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Review Outcome

Description of the service or services in dispute:

Selective nerve block at the left C7 under anesthesia with fluoroscopic guidance

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)

XX who was diagnosed with cervical disc disorder with radiculopathy, unspecified cervical region (M50.10) and other cervical disc displacement, unspecified cervical region (M50.20). XX date of the injury was XXXX. The mechanism of the injury was noted as a XXXX.

On XXXX, XX was seen by XX. XX was status post cervical epidural steroid injections (XXXX), which produced at least 50% reduction in the pain levels for XX. XX had noticed resolution of paresthesias that XX was experiencing in the right upper extremity but continued to have numbness/paresthesias in the C7 dermatome on the left. The symptoms were aggravated by increased walking distance. The pain was rated as 4/10. XX was not quite gaining enough relief with the ongoing medications. XX also reported lower back pain. XX had noticed some extension into the buttock region on the left. There was numbness in the L5 dermatomal area. The back examination revealed flexion of the lumbar spine to 20-25 degrees with pain and thereafter extension decreased. The range of motion of the cervical spine was associated with pain, especially with side bending. The Spurling test was slightly positive on the left side. The neurological examination revealed a sensory decrease of the left C7 dermatome and L5 dermatome. The seated straight leg raising test was positive on the left.

The treatment to date included medications (XX, XX, XX and XX), ice/heat, activity modification, chiropractic therapy, physical therapy, cervical epidural steroid injections which resulted in at least 50% reduction in pain levels for XX.

An MRI of the cervical spine dated XXXX showed a subligamentous disc herniation of 3.6 mm at C6-C7 as well as left disc protrusion at C5-C6.

Per a utilization review decision letter dated XXXX, the requested service was denied. The requested service was not appropriate or medically necessary for the diagnosis and clinical findings. Generally, cervical epidural injections were discouraged given Food and Drug Administration (FDA) warning regarding significant risks for morbidity and mortality with regard to the procedure. XX did recently undergone a cervical epidural injection. A repeat injection was not recommended unless there was clear documentation of sustained subjective improvement and also objective functional benefit from the injection. The records did not clearly document objective functional benefit or medication reduction from the prior cervical epidural injection. Given the Food and Drug Administration (FDA) guidance, against cervical epidural injections, repeat injections would particularly be discouraged as not likely to be of meaningful benefit considering the overall risk versus benefit factors involved. For these multiple reasons, the request was not medically necessary at the time.

Case Number: XXXXXX Date of Notice: XXXX

XX wrote an appeal letter on XXXX. XX stated that XX did gain relief with a cervical epidural steroid injection performed on XXXX to with 50% reduction in pain levels for XX (pain levels reduced from 9/10 on the VAS scale to 4/10). XX was able to reduce reliance on medication at that time. It was also noted that XX had resolution of paresthesias XX was experiencing in the right upper extremity. At the time, XX continued to have numbness/paresthesias in the C7 dermatome on the left. An MRI of the cervical spine indicated moderate bilateral foraminal stenosis at C6/C7 due to posterior disc protrusion at the level. MRI cervical spine had demonstrated subligamentous disc herniation of 3.6 mm at C6-C7. The physical examination showed decreased sensory at the C7 dermatome. Given the continuing symptoms in the left upper extremity, the above procedure was requested to reduce symptoms/pain and allow XX to be more functional and participate in therapy. Per XX, XX did meet ODG guidelines as far as proceeding with a slightly different injection (selective nerve root block on the left at C7), given the fact XX had failed conservative treatment has documented MRI findings that correlated with his physical examination. The purpose of the selective nerve root block was to reduce pain/inflammation, ongoing symptoms and allow participation in physical therapy program as well as reduce reliance on medication. XX did not agree with the denial.

Per a utilization review decision letter dated XXXX, the requested service was not approved. The requested treatment had been recommended as an option for treatment of radicular pain (defined as pain in dermatomal distribution with corroborative findings of radiculopathy) when specific criteria were met. XX presented with persistent grade 4/10 pain and left upper extremity numbness/paresthesia. The clinical examination findings documented a left C7 sensory loss, correlated with reported C6-C7 disc pathology with moderate bilateral foraminal stenosis. The conservative treatment including activity modification, chiropractic therapy and medications had failed to provide adequate relief. XX underwent a cervical epidural steroid injection on XXXX with XX of 50% pain relief and medication reduction and a resolution of right upper extremity symptoms. A repeat injection on the left side was under consideration. The guidelines did not currently recommended cervical epidural steroid injections. Repeat injections have been supported when there was documentation of at least 50% pain relief for 6 to 8 weeks. There was no compelling rationale presented to support the medical necessity of an exception to guidelines in the case. Therefore, the request for selective nerve block at left C7 under anesthesia with fluoroscopic guidance was not medically necessary.

