US Decisions Inc.

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Description of the service or services in dispute:

62321	Under Injection, Drainage, or Aspiration Procedures on the Spine and Spinal Cord
01992 / QZ	Under Anesthesia for Other Procedures / CRNA without medical direction by a physician. Cervical epidural blockade at C7-T1 utilizing a catheter approach under fluoroscopy with intravenous sedation. XXXX would need anesthesia due to anxiety.

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

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)

XXXX is a XXXX -year-old XXXX with date of injury XXXX. XXXX was diagnosed with other cervical disc displacement, unspecified cervical region (M50.20). The additional diagnoses included cervicalgia (M54.2) and radiculopathy, cervical region (M54.12).

On XXXX, XXXX evaluated XXXX for further care of XXXX back, buttock and leg pain, which was associated with XXXX work injuries. XXXX was using XX off and on. XXXX was also taking XX for breakthrough pain. On examination, XXXX had moderate lumbar interspinous tenderness and pain with extension and side bending consistent with facet syndrome. XXXX radicular symptoms below the level of the knee had improved. XXXX had pain with extension. XXXX also had pain above the level of the thigh and knee. XXXX had exquisite tenderness over the L4-L5 and L5-S1 interspaces, which was aggravated by side bending and extension. XXXX was advised to avoid heavy lifting, bending or twisting while working. XXXX described rehabilitative and core therapy in conjunction with facet injection therapy and continuing exercise. XXXX suggested core strengthening, abdominal William flexion exercise and continuing rehabilitative care with XXXX. XXXX intake urinalysis had been consistent with the agents received from XXXX.

XXXX returned to XXXX on XXXX for continued moderate-to-severe neck, right shoulder, arm and hand pain associated with cervical disc disruption, cervical radiculopathy and herniated protruding disc at C5-C6 and C6-C7 following a XXXX injury while at work. XXXX had exhausted physical therapy rehabilitative care. XXXX had poor kidney function and could not receive support with non-steroidal anti-inflammatory drugs. XXXX was on a combination of neuropathic pain medicine, which was helping with the shooting pain. However, it was downgraded from 8 to 7/10 only with this

medicine. XXXX sleep had improved with XX at night. The examination revealed decreased neck range of motion, decreased grip strength with a positive Spurling's test with pain into the C5 distribution on the right as evidenced by decreased grip strength and pinprick sensation.

The treatment to date included medications (XX and XX), physical therapy and rehabilitation therapy.

An MRI of the cervical spine dated XXXX revealed broad 1-mm disc bulge at the C2-C3, C3-C4 and C4-C5 levels and a broad 1-mm disc protrusion / herniation with a 2-mm right posterolateral component at C5-C6. There was a mild bilateral neural foraminal narrowing, right greater than left. A broad 2-mm disc protrusion / herniation with borderline thecal cell stenosis and moderate right and mild left neural foraminal narrowing at C6-C7 were noted. The right C7 nerve root impingement was potentially impinged upon.

Per a utilization review decision letter dated XXXX, the requested service was denied. The primary reason for determination was the requested service was not medically necessary. XXXX had a complaint of neck pain with some radiation to the upper extremities, and the provider was requesting a cervical epidural steroid injection. There was no documentation of exceptional factors to support an epidural steroid injection outside of current evidence-based guideline recommendations that specifically indicated lack of support for this procedure. In addition, the documentation did not substantiate there had been a prior failure of comprehensive conservative measures. There was no objective documentation of failure of conservative treatment measures specifically addressed to the cervical spine to support the need for the requested procedure as the actual physical therapy (PT) reports were not submitted for review. The references were used from Official Disability Guidelines (ODG) in support of the decision.

Per a reconsideration utilization review decision letter dated XXXX, the requested service was not approved. An epidural steroid injection (ESI) was warranted based on the magnetic resonance imaging (MRI), examination findings and failure of physical therapy to help the injured worker. However, the sedation was not medically necessary, as sedation was not recommended with this injection. Per Official Disability Guidelines (ODG), it did not have any evidence of any significant psychological or medical issues that would support this.

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

This patient was injured while working for XXXX which eventually led to neck pain with radiation of pain and sensory symptoms in the right hand. The patient tried medications and PT which was ineffective. An MRI showed disc disease and possible C7 nerve impingent by disc material. The provider plans to do a cervical ESI with a catheter which should treat the affected levels.

