EPIDURAL INJECTIONS including EPIDURAL STEROID INJECTIONS

Policy Number: 2016M0014B  Effective Date: January 1, 2016

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INSTRUCTIONS:

“Medical Policy assists in administering UCare benefits when making coverage determinations for members under our health benefit plans. When deciding coverage, all reviewers must first identify enrollee eligibility, federal and state legislation or regulatory guidance regarding benefit mandates, and the member specific Evidence of Coverage (EOC) document must be referenced prior to using the medical policies. In the event of a conflict, the enrollee’s specific benefit document and federal and state legislation and regulatory guidance supersede this Medical Policy. In the absence of benefit mandates or regulatory guidance that govern the service, procedure or treatment, or when the member’s EOC document is silent or not specific, medical policies help to clarify which healthcare services may or may not be covered. This Medical Policy is provided for informational purposes and does not constitute medical advice. In addition to medical policies, UCare also uses tools developed by third parties, such as the InterQual Guidelines®, to assist us in administering health benefits. The InterQual Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. Other Policies and Coverage Determination Guidelines may also apply. UCare reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary and to provide benefits otherwise excluded by medical policies when necessitated by operational considerations.”
POLICY DESCRIPTION:
This policy describes the use of epidural injections for diagnostic and therapeutic purposes. Diagnostic injections can be used to differentiate, identify and evaluate. Therapeutic injections may utilize steroids, as in cases of intervertebral disc disease or anesthetics, as in cases of other disease processes. Epidural injections with Enbrel (etanercept) for treatment of low back pain are also addressed.

COVERAGE RATIONALE / CLINICAL CONSIDERATIONS:
Diagnostic transforaminal epidural injections may be considered MEDICALLY NECESSARY for the following purposes:
- To differentiate the level of radicular nerve root pain,
- To differentiate radicular from nonradicular pain,
- To evaluate a discrepancy between imaging studies and clinical findings,
- To identify the source of pain in the presence of multi-level nerve root compression,
- To identify the level of pathology at a previous operative site.

Therapeutic epidural injections:
A. Epidural steroid injections may be considered MEDICALLY NECESSARY for patients with acute and chronic low back pain and/or sciatica who have tried and failed conservative therapy which must include:
   - Pharmacological therapy AND
   - Physical therapy and/or a home exercise program.
B. Epidural Injections may be considered MEDICALLY NECESSARY for cancer pain management
C. Epidural injections (interlaminar/translaminar or caudal) may be considered MEDICALLY NECESSARY for the following:
   - Acute obstetric, post traumatic and postoperative pain,
   - Advanced cancer pain, primary or metastatic,
   - Acute/subacute and chronic pain syndrome including cervical, thoracic and lumbar pain with radiculopathy and intervertebral disc disease (with neuritis or radiculitis) with or without myelopathy that has failed to respond to adequate conservative management,
   - Nerve root injuries and neuropathic pain and post traumatic including post laminectomy syndrome (failed back syndrome),
   - Spinal cord myelopathy,
   - Complex regional pain syndrome,
   - Epidural scarring from prior infection, hemorrhage and/or surgery,
   - Multiple rib fractures,
   - Vertebral compression fractures,
   - Post herpetic neuralgia and herpes zoster,
   - Phantom limb pain.
D. **Therapeutic transforaminal epidural injections** may be considered **MEDICALLY NECESSARY** for the following purposes:
   - Radicular pain resistant to more conservative measures or when surgery is contraindicated,
   - Post-decompressive radiculitis or post surgical scarring,
   - Monoradicular pain, confirmed by diagnostic block in which a surgically correctible lesion cannot be identified,
   - Treatment of acute herpes zoster or post herpetic neuralgia.

E. Epidural injections of Enbrel (etanercept) for treatment of low back pain due to lumbar disc disease is **CONSIDERED NOT MEDICALLY NECESSARY** due to insufficient published, scientific, peer-reviewed literature regarding safety and efficacy or improved patient outcomes.

