PROPOSED/DRAFT Local Coverage Determination (LCD):
Epidural Injections for Pain Management (DL36920)

Please note: This is a Proposed/Draft policy.
Proposed/Draft LCDs are works in progress that are available on the Medicare Coverage Database site for public review. Proposed/Draft LCDs are not necessarily a reflection of the current policies or practices of the contractor.

Contractor Information

<table>
<thead>
<tr>
<th>Contractor Name</th>
<th>Contract Type</th>
<th>Contract Number</th>
<th>Jurisdiction</th>
<th>State(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Novitas Solutions, Inc.</td>
<td>A and B MAC</td>
<td>04111 - MAC A</td>
<td>J - H</td>
<td>Colorado</td>
</tr>
<tr>
<td>Novitas Solutions, Inc.</td>
<td>A and B MAC</td>
<td>04112 - MAC B</td>
<td>J - H</td>
<td>Colorado</td>
</tr>
<tr>
<td>Novitas Solutions, Inc.</td>
<td>A and B MAC</td>
<td>04211 - MAC A</td>
<td>J - H</td>
<td>New Mexico</td>
</tr>
<tr>
<td>Novitas Solutions, Inc.</td>
<td>A and B MAC</td>
<td>04212 - MAC B</td>
<td>J - H</td>
<td>New Mexico</td>
</tr>
<tr>
<td>Novitas Solutions, Inc.</td>
<td>A and B MAC</td>
<td>04311 - MAC A</td>
<td>J - H</td>
<td>Oklahoma</td>
</tr>
<tr>
<td>Novitas Solutions, Inc.</td>
<td>A and B MAC</td>
<td>04312 - MAC B</td>
<td>J - H</td>
<td>Oklahoma</td>
</tr>
<tr>
<td>Novitas Solutions, Inc.</td>
<td>A and B MAC</td>
<td>04411 - MAC A</td>
<td>J - H</td>
<td>Texas</td>
</tr>
<tr>
<td>Novitas Solutions, Inc.</td>
<td>A and B MAC</td>
<td>04412 - MAC B</td>
<td>J - H</td>
<td>Texas, Colorado, New Mexico, Oklahoma, Texas</td>
</tr>
<tr>
<td>Novitas Solutions, Inc.</td>
<td>A and B MAC</td>
<td>04911 - MAC A</td>
<td>J - H</td>
<td>Colorado, New Mexico, Oklahoma, Texas</td>
</tr>
<tr>
<td>Novitas Solutions, Inc.</td>
<td>A and B MAC</td>
<td>07101 - MAC A</td>
<td>J - H</td>
<td>Arkansas</td>
</tr>
<tr>
<td>Novitas Solutions, Inc.</td>
<td>A and B MAC</td>
<td>07102 - MAC B</td>
<td>J - H</td>
<td>Arkansas</td>
</tr>
<tr>
<td>Novitas Solutions, Inc.</td>
<td>A and B MAC</td>
<td>07201 - MAC A</td>
<td>J - H</td>
<td>Louisiana</td>
</tr>
<tr>
<td>Novitas Solutions, Inc.</td>
<td>A and B MAC</td>
<td>07202 - MAC B</td>
<td>J - H</td>
<td>Louisiana</td>
</tr>
<tr>
<td>Novitas Solutions, Inc.</td>
<td>A and B MAC</td>
<td>07301 - MAC A</td>
<td>J - H</td>
<td>Mississippi</td>
</tr>
<tr>
<td>Novitas Solutions, Inc.</td>
<td>A and B MAC</td>
<td>07302 - MAC B</td>
<td>J - H</td>
<td>Mississippi</td>
</tr>
<tr>
<td>Novitas Solutions, Inc.</td>
<td>A and B MAC</td>
<td>12101 - MAC A</td>
<td>J - L</td>
<td>Delaware</td>
</tr>
<tr>
<td>Novitas Solutions, Inc.</td>
<td>A and B MAC</td>
<td>12102 - MAC B</td>
<td>J - L</td>
<td>Delaware</td>
</tr>
<tr>
<td>Novitas Solutions, Inc.</td>
<td>A and B MAC</td>
<td>12201 - MAC A</td>
<td>J - L</td>
<td>District of Columbia</td>
</tr>
<tr>
<td>Novitas Solutions, Inc.</td>
<td>A and B MAC</td>
<td>12202 - MAC B</td>
<td>J - L</td>
<td>District of Columbia</td>
</tr>
<tr>
<td>Novitas Solutions, Inc.</td>
<td>A and B MAC</td>
<td>12301 - MAC A</td>
<td>J - L</td>
<td>Maryland</td>
</tr>
<tr>
<td>Novitas Solutions, Inc.</td>
<td>A and B MAC</td>
<td>12302 - MAC B</td>
<td>J - L</td>
<td>Maryland</td>
</tr>
<tr>
<td>Novitas Solutions, Inc.</td>
<td>A and B MAC</td>
<td>12401 - MAC A</td>
<td>J - L</td>
<td>New Jersey</td>
</tr>
<tr>
<td>Novitas Solutions, Inc.</td>
<td>A and B MAC</td>
<td>12402 - MAC B</td>
<td>J - L</td>
<td>New Jersey</td>
</tr>
<tr>
<td>Novitas Solutions, Inc.</td>
<td>A and B MAC</td>
<td>12501 - MAC A</td>
<td>J - L</td>
<td>Pennsylvania</td>
</tr>
<tr>
<td>Novitas Solutions, Inc.</td>
<td>A and B MAC</td>
<td>12502 - MAC B</td>
<td>J - L</td>
<td>Pennsylvania, District of Columbia, Delaware, Maryland, New Jersey, Pennsylvania</td>
</tr>
<tr>
<td>Novitas Solutions, Inc.</td>
<td>A and B MAC</td>
<td>12901 - MAC A</td>
<td>J - L</td>
<td>Pennsylvania, District of Columbia, Delaware, Maryland, New Jersey, Pennsylvania</td>
</tr>
</tbody>
</table>

Proposed/Draft LCD Information

Document Information

Source LCD ID
N/A

Printed on 9/23/2016. Page 1 of 14
Proposed LCD ID
DL36920

Proposed LCD Title
Epidural Injections for Pain Management

AMA CPT / ADA CDT / AHA NUBC Copyright Statement
CPT only copyright 2002-2016 American Medical Association. All Rights Reserved. CPT is a registered trademark of the American Medical Association. Applicable FARS/DFARS Apply to Government Use. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein.

