EPIDURAL STEROID INJECTIONS

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BACKGROUND

CLINICAL BACKGROUND *(excerpted directly from Hayes 2017)*

"Approximately 25% of the adults in the United States reported low back pain in the past 3 months (Deyo et al., 2006), and low back pain is a global health issue that is likely to increase over future decades (Hoy et al., 2012). According to some estimates, the total annual economic cost for patients with low back pain in the United States approaches $100 billion (Crow and Willis, 2009).

Despite the increased sensitivity of diagnostic tools in detecting abnormalities in the structures of the lumbar spine, the cause of back pain may remain unknown in many patients. However, if back pain is not due to malignancy or underlying infection, 90% of patients will experience symptom resolution in ≤ 2 months. Causes that are identified include herniation of a lumbar intervertebral disc and spinal stenosis, or narrowing of the spinal canal (Valat et al. 2010; Jacobs et al., 2011). Conservative treatments for low back pain and sciatica include rest, analgesics, and anti-inflammatory medications; physical therapy; and advice regarding posture and exercise (Manchikanti et al., 2012a).

If symptoms persist, injections of local anesthetics and/or steroids along the nerve root or into the epidural space can provide a nonsurgical treatment option for some patients. Since low back pain and sciatica may also be due to other potentially serious spinal conditions, such as spinal tumor, infection, fracture, or cauda equina syndrome, these conditions must be ruled out based on medical history, physical examination, and laboratory and imaging studies before epidural steroid injections (ESIs) are considered (WebMD Medical Reference, 2012).

The rationale for the use of ESIs to treat low back pain and sciatica rests on the idea that steroids reduce inflammation and decrease pain by inhibition of inflammatory mediators such as phospholipase A2, stabilization of hyperexcitable nerve membranes, and reduction of capillary permeability.

Delivery of steroids directly into the epidural space exposes the spinal nerve roots to higher concentrations of medications for a longer period of time than systemic administration. Although positive reports of pain reduction by ESIs have led to widespread acceptance and prescription of this treatment, some studies have suggested that steroids do not provide additional pain relief beyond the anesthetic that is typically included in ESIs, and safety concerns have been raised (Price et al., 2005; Abdi et al., 2007)."

POLICY AND CRITERIA

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	L39242
Local Coverage Article	A58995
Kaiser Permanente Medical Policy	For Medicare lines of business, apply the criteria in the LCD to determine medical necessity.

For non-Medicare Members

For patients initiating epidural steroid treatment
The patient may receive up to 2 epidural steroid injections at least 2 weeks apart to determine adequacy of response if the following criteria are met:

A) The patient has neck or back pain with a radicular component, AND

B) Pain has been present for at least 1 month duration without improvement despite medical treatment OR has severe radicular pain with concordant structural abnormality, AND

C) The patient has none of the following contraindications for epidural steroid injection:
   a. Use of Coumadin or platelet inhibitors, or other signs of compromised blood clotting status*
   b. Local site infection
   c. Ongoing infection (acute viral or bacterial illness)
   d. Patient refusal
   e. Allergy to steroid or anesthetics

   *NOTE: this contraindication does not apply if there is documentation that antiplatelet/anticoagulant medications can be stopped prior to the injection, or if compromised clotting status due to other causes (if present) will be corrected.

Additional injections for patients not experiencing at least 50% reduction in pain during the 6 weeks following the first one or two injections are not medically necessary.

Subsequent injections

D) The patient has experienced a documented reduction in pain of at least 50% for at least three months following the first injection; AND

E) The patient has NOT received an epidural steroid injection within the previous 6 weeks for the same pain; AND

F) The patient has NOT received 4 epidural steroid injections within the past twelve months in the same spinal region.

Repeat injections extending beyond 12 months will be reviewed for continued medical necessity.

NOTE: A particular patient will often exhibit a fair amount of variability in terms of response from one injection to another. If a patient has an established pattern of responsiveness to ESI prior to an ineffective ESI, subsequent injections may still be beneficial.

1. There are different techniques for ESI.
   a. No individual technique has been proven consistently superior across patients.
   b. Individual patients may respond better to a particular technique.
2. At different points in time, the same patient may have different generator(s) of similar symptoms, that could benefit from injection(s) at different location and/ or with different technique.
3. ESI often has significant advantage over other interventions in terms of cost, access, and potential risk.

RATIONALE

EVIDENCE BASIS

"For radiculopathy due to herniated lumbar disc, evidence on benefits of epidural steroid injection is mixed, with some trials finding moderate short-term benefits and others finding no differences. There is no convincing evidence that epidural steroids are associated with long-term benefits and most trials found no reduction in rates of subsequent surgery. For non-radicular low back pain, there is likewise no convincing evidence that injections and other interventional therapies are effective, while there is consistent evidence that facet joint steroid injection, prolotherapy and intradiscal steroid injections are no more effective than sham therapies." (HERC 2017)

"For radiculopathy due to herniated lumbar disc, evidence on benefits of epidural steroid injection is mixed. Although some higher-quality trials found epidural steroid injection associated with moderate short-term (through up to 6 weeks) benefits in pain or function, others found no differences versus placebo injection. Reasons for the discrepancies between trials is uncertain, but could be related to the type of comparator treatment, as trials that compared an epidural steroid injection to an epidural saline or local anesthetic injection tended to report poorer results than trials that compared epidural steroid injection to a soft-tissue (usually interspinous ligament) placebo injection. Regardless of the comparator intervention, there is no convincing evidence that epidural steroids are associated with long-term benefits and most trials found no reduction in rates of subsequent surgery. Although serious complications following epidural steroid injection are rare in clinical trials, there are case reports of paralysis and infections. There is insufficient evidence on clinical outcomes to recommend a specific approach for performing epidural steroid injection, or on use of fluoroscopic guidance. In addition, insufficient evidence exists to recommend how many epidural injections to perform, though one higher-quality trial found that if an initial epidural steroid injection did not result in benefits, additional injections over a 6-week period did not improve outcomes." (HERC 2017)