Epidural (interlaminar/translaminar or caudal) and transforaminal epidural corticosteroid injections should not exceed a series of three, per spinal region, within a six-month period when used as treatment for a pain disorder other than treatment for cancer pain. These may be performed at intervals of one week or greater. With each subsequent injection, it must be a significant improvement in the patient's symptoms from the prior injection.

Epidural steroid injections for chronic pain performed without imaging guidance will be **CONSIDERED NOT MEDICALLY NECESSARY**.

Epidural steroid injections for all other indications are considered **UNPROVEN AND MEDICALLY UNNECESSARY**.

**Clinical Considerations:**
Before receiving an epidural steroid injection (ESI), a patient usually undergoes an imaging test such as a computed tomography (CT) or magnetic resonance imaging (MRI) scan to identify the potential causes of the back pain.

**Possible Complications:** Infection, pain, puncture of the dura, headache, hematoma, transient paralysis, paraplegia, meningitis, transient blindness, osteomyelitis, and epidural abscess have been reported. A recent outbreak of meningitis was traced to ESIs containing contaminated steroids from a compounding center. Concern has been raised regarding reports of arachnoiditis in patients who have received epidural steroid injections. ESIs have been associated with increased blood glucose levels, which should be taken into account for diabetic patients.

**BACKGROUND:**

Back pain and sciatica, or leg pain originating from injury to or pressure on the sciatic nerve, are major causes of disability in adults, occurring in 15% to 20% of the working-age population annually and 70% to 90% of adults at some point in their lives. Men and women are affected equally, but women > 60 years of age report back symptoms more often than men. 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). Risk factors include involvement in occupations that require repetitive lifting in a forward, bent-and-twisted
position, especially when the lifting exceeds the worker’s capacity, exposure to vibrations, such as those caused by vehicles or industrial machinery, biomechanical aspects of the spine, obesity and sedentary lifestyle, psychosocial issues, and cigarette smoking.

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. Conservative treatments for low back pain and sciatica include rest, analgesics and anti-inflammatory medications, physical therapy, and advice regarding posture and exercise. If symptoms persist, injections of local anesthetics and/or steroids along the nerve root or into the epidural space provide a nonsurgical treatment option for some patients.

The rationale for the use of epidural steroid injection (ESI) to treat low back pain and sciatica rests on the idea that steroids reduce inflammation and decrease pain by inhibition of 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 steroid concentrations for a longer period of time than systemic application. An anesthetic is frequently added to the steroids to provide temporary pain relief. ESIs are not considered a cure for lower back pain or sciatica: the goal is to provide pain relief in order to allow patients to progress with their rehabilitation program and to allow natural healing processes.

There are three main approaches for ESIs: caudal, interlaminar, and transforaminal (Benny and Azari, 2011; Benyamin et al., 2012; Parr et al., 2012). The choice of injection location is based on several factors. Primarily, one approach is chosen over another because of the anatomic location of the suspected pain generator. Most disc and nerve root pathology occurs in the anterior epidural space. Interlaminar approaches deliver the injection fluid into the posterior epidural compartment, without the guarantee that it will flow to the anterior epidural compartment. During caudal injections, the needle is advanced through the sacrococcygeal ligament and sacral hiatus into the caudal epidural space, which communicates with the posterior lumbar epidural space. Transforaminal injections target the anterior epidural space and the spinal nerve as it exits the neural foramen, and are considered the most “targeted” injections, allowing for use of the lowest steroid concentrations (Young et al., 2007).

Common corticosteroids used in epidural injections include betamethasone sodium phosphate and betamethasone acetate (e.g., Celestone Soluspan), methylprednisolone acetate (e.g., Depo-Medrol), triamcinolone acetonide (e.g., Kenalog-10, Kenalog-40, Aristopan), and prednisolone acetate (Silbergleit et al., 2001; Hession et al., 2004).

