WSI
North Dakota Workforce Safety & Insurance

Treatment Policy

Epidural Steroid Injection (ESI) – Cervical

Effective Date: 07/18/2005 Revised Date: 09/15/2020

Responsible Department: Utilization Review Reviewed Date: 09/15/2020

Introduction
Workforce Safety & Insurance (WSI) utilizes ODG by MCG in determining medical necessity for cervical epidural steroid injections (ESI). The following policy is an excerpt from ODG by MCG's neck and upper back section last accessed on 09/15/2020.

Policy
WSI will enforce the following treatment guideline for utilization review and claim management processes involving ESI.

Conditionally Recommended
Recommended on a case-by-case basis as a short-term treatment for intervertebral disc herniation, degenerative changes, and/or spinal stenosis leading to radicular pain (defined as pain in a dermatomal distribution with corroborative findings of radiculopathy). Cervical interlaminar epidural steroid injections (ESIs) at a level no higher than C6-7 are the only recommended approach; cervical transforaminal ESIs are not recommended. This treatment should be administered in conjunction with active rehabilitation efforts, and all patients should be informed of the extreme risk of this treatment in the cervical region and the lack of quality evidence of sustained benefit. ESIs are not recommended as a treatment for axial neck pain or for non-specific neck pain.

While only conditionally recommended, cervical epidural steroid injections (ESIs) may be supported on a case-by-case basis by the following documentation:

Patient criteria for ESI:
(1) Radiculopathy (irritation or injury to a nerve root that typically causes pain and/or numbness or weakness in the part of the body supplied with the nerves from that root) must be well documented, along with objective neurological findings on physical examination. Acute radiculopathy must be corroborated by imaging studies. A request for a procedure in a patient with chronic radiculopathy requires additional documentation of recent symptom worsening associated with deterioration of neurological state.

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

Criteria for use of ESIs:
Note: The primary purpose of ESI treatment is to reduce pain and inflammation, thereby facilitating progress in more active treatment programs during healing. There is no evidence that ESIs alone offer any meaningful long-term functional benefit.

(1) Injections should be administered using fluoroscopy (live X-ray) and injection of contrast for guidance. Ultrasound guidance is not recommended.

(2) Additional criteria based on evidence of risk in the cervical region

(i) Interlaminar ESI is not recommended higher than the C6-7 level.

(ii) Transforaminal ESI is not recommended.

(iii) Particulate steroids (Solu Medrol and Depo Medrol) are not recommended for cervical transforaminal injections (if they are administered despite their Not Recommended status). (Van Boxem, 2019)

(iv) Interlaminar injections can include particulate corticosteroid or dexamethasone. (Benzon, 2015) (Van Boxem, 2019)

(v) All patients should be informed of the extreme risk of undergoing this treatment in the cervical region and lack of quality evidence of sustained benefit.

(3) *Initial injection:* At the time of initial use of an ESI for an acute, new onset episode, a maximum of 1 to 2 injections should be administered. A repeat block is not recommended if there is inadequate response to the first block (with an initial adequate response defined as pain relief and improved function of at least 50% for a minimum of 2 to 3 weeks). Approval of a second block requires documented response to the first block. There should be an interval of at least 2 weeks between injections. This recommendation only applies to the initial injection treatment.

(4) *Repeat therapeutic injections:* Repeat blocks are not routinely recommended unless there is evidence of an acute pain exacerbation after a symptom-free period. This criterion is based on an emerging concept that the true natural history of radicular pain due to intervertebral disc herniation often follows that of a relapsing remitting disease, with temporary occurrences of symptoms over the years. (Kennedy, 2018) Evidence indicates that ESIs should be restricted to patients with continuous radicular pain for less than 6 months. (Van Boxem, 2019) Therefore, the following criteria should be considered:

(i) Repeat injection should require documentation that previous block/block(s) produced a minimum of 50-70% pain relief and improved function for at least 6-8 weeks.

(ii) Repeat block is better supported with documentation of decreased medication requirement after the previous procedure.

(iii) Based on general consensus, no more than 3 to 4 blocks per region should be administered within a 12-month period.

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

(6) Best evidence does not support routine use of "series-of-three" injections during for initial or repeat treatment. No more than two ESIs are recommended for the initial phase, and rarely more than two (total) for repeat treatment for exacerbation of symptoms, particularly for treatment of mono-radiculopathy.

(7) It is currently not recommended to administer epidural blocks on the same day as facet blocks, stellate ganglion blocks, sympathetic blocks, or trigger point injections, as doing so may lead to improper diagnosis or unnecessary treatment.

(8) Cervical and lumbar ESIs should not be administered on the same day to avoid excessive steroid dosing and other adverse effects.

(9) Sedation is not generally recommended. When required for extreme anxiety, a patient should remain alert enough to reasonably converse.

(10) Epidural injection is not a stand-alone procedure. There should be evidence of active rehabilitation in association with injection. This can include a continuing home exercise program.

Evidence Summary
Cervical interlaminar epidural injections are recommended on a case-by-case basis at a level no higher than C6-7 based on limited positive evidence. Research is limited, in part, due to lack of placebo control treatment groups. The methodology of study design is heterogenous. Various definitions of clinical effectiveness are utilized in studies, and functional outcome are inconsistent. Studies reporting long-term (ie, 1 year) clinical benefit often use multiple repeat injections as part of their protocol. No randomized trials have assessed the efficacy of cervical transforaminal epidural injections.