A review in XXXX denied the request stating that "the documentation did not substantiate there had been a prior failure of comprehensive conservative measures. There was no objective documentation of failure of conservative treatment measures specifically addressed to the cervical spine to support the need for the requested procedure as the actual physical therapy (PT) reports were not submitted for review." However, XXXX states in XXXX clinical examinations that the patient tried 4 sessions of PT without eventual success. Medical management was also unsuccessful. So, I do not agree with this review.

A second review also in XXXX, also denied the request. However, the reviewer agreed that the cervical MRI was indicated but not the sedation. However, the provider's notes state that the patient has anxiety and needs sedation. The provider also cites the requirement for the patient to be

motionless. The patient also reports sleep disturbance. So, my impression is that the patient has met the "anxiety" test and will need sedation.

The provider has clarified that the technique XXXX plans to use is via C7-T1 which correlates with ODG recommendation to avoid going above C6. The needle will enter the epidural space via C7-T1 but the catheter will be directed to higher levels, atruamatically.

This approval is an exception to the ODG. The patient was a highly active XXXX worker prior to the injury. XXXX has no major comorbidities that would decrease the likelihood of a successful response to the ESI. The disc lesion at C7 may require surgery if neuraxial interventions are not attempted. The patient is motivated to archive functional independence. Given the documentation available, the requested service(s) is considered 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

Neck and Upper Back (Acute and Chronic) (updated 05/04/18)

<u>Epidural steroid injection (ESI)</u>

Not recommended based on recent evidence, given the serious risks of this procedure in the cervical region and the lack of quality evidence for sustained benefit. This treatment had been recommended as an option for treatment of radicular pain (defined as pain in dermatomal distribution with corroborative findings of radiculopathy), with specific criteria for use below.

While not recommended, cervical ESIs may be supported using Appendix D, Documenting Exceptions to the Guidelines, in which case:

Criteria for the use of Epidural steroid injections, therapeutic:

Note: The purpose of ESI is to reduce pain and inflammation, thereby facilitating progress in more active treatment programs, and avoiding surgery, but this treatment alone offers no significant long-term functional benefit.

(1) Radiculopathy must be documented by physical examination and corroborated by imaging studies and/or electrodiagnostic testing.

(2) Initially unresponsive to conservative treatment (exercises, physical methods, NSAIDs and muscle relaxants).

(3) Injections should be performed using fluoroscopy (live X-ray) for guidance

(4) No more than two nerve root levels should be injected using transforaminal blocks.

(5) No more than one interlaminar level should be injected at one session.

(6) In the therapeutic phase, repeat blocks should only be offered if there is at least 50% pain relief for six to eight weeks, with a general recommendation of no more than 4 blocks per region per year.

(7) Repeat injections should be based on continued objective documented pain and function response.

(8) Current research does not support a "series-of-three" injections in either the diagnostic or therapeutic phase. We recommend no more than 2 ESI injections.

(9) It is currently not recommended to perform epidural blocks on the same day of treatment as facet blocks or stellate ganglion blocks or sympathetic blocks or trigger point injections as this may lead to improper diagnosis or unnecessary treatment.

(10) Cervical and lumbar epidural steroid injection should not be performed on the same day;

(11) Additional criteria based on evidence of risk:

(i) ESIs are not recommended higher than the C6-7 level;

(ii) Cervical transforaminal ESI is not recommended;

(iii) Particulate steroids should not be used. (Benzon, 2015)

(12) Excessive sedation should be avoided.

Criteria for the use of Epidural steroid injections, diagnostic:

If used for diagnostic purposes, a maximum of two injections should be performed. A second block is not recommended if there is inadequate response to the first block. Diagnostic blocks should be at an interval of at least one to two weeks between injections.

To determine the level of radicular pain, in cases where diagnostic imaging is ambiguous, including the examples below:

(1) To help to evaluate a pain generator when physical signs and symptoms differ from that found on imaging studies;

(2) To help to determine pain generators when there is evidence of multi-level nerve root compression;

(3) To help to determine pain generators when clinical findings are suggestive of radiculopathy (e.g., dermatomal distribution), and imaging studies have suggestive cause for symptoms but are inconclusive;

(4) To help to identify the origin of pain in patients who have had previous spinal surgery.

In a previous Cochrane review, there was only one study that reported improvement in pain and function at four weeks and at one year in individuals with radiating chronic neck pain. (Peloso-Cochrane, 2006) (Peloso, 2005) Other reviews have reported moderate short-term and long-term evidence of success in managing cervical radiculopathy with interlaminar ESIs. (Stav, 1993) (Castagnera, 1994) Some have also reported moderate evidence of management of cervical nerve root pain using a transforaminal approach. (Bush, 1996) (Cyteval, 2004) A previous retrospective review of interlaminar cervical ESIs found that approximately two-thirds of patients with symptomatic cervical radiculopathy from disc herniation were able to avoid surgery for up to 1 year with treatment. Success rate was improved with earlier injection (< 100 days from diagnosis). (Lin, 2006) There have been case reports of cerebellar infarct and brainstem herniation as well as spinal cord infarction after cervical transforaminal injection. (Beckman, 2006) (Ludwig, 2005) Quadriparesis with a cervical ESI at C6-7 has also been noted (Bose, 2005) and the American Society of Anesthesiologists Closed Claims Project database revealed 9 deaths or cases of brain injury after cervical ESI (1970-1999). (Fitzgibbon, 2004) These reports were in contrast to a retrospective review of 1,036 injections that showed that there were no catastrophic complications with the procedure. (Ma, 2005) The American Academy of Neurology concluded that epidural steroid injections may lead to an improvement in radicular lumbosacral pain between 2 and 6 weeks following the injection, but they do not affect impairment of function or the need for surgery and do not provide long-term pain relief beyond 3 months, and there is insufficient evidence to make any recommendation for the use of epidural steroid injections to treat radicular cervical pain. (Armon, 2007) In other studies, there was evidence for short-term symptomatic improvement of radicular symptoms with epidural or selective root injections with corticosteroids, but these treatments did not appear to decrease the rate of open surgery. (Haldeman, 2008) (Benyamin, 2009) Some experts have said epidural steroid injections should be reserved for those who may otherwise undergo open surgery for nerve root compromise. (Bigos, 1999) There is limited evidence of the effectiveness of epidural injection of methyl prednisolone and lidocaine for chronic MND with radicular findings. (Peloso-Cochrane, 2006) The FDA has warned that injection of corticosteroids into the epidural space of the spine may result in rare but serious adverse events, including loss of vision, stroke, paralysis, and death. (FDA, 2014)

Sedation: The use of sedation during ESI remains controversial. Excessive sedation should be avoided because it prevents the patient from reporting pain and from participating in neurologic evaluation after receiving a test dose of local anesthetic. However, some experts have promoted the use of mild sedation to prevent complications due to sudden movements (Malhotra, 2009) A multidisciplinary collaboration led by the FDA recommended that sedation for ESI remain light enough to allow the patient to communicate during the procedure. (Rathmell, 2015) For a more extensive discussion, see the Pain Chapter. See also the Low Back Chapter.

Recent evidence: ESIs should not be recommended in the cervical region, the FDA's Anesthetic and Analgesic Drug Products Advisory Committee concluded. Injecting a particulate steroid in the cervical region, especially using the transforaminal approach, increases the risk for sometimes serious and irreversible neurological adverse events, including stroke, paraplegia,

spinal cord infarction, and even death. The FDA has never approved an injectable corticosteroid product administered via epidural injection, so this use, although common, is considered off-label. Injections into the cervical region, as opposed to the lumbar area, are relatively risky due to the narrower epidural space, and the risk for accidental injury in the arterial system is greater in this location. (FDA, 2015) An AMA review suggested that ESIs are not recommended higher than the C6-7 level; no cervical interlaminar ESI should be undertaken at any segmental level without preprocedural review; and particulate steroids should not be used in therapeutic cervical transforaminal injections. (Benzon, 2015) According to the American Academy of Neurology (AAN), ESIs do not improve function, lessen need for surgery, or provide long-term pain relief, and the routine use of ESIs is not recommended. They further said that there is in particular a paucity of evidence for the use of ESIs to treat radicular cervical pain. (AAN, 2015) In this comparative-effectiveness study, no significant differences were found between ESI and conservative treatments. (Cohen, 2014)

Appendix D

Documenting Exceptions to the Guidelines

The purpose of this section is to outline a process so patients can receive appropriate medical treatment even if it is not covered in ODG. As explained on the Copyright Page:

"These publications are guidelines, not inflexible proscriptions, and they should not be used as sole evidence for an absolute standard of care. Guidelines can assist clinicians in making decisions for specific conditions and also help payors make reimbursement determinations, but they cannot take into account the uniqueness of each patient's clinical circumstances."

ODG outlines a system for ranking the medical evidence, using an alphanumeric rating system from 1a to 11c. It is explained in the Chapter Explanation of Medical Literature Ratings located here: http://www.odg-twc.com/odgtwc/ExplanationofMedicalLiteratureRatings.htm. The highest quality evidence would be a Systematic Review/Meta-Analysis or a Randomized Controlled Trial (RCT), that have been accepted for publication in a peer reviewed journal included in Medline® by the National Library of Medicine. Users can search for these studies online at www.nlm.nih.gov. When other medical treatment guidelines are based on the high quality evidence, they can also be good sources to summarize the evidence and make concrete recommendations, so these other treatment guidelines can be valuable as well. The Agency for Healthcare Research and Quality (AHRQ) in the United States maintains a searchable database of clinical practice guidelines that have met their criteria, at www.guideline.gov. This would be a recommended source of medical treatment guidelines for conditions that are not covered in ODG.

There will be situations where injured workers will need medical care outside of the guidelines. There are a variety of ways that this can be achieved, including understandings, both formal and informal, where an insurance carrier and a provider have agreed, as a result of proven outcomes and adherence to evidence-based treatment guidelines from that provider that the insurance carrier will defer to the provider's recommendations for a particular course of medical care. This document is meant to address situations where such agreements do not exist. The following topics are covered in detail below.

I. Instructions for Providers

A. Situations not addressed in the guidelines

1. Conditions not commonly seen in workers compensation

2. Documenting functional improvement & patient co-morbidities

3. Examples not addressed in the guidelines

B. Treatments that are covered but not recommended

1. Patient co-morbidities

2. Documenting functional improvement

3. Examples not recommended in the guidelines

II. Instructions for Carriers

A. Limitations of guidelines

B. Peer to peer discussions recommended

I. INSTRUCTIONS FOR PROVIDERS

As a first step, health care providers should have access to the guidelines. ODG covers over 99% of cases seen in workers' compensation, and covers practically all of the high quality evidence for these cases, so it is very likely that health care providers will find the latest evidence in ODG that relates to what they are recommending for their patients. When health care providers access the guidelines, they can plan and describe their treatments to be in line with the guidelines rather than be exceptions. When seeking preauthorization, it is recommended that health care providers cite ODG, and copy and paste the relevant section of ODG into their request. This procedure is explained in every ODG Users Guide, and online at: http://www.odg-twc.com/how_to.htm#Copy

If ODG does not seem to support the health care provider's recommendation, WLDI encourages use of the ODG Helpdesk. First of all, the requested treatment may actually be supported in ODG, but the provider may need assistance in locating the correct section of ODG. Secondly, if it is not covered or supported in ODG, and the health care provider feels this is incorrect, the ODG editors can review the most current medical evidence to re-evaluate the recommendation, or they can add a topic that may have been missing due to lack of evidence in the past, or because it was relatively uncommon. The Process for suggesting ODG updates is explained at this link: http://www.odg-twc.com/odgtwc/ExplanationofMedicalLiteratureRatings.htm#ProcessforsuggestingODGupdates. This is also referenced on the ODG Homepage at http://www.odg-twc.com.

In cases where the medical care is an exception to ODG, the health care provider should document: (1) extenuating circumstances of the case that warrant performance of the treatment including the rationale for procedures not addressed in ODG; (2) patient co-morbidities, (3) objective signs of functional improvement for treatment conducted thus far; (4)

measurable goals and progress points expected from additional treatment; and (5) additional evidence that supports the health care provider's case.

The process for documenting exceptions to guidelines is supported by medical research. According to a study published in the February 2010 edition of the Annals of Internal Medicine, funded by the Agency for Healthcare Research and Quality, exceptions to treatment guidelines that are documented by physicians during their regular workflow and reviewed by peers are appropriate most of the time. Of over 600 exceptions to the treatment guidelines, 94% (95% CI, 91.4% - 95.4%) were determined to be medically appropriate, 3% were inappropriate, and 3% were of indeterminate appropriateness. When physicians report exceptions to standard practices, it affirms their ability to make decisions and helps them aim for high performance levels while avoiding treatment delays, study authors noted. (Persell, 2010)

If ODG does not support the health care provider's recommendation, there may be two reasons for this:

A. Situations not addressed in the guidelines

B. Treatments that are covered but not recommended

A. Situations not addressed in the guidelines

1. Conditions not commonly seen in workers' compensation

ODG already covers over 99% of medical conditions seen in workers' compensation, but it does not cover many common conditions seen outside of workers' compensation, such as diabetes, cancer, heart disease, cosmetic surgery, etc. There may be instances where a treatment that is typically not used in the occupational injury arena is indicated for a particular occupational injury. This may be reasonable either based on evidence from the non-occupational injury arena; or in the absence of adequate evidence, a reasonable clinical rationale. In making clinical decisions for conditions not covered by ODG, or for treatments not mentioned in ODG, health care providers should rely on the medical evidence as much as possible.

2. Documenting functional improvement & patient co-morbidities

In those situations where the treatment at issue is not addressed in ODG, the health care provider should demonstrate how functional improvement would be the expected result of the treatment. Providers should also document any relevant co-morbidities (if applicable) that may increase the likelihood that this treatment would be appropriate for their patient.

3. Examples of treatments not addressed in the guidelines

a. Conditions not commonly seen in workers' compensation

An employee sustains a work related injury, where a XXXX XXXX in the face, breaking XXXX two front teeth. XXXX is referred to a dentist who proposes to replace the 2 broken teeth. This procedure is not addressed by ODG as it is not a common occupational injury, yet it is

medically reasonable as there is evidence from the dental literature to support the procedure recommended by the dentist.

Oher examples include the following:

Renal ultrasound for hydronephrosis for a patient high cervical spinal cord injury quadraplegic patient

Cosmetic surgery for a burn patient

b. Conditions commonly seen in workers' compensation, but in unusual presentations

A XXXX year old employee sustains a severely comminuted femoral condyle fracture as a result of a XXXX. The orthopedic surgeon recommends a total knee replacement (TKR), due to the severity of the fracture. While a TKR is not typically indicated in a XXXX year old patient, it is reasonable in this circumstance given the inability to reduce the severely comminuted femoral condyle fracture.

B. Treatments that are covered but not recommended

When a treatment and condition are already covered in ODG, but specifically not recommended in ODG (or ODG has a patient selection criteria that would not include the case under consideration), the health care provider requesting the treatment should provide documentation specific to XXXX or XXXX case to support the use of the treatment outside of the guidelines. This is because the highest quality scientific evidence for this situation should already be in the guidelines, so it would not be likely to find evidence that could trump the evidence already in the guidelines. Patients with co-morbidities and/or documented functional improvement warrant additional consideration and the health care provider should adequately document these factors if present.

1. Patient co-morbidities

In documenting why their patient may be an exception to the guidelines, providers will want to explain how their patient is different from the ones used in the studies that may have resulted in a negative recommendation or exclusion. Co-morbidities may also require additional treatments beyond ODG recommendations. This will typically involve co-morbidities, for example, obesity, or diabetes that may increase the likelihood that this treatment would be appropriate for their patient. This may also include vocational, recreational and/or other functional factors. There could be specifics of the injury or condition that put the injured worker outside of the type of patients covered in the high quality studies.

2. Documenting functional improvement

A significant goal of any medical treatment in the workers' compensation system is to return the patient to XXXX prior level of function to allow injured workers to go back to the life they had prior to injury, including return to work. The provider should demonstrate how this functional improvement would be the expected result of the treatment in this case, either from past experience or from an explanation about the mechanism of injury and the effect of the treatment, and documenting points where this improvement can be measured.

3. Examples of treatments not recommended in the guidelines

a. Co-morbid conditions supporting the performance of a treatment not recommended by ODG

A XXXX year old chronic diabetic patient complains of low back and leg pain following a work related lifting injury. On exam the pain is in a non-dermatomal distribution. A lower extremity nerve conduction velocity study may be indicated to assess for peripheral neuropathy.

b. Functional improvement supporting treatment exceeding ODG

A XXXX year old XXXX sustains a medial meniscal tear while working and undergoes an arthroscopic menisectomy. XXXX completes the ODG recommended level of post-operative physical therapy with documented and specific objective functional improvement, but XXXX still has objective functional deficits. An additional course of physical rehabilitation to address the functional deficit is reasonable.

☐ 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)