Clear Resolutions Inc.

An Independent Review Organization
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Notice of Independent Review Decision

Review Outcome

Description of the service or services in dispute:

Denied inpatient with length of stay three days, lumbar spine, anterior lumbar interbody fusion at L4-L5 and L5-S1, with minimal invasive surgery screws and a possible transforaminal lumbar interbody fusion (TLIF)
22558 – Lumbar fusion, anterior approach
22585 – Lumbar fusion, anterior approach, each additional interspace
22853 – Insertion of biomechanical device(s)
20930 – Spinal bone allograft
22842 – Instrumentation for spine, posterior, segmental, three to six vertebral segments
22633 – Lumbar spine fusion combined
20936 – Spinal bone autograft

Description of the qualifications for each physician or other health care provider who reviewed the decision:

Orthopedic Surgeon

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

☐ Overturned (Disagree)
☑ Upheld (Agree)
☐ Partially Overturned (Agree in part / Disagree in part)

Patient Clinical History (Summary)

XX is a XX who was diagnosed with intervertebral disc degeneration of the lumbosacral region (M51.37). On XX, XX was working as a XX and was XX a XX , when XX felt a pop, which resulted in a low back injury.

XX was seen by XX, MD on XX for the complaints of low back pain radiating over the posterior and lateral right thigh and calf. The prior epidural XX injections had helped XX 40% at the L5 level and 50% at the S1 level for several weeks. At the time on that day, XX pain was almost back to baseline. XX had an episode of an inability to control XX bladder function several weeks prior. XX reported having weakness in the right leg, especially with exertion. On examination, 5/5 muscle strength was noted in all the muscles of both lower extremities. XX walked with no limp and was able to stand up from sitting position with no difficulty. XX had decreased sensation to light touch over the posterior calf and medial and plantar right foot. XX had 3+ reflexes in the left patellar and Achilles tendons and 1+ reflexes on the right side in these tendons. There were three surgical well-healed incisions noted with no signs of inflammation. Dr. XX felt that XX had some sort of dynamic stenosis since XX pain had presented after certain movements in certain position of XX body. XX opined that XX had a reasonable chance of improvement with indirect decompression and stabilization between L4-L5 and L5-S1 levels, which might be accomplished with anterior lumbar interbody fusion.

XX was evaluated by XX MD on XX for the complaints of low back pain radiating to the right lower extremity. XX pain was severe and worsened with bending or lifting. XX pain was improved with XX (which was left over from XX surgery). XX continued the XX. XX reported subjective weakness of the right lower extremity. XX also reported depression due to XX pain and after not having been at work. The examination revealed tenderness to palpation of the midline in the lower lumbar spine and right paraspinous muscles. The range of motion of the spine showed forward flexion to 40 degrees, extension to 10 degrees, left and right lateral bending to 20 degrees and left and right rotation to 30 degrees. The straight leg raise test was positive on the right side. The muscle strength was 4/5 during right plantarflexion. The sensation was decreased over the right posterior thigh and lateral calf. The diagnoses were intervertebral disc displacement of the lumbar region, lumbar postlaminectomy syndrome, and lumbar radiculopathy.

A CT myelogram of the lumbar spine dated XX identified disc protrusion at the L3-L4 level extending posterior to the lower L3 vertebral body, causing only mild spinal canal narrowing without evidence of nerve root compression. Degenerative disc disease was noted at the L4-L5 level, not causing any significant spinal and only mild right-sided foraminal narrowing. Minimal degenerative changes were seen at the L5-S1 level with no significant spinal or foraminal stenosis. A CT scan of the lumbar spine dated XX revealed mild-to-moderate spondylitic changes and facet arthropathy of the lumbar spine most significant from L3 through S1. There was moderate right foraminal and mild-to-moderate extraforaminal encroachment on the exiting L4 nerve root at the L4-L5 level. Multilevel mild spinal canal stenosis and mild foraminal encroachment was noted.

The treatment to date consisted of medications (XX); physical therapy, chiropractic therapy, epidural steroid injections, right L3-L4 microdiscectomy in XX, and implantation of a spinal cord stimulator in XX.

An Initial Adverse Determination letter was documented on XX by XX, DO. Per the letter, the request for inpatient with length of stay XX, anterior lumbar interbody fusion at L4-L5 and L5-S1 with minimally invasive surgery, screws, and a possible transforaminal lumbar interbody fusion at XX was not certified. Rationale: “The records do not reflect flexion / extension x-rays documenting instability as required by the guidelines. The MRI reported no evidence of nerve root impingement. The most recent electrodiagnostic studies documented no evidence of lumbar radiculopathy. Lumbar fusion is not supported for degenerative disc disease. The records do not reflect a recent psychological screening with confounding issues addressed specifically for the lumbar fusion. The request for a XX length of stay, anterior lumbar interbody fusion at L4-S1 with minimally invasive surgery, screws, and possible transforaminal lumbar interbody fusion at L4-S1 is not certified.”

An appeal letter dated XX by XX indicated XX had low back pain radiating into the right leg over the posterior right thigh and calf. XX had 50% of the pain in the lower back and 50% of the pain in the right leg. The CT myelogram dated XX had demonstrated narrowing in the disc at the L4-L5 and L5-S1 level with air within the disc space of L5-S1, cyst and irregular endplates in the L4-L5 level. XX had A right-sided bone spur outside of the neural foramen and neural foraminal narrowing at the L4 level on the right side. The electromyography and nerve conduction study demonstrated right L4 radiculopathy. XX received right L5 and S1 transforaminal epidural injections, both of which had helped XX 40% to 50% for several weeks. It was felt that considering XX local anatomy and the fact that XX had 50% of the pain in the leg and 50% of the pain in the lower back, direct decompression at the L4-L5 level would not provide XX with sufficient pain relief. The only surgical option was anterior lumbar interbody fusion at the L4-L5 and L5-S1 levels with percutaneous “MIS” screws, which would provide indirect decompression of the nerve structures and stabilize the degenerated levels of L4-L5 and L5-S1. Considering the fact that XX had been through extensive nonoperative treatments and continued significant pain, Dr. XX appealed to proceed with the surgery.

Per an Appeal Determination Denial letter dated XX by XX, MD, the request was denied. Rationale: “According to the Official Disability Guidelines, surgical consideration is indicated when there is documentation noting neurological deficits on physical examination that corroborate with imaging despite conservative care. Fusions are indicated on the basis of documentation noting instability, spondylolisthesis, and/or fracture. Psychological evaluations are recommended prior to undergoing lumbar fusion. The guidelines indicate that hospital length of stay for the requested surgical procedure is XX. The request was previously denied as psychological evaluation was not provided and there was no documentation noting radiculopathy on physical examination and imaging. The clinical documentation submitted for review indicated this patient had low back pain that radiated to the right lower extremity with diminished sensation and deep tendon reflexes despite conservative care, however, there was no documentation noting nerve compression on MRI and a psychological evaluation was not provided. I discussed the case with Dr.XX stated that XX thought the patient had already had a psychological consult, but XX could not provide that to me for review. We discussed that there was no significant nerve compromise on examination. XX did not provide any new clinical information during our discussion. Consequently, the request is not supported.”

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Notice of Independent Review Decision

Case Number: XXXX Date of Notice: 07/24/18

Analysis and Explanation of the Decision include Clinical Basis, Findings and Conclusions used to support the decision.

The records submitted for review noted a history of chronic low back and radicular pain. The claimant's imaging of the lumbar spine did note some foraminal narrowing but no significant evidence of severe spondylolisthesis or motion segment instability contributing to nerve root impingement or compression. Further, the records did not include a recent pre-operative psychological consult that ruled out any confounding issues as recommended by current evidence based guidelines. Given these issues which do not meet guideline recommendations, it is this reviewer's opinion that medical necessity is not established for the proposed procedures and the prior denials are upheld. A letter from a patient received and reviewed on XX does not impact the recommendation as it doesn't contain any objective medical data. It wouldn't change the determination in any way. Given the documentation available, the requested service(s) is considered not medically necessary.

A description and the source of the screening criteria or other clinical basis used to make the decision:

- ☐ ACOEM-America College of Occupational and Environmental Medicine um knowledgebase
- ☐ AHRQ-Agency for Healthcare Research and Quality Guidelines DWC-Division of Workers
- ☐ Compensation Policies and Guidelines European Guidelines for Management of Chronic Low Back
- ☐ Pain Interqual Criteria
- ☑ Medical Judgment, Clinical Experience, and expertise in accordance with accepted medical standards
- ☐ Mercy Center Consensus Conference Guidelines
- ☐ Milliman Care Guidelines
- ☑ ODG-Official Disability Guidelines and Treatment Guidelines

Recommended as an option for spondylolisthesis, unstable fracture, dislocation, acute spinal cord injury with post-traumatic instability, spinal infections with resultant instability, scoliosis, Scheuermann's kyphosis, or tumors, as indicated in the Patient Selection Criteria below. Not recommended in workers' compensation patients for degenerative disc disease (DDD), disc herniation, spinal stenosis without degenerative spondylolisthesis or instability, or nonspecific low back pain, due to lack of evidence or risk exceeding benefit.
See Adjacent segment disease/degeneration (fusion) and Iliac crest donor-site pain treatment.
Patient Selection Criteria for Lumbar Spinal Fusion:
(A) *Recommended* as an option for the following conditions with ongoing symptoms, corroborating physical findings and imaging, and after failure of non-operative treatment (unless contraindicated, e.g., acute traumatic unstable fracture, dislocation, spinal cord injury) subject to criteria below:
(1) Spondylolisthesis (isthmic or degenerative) with at least one of these:
(a) instability, and/or
(b) symptomatic radiculopathy, and/or
(c) symptomatic spinal stenosis;

(2) Disc herniation with symptomatic radiculopathy undergoing a third decompression at the same level;
(3) Revision of pseudoarthrosis (single revision attempt);
(4) Unstable fracture;
(5) Dislocation;
(6) Acute spinal cord injury (SCI) with post-traumatic instability;
(7) Spinal infections with resultant instability;
(8) Scoliosis with progressive pain, cardiopulmonary or neurologic symptoms, and structural deformity;
(9) Scheuermann's kyphosis;
(10) Tumors.

(B) *Not recommended* in workers' compensation patients for the following conditions:
(1) Degenerative disc disease (DDD);
(2) Disc herniation;
(3) Spinal stenosis without degenerative spondylolisthesis or instability;
(4) Nonspecific low back pain.

(C) *Instability criteria:* Segmental Instability (objectively demonstrable) - Excessive motion, as in isthmic or degenerative spondylolisthesis, surgically induced segmental instability and mechanical intervertebral collapse of the motion segment and advanced degenerative changes after surgical discectomy, with relative angular motion greater than 15 degrees L1-2 through L3-4, 20 degrees L4-5, 25 degrees L5-S1. Spinal instability criteria include lumbar inter-segmental translational movement of more than 4.5 mm. (Andersson, 2000) (Luers, 2007) (Rondinelli, 2008)

(D) After failure of two discectomies on the same disc [*(A)(2) above*], fusion may be an option at the time of the third discectomy, which should also meet the ODG criteria. (See the section "ODG Indications for Surgery™ -- Discectomy/laminectomy" in Discectomy/ laminectomy.)

(E) Revision Surgery for failed previous fusion at the same disc level [*(A)(3) above*] if there are ongoing symptoms and functional limitations that have not responded to non-operative care; there is imaging confirmation of pseudoarthrosis and/or hardware breakage/malposition; and significant functional gains are reasonably expected. Revision surgery for purposes of pain relief must be approached with extreme caution due to the less than 50% success rate reported in medical literature. Workers compensation and opioid use may be associated with failure to achieve minimum clinically important difference after revision for pseudoarthrosis (Djurasovic, 2011) There is low probability of significant clinical improvement from a second revision at the same fusion level(s), and therefore multiple revision surgeries at the same level(s) are not supported.

(F) *Pre-operative clinical surgical indications* for spinal fusion should include all of the following:
(1) All physical medicine and manual therapy interventions are completed with documentation of reasonable patient participation with rehabilitation efforts including skilled therapy visits, and performance of home exercise program during and after formal therapy. Physical medicine and manual therapy interventions should include cognitive behavioral advice (e.g., ordinary activities are not harmful to the back, patients should remain active, etc.);
(2) X-rays demonstrating spinal instability and/or myelogram, CT-myelogram, or MRI demonstrating nerve root impingement correlated with symptoms and exam findings;
(3) Spine fusion to be performed at one or two levels;

(4) Psychosocial screen with confounding issues addressed; the evaluating mental health professional should document the presence and/or absence of identified psychological barriers that are known to preclude post-operative recovery;

(5) For any potential fusion surgery, it is recommended that the injured worker refrain from smoking for at least six weeks prior to surgery and during the period of fusion healing; (Colorado, 2001) (BlueCross, 2002)

(6) There should be documentation that the surgeon has discussed potential alternatives, benefits and risks of fusion with the patient;

- ☐ Pressley Reed, the Medical Disability Advisor
- ☐ Texas Guidelines for Chiropractic Quality Assurance and 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)

Appeal Information

You have the right to appeal this IRO decision by requesting a Texas Department of Insurance, Division of Workers' Compensation (Division) Contested Case Hearing (CCH). A Division CCH can be requested by filing a written appeal with the Division's Chief Clerk no later than 20 days after the date the IRO decision is sent to the appealing party and must be filed in the form and manner required by the Division.

Request for or a Division CCH must be in writing and sent to:
Chief Clerk of Proceedings Texas Department of Insurance
Division of Workers' Compensation P. O. Box 17787
Austin, Texas, 78744

For questions regarding the appeals process, please contact the Chief Clerk of Proceedings at 512-804-4075 or 512- 804-4010. You may also contact the Division Field Office nearest you at 1-800-252-7031.