The Code on Dental Procedures and Nomenclature (Code) is published in Current Dental Terminology (CDT). Copyright © American Dental Association. All rights reserved. CDT and CDT-2016 are trademarks of the American Dental Association.

UB-04 Manual. OFFICIAL UB-04 DATA SPECIFICATIONS MANUAL, 2014, is copyrighted by American Hospital Association ("AHA"), Chicago, Illinois. No portion of OFFICIAL UB-04 MANUAL may be reproduced, sorted in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, recording or otherwise, without prior express, written consent of AHA.” Health Forum reserves the right to change the copyright notice from time to time upon written notice to Company.

CMS National Coverage Policy This LCD supplements but does not replace, modify or supersede existing Medicare applicable National Coverage Determinations (NCDs) or payment policy rules and regulations for epidural injections. Federal statute and subsequent Medicare regulations regarding provision and payment for medical services are lengthy. They are not repeated in this LCD. Neither Medicare payment policy rules nor this LCD replace, modify or supersede applicable state statutes regarding medical practice or other health practice professions acts, definitions and/or scopes of practice. All providers who report services for Medicare payment must fully understand and follow all existing laws, regulations and rules for Medicare payment for epidural injections and must properly submit only valid claims for them. Please review and understand them and apply the medical necessity provisions in the policy within the context of the manual rules. Relevant CMS manual instructions and policies may be found in the following Internet-Only Manuals (IOMs) published on the CMS Web site:

- CMS Internet-Only Manual (IOM), Publication 100-02, Medicare Benefit Policy Manual, Chapter 15, Section 50-50.6, addresses coverage of drugs and biologicals.
- CMS IOM, Publication 100-03, Medicare National Coverage Determinations (NCD) Manual, Chapter 1, Section 30.3, defines acupuncture as a non-covered service, Section 220.1 provides coverage for computerized tomography, including reasonable and necessary guidelines and criteria for approved Computed Tomography (CT) equipment.
- CMS IOM, Publication 100-04, Medicare Claims Processing Manual,
  - Chapter 12, Section 70
  - Chapter 13, Section 10, 20, and 30 provide payment guidelines for radiology services
- CMS IOM, Publication 100-08, Medicare Program Integrity Manual, Chapter 13, Section 13.5.1 provide guidelines for reasonable and necessary services.

Social Security Act (Title XVIII) standard References, Sections:

Printed on 9/23/2016. Page 2 of 14
Coverage Guidance

Coverage Indications, Limitations, and/or Medical Necessity

Notice: It is not appropriate to bill Medicare for services that are not covered (as described by this entire LCD) as if they are covered. When billing for non-covered services, use the appropriate modifier.

Compliance with the provisions in this policy may be monitored and addressed through post payment data analysis and subsequent medical review audits.

History/Background and/or General Information

The epidural space lies outside the dural membrane but inside the spinal canal. It runs the length of the spine and, in addition to traversing nerves, contains fatty tissue and blood vessels. The spinal nerve roots can be affected by a number of processes as they travel through the epidural space, including but not limited to compression from herniation of the nucleus pulposus of the intervertebral discs, degenerative changes involving combinations of the spinal ligaments, discs, zygapophyseal (facet) joints, intraspinal synovial cysts, osteophytes, and mechanical derangements of the spine such as spondylolisthesis. As a result of mechanical irritation, inflammation, injury to a spinal nerve root or other processes, the spinal nerve roots can become a significant and disabling source of radicular pain.

The procedures typically involve the injection of a solution containing anti-inflammatory agents or corticosteroids and anesthetics into the epidural space, although saline may be included at times. The treatment of individuals with spinal disorders, including pain, can be complex, and it is recommended that all individuals being considered for interventional spinal care undergo a thorough evaluation and be treated following development of a comprehensive care plan.

Pain is subjective and consequently difficult to describe accurately and consistently, therefore the following measures will be used for the purposes of this policy when addressing pain levels or functional capacity. Current tools commonly used to evaluate pain include the Numeric Pain Rating Scale (NPRS) and the Visual Analog Scale (VAS). The following pain level determinations will be used in this policy:

- for the NPRS: a pain rating of <3 represents a pain level of none/minimal while a NPRS pain rating of ≥3 represents a pain level of moderate or severe/significant.
- pain levels for VAS may be described as none/minimal, or moderate, or severe/significant.

A favorable response to treatment using NPRS is a pain level <3. A favorable response using the VAS is obtaining moderate or significant relief.

Sometimes pain levels may be assigned a percentage value or described secondarily as a decreased functional capacity to perform activities of daily living (ADLs). Often a systematic functional screen differentiates normal aging changes from physical diagnoses. For the purposes of this policy, a functional deficit is documented positive findings from a review of key components which may include, but is not limited to, sensory status, mobility/function, or incontinence/elimination issues. These may be recorded using measures such as a Functional Self-Assessment Scale, an Oswestry Disability Index or other similar evaluation tools. Pain relief or pain reduction or a functional ADL performance improvement of ≥50% is considered a favorable response to treatment.

Diagnostic injections are used to evaluate a patient’s potential benefit from an epidural injection (EI) for treatment of radicular pain and may be used in planning and decision making. Transforaminal epidural injections of local anesthetic agent only are used diagnostically and allow relief benefit for the duration of the effect of the agent.
Epidural injections (EIs) have been shown to reduce radicular pain, and their use may have the effect of lowering surgical rates for specific spinal disorders. The effect of these injections on pain is not curative, but palliative and repeat injections may be beneficial in the management of patients who have a favorable response to an initial injection. The data supporting the use of EIs in the treatment of axial low back pain without radicular origin does not strongly support their use in these circumstances and should not be considered part of routine management of radicular pain.

The use of imaging guidance, particularly fluoroscopy or CT, with the use of injectable radio-opaque contrast material has been shown to enhance the accuracy and safety of needle placement for all epidural spinal injection procedures. Sufficient contrast medium should be used to allow for identification of proper injectate flow and to exclude vascular, subarachnoid or subdural flow. There are circumstances, however, where the use of imaging guidance with contrast media is contraindicated.

As with other medical procedures, there are specific risks associated with the performance of EIs, both arising from the procedures themselves as well as the injected agents. These risks include, but are not limited to, the potential for:

- allergic reactions
- intravascular placement with complications that can include neurologic injury
- violation of the dural membrane with the potential for leaks of cerebrospinal fluid (CSF) and further neurological injury from the effects of CSF loss
- infection
- systemic reactions or side effects resulting from the systemic biological effects of corticosteroids

When considering the presence of these risks with the potential for benefit, both patient selection and appropriate image guidance/contrast verification is of paramount importance in order to minimize risks while treating those individuals for whom the injections offer significant benefit. These factors are reflected in the coverage indications that follow.

**Covered Indications**

Epidural Injections are generally performed to treat pain arising from spinal nerve roots. EIs can be performed via an interlaminar or caudal approach or a transforaminal approach.

An epidural injection is considered reasonable and necessary in the following situations:

Each patient must be thoroughly evaluated by a physician or non-physician practitioner whose license and state scope of practice allow evaluation and treatment outlined in this LCD. A central or systemic source of pain or neurologic deficit shall be determined prior to epidural injection. If a central or systemic process is present, but the pain or neurologic deficit is clearly unrelated, injection therapy or EI may still be indicated when at least one of the indications listed below is present.

1. Pain from Herpes Zoster or suspected radicular pain based on radiation of pain along the dermatome of a nerve.
2. Pain from Neurogenic claudication that includes any of the following:
   - Pain severe enough to cause some degree of functional deficit
   - Failure of at least four weeks of noninvasive care*
   - Imaging demonstrating a correlative region of nerve/cord impingement
3. Pain from CervicoThoracic or Lumbar radicular pain with any of the following:
   - Pain severe enough to cause some degree of functional deficit
   - Failure of at least four weeks of non-invasive care*
   - Imaging demonstrating a correlative region of nerve impingement.
4. Back pain without lower extremities symptoms and failure of four weeks of non-surgical, non-injection care* with either:
   - documented VAS for pain or NPRS &gt;8805 3/10 (moderate to severe pain) OR
   - functional impairment in ADLs AND
     the pain or functional impairment is associated with any of the following:
- substantial imaging abnormality, such as a central disc herniation or high intensity zone;
- documented severe degenerative disc disease or central spinal stenosis;
- discogenic pain, after ruling out facet joint and sacroiliac joint pain.

*It is generally accepted that the majority of back radicular pain will improve with conservative treatment over a four week period. All appropriate non-surgical, non-injection treatments which includes appropriate oral medications and physical therapy (to the extent tolerated) should be considered along with a rationale for interventional treatment. Exceptions to the four week non-surgical/non-injection care, beginning at the onset of pain, before receiving an EI should be documented. These may include, but are not limited to one or more of the following:
  - Pain from Herpes Zoster;
  - Severe pain unresponsive to outpatient medical management;
  - Inability to tolerate non-surgical, non-injection care due to co-existing medical conditions(s);
  - At least moderate pain with significant functional loss at work or home;
  - Prior successful lumbar ESI for same specific condition.

**Procedural Requirements**

1. An appropriately comprehensive evaluation of all potential contributing pain generators and treatment in accordance with an established and documented treatment plan.
2. Plain films may be appropriate as a basic requirement to rule out red flag conditions if potential issues of trauma, osteomyelitis or malignancy are a concern.
3. The standard of care for all elective (non-emergent) Epidural injections is for them to be done with image-guidance. Fluoroscopy and CT are the only two validated imaging methods considered reasonable and necessary for EIs.
4. Contrast medium should be injected during epidural injection procedures unless a patient has a contraindication to the injection such as a significant history or a high risk for an adverse event if contrast material is used, e.g. contrast or iodine allergy. In these cases, it is recommended that physicians or non-physician practitioners:
   - consider using a test-dose injection prior to injecting any particulate steroids and/or use only non-particulate solutions, and
   - for cases where it is contraindicated, document in the procedure report the reasons for not using contrast
5. Diagnostic selective nerve root blocks (DSNRB) with anesthetic only, performed in a manner similar to transforaminal EIs, may be considered in order to further evaluate the anatomical level of radicular pain. If a diagnostic transforaminal injection is planned then baseline (pre-injection) identification of the patient’s index pain, intensity of pain (via a visual analog scale or numeric pain rating), neurologic deficits (if they exist) and provocation maneuvers that exacerbate the patient’s index pain should be performed.
6. When a diagnostic epidural injection is performed, post treatment assessment of percentage pain relief, NPRS or functional improvement must be performed and documented in the medical record.
7. According to presently accepted standards of care, for each session, injection totals of no more than 80 mg of triamcinolone, 80 mg of methylprednisolone, 12 mg of betamethasone, 15 mg of dexamethasone or equivalent corticosteroid dosing should be administered. Consideration should be given to particulate free steroids such as dexamethasone as first line steroid for EIs with randomized controlled trial evidence of therapeutic equivalency of dexamethasone to particulate steroid.

**Additional Suggested Procedural Requirements/Considerations**
1. Advanced imaging may be appropriate prior to performing an EI to rule out or establish conditions that would contraindicate or limit effectiveness of injection therapy.

2. Methods to reduce risk of inadvertent vascular injection of particulate steroids with subsequent spinal cord ischemia during performance of transforaminal EIs should be understood and are strongly encouraged. At a minimum, this entails the use of live fluoroscopy with injection of contrast medium to identify any evidence of central vascular uptake. If available, digital subtraction angiography may improve the practitioner’s ability to recognize inadvertent vascular uptake. It is standard of care that active agents (e.g., anesthetic and/or corticosteroid) are not injected when central vascular uptake is involved. Safety is enhanced, at the L3 level and above, when only non-particulate corticosteroids are injected when performing transforaminal injections.

**Limitations**

The following are considered not reasonable and necessary and therefore will be denied:

**Contraindications to Epidural Injection or Diagnostic Selective Nerve Root Block**

1. **Cancer**
   - New onset of (low) back pain with a history of cancer, multiple risk factors for cancer or a strong clinical suspicion for cancer in the absence of advanced imaging studies to rule out local metastasis. If cancer is present, but the pain is clearly unrelated, an epidural may be indicated if one of the “Indications” previously listed is present.
   - Epidural injections may be considered if cancer is ruled-out or if the patient’s pain is felt to be unrelated to the cancer and one of the above criteria for treatment is met.

2. **Infection**:
   - New onset of neck or back pain with fever in the absence of advanced imaging studies (to rule out local infection)
   - Risk factors for spinal infection including fever, history of intravenous drug use
   - History of recent or ongoing bacterial or fungal infection
   - Immunosuppression

3. **Cauda Equina Syndrome**
   - New onset of urinary retention, fecal incontinence or saddle anesthesia
   - Rapidly progressing (or other) neurologic deficits

4. **A medical condition that contraindicates the intervention, (e.g., epidural hematoma, subarachnoid hemorrhage, epidural mass, spinal cord ischemia, trauma).**

5. **A co-existing medical condition or therapy that precludes the safe performance of the procedure (e.g., uncontrolled coagulopathy or active anti-coagulation therapy, sepsis).**

6. **The potential presence of a Central Nervous System process resulting in the presenting symptoms, (e.g., transverse myelitis, central demyelination) suggested by numbness or weakness without paresthesia/dysesthesia or pain.**

7. **Epidural injections, regardless of approach or indication, are subject to the following requirements and limitations:**
- Interlaminar and transforaminal epidural injections using ultrasound guidance are not recommended and are non-covered.
- For a patient with back pain only, the radiologic findings of a simple disc bulge without correlating symptoms is insufficient to justify performance of an epidural diagnostic or therapeutic injection.
- Injections are performed independently based on the patient's symptoms and response to prior injections and approach (if performed). There is no role for a routine “series of 3” or undocumented response “test dosing”. Repeat or serial test or diagnostic injections without documented response are not considered reasonable and necessary. Response to each epidural injection should be determined prior to determining the value of a repeat injection and the specific methods used for subsequent epidurals.
- If a prior epidural injection procedure provided limited or no relief (NPRS<3), a second epidural injection utilizing the same method, technique or medication to the same level will be considered not medically reasonable and necessary. A second injection will be considered following re-evaluation of the patient, if change in techniques or medication is indicated.
- If a patient does not obtain significant relief with a diagnostic selective nerve block (DSNRB), therapeutic injections (EI) in that same area will be considered not medically necessary.
- For caudal or interlaminar injections, only one level may be performed, and NOT in conjunction with transforaminal injection in the same region. Caudal or interlaminar injection is not considered medically reasonable and necessary in conjunction with transforaminal injections at the same session, for the same level, or within three contiguous levels of the same region (lumbosacral or cervicothoracic).
- It should not be necessary to perform both transforaminal epidural and paravertebral facet joint injections at the same spinal level at the same encounter unless a synovial cyst is compressing the nerve root. In this situation, EI may provide relief for the radicular pain while the cyst rupture allows nerve root decompression. It is not expected that additional injection whether EI or Paravertebral Facet Joint at a different level would be performed on the same day. When a facet joint injection and an epidural injection are performed for the purpose of rupturing a cyst, the facet joint injection counts as one of the two injections allowed on the same day.
- If the muscles surrounding the lumbar joint are injected in lieu of the epidural space, an epidural injection should not be reported as this would not support the service. A transforaminal injection without documentation of imaging will be considered not medically reasonable and necessary.
- It is considered not reasonable and necessary to perform more than 2 epidural injections in a single setting (e.g., single level bilaterally or two levels unilaterally).

8. Levels per session:
   - No more than two epidural injections (CPT codes 64479, 64480, 64483, or 64484) may be performed at a single session (i.e., single level bilaterally or two levels unilaterally)
   - One caudal or interlaminar injection (CPT codes 62310, 62311, 62318, or 62319), not in conjunction with a transforaminal injection (CPT codes 64479, 64480, 64483, or 64484) of the same region, may be performed per session.

9. For each session, doses greater than 80 mg of triamcinolone, 80 mg of methylprednisolone, 12 mg of betamethasone, 15 mg of dexamethasone or equivalent corticosteroid are considered standard of care. Administration of dosing greater than these levels is considered not medically reasonable and necessary.

Anesthesia

Standard medical practice utilizes local anesthesia for epidural injection procedures.

Occasionally, minimal to moderate conscious sedation for epidural injections may be appropriate.

Use of General Anesthesia (GA), Moderate Sedation and Monitored Anesthesia Care (MAC) is usually unnecessary or rarely required for these injections. Documentation must clearly establish the need for such sedation in the specific patient. Please refer to LCD L35049, Monitored Anesthesia Care, for information related to MAC.

Provider Qualifications
The CMS Manual System, Publication 100-08, Program Integrity Manual, Chapter 13, Section 13.5.1 states that "reasonable and necessary" services are "ordered and/or furnished by qualified personnel."

Services will be considered medically reasonable and necessary only if performed by appropriately trained providers in the appropriate setting. Procedures listed and included in this LCD do not constitute anesthesia services. Evaluation, methods and techniques specified are not considered routine for surgical or perioperative anesthesia.

Patient safety and quality of care mandate that healthcare professionals who perform epidural injections for management of chronic pain (not surgical anesthesia) are appropriately trained and are competent to perform all aspects of these procedures safely and effectively. The core curriculum of any training program should include the performance and management of the procedures addressed in this policy with documentation of assessment included in the certifying exam and/or case history document. At a minimum, training must cover and develop an understanding of anatomy and drug pharmacodynamics and kinetics, proficiency in diagnosis and management of disease necessitating the procedures, the technical performance of the procedure with utilization of the required associated imaging modalities, as well as the diagnosis and management of potential complications from the intervention. All aspects of care must be within the provider’s medical licensure. If a procedure requires facility credentialing or privilege approval when performed in an inpatient or outpatient hospital setting, the provider must possess those credentials in order to receive reimbursement for that procedure whether performed in a hospital facility or elsewhere. Only those settings with immediate availability of equivalent support services and personnel as those in a hospital will be considered appropriate for places of service for purposes of Medicare reimbursement.

Acceptable training or certification may be evidenced by one of the following means:

1. Satisfactory completion of an Accreditation Council for Graduate Medical Education (ACGME) or American Osteopathic Association (AOA) accredited residency and/or fellowship program in a relevant specialty (e.g., Interventional Pain Management, Anesthesiology)
2. Board certification in relevant specialty by an American Board of Medical Specialties (ABMS) member board or equivalent AOA board.
3. Satisfactory completion of substantially equal training via an accredited non-physician practitioner educational program that renders the trainee eligible to sit for a non-physician practitioner licensing examination that directly assesses trainee competence to perform services included in this policy. The core curriculum of such programs must include the performance and management of the procedures addressed in this policy with documentation of assessment by examination.
4. Satisfactory performance and reporting to Medicare for payment of the specific interventional pain management services in this policy on a regular basis over the five years immediately preceding implementation of this policy. Medicare considers an average of ten services per month to meet this requirement as demonstrated by Medicare claim history.

Reimbursement for procedures utilizing imaging techniques may be made to providers who meet training requirements for the procedures in this policy only if their respective state allows such in their practice act and formally licenses or certifies the practitioner to use and interpret these imaging modalities (ionizing radiation, magnetic resonance imaging, ultrasound and associated contrast material). Medicare will not allow payment for services billed by providers without training and certification (by nationally recognized accrediting agency) documenting training, experience and safety.

For frequency limitations please refer to the Utilization Guidelines section below.

**Notice:** This LCD imposes frequency limitations as well as diagnosis limitations that support diagnosis to procedure code automated denials. However, services performed for any given diagnosis must meet all of the indications and limitations stated in this policy, the general requirements for medical necessity as stated in CMS payment policy manuals, any and all existing CMS national coverage determinations, and all Medicare payment rules. (NOTE: This may need altered if there are no frequency or diagnosis limitations applied.)

As published in CMS IOM 100-08, Chapter 13, Section 13.5.1, in order to be covered under Medicare, a service shall be reasonable and necessary. When appropriate, contractors shall describe the circumstances under which the proposed LCD for the service is considered reasonable and necessary under Section 1862 (a)(1)(A). Contractors shall consider a service to be reasonable and necessary if the contractor determines that the service is:
Safe and effective.
Not experimental or investigational (exception: routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000, that meet the requirements of the Clinical Trials NCD are considered reasonable and necessary).
Appropriate, including the duration and frequency that is considered appropriate for the service, in terms of whether it is:
- Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient’s condition or to improve the function of a malformed body member.
- Furnished in a setting appropriate to the patient’s medical needs and condition.
- Ordered and furnished by qualified personnel.
- One that meets, but does not exceed, the patient's medical needs.
- At least as beneficial as an existing and available medically appropriate alternative.

The redetermination process may be utilized for consideration of services performed outside of the reasonable and necessary requirements in this LCD.

### Proposed/Draft Process Information

#### Synopsis of Changes

**Changes**  
Not Applicable N/A

**Associated Information**

**Proposed/Draft Process Information**

**Documentation Requirements**

1. All documentation must be maintained in the patient’s medical record and made available to the contractor upon request.
2. Every page of the record must be legible and include appropriate patient identification information (e.g., complete name, dates of service(s)). The documentation must include the legible signature of the physician or non-physician practitioner responsible for and providing the care to the patient.
3. The submitted medical record should support the use of the selected ICD-10-CM code(s). The submitted CPT/HCPCS code should describe the service performed.
4. The medical record documentation must support the medical necessity of the services for each date of service billed and the frequency as directed in this policy. The documentation must include the patient’s history (complete pain history and inclusion of failed conservative measures), physical examination and adequate follow-up documentation specific to patient response to the EIs. When the documentation does not meet the criteria for the service rendered, or the documentation does not establish the medical necessity for the services, such services will be denied as not reasonable and necessary under Section 1862(a)(1) of the Social Security Act.
5. The patient’s record should document an appropriate history and physical examination by the anesthesiologist/anesthetist specifying the medical indications requiring his/her presence when applicable. The indications should be recorded by both the anesthesiologist/anesthetist and the provider performing the injection in their respective notes.
6. Films that adequately document final needle position and injectate flow must be retained and made available upon request.
7. For planned diagnostic EIs, baseline (pre-injection) identification of the patient’s index pain, intensity of pain (via VAS or NPSR), any pertinent neurologic deficits, and provocation maneuvers that exacerbate the patient’s index pain should be evaluated and documented. When a diagnostic epidural injection is performed, post treatment assessment of pain relief (e.g., percentage of pain relief, NPRS, or functional improvement) must be performed and documented in the medical record.
8. The medical record must support the necessity of advanced imaging.
9. The pre-procedure evaluation or the reasoning behind the need for an epidural injection must be explicitly documented in the patient’s medical record along with post procedure conclusions.
Pre-Procedure History should include history sufficient to establish indication for the EI and exclude contraindications.

Pre-Procedure Physical Examination should include basic musculoskeletal examination and focused neurological examination sufficient to establish indication for the EI and exclude contraindications.

Pre-Procedure imaging should include documentation of abnormalities in the lumbar region of the spine to establish and support "Covered Indications."

10. Patients receiving or considering an EI should be informed of specific potential complications of the proposed approach. Documentation (e.g., Shared Decision Making/Informed Consent) that patients receiving or considering epidural injections for management of pain have been informed of the options and the risks/benefits of each including, but not limited to medication management, natural history, exercise-based therapy and surgical interventions. However, there is no mandate to use any of the options post-injection.

Utilization Guidelines

In accordance with CMS Ruling 95-1 (V), utilization of these services should be consistent with locally acceptable standards of practice.

For purposes of this policy, a “session” is defined as all EIs, diagnostic selective nerve root blocks (DSNRBs) or spinal injection procedures performed on a single day.

An injection is defined as the placement of a needle into the epidural space (or paravertebral facet joint). Injecting one level bilaterally would be considered two injections. Injecting two levels, each unilaterally would be considered two injections. A maximum of two injections comprises a session, regardless of level, laterality or approach.

A diagnostic selective nerve root block (DSNRB) is identically coded as an Epidural Injection and constitutes one of the two injections allowed in a single session. No more than 3 epidural injection sessions (6 injections, CPT codes 62310, 62311, 62318, 62319, 64479, 64480, 64483, or 64484) may be performed in a 6 month period and no more than 6 epidural sessions (12 injections, including both diagnostic and therapeutic injections) may be performed in all anatomic regions in a 12-month period regardless of the number of levels involved.

Additional procedures will be considered on redetermination (appeal) of those services denied for exceeding the medically reasonable and necessary criteria.

Notice: This LCD imposes utilization guideline limitations. Despite Medicare allowing up to these maximums, each patient’s condition and response to treatment must medically warrant the number of services reported for payment. Medicare requires the medical necessity for each service reported to be clearly demonstrated in the patient’s medical record. Medicare expects that patients will not routinely require the maximum allowable number of services.

Utilization of epidural injections routinely exceeding the expected frequency may be subjected to focused pre-payment or post payment review.

Sources of Information and Basis for Decision

Contractor is not responsible for the continued viability of websites listed.


Original JL ICD-10 LCD L34892 Transforaminal Epidural, Paravertebral Facet and Sacroiliac Joint Injections Novitas Solutions

LCD L35094, Services That Are Not Reasonable and Necessary, for information regarding Category III codes.

LCD L35049, Monitored Anesthesia Care.

Other Contractor’s Policies

LCD L34983 Lumbar Epidural injections, Noridian Healthcare Solutions, October 1, 2015

LCD L34807 Lumbar Epidural Steroid Injections, CGS Administrators, LLC. October 1, 2015
Meeting Date: 09/29/2016

Meeting Type: Open Meeting

Meeting State(s):
- Arkansas
- Colorado
- Delaware
- District of Columbia
- Louisiana
- Maryland
- Mississippi
- New Jersey
- New Mexico
- Oklahoma
- Pennsylvania
- Texas

Meeting Information:
The open meeting is a joint meeting for both JL and JH. The meeting will be held at the Mechanicsburg office. Novitas-Solutions, Inc. 2020 Technology Parkway Mechanicsburg, PA 17050

Comment Period Start Date
09/15/2016

Comment Period End Date
11/03/2016

Released to Final LCD Date
N/A

Reason for Proposed LCD
- Automated Edits to Enforce Reasonable & Necessary Requirements

Proposed Contact
Novitas Solutions Medical Policy Department
Union Trust Building Suite 600
501 Grant Street
Pittsburgh, PA 15219-4407
DraftLCDComments@novitas-solutions.com Back to Top

Coding Information

Bill Type Codes:
Contractors may specify Bill Types to help providers identify those Bill Types typically used to report this service. Absence of a Bill Type does not guarantee that the policy does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the policy should be assumed to apply equally to all claims.

011x Hospital Inpatient (Including Medicare Part A)
012x Hospital Inpatient (Medicare Part B only)
013x Hospital Outpatient
083x Ambulatory Surgery Center
085x Critical Access Hospital

Revenue Codes:
Contractors may specify Revenue Codes to help providers identify those Revenue Codes typically used to report this service. In most instances Revenue Codes are purely advisory. Unless specified in the policy, services reported under other Revenue Codes are equally subject to this coverage determination. Complete absence of all Revenue Codes indicates that coverage is not influenced by Revenue Code and the policy should be assumed to apply equally to all Revenue Codes.

**Note:** The contractor has identified the Bill Type and Revenue Codes applicable for use with the CPT/HCPCS codes included in this LCD. Providers are reminded that not all CPT/HCPCS codes listed can be billed with all Bill Type and/or Revenue Codes listed. CPT/HCPCS codes are required to be billed with specific Bill Type and Revenue Codes. Providers are encouraged to refer to the CMS Internet-Only Manual (IOM) Pub. 100-04, Claims Processing Manual, for further guidance.

<table>
<thead>
<tr>
<th>CPT/HCPCS Codes</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Group 1 Paragraph:</strong> Provide the long descriptors of the CPT codes in their CPT book.</td>
</tr>
</tbody>
</table>

**Group 1 Codes:**
- 62310 Inject spine cerv/thoracic
- 62311 Inject spine lumbar/sacral
- 62318 Inject spine w/cath cerv/thoracic
- 62319 Inject spine w/cath lumbar/sacral
- 64479 Inj foramen epidural c/t
- 64480 Inj foramen epidural add-on
- 64483 Inj foramen epidural l/s
- 64484 Inj foramen epidural add-on

**ICD-10 Codes that Support Medical Necessity**

**Group 1 Paragraph:** It is the provider’s responsibility to select codes carried out to the highest level of specificity and selected from the ICD-10-CM code book appropriate to the year in which the service is rendered for the claim(s) submitted.

Medicare is establishing the following limited coverage for CPT/HCPCS codes: 62310, 62311, 62318, 62319, 64479, 64480, 64483, 64484.

**Group 1 Codes:**

<table>
<thead>
<tr>
<th>ICD-10 Codes</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>B02.23</td>
<td>Postherpetic polyneuropathy</td>
</tr>
<tr>
<td>B02.7</td>
<td>Disseminated zoster</td>
</tr>
<tr>
<td>B02.8</td>
<td>Zoster with other complications</td>
</tr>
<tr>
<td>B02.9</td>
<td>Zoster without complications</td>
</tr>
<tr>
<td>G54.4</td>
<td>Lumbosacral root disorders, not elsewhere classified</td>
</tr>
<tr>
<td>G89.18</td>
<td>Other acute postprocedural pain</td>
</tr>
<tr>
<td>G96.12*</td>
<td>Meningeal adhesions (cerebral) (spinal)</td>
</tr>
<tr>
<td>G96.19*</td>
<td>Other disorders of meninges, not elsewhere classified</td>
</tr>
<tr>
<td>G97.1</td>
<td>Other reaction to spinal and lumbar puncture</td>
</tr>
<tr>
<td>M43.12</td>
<td>Spondylolisthesis, cervical region</td>
</tr>
<tr>
<td>M43.13</td>
<td>Spondylolisthesis, cervicothoracic region</td>
</tr>
<tr>
<td>M43.14</td>
<td>Spondylolisthesis, thoracic region</td>
</tr>
<tr>
<td>M43.15</td>
<td>Spondylolisthesis, thoracolumbar region</td>
</tr>
<tr>
<td>M43.16</td>
<td>Spondylolisthesis, lumbar region</td>
</tr>
<tr>
<td>M47.22</td>
<td>Other spondylosis with radiculopathy, cervical region</td>
</tr>
</tbody>
</table>

Printed on 9/23/2016. Page 12 of 14
<table>
<thead>
<tr>
<th>ICD-10 Codes</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>M47.23</td>
<td>Other spondylosis with radiculopathy, cervicothoracic region</td>
</tr>
<tr>
<td>M47.24</td>
<td>Other spondylosis with radiculopathy, thoracic region</td>
</tr>
<tr>
<td>M47.25</td>
<td>Other spondylosis with radiculopathy, thoracolumbar region</td>
</tr>
<tr>
<td>M47.26</td>
<td>Other spondylosis with radiculopathy, lumbar region</td>
</tr>
<tr>
<td>M47.27</td>
<td>Other spondylosis with radiculopathy, lumbosacral region</td>
</tr>
<tr>
<td>M47.812</td>
<td>Spondylosis without myelopathy or radiculopathy, cervical region</td>
</tr>
<tr>
<td>M47.813</td>
<td>Spondylosis without myelopathy or radiculopathy, cervicothoracic region</td>
</tr>
<tr>
<td>M47.814</td>
<td>Spondylosis without myelopathy or radiculopathy, thoracic region</td>
</tr>
<tr>
<td>M47.815</td>
<td>Spondylosis without myelopathy or radiculopathy, thoracolumbar region</td>
</tr>
<tr>
<td>M47.816</td>
<td>Spondylosis without myelopathy or radiculopathy, lumbar region</td>
</tr>
<tr>
<td>M47.817</td>
<td>Spondylosis without myelopathy or radiculopathy, lumbosacral region</td>
</tr>
<tr>
<td>M48.02</td>
<td>Spinal stenosis, cervical region</td>
</tr>
<tr>
<td>M48.03</td>
<td>Spinal stenosis, cervicothoracic region</td>
</tr>
<tr>
<td>M48.04</td>
<td>Spinal stenosis, thoracic region</td>
</tr>
<tr>
<td>M48.05</td>
<td>Spinal stenosis, thoracolumbar region</td>
</tr>
<tr>
<td>M48.06</td>
<td>Spinal stenosis, lumbar region</td>
</tr>
<tr>
<td>M48.07</td>
<td>Spinal stenosis, lumbosacral region</td>
</tr>
<tr>
<td>M50.121</td>
<td>Cervical disc disorder at C4-C5 level with radiculopathy</td>
</tr>
<tr>
<td>M50.122</td>
<td>Cervical disc disorder at C5-C6 level with radiculopathy</td>
</tr>
<tr>
<td>M50.123</td>
<td>Cervical disc disorder at C6-C7 level with radiculopathy</td>
</tr>
<tr>
<td>M50.13</td>
<td>Cervical disc disorder with radiculopathy, cervicothoracic region</td>
</tr>
<tr>
<td>M51.14</td>
<td>Intervertebral disc disorders with radiculopathy, thoracic region</td>
</tr>
<tr>
<td>M51.15</td>
<td>Intervertebral disc disorders with radiculopathy, thoracolumbar region</td>
</tr>
<tr>
<td>M51.16</td>
<td>Intervertebral disc disorders with radiculopathy, lumbar region</td>
</tr>
<tr>
<td>M51.17</td>
<td>Intervertebral disc disorders with radiculopathy, lumbosacral region</td>
</tr>
<tr>
<td>M51.24</td>
<td>Other intervertebral disc displacement, thoracic region</td>
</tr>
<tr>
<td>M51.25</td>
<td>Other intervertebral disc displacement, thoracolumbar region</td>
</tr>
<tr>
<td>M51.26</td>
<td>Other intervertebral disc displacement, lumbar region</td>
</tr>
<tr>
<td>M51.27</td>
<td>Other intervertebral disc displacement, lumbosacral region</td>
</tr>
<tr>
<td>M51.34</td>
<td>Other intervertebral disc degeneration, thoracic region</td>
</tr>
<tr>
<td>M51.35</td>
<td>Other intervertebral disc degeneration, thoracolumbar region</td>
</tr>
<tr>
<td>M51.36</td>
<td>Other intervertebral disc degeneration, lumbar region</td>
</tr>
<tr>
<td>M51.37</td>
<td>Other intervertebral disc degeneration, lumbosacral region</td>
</tr>
<tr>
<td>M54.12</td>
<td>Radiculopathy, cervical region</td>
</tr>
<tr>
<td>M54.13</td>
<td>Radiculopathy, cervicothoracic region</td>
</tr>
<tr>
<td>M54.14</td>
<td>Radiculopathy, thoracic region</td>
</tr>
<tr>
<td>M54.15</td>
<td>Radiculopathy, thoracolumbar region</td>
</tr>
<tr>
<td>M54.16</td>
<td>Radiculopathy, lumbar region</td>
</tr>
<tr>
<td>M54.17</td>
<td>Radiculopathy, lumbosacral region</td>
</tr>
<tr>
<td>M54.18</td>
<td>Radiculopathy, sacral and sacrococcygeal region</td>
</tr>
<tr>
<td>M54.31</td>
<td>Sciatica, right side</td>
</tr>
<tr>
<td>M54.32</td>
<td>Sciatica, left side</td>
</tr>
<tr>
<td>M96.1</td>
<td>Postlaminectomy syndrome, not elsewhere classified</td>
</tr>
<tr>
<td>M99.21</td>
<td>Subluxation stenosis of neural canal of cervical region</td>
</tr>
<tr>
<td>M99.22</td>
<td>Subluxation stenosis of neural canal of thoracic region</td>
</tr>
<tr>
<td>M99.23</td>
<td>Subluxation stenosis of neural canal of lumbar region</td>
</tr>
<tr>
<td>M99.31</td>
<td>Osseous stenosis of neural canal of cervical region</td>
</tr>
<tr>
<td>M99.32</td>
<td>Osseous stenosis of neural canal of thoracic region</td>
</tr>
<tr>
<td>M99.33</td>
<td>Osseous stenosis of neural canal of lumbar region</td>
</tr>
<tr>
<td>M99.41</td>
<td>Connective tissue stenosis of neural canal of cervical region</td>
</tr>
<tr>
<td>M99.42</td>
<td>Connective tissue stenosis of neural canal of thoracic region</td>
</tr>
<tr>
<td>M99.43</td>
<td>Connective tissue stenosis of neural canal of lumbar region</td>
</tr>
<tr>
<td>M99.51</td>
<td>Intervertebral disc stenosis of neural canal of cervical region</td>
</tr>
<tr>
<td>M99.52</td>
<td>Intervertebral disc stenosis of neural canal of thoracic region</td>
</tr>
<tr>
<td>M99.53</td>
<td>Intervertebral disc stenosis of neural canal of lumbar region</td>
</tr>
<tr>
<td>M99.61</td>
<td>Osseous and subluxation stenosis of intervertebral foramina of cervical region</td>
</tr>
<tr>
<td>M99.62</td>
<td>Osseous and subluxation stenosis of intervertebral foramina of thoracic region</td>
</tr>
<tr>
<td>M99.63</td>
<td>Osseous and subluxation stenosis of intervertebral foramina of lumbar region</td>
</tr>
</tbody>
</table>
ICD-10 Codes Description
M99.71 Connective tissue and disc stenosis of intervertebral foramina of cervical region
M99.72 Connective tissue and disc stenosis of intervertebral foramina of thoracic region
M99.73 Connective tissue and disc stenosis of intervertebral foramina of lumbar region

Group 1 Medical Necessity ICD-10 Codes Asterisk Explanation: Note: ICD-10 codes G96.12 and G96.19 are to be used to describe lumbar epidural fibrosis, not otherwise described by ICD-10 codes.

ICD-10 Codes that DO NOT Support Medical Necessity

Group 1 Paragraph: All those not listed under the “ICD-10 Codes that Support Medical Necessity” section of this policy.

Group 1 Codes: N/A

ICD-10 Additional Information

N/A

Associated Documents

Attachments N/A

Related Local Coverage Documents LCD(s) L35049 - Monitored Anesthesia Care L35094 - Services That Are Not Reasonable and Necessary

Related National Coverage Documents N/A

Keywords

N/A

Printed on 9/23/2016. Page 14 of 14