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

I disagree with the prior adverse determination. I find the requests for selective nerve block at the left C7 under anesthesia with fluoroscopic guidance is medically necessary.

XX had a prior cervical ESI in XXXX reporting 50% pain relief for XX with concomitant decreased pain medication usage and increased function. The presumed level of the cervical ESI was C6-7. XX is now left with persistent left C7 dermatomal paresthesia together with loss of sensation. This appears to be a classical early denervation phenomenon because the MRI shows a left-sided disc herniation at C6-7.

Two prior reviews and an appeal letter have been reviewed. In XXXX, the review correctly noted that the pain response was limited and therefore did not meet the criteria for a repeat intervention based on ODG criteria. An appeal letter by the provider in XXXX disagreed with this review, noting XX response to the ESI and citing some communication issues during a phone call. A subsequent review in XXXX supported the prior review in XXXX for the exact same reason.

Both reviews are technically correct. However, they fail to note the caveat within the ODG. If the response to the first diagnostic ESI is equivocal, a second diagnostic ESI is allowed, if the technical approach is changed and/or if there is evidence of a diagnosis needing clarification with respect to the pain generator. The second diagenetic ESI, also known as a selective nerve root block is indicated in this patient to address the herniated disc at the left C6-7 level. This appears reasonable and necessary, since the approach has changed and there is dermatomal evidence pointing to the left C7 level.

Notice of Independent Review Decision

Case Number: XXXXXX Date of Notice: XXXX

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

ODG Integrated Treatment/Disability Duration Guidelines

Neck and Upper Back (Acute and Chronic) (updated 10/12/17)

Cervical Epidural Steroid Injections

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) Quadraparesis 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)

Epidural steroid injections, "series of three"

Not recommended. Original recommendations that suggested a "series of three injections" generally did so prior to the advent of fluoroscopic guidance. These previous recommendations were based primarily on case studies and anecdotal evidence (Class IV and V data). (Abram, 1999) (Warr, 1972) (Hickey, 1987)

There does not appear to be any evidence to support the current common practice of a series of injections. (Novak, 2008) Contemporary research studies with higher levels of evidence (including two controlled trials) have suggested that on average, two or less ESIs are required in patients with successful outcomes from the use of ESIs to treat disc related lumbar radiculopathy. (Lutz, 1998) (Vad, 2002) (Riew, 2000) While all of these latter studies have utilized repeat injections, there has been no evidence-based research to explain why this practice is required, or the mechanism for possible action. Since the introduction of fluoroscopically guided ESIs, it has been suggested that there is little evidence to repeat an accurately placed epidural injection in the presence of mono-radiculopathy, regardless of whether there is partial or no response. (McLain, 2005) A recent randomized controlled trial of blind ESIs found no evidence to support repeat injections, because at six weeks there was no significant difference found between the ESI group and a placebo-controlled group in terms of any measured parameter. (Price, 2005)

A repeat injection has been suggested if there is question of accurate dermatomal diagnosis, if pain may be secondary to a different generator, or in the case of multilevel pathology. (McLain, 2005) There is a lack of support for 2nd epidural steroid injection if the 1st is not effective. (Cuckler, 1985) With fluoroscopic guidance, there is little support to do a second epidural if there is no response to the first injection. There is little to no guidance in current literature to suggest the basis for the recommendation of a third ESI, and the routine use of this practice is not recommended.

Epidural steroid injections, diagnostic

Recommended in selected cases as indicated below.

Indications for diagnostic epidural steroid injections:

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

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

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

4) To help to determine pain generators when clinical findings are consistent with radiculopathy (e.g., dermatomal distribution) but imaging studies are inconclusive;

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

Diagnostic epidural steroid transforaminal injections are also referred to as selective nerve root blocks, and they were originally developed, in part, as a diagnostic technique to determine the level of radicular pain. The role of these blocks has narrowed with the advent of MRIs. Few studies are available to evaluate diagnostic accuracy or post-surgery outcome based on the procedure and there is no gold standard for diagnosis. No more than 2 levels of blocks should be performed on one day. The response to the local anesthetic is considered an important finding in determining nerve root pathology. (CMS, 2004) (Benzon, 2005) When used as a diagnostic technique a small volume of local is used (<1.0 ml) as greater volumes of injectate may spread to adjacent levels. (Sasso, 2005) (Datta, 2013) (Beynon, 2013)

- ☐ 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)