"There is insufficient evidence to guide specific recommendations for timing of epidural steroid injection, though most trials enrolled patients with at least subacute (greater than 4 weeks) symptoms. Evidence on efficacy of epidural steroid injection for spinal stenosis is sparse and shows no clear benefit, though more trials are needed to clarify effects. Although chymopapain chemonucleolysis is effective for radiculopathy due to herniated lumbar disc, it is less effective than discectomy and is no longer widely available in the United States, in part due to risk of severe allergic reactions. Three trials suggest that intradiscal steroid injection has similar efficacy to chemonucleolysis, although none were placebo controlled." (HERC 2017)

"For local injections, there is insufficient evidence to accurately judge benefits because available trials are small, lower-quality, and evaluate heterogeneous populations and interventions. Trials of IDET and radiofrequency denervation reported inconsistent results. There were a small number of higher quality trials, and in the case of radiofrequency denervation, the trials had technical or methodologic shortcomings, making it difficult to reach conclusions about benefits. For other interventional therapies, data are limited to one to two small placebo-controlled randomized trials (botulinum toxin injection, epidural steroid injection for nonradicular low back pain, PIRFT and sacroiliac joint steroid injection), or there are no placebo-controlled randomized trials (therapeutic medial branch block, coblation nucleoplasty….or other medications)." (HERC 2017)

A 2019 Health Technology Assessment of epidural steroid injections for cervical radiculopathy identified 6 RCTs evaluating ESI for treatment of cervical radiculopathy and determined that the overall quality of the evidence was low due to individual study limitations and a small quantity of evidence for each comparison of ESI to alternate treatment options. This report concluded that the evidence on ESI for cervical radiculopathy failed to demonstrate beneficial effects of ESI on pain or disability associated with cervical radiculopathy compared with an epidural injection of anesthetic alone. No available studies included a placebo group, thus it is unclear whether and to what extent any observed improvements after ESI are attributable to the anesthetic, the injection itself, placebo effects, or other factors. Based on the available evidence reviewed in the report, ESI appeared safe and well-tolerated, with reported AEs generally mild and transient. ESI does have potential for serious AEs, including paralysis. The report notes a need for

additional information to determine whether effectiveness of ESI varies by patient characteristics, type of ESI, and how ESI compares to well-defined controls as well as evidence for long-term outcomes in those treated with ESI. (Hayes 2019)

RELEVANT GUIDELINES

In guidelines issued by the American Society of Interventional Pain Physicians (ASIPP), patients may receive diagnostic injections (no more than two) at least one week apart (preferably two). If patients experience at least a 50% reduction in pain, they are eligible for therapeutic injections, to be provided every two to three months if there is evidence of at least 8 weeks of at least 50% pain relief. (ASIPP 2009).

CODES

CPT Code	Description
62310	Injection, single (not via indwelling catheter), not including neurolytic substances, with or without contrast (for either localization or epidurography), of diagnostic or therapeutic sybstance(s) (including anesthetic, antispasmodic, opioid, steroid, other solution), epidural or arachnoid; cervical or thoracic
62311	Injection, single (not via indwelling catheter), not including neurolytic substances, with or without contrast (for either localization or epidurography), of diagnostic or therapeutic sybstance(s) (including anesthetic, antispasmodic, opioid, steroid, other solution), epidural or arachnoid; lumar, sacral (caudal)
64479	Injection, anesthetic agent and/or steroid, transforaminal epidural, cervical or thoracic, single level
64480	Injection, anesthetic agent and/or steroid, transforaminal epidural; cervical or thoracic, each additional level
64483	Injection(s), anesthetic agent and/or steroid, transforaminal epidural, with imaging guidance (fluoroscopy or CT); lumbar or sacral, single level
64484	Injection(s), anesthetic agent and/or steroid, transoframinal epidural, with imaging guidance (fluoroscopy or CT); lumbar or sacral, each additional level (List separately in addition to code for primary procedure)
77003	Fluoroscopic guidance and localization of needle or catheter tip for spine or paraspinous diagnostic or therapeutic injection procedures (epidural, subarachnoid, or sacroiliac joint), including neurolytic agent destruction
77012	Computed tomography guidance for needle placement (eg, biopsy, aspiration, injection, localization device), radiological supervision and interpretation
J1020	Injection, methylprednisone acetate, 20mg
J1030	Injection, methylprednisone acetate, 40mg
J1040	Injection, methylprednisone acetate, 80mg

ICD-10 Code	Description
M47.20 – M47.28	Other spondylosis with radiculopathy
M50.10 – M50.13	Cervical disc disorder with radiculopathy
M51.14 – M51.17	Intervertebral disc disorders with radiculopathy
M53.0 – M53.1	Cervicocranial – cervicobrachial syndrome
M53.81 – M53.83	Other specified dorsopathies [cervical region]
M54.10 – M54.18	Radiculopathy
M54.2	Cervicalgia
M54.30 – M54.5	Sciatica and lumbago
M54.6	Pain in thoracic spine
M54.9	Dorsalgia, unspecified

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