4 and C5.

On August 17, 2011, evaluated the patient for neck pain. He noted that the patient was quite symptomatic, not only in terms of pain but it appeared that it was causing some evidence of myelopathy. The patient wanted to proceed with surgery. recommended getting an authorization for C3-C4 discectomy and fusion to address both the cord compression and the disc.

On September 14, 2011, noted that the surgery was denied for the neck. He recommended continuing pain management for low back and starting physical therapy (PT).

2012: On January 3, 2012, noted that the patient was still symptomatic and he had a lot of pain medications for his low back. He still had significant limitation of activity. He was unable to work due to both the standing and sitting intolerance, as well as the large amount of narcotics he had to use to control the pain. Those narcotics made it difficult for him to concentrate or focus on any tasks at hand, as well as made him quite sedated.

On March 5, 2012, the patient was evaluated.

On December 3, 2012, CT scan of the lumbar spine showed: (1) Mild degenerative changes of bilateral sacroiliac (SI) joints with right iliac subchondral cysts. (2) Mild scattered subdural contrast. (3) At L2-L3 and L3-L4, congenitally narrowed spinal canal and mild posterior disc bulge. (4) At L3-L4, mild bilateral facet arthropathy. (5) At L4-L5, posterior disc bulge causing mild bilateral lateral recess narrowing. Bilateral facet arthropathy and mild right foraminal narrowing. (6) At L5-S1, posterior fusion with right L5 and bilateral S1 transpedicular screws and interconnecting rods and disc graft material. There was partial fusion of L5-S1 disc graft and posterior elements of L5-S1. Right L5 and right S1 transpedicular screws protruded slightly beyond the anterior cortex of the

respective vertebral body. There were right laminectomy changes. (7) Abnormal tissue in the right lateral recess and right foramen could be postsurgical or due to disc material. There was non-filling of the exiting right L5 nerve root.

On December 6, 2012, MRI of the thoracic spine showed severe right-sided facet hypertrophy at T12-L1, narrowing the corresponding neural foramina. Bone overgrowth compressed the thecal sac from the right side and the right measured approximately 14 mm in a maximal transverse dimension. Facets were also hypertrophic bilaterally at L1-L2.

On December 10, 2012, MRI of the lumbar spine showed: (1) There was mild-to-moderate epidural lipomatosis, most prominent at L4-L5. The posterior epidural fat measured a maximal anteroposterior (AP) dimension a 9 mm. (2) At T12-L1, there was mild left facet hypertrophy without canal or neural foraminal stenosis. (3) At L2-L3, a very small broad-based disc bulge and mild bilateral facet hypertrophy were present. Both neural foramina were moderately narrowed. The thecal sac measured 12 mm in maximal AP dimension. (4) At L3-L4, there was a moderate sized broad-based disc bulge and mild-to-moderate bilateral facet hypertrophy. Both neural foramina appeared moderately narrowed, left greater than right. Maximal AP dimension of the spinal canal was 9 mm. (5) At L4-L5, there was a small broad-based disc bulge and bilateral facet hypertrophy (moderate on the left and severe on the right). Disc material encroached upon both lateral recesses. The thecal sac measured 9 mm in maximal AP dimension. Both neural foramina were moderate-to-severely stenotic. (6) At L5-S1, surgical changes noted at the level. The previously described abnormal tissue in the right lateral recess and neural foramen appeared most consistent with enhancing granulation tissue. The neural foramina were suboptimally evaluated due to metallic susceptibility artifact. They both appeared moderately narrowed, right greater than left.

2013: On February 19, 2013 evaluated the patient for neck and back pain. She noted that the patient had undergone lumbar laminectomy and discectomy twice in 2000 and 2003. reviewed the diagnostic studies and diagnosed myofascial pain syndrome, cervical DDD, cervicalgia/neck pain. She refilled oxycodone and recommended starting hydromorphone.

On April 19, 2013, refilled oxycodone and hydromorphone.

On April 30, 2013, noted that the patient's back had gotten worse with pain both in back going down the legs. He asked the patient to bring the myelogram to review it in more detail.

On May 28, 2013, noted that the patient had pain in the back in the lower part. The patient also had numbness and tingling in the bottom of his feet. reviewed the CT myelogram findings that showed the hardware at L5-S1 with some disc protrusion or scar tissue on the right at L5-S1 affecting the right L5 nerve root. There seemed to be some bone growth in the disc space. recommended considering a hardware removal and exploration of fusion and possible revision

fusion. He would then explore the right L5 nerve root area and see if that could be decompressed further.

On June 14, 2013, evaluated the patient for neck and back pain. She refilled oxycodone and hydromorphone and recommended starting Phenergan.

On June 19, 2013, recommended going ahead and proceeding with hardware exploration and fusion, decompression with possible revision fusion. He noted that the patient had decreased ROM with pain on motion of the back and positive SLR on the right.

Per utilization review dated July 2, 2013, the request for hardware removal with exploration and fusion, decompression and possible revision fusion at L5-S1 level between June 27, 2013, and August 26, 2013, was denied based on the following rationale: *"The most recent medical report dated June 19, 2013, states that the patient has pain in his low back that radiates down to his leg. He feels like his back is unstable. On examination, there is decreased ROM with pain in the back and positive SLR on the right. The referenced guidelines do 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. There is no evidence that this patient has a broken hardware or evidence of nonunion. Also a psychological evaluation that addresses issues that may affect the surgical outcome is not mentioned. Moreover, failure and exhaustion of recent conservative treatment with physical therapy and medications were not submitted. Hence the medical necessity of this request has not been substantiated."*

On July 19, 2013, preauthorization request for 12 sessions of physical therapy for the lumbar spine was denied.