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 that provided by the anesthetic that is typically included in ESIs. In addition, safety concerns have been raised regarding reports of arachnoiditis in patients who have received ESIs, and regarding the recent meningitis outbreak, which was traced to contaminated steroids in ESIs.

**REGULATORY STATUS:**

1. **U.S. FOOD AND DRUG ADMINISTRATION (FDA):**
   
   The two most common local anesthetics used for epidural injections and facet joint pain treatment,
lidocaine and bupivacaine, are not specifically indicated for epidural injections and facet joint blockade. Instead, the indications for these drugs are more general. The indications for local anesthetics include production of local and regional anesthesia or analgesia for diagnostic and therapeutic procedures.

A number of steroid formulations have been approved by the FDA, but none are specifically approved for epidural injection. The corticosteroids used in the studies reviewed for the present report included methylprednisolone, prednisolone, triamcinolone, betamethasone, and dexamethasone phosphate.

Of note is the FDA’s involvement in an investigation concerning the suspected transmission of fungus via epidural steroid injections (ESIs) in September 2012 (FDA, 2012a; FDA, 2012b). In September 2012, multiple cases of fungal meningitis were documented, and these cases were later tied to the administration of epidural steroids (FDA, 2012b; Kainer et al., 2012; Kauffman et al., 2012; CDC, 2013). The first FDA release concerning the meningitis outbreak associated with epidural steroids was dated October 5, 2012 (FDA, 2012b). The steroid linked to this outbreak concern was methylprednisolone acetate (MPA), which was distributed from the New England Compounding Center (NECC) on September 26, 2012 (CDC, 2013).

The Centers for Disease Control and Prevention (CDC) and the FDA have confirmed the presence of a fungus known as *Exserohilum rostratum* (JPG - 183 KB) in unopened medication vials of preservative-free MPA from three implicated lots (#05212012@68, BUD 11/17/2012; #06292012@26, BUD12/26/2012; #08102012@51, BUD 2/6/2013). The laboratory confirmation further links steroid injections from these NECC lots to the outbreak (CDC, 2013).

The latest update from the FDA at the time of this report (December 12, 2012) stated that the FDA and CDC have identified bacterial and/or fungal contamination in unopened vials of betamethasone, cardioplegia, and triamcinolone solutions distributed and recalled from the NECC (FDA, 2012a). Identified contaminants include bacteria known as *Bacillus* and fungal species, including *Aspergillus tubingensis*, *Aspergillus fumigatus*, *Cladosporium* species, and *Penicillium* species. Although rare, some of the identified *Bacillus* species can be human pathogens. Some of the fungal organisms identified, particularly *Aspergillus fumigatus*, are known to cause disease in humans. The FDA stated that it is not known how product contamination with these organisms could affect patients clinically (FDA, 2012a).

Immunex Corp. received a biologics license application (BLA) approval (BLA103795) on November 2, 1998, for Enbrel (etanercept) for use in reducing the signs and symptoms of moderately to severely active rheumatoid arthritis in patients who had an inadequate response to one or more disease-modifying antirheumatic drugs (DMARDS) (CDER 2001).

According to the most recent prescribing information (Immunex Corp., 2013), etanercept is approved for use to treat rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, and plaque psoriasis in adults, and polyarticular juvenile idiopathic arthritis in patients aged 2 years or older. Therefore its use to treat LBP is off label unless the back pain is related to one of the conditions listed as an approved indication.

2. **CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS):**

   No National Coverage Determination (NCD) for specific types of injections for low back pain and sciatica was identified on the CMS website (CMS, 2013).
Local Coverage Determinations (LCD) which address injections for pain exist and compliance with these policies is required where applicable.

- Epidural injections are used for acute and chronic pain, in addition to cancer pain management. Epidural injections are utilized both for diagnostic and therapeutic purposes.
- A multi-disciplinary or collaborative comprehensive evaluation (e.g. orthopedics, neurologist, neurosurgeon, physiatrist, anesthesiologist, pain medicine specialist, and/or attending physician), is recommended prior to initiating a trial of these injections for relief of chronic recurrent pain.
- Epidural steroid injections, both interlaminar/translaminar and transforaminal should be used only in the presence of radiculopathy.

Indications for Diagnostic and Therapeutic Epidural Injections

1. **Diagnostic**: Interlaminar/translaminar or caudal epidural steroid injections are seldom used. Although the medication injected can sometimes be confined to a limited area, bilateral effects and spread to adjacent levels often occur.

2. **Therapeutic**: Interlaminar/translaminar or caudal epidural injections and infusions of opioid, local anesthetic, or other medications may be used for the treatment of acute and chronic pain or cancer pain.

Epidural injections (interlaminar/translaminar or caudal) may be used for the following:

- Acute obstetric, post traumatic and postoperative pain
- Advanced cancer pain, primary or metastatic
- Acute/sub acute and chronic pain syndrome including cervical, thoracic and lumbar pain with radiculopathy and intervertebral disc disease (with neuritis or radiculitis) with or without myelopathy that has failed to respond to adequate conservative management.
- Nerve root injuries and neuropathic pain and post traumatic including post laminectomy syndrome (failed back syndrome).
- Spinal cord myelopathy
- Complex regional pain syndrome
- Epidural scarring from prior infection, hemorrhage and/or surgery
- Multiple rib fractures
- Vertebral compression fractures
- Post herpetic neuralgia and herpes zoster
- Phantom limb pain

Indications for Diagnostic and Therapeutic Transforaminal Epidural Injections

Transforaminal epidural injection is a selective injection of the cervical, thoracic, lumbar or sacral nerve roots with proximal spread of contrast or local anesthetic through the neural foramen to the epidural space. With the aid of fluoroscopic or computed tomography (CT) imaging, the needle tip is placed within or adjacent to the lateral margin of the neural foramen and contrast material is injected to obtain a neurogram and visualize spread of the injected solution.

A small volume of local anesthetic is injected (less than or equal to 1.0 ml) in order to perform a diagnostic reproducible blockade of a specific nerve root. The diagnostic usefulness is lost if more than 1.0 ml of local anesthetic is injected (the block becomes unreliable since the spread of anesthetic to adjacent levels and structures likely occurs).

- **Diagnostic transforaminal epidural injections** are appropriate for the following purposes:
To differentiate the level of radicular nerve root pain.
To differentiate radicular from non-radicular pain
To evaluate a discrepancy between imaging studies and clinical findings
To identify the source of pain in the presence of multi-level nerve root compression
To identify the level of pathology at a previous operative site

It might be necessary to perform injections at two different nerve root levels on the same date of service. When multiple levels of nerve root compression or stenosis is suspected to be responsible for the patient’s symptoms, presence of the compression or stenosis on imaging studies should be documented in the medical record.

- **Therapeutic transforaminal epidural injections** are appropriate for the following purposes:
  - Corticosteroid can be added as a therapeutic measure. Injections for therapeutic reasons can be of greater volume. The transforaminal injection can be performed for diagnostic, therapeutic or both purposes.
    - Radicular pain resistant to more conservative measures or when surgery is contraindicated.
    - Post-decompressive radiculitis or post surgical scarring
    - Monoradicular pain, confirmed by diagnostic block in which a surgically correctible lesion cannot be identified
    - Treatment of acute herpes zoster or post herpetic neuralgia

**General Indications and Limitations**

- Epidural (interlaminar/translaminar or caudal) and transforaminal epidural corticosteroid injections should not exceed a series of three, per spinal region, within a six-month period when used as treatment for a pain disorder other than treatment for cancer pain. These may be performed at intervals of one week or greater. With each subsequent injection the medical record should clearly document the interval effects from the prior injection(s). Appropriate reasons for a repeat injection are:
  1. Significant improvement in the patient’s symptoms from the prior injection, even if relapsed, or
  2. Carefully documented technical reasons that it is appropriate to repeat the procedure even if no prior improvement and
  3. Patients with persistent pain in whom the imaging findings suggest that the pathology should respond to corticosteroid injection.