Complications: Complications associated with cervical epidural steroid injections (ESIs) include axial neck pain, neck pain that is not position related, flushing in the face, nausea and vomiting, fever on the night of injection, sensitivity at the injection site, hypotension, respiratory insufficiency, subjective weakness in the arms, and insomnia. Accidental dural puncture can result in pneumocephalus (air in the subarachnoid space). The intervertebral disc can be injected. Infection (abscess and meningitis) and bleeding (epidural hematoma) rarely occur. Trauma to the anterior spinal artery has been reported with transforaminal injections. The current estimated risk of complication with transforaminal injections ranges from 1/100,000 to 1/1,000,000. (Ali, 2019) (Epstein, 2018)

Neurological complications: More major neurological complications are associated with procedures in the cervical region than the lumbar region. This difference is most likely due to the greater proximity of the spinal cord and vascular structures. As a result, image guidance is considered mandatory. The interlaminar route can create direct spinal cord injury secondary to needle trauma. Neurovascular complications are more common with the transforaminal technique, with possible infarction of the spinal cord, the brain stem, the cerebrum, or the cerebellum. Death has been reported due to this complication. The etiology of infarction can include occlusion of the vertebral or radicular artery. This can be caused by artery trauma, vasospasm, and extrinsic compression by the injected product, arterial dissection, or particulate steroid embolism via intra-articular injection. The rate of intravascular instead of foraminal injection is about 10.8%. (Ali, 2019) Death has been reported. (Van Boxem, 2019) (Schneider, 2018)

Side effects from corticosteroids: Side effects can include flushing, fluid retention, weight gain, elevated blood sugar, and mood swings. (Patel, 2019) Other physiological effects can include the following. (1) Bone demineralization, which can increase fracture risk. This leads to a

recommendation to keep corticosteroid exposure to a minimum, particularly in high-risk patients (such as post-menopausal women, elderly patients, or those with osteopenia or osteoporosis). (2) Suppression of the hypothalamic-pituitary-adrenal (HPA) axis. Without the presence of Cushing's symptoms, this effect can last for 3 to 6 weeks. (3) Dose-dependent suppression of the immune system. Patients at particular risk include those with immunosuppressive conditions (ie, patients with diabetes or cancer, those on oral corticosteroids, and/or those with history of infection). (4) Increase in glucose levels, particularly in diabetics. (Van Boxem, 2019) Other factors that may lead to risk of cortisol suppression after epidural injections may include thyroid disease, obesity, liver disease, and kidney disease. Longer-acting corticosteroid formulations (methylprednisolone and triamcinolone) cause more cortisol suppression (compared to betamethasone or dexamethasone). (Friedly, 2018)

Choice of glucocorticoid: Choice of the corticosteroid to be injected is particularly important when administering cervical transforaminal ESI (which is not recommended by ODG). Particulate corticosteroids (ie, triamcinolone, methylprednisolone, and betamethasone) have been found in multiple case reports to produce permanent neurological compromise after a transforaminal procedure due to inadvertent intra-arterial damage (vertebral artery and radiculomedullary arteries) during the procedure. This is the result of occlusion and subsequent embolic infarction. Other mechanisms of injury have been suggested, including arterial vasospasm or dissection. Dexamethasone, a non-particulate corticosteroid is therefore recommended. (Van Boxem, 2019) (Schneider, 2018)

Sedation: Sedation is not recommended when administering cervical ESI. If sedation is to be utilized, the patient should be alert enough to be able to recognize and warn of symptoms that alert the clinician to potential adverse neurological effects. (Rathmell, 2015) These can include unexpected, unfamiliar, or undesired sensation. However, some experts have promoted the use of mild sedation to prevent complications due to sudden movements. (Malhotra, 2009) (House, 2018) (Schneider, 2018)

Research

Manchikanti et al., 2014: The authors state that overall, there is good evidence for the effectiveness of cervical interlaminar epidural injections in management cervical disc herniation. Evidence is considered poor for cervical transforaminal epidural injections. Complications are more common with interlaminar than transforaminal injections, and those with the latter can be fatal. (Manchikanti, 2014)

Manchikanti et al., 2015: A systematic review analyzed literature from 1966 to October 2014. The objective was to evaluate the long-term efficacy of cervical interlaminar and transforaminal epidural injections in the treatment of cervical disc herniation, spinal stenosis, discogenic pain without facet joint pain, and post-surgery syndrome. Seven papers were included. Of the 7, only 4 were considered high quality. Evidence was considered "level II" for the support of cervical interlaminar epidural injections for disc herniation. This was based on a "high-quality" randomized controlled trial comparing epidural injections of local anesthetic with or without steroids as the comparators. (Manchikanti, 2013) There were also 3 moderate-quality small randomized trials. There was no randomized trial assessing the efficacy of cervical transforaminal epidural injections. (Manchikanti, 2015)

Manchikanti et al., 2018: A randomized, active-controlled trial compared cervical interlaminar epidural injections in post-surgery syndrome (a total of 116 patients). The comparators were ESI

with a local anesthetic versus a local anesthetic and steroid. The level injected was between C5-6 and C7-T1. The steroid used was betamethasone 6 mg. Over 2 years, the average number of injections was 5 to 6, with an average of approximately 12 weeks of improvement per procedure. Both groups had similar improvement (69% in the local alone, and 71% in the steroid group). (Manchikanti, 2018)

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