In a letter dated July 24, 2013, stated that the patient had a long history of back problems. He had multiple courses of conservative treatment including injections and PT. Any additional PT would not help the patient. The patient did have residual pain. To address the residual symptoms, the patient has been recommended hardware, exploration of fusion and possible revision fusion with also decompression of the residual stenosis. The patient wanted to proceed with that.

Per reconsideration review dated July 31, 2013, the appeal for hardware removal with exploration and fusion, decompression and possible revision fusion at L5-S1 level between July 26, 2013, and September 24, 2013, with three days of inpatient hospital stay between July 31, 2013 and September 29, 2013, was denied based on the following rationale: "*The appeal letter dated July 24, 2013, indicates that the patient has a long history of back problems. He had multiple surgeries with multiple courses of conservative treatment including injections and physical therapy. While the patient has ongoing low back pain with a history of multiple lumbar surgeries, the records submitted for review did not contain specific objective findings such as sensorimotor deficits to support the diagnosis of a failed*

back syndrome. Also, recent imaging studies of the lumbar spine showed no evidence of pseudoarthrosis or hardware breakage and loosening. There was no evidence in the medical reports submitted that the patient has had recent conservative treatment such as physical therapy including a weight loss program and smoking cessation prior to the proposed surgery. Also, a pre-operative psychological evaluation was not submitted for review. In agreement with the previous determination, the medical necessity of the request for surgery has not been substantiated. Therefore, the need for three days inpatient stay has also not been demonstrated."

On August 14, 2013 noted that Workers Compensation had denied the surgery. Examination of the back showed decreased ROM with pain on motion. diagnosed L5-S1 stenosis, hardware pain and possible pseudoarthrosis and recommended going ahead and appealing for the surgery.

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

The records forwarded for review begin in 2007, noting that the patient had been referred for consultation. The patient had pain in the back for a considerable time since his original pain started in xxxx. The patient was complaining of buttock, thigh, calf and feet involvement with spasm into the legs. The patient had had epidurals without improvement. He was taking Vicodin. The patient did admit to being a tobacco user. Options were discussed with the patient. Fusion was proposed.

The procedure of March 2, 2007, was an L5-S1 revision laminectomy, decompression, discectomy and spinal fusion. This was done at L5-S1.

The patient did initially symptomatically improve.

By July 2007 noted the patient could do most activities without a problem suggesting that he was having some residual issues.

There were no records for 2008. In 2009, the patient presented with increasing back pain over the last few months into the left buttock to the back of the thigh. The straight leg raise was positive on the left.

The patient subsequently had an MRI completed on May 28, 2009. It was noted that there was no evidence of fusion healing at the L5-S1 level per the MRI at least.

The patient then had re-assessment who noted that a myelogram-CT scan would be ultimately required to evaluate for more subtle involvement.

This lumbar myelogram CT scan was completed on December 3, 2012. As interpreted this study showed postsurgical changes at L5-S1 as well as abnormal tissue in the right lateral recess and right foramen with non-filling at the exiting

right L5 nerve root. Those changes were considered to be postsurgical or due to disc protrusion. Of interest, there was no left-sided abnormality identified.

The L4-L5 level showed only mild bilateral lateral recess narrowing and mild right foraminal narrowing.

The patient then subsequently had an MRI on December 10, 2012, which was interpreted. The previously described abnormal tissue within the lateral recess on the right neural foramen at L5-S1 was most consistent with enhancing granulation tissue. There was noted to be degenerative changes.

The patient also had a thoracic spine MRI which was noted to show facet hypertrophy at T12-L1 but no other significant abnormality. The patient throughout this timeframe was being re-assessed and provided medication managements. The patient was utilizing oxycodone and hydromorophone.

The patient continued to be seen who noted the patient's decreased range of motion with pain on motion. However, there is not a specific neurological assessment provided. However, proposed that the patient have revision of his fusion if there was a pseudoarthrosis.

continued to provide medication support. On June 19, 2013, provided a clinic note noting that the patient had decreased range of motion of the spine. Straight leg raise was positive on the right. There were no other neurological findings reported.

In July 2013 noted in his utilization review that the patient had the previous L5-S1 laminectomy with revision laminectomy and subsequent spinal fusion on March 2, 2007. The myelogram CT scan had shown abnormal tissue but this was not confirmed to be anything except scar tissue on the subsequent MRI. The request for revision L5-S1 hardware removal and possible refusion was denied.

Reconsideration of this proposed surgery was done who also noted that there was inadequate support to do this repeat surgery based on evidence based medicine.

on July 24, 2013, noted the patient did have residual pain but did not consider that there was any need for formal therapy.

Thus in overall summary, the patient has had previous decompression surgeries in the early 2000 timeframe. There was subsequent revision laminectomy, decompression and fusion in March 2007. The patient in 2009 was noted to have left leg pain on presentation. However, the patient's symptoms have included his bilateral feet. The CT myelograms of December 3, 2012, had shown abnormal tissue in the right lateral recess and the right foramen, and non-filling of the right L5 nerve root; however, on subsequent MRI on December 10, 2012, this tissue appeared to be postsurgical change without new disc material. The CT scan after the myelogram had shown that there was healing across part of the disc space as far as the fusion. There was no loosening of the hardware of the lumbar spine.

The neurological assessment provided does not provide any validated objective neurological deficit that can be identified specifically to the L5 nerve root that he is proposing to decompress. Please recall that the patient's original symptoms in 2009 were that into his left leg.

There were no psychological assessments of the patient's pain understanding and dealing with pain.

Thus, the need for the proposed surgery to include hardware removal, exploration of fusion and decompression of the L5 nerve root is not validated by these records. I did note that the description of service or services in dispute did not list specifically exploration and decompression of the L5 nerve root; however, that is what had proposed in his records.

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

☒ **ODG- OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES**