Medical Affairs Policy

Service: Back Pain Procedures-Epidural Injection (Caudal Epidural, Selective Nerve Root Block, Interlaminal, Transforaminal, Translaminial Epidural Injection)
PUM 250-0015-1706

<table>
<thead>
<tr>
<th>Medical Policy Committee Approval</th>
<th>06/16/17</th>
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</thead>
<tbody>
<tr>
<td>Effective Date</td>
<td>08/21/17</td>
</tr>
<tr>
<td>Prior Authorization Needed</td>
<td>Yes</td>
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</tbody>
</table>

Related Medical Policies:
- Back Pain Procedures-Sacroiliac Injections and Coccydynia Treatments
- Back and Nerve Pain Procedures-Radiofrequency Ablation, Facet and Other Injections
- Non-covered Services and Procedures
- Occipital Nerve Block and Headache Treatments

Disclaimer: This policy is for informational purposes only and does not constitute medical advice, plan authorization, an explanation of benefits, or a guarantee of payment. Benefit plans vary in coverage and some plans may not provide coverage for all services listed in this policy. Coverage decisions are subject to all terms and conditions of the applicable benefit plan, including specific exclusions and limitations, and to applicable state and federal law. Some benefit plans administered by the organization may not utilize Medical Affairs medical policy in all their coverage determinations. Contact customer services as listed on the member card for specific plan, benefit, and network status information.

Medical policies are based on constantly changing medical science and are reviewed annually and subject to change. The organization uses tools developed by third parties, such as the evidence-based clinical guidelines developed by MCG to assist in administering health benefits. This medical policy and MCG guidelines are intended to be used in conjunction with the independent professional medical judgment of a qualified health care provider. To obtain additional information about MCG, email medical.policies@wpsic.com.

Many member health plans have set maximum limits for pain injections per plan year or calendar year. These services are covered subject to medical necessity review. If a limit is not specified in the member health plan, the maximum follows the medical necessity guidelines in this policy. If a year is not described in the member health plan (e.g. per calendar year), a year is defined as the 12-month period starting from the date of service of the first approved injection.

Description:

This policy addresses Epidural Steroid Injection (ESI) and Hardware Injection. This policy does not address obstetric or surgical anesthetic epidural injection.

For Sacroiliac Joint (SI Joint) injection and Coccydynia Injections see: Back Pain-Sacroiliac and Coccydynia Treatments Medical Policy

An epidural injection is an injection of a medication into the epidural space of the spine. For purposes of this policy, caudal epidural, and selective nerve root block, interlaminal, transforaminal epidural, and translaminial epidural injections are all considered epidural
injections. The injection is used to treat swelling, pain, and inflammation associated with physical conditions that affect the spinal cord and/or nerve roots. Local anesthetic, a steroid, or a combination of both can be used. These procedures are traditionally aided with fluoroscopic guidance. Computerized tomography (CT) guidance is also used.

There is controversy among interventional pain management specialists regarding how to diagnose and manage spinal pain; there is a lack of consensus about the type and frequency of spinal interventional techniques for treatment of spinal pain. Much of the published evidence is conflicting: limited by the heterogeneous character of the patient populations, variability of treatment methods, variability of procedure (injection method and injection site), co-administration of drugs, postoperative evaluation times, and nonstandardization of outcome measures. Randomized Controlled Trials (RCTs) often compare the experimental treatment with a “standard” but also unproven treatment.

Evidence for lumbar epidural injection indicates at least a moderate certainty of moderate benefit in short term management of radicular back pain. Evidence for cervical and thoracic epidural steroid injection demonstrates less than moderate certainty of benefit and lower quality of studies, however there is expert consensus for cervical epidural injection in some circumstances.

Rare but serious complications after spinal and spinal steroid injections include cauda equina syndrome, septic facet joint arthritis, discitis, paraplegia, paraspinal abscess, alterations in blood glucose and HbA1c. With steroid injections, there may be a dose dependent suppression of the HPA (hypothalamic pituitary adrenal) axis lasting between one and three months. In 2014, the Food and Drug Administration (FDA) issued a safety announcement warning of rare but serious adverse events associated with corticosteroids injected into the epidural space. Corticosteroids are not approved by the FDA for injection into the epidural space of the spine.

**Definitions:**

Radicular pain (for purposes of this policy) is pain that radiates from the spine into the extremity along the course of the spinal nerve root; the pain should follow the pattern of the sensory dermatome associated with the nerve root(s) identified. The pain may also be described as a burning or tingling sensation. Radiculopathy is a term often used interchangeably with the term radicular pain. Radiculopathy is radicular pain accompanied by sensory or motor findings.

Caudal epidural injections, with steroids, are used to treat back and lower extremity pain, accessing the epidural space through the sacral hiatus, providing access to the lower nerve roots of the spine. Failed back surgery syndrome is the most common reason for the caudal approach.

Interlaminar/ intraluminal epidural injections with steroids, access the epidural space between two vertebrae (interlaminar) to treat cervical, lumbar or thoracic radicular pain.
with radicular pain. Medication via this injection typically spreads to multiple levels bilaterally. Interlaminar epidural injections are the most common type of epidural injection.

**Sacroiliac (SI) joint injection** is an injection of local anesthetic and / or a steroid into the articular space between the spinal column and pelvis. Although a steroid may be used, it is not an injection into the epidural space. See Back Pain-Sacroiliac and Coccydynia Treatments Medical Policy

**Transforaminal epidural injections** (also called selective nerve root blocks) access the epidural space via the intervertebral foramen where the spinal nerves exit the spinal column. The injection is delivered to one nerve root unilaterally.

**Indications of Coverage:**

- Fluoroscopic guidance is required for epidural injections.

**A. Cervical or Lumbar Epidural Injection**: is considered medically necessary if all the following are documented:

1. Symptoms of cervical or lumbosacral **radicular pain** that follow a dermatomal distribution for each level of location(s) to be injected. Note: transforaminal injection requires documentation of radiculopathy at each nerve being targeted.

2. Physical exam findings consistent with radiculopathy (e.g. positive straight leg raising test), Spurling’s test (to assess cervical radicular pain) diminished sensation, diminished or absent reflex, and / or muscle weakness.

3. Documentation of functional status and average pain levels of ≥ 6 on a scale of 0 to 10, or intermittent or continuous pain causing functional disability.

4. Symptoms that have failed to respond to a six-week trial* within the last 6 months, of all the following:

   a. Medications such as anti-inflammatory, muscle relaxants, analgesic, opioids, gabapentin, and pregabalin.

   b. Therapy: Physical therapy/chiropractic manipulations performed, at some point, after the onset of the current episode of symptoms. (Documentation of therapy administered by a Certified Athletic Trainer or regular participation in programs such as the Arthritis Foundation Exercise Program may also meet medical criteria for therapy)
*Note: If the symptoms are severe (requiring urgent medical care), the trial of conservative treatments may not be required.

If the above criteria are met, allow one (1) epidural injection, at the cervical or lumbosacral spinal nerve level(s) requested.

B. Subsequent Epidural Injections: Repeat cervical or lumbosacral epidural injection at the same location is considered medically necessary when all the following are met:

1. The previous injection diminished the pain by at least 50 percent

2. A minimum of 6 weeks has passed since the previous injection

3. Post injection physical therapy, chiropractic or home exercise program to increase range of motion (ROM) and core strength has been attempted.

4. Documentation of functional status compared to the pre-injection report

If a limit is not specified in the member health plan, a maximum of three epidural injections regardless of level, location, or side in a year will be considered medically necessary when criteria are met for each injection.

C. Diagnostic Lumbosacral Hardware Injection: A single epidural injection is considered medically necessary for diagnostic purposes to direct further care (e.g. prior to spinal surgery including surgery for purposes of removing hardware) when all the following conditions are met: (Note: this will count toward the limit of 3 injections)

1. The patient has been evaluated by a surgeon who has recommended possible surgery

2. All criteria for the specific surgical procedure that is recommended are met

3. There is a discrepancy between clinical findings and imaging studies. For instance: Chronic symptoms in an extremity are described, but the imaging reports do not confirm the presence of nerve root impingement (compression, entrapment, displacement) or irritation that is consistent with the patient’s physical symptoms

4. The injection will be performed at the level that is suspected to be symptomatic or to identify the level of pathology at the site of previous surgery
Limitations of Coverage:

A. Review health plan and endorsements for exclusions and prior authorization or benefit requirements.

B. If used for a condition/diagnosis other than is listed in the Indications of Coverage, deny as experimental, investigational, and unproven to affect health outcomes.

C. If used for a condition/diagnosis that is listed in the Indications of Coverage, but the criteria are not met, deny as not medically necessary.

D. If used for Post-herpetic Neuralgia or Reflex Sympathetic Dystrophy (also known as Complex Regional Pain Syndrome), deny as not medically necessary.

E. If a limit is not specified in the member health plan, more than three injections regardless of location and level (including therapeutic and diagnostic) in a year are considered not medically necessary. Note that a bilateral injection will be counted as two (2) injections.

F. An epidural injection provided less than six (6) weeks after the previous injection is considered not medically necessary.

G. Epidural injections provided without the use of fluoroscopic or CT guidance are not current standard medical practice and are considered not medically necessary.

H. Epidurography is considered a component of an epidural injection according to Correct Coding Initiative (CCI) edits, and is not reimbursed separately.

I. Perioperative epidural injections associated with spinal surgery are considered not medically necessary.

J. If more than one type of pain treatment is requested/ performed on the same day, only one type will be considered medically necessary at the discretion of the health plan.

K. Ultrasound guided epidural injections are considered experimental, investigational, and unproven to affect health outcomes.

L. Thoracic Epidural Injection is considered experimental, investigational and unproven to affect health outcomes.

M. Epidural Injection for Non-Radicular Pain is considered experimental, investigational and unproven to affect health outcomes.

N. Epidural Injection of Enbrel (etanercept) is considered experimental, investigational and unproven to affect health outcomes.
O. Repeat epidural steroid injection after an ineffective epidural injection at the same level is considered not medically necessary

Documentation Required:

- Office notes
- Documentation of pain level and ‘Functional Status’ pre-injection and post-injection which includes:
  - Work status/ Work restrictions
  - Specific Activities of Daily Living (ADL)
  - Current pain medication use
  - Measurable Physical status indicators (e.g. Range of Motion, Muscle strength)
- Procedure reports

References:


18. Up to Date. Subacute and chronic low back pain: nonsurgical interventional treatment. Literature review current through: April 2015. This topic last updated: May 13, 2014


References Added 2016:


2. Up to Date. Subacute and chronic low back pain: Nonsurgical interventional treatment. Literature review current through: April 2015. This topic last updated: Apr 1, 2016


References Added 2017:


5. UpToDate. Subacute and chronic low back pain: Nonsurgical interventional treatment. Literature review current through Apr 2015 This topic last updated: Apr 1, 2016


**WPS/Arise Review History:**

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<thead>
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<td>06/13/14, 06/12/15, 06/03/16, 06/16/17</td>
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<tr>
<td>Reviewed</td>
<td>06/13/14, 06/12/15, 06/03/16, 06/16/17</td>
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<td>Revised</td>
<td>06/12/15, 06/03/16, 06/16/17</td>
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➢ Note: For review/revision history prior to 2014 see previous Medical Policy or Coverage Policy Bulletin

<table>
<thead>
<tr>
<th>Nerve Root</th>
<th>Distribution</th>
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<tbody>
<tr>
<td>C2</td>
<td>Jaw, ears, top of head, posterior head</td>
</tr>
<tr>
<td>C3</td>
<td>Upper anterior and posterior neck</td>
</tr>
<tr>
<td>C4</td>
<td>Lower anterior and posterior neck and collar area</td>
</tr>
<tr>
<td>C5</td>
<td>Anterior chest at the level of the clavicle, lateral upper arm, lateral forearm, lower posterior neck, bicep muscle</td>
</tr>
<tr>
<td>C6</td>
<td>Lateral (along the radius) arm and thumb, wrist extensor muscles</td>
</tr>
<tr>
<td>C7</td>
<td>Index and long fingers, posterior medial arm, tricep muscle</td>
</tr>
<tr>
<td>C8</td>
<td>Lateral (along the ulna) arm, ring and little fingers, finger flexor muscles</td>
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<tr>
<td>T1</td>
<td>Circumferential thorax below the level of the clavicle, medial arm and forearm above the wrist</td>
</tr>
<tr>
<td>T2</td>
<td>Circumferential thorax at the level of the axilla</td>
</tr>
<tr>
<td>T3</td>
<td>Circumferential thorax below the level of the axilla</td>
</tr>
<tr>
<td>T4</td>
<td>Circumferential thorax at the lower level of the pectoralis major</td>
</tr>
<tr>
<td>T5</td>
<td>Circumferential thorax at the level of the inframammary line</td>
</tr>
<tr>
<td>T6</td>
<td>Circumferential thorax at the level of the upper xiphoid</td>
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<tr>
<td>T7</td>
<td>Circumferential thorax at the level of the lower xiphoid</td>
</tr>
<tr>
<td>T8</td>
<td>Circumferentially at the level of the upper abdomen</td>
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<td></td>
<td>Definition</td>
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<tr>
<td>T9</td>
<td>Circumferentially above the level of the umbilicus</td>
</tr>
<tr>
<td>T10</td>
<td>Circumferentially at the level of the umbilicus</td>
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<tr>
<td>T11</td>
<td>Circumferentially below the level of the umbilicus</td>
</tr>
<tr>
<td>T12</td>
<td>Circumferentially at the level of the pubic bones</td>
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<tr>
<td>L1</td>
<td>Anterior inguinal region, posterior lower back</td>
</tr>
<tr>
<td>L2</td>
<td>Upper medial and lateral thigh, posterior lower back, hip flexor (psoas) muscles</td>
</tr>
<tr>
<td>L3</td>
<td>Anterior lower medial and lower lateral thigh, inner leg above and below the knee, posterior back, quadriceps muscles</td>
</tr>
<tr>
<td>L4</td>
<td>Anterior lower thigh, anterior knee, inner lower leg and ankle, great toe, posterior back, anterior tibialis muscles</td>
</tr>
<tr>
<td>L5</td>
<td>Lateral leg, medial foot, posterior back, hallucis longus muscles</td>
</tr>
<tr>
<td>S1</td>
<td>Posterior back, posterior lateral leg, outer ankle, heel, small toe, gastrocnemius muscles</td>
</tr>
<tr>
<td>S2</td>
<td>Genitalia, posterior back, posterior medial leg to the ankle</td>
</tr>
<tr>
<td>S3</td>
<td>Genitalia, perineum</td>
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Approved by the Medical Director