In the absence of a compelling technical reason, it is not appropriate to repeat a procedure a third time if there has been no improvement from the two preceding.

- If corticosteroids are used, consideration should be given to the potential complications of repetitive corticosteroid administration.
- Many of these procedures, such as those in the peri-operative period, may not require fluoroscopy.
- For treatment of chronic pain, the standard of care is that these procedures be performed under fluoroscopic or CT guided imaging. Therefore injections for chronic pain performed without imaging guidance will be considered not medically necessary.
- Fluoroscopic guidance must be utilized in the performance of single nerve root/transforaminal injections to ensure the precise placement of the needle and medications injected.

3. **MINNESOTA DEPARTMENT OF HUMAN SERVICES (DHS):**

Minnesota DHS does not have a policy statement regarding injections for low back pain and sciatica in
CLINICAL EVIDENCE:

Evidence for this report was obtained from a search in PubMed databases spanning 1997 to December 2012. Studies were included if they were prospective and compared epidural injections with steroids or with steroids plus anesthetics with epidural placebo injections or an active control. A total of 18 randomized control trials (RCTs) were selected for review (Carette et al., 1997; Kraemer et al., 1997; Fukusaki et al., 1998; Riew et al., 2000; Karppinen et al., 2001; Vad et al., 2002; Valat et al., 2003; Arden et al., 2005; Ng et al., 2005; Wilson-MacDonald et al., 2005; Gahreman et al. et al., 2010; Iversen et al., 2011; Cohen et al., 2012; Ohtori et al., 2012; Manchikanti et al., 2012a; Manchikanti et al., 2012b; Manchikanti et al., 2012c; Manchikanti et al., 2012d).

SUMMARY

Quality of the Evidence: Overall, the quality of the body of evidence was low due to limitations of the individual studies, including a limited follow-up period (< 1 year) and relatively small sample sizes per group (e.g., ≤ 35 patients). The limited follow-up period was a substantial shortcoming since the efficacy of pain treatments cannot be assessed adequately without sufficient follow-up. Sample sizes were relatively small, with 11 of 18 studies, including ≤ 100 patients (range, 48 to 228). Lastly, comparison across studies was hampered by differences in patient populations (e.g., age, sex), the underlying cause of back pain, and varied injection procedures (caudal, interlaminar, transforaminal).

Conclusions:

- Multiple randomized controlled trials suggest that epidural injections may produce transient pain relief in patients with low back pain and sciatica. However, most of the studies did not include a placebo group, and the few studies that did include a placebo group yielded contradictory results. Thus, the possibility of spontaneous recovery cannot be ruled out.
- The pain relief reported in many studies appears attributable to the anesthetics that are typically included in ESIs, and steroids provide little or no additional pain relief.
- Pain reduction by epidural steroid injections (ESI) plus anesthetics is transient.
- ESIs did not improve disability or reduce the need for surgery in most of the studies.
- Although complications reported in the reviewed studies were generally mild and transient, serious adverse events have occurred, including arachnoiditis, paraplegia, meningitis, and epidural abscess. A recent meningitis outbreak was traced to ESIs with contaminated compounded steroids, and concern has been raised regarding reports of arachnoiditis in patients who have received ESIs.

APPLICABLE CODES:

The Current Procedural Terminology (CPT®) codes and HCPCS codes listed in this policy are for reference purposes only. Listing of a service or device code in this policy does not imply that the service described by this code is a covered or non-covered health service. The inclusion of a code does not imply any right to reimbursement or guarantee claims payment. Other medical policies and coverage determination guidelines may apply.

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REFERENCES:


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