Article - Response to Comments: Epidural Steroid Procedures Injections for Pain Management (A58899)

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Article Guidance

Article Text

This article is the response to comments received by CGS Administrators, First Coast Service Options, National Government Services (NGS), Novitas Solutions, Palmetto GBA, and Wisconsin Physician Services (WPS) regarding the proposed Epidural Procedures for Pain Management which was posted for comment on June 24, 2021 through August 24, 2021 and presented at the July 13, 2021 Open Meeting for CGS Administrators. All comments were reviewed, and the responses are provided in this document. Comments on the same topic are grouped.

Response to Comments

NUMBER	COMMENT	RESPONSE
1	Medtronic submitted a comment for the B&C article requesting an exception be added for CPT code 62323 when used to report the trial phase for an implantable infusion pump for the treatment of severe spasticity, which falls under NCD on infusion pumps.	Thank you for the comment. Services payable under a *Medicare National Coverage Determination (NCD)* would not be subject to denial by local coverage determinations. In the trial for the implantable pump, it would be an exception for this LCD. Clarification has been added to the billing and coding (B&C) article that indicates services reported using CPT code 62323 for an implantable infusion pump for treatment of severe spasticity would not fall under restrictions of this LCD/article and would be subject to any restrictions outlined by reasonable and necessary requirements for infusion pump trial by the individual MAC and in NCD 280.14 Infusion Pumps.
2	A multi-society letter was sent from the Spine Intervention Society and signed by: American Academy of Pain Medicine, American Academy of Physical Medicine and Rehabilitation, American Society of Anesthesiologists, American Society of Regional Anesthesia and Pain Medicine, North American Neuromodulation Society, North American Spine Society, Pain Society of the Carolinas, Society of Interventional Radiology, and Tennessee Pain Society. Comments 2-18 were from this group. The first comment in this letter was: Physical exam findings are not adequate for establishing a diagnosis of lumbar radiculopathy and should not be required. The straight leg raise is the most sensitive for radiculopathy of the physical exam tests used, with a sensitivity of 64% (56-71%) and specificity of 57% (47-66%). Three references were cited.	Thank you for supporting references. We acknowledge that a physical exam alone is often insufficient for the diagnosis of lumbar radiculopathy. The LCD criteria required a correlation of history, physical exam, and radiological images. While sensitivity may be low, as reported in Hooten 2015 and Vroomen 1999 submitted, specificity is often high and can be a valuable tool for differential diagnosis. In the submitted Cochrane review, Van Der Windt et al. (2010) state that certain physical exam findings may help predict better outcomes for surgery and procedures. Therefore, the physical exam requirement will remain and is expected to be performed and documented as part of the evaluation and diagnosis. However, we understand there are times there will be an absence of a physical exam. When physical exam findings are absent, this should be documented, and the correlation of the history, exam and radiological images should support one of the covered diagnoses. Therefore, the absence of physical findings will not result in a patient not

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		meeting eligibility if the diagnosis is supported by the remaining requirements and the exam does not suggest an alternative etiology.
3	Radiculopathy should be replaced with radicular pain. These terms are often used interchangeably; however, these procedures have proven successful in treating radicular pain, not radiculopathy. This was also addressed in a letter from the American Society of Regional Anesthesia and Pain Medicine (ASRA): Under Covered Indication #1 (Requirement 1), the draft specifies that epidural steroid injections (ESIs) may be considered medically necessary with a diagnosis of radiculopathy. Radiculopathy implies neurologic symptoms and signs that are not present in many patients who benefit from epidural steroid injections (ESIs). We recommend that the draft LCD terminology be updated to reference "radicular pain" rather than "radiculopathy" to ensure that patients without neurologic symptoms and signs but who otherwise qualify could have access to medically necessary and appropriate ESI.	Thank you for the comment. The term radiculopathy is used throughout the literature on epidural injections. We agree there are times radicular pain may be appropriate. The term radiculopathy will be used in the LCD when that is the term used in reference to the supporting literature. Outside of references, this change has been made throughout the finalized LCD.
4	Suggest omitting "central" disc herniation. Radicular pain due to disc herniation, whether central and paracentral, is an appropriate indication for an epidural steroid injection (ESI). This was also requested in comments submitted by the Florida Society of Interventional Pain Physicians (FSIPP). This letter expressed concerns about the LCD and its potential impacts on the Medicare population. The letter did not include supporting literature or references.	Thank you for the comment. The term "central" was removed in the finalized LCD.
5	Suggest adding spondylolisthesis as a diagnosis for which ESI is indicated. This was also included in the FSIPP comments. A CAC member from JL stated the following: In many patients, especially with spondylolisthesis, an increasingly common problem in the population of aging Medicare beneficiaries, there is both foraminal stenosis and lateral recess stenosis such that often 3 or 4 nerves are involved in pain production or	Thank you for the comment. Supporting literature for the addition of this diagnosis was not provided. We will consider this addition with the submission of supportive literature as part of the LCD Reconsideration Process to request a revision once the LCD becomes effective.

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	producing weakness. Weakness, especially in the L5 nerve root distribution is a very common cause of tripping and falls and ignoring the risks of non-treatment is a poor decision strategy.	
6	The requirement of 4 weeks pain duration is confusing as written, and it is unrealistic to expect a patient with acute radicular pain from a disc herniation to delay an ESI. These are the patients most likely to benefit from the procedure. If patients cannot return to work or perform normal activities of daily living (ADLs), the procedure may be considered before the 4-week interval, and documentation should indicate this. One reference was cited (Kennedy 2014), and suggested wording was provided. This was also included in the ASRA's letter: Under Covered Indication #1 (Requirement 3), the draft specifies that ESIs may be considered medically necessary when there is pain duration of at least four weeks, and there is either inability to tolerate non-invasive conservative care, or there is medical documentation of failure to respond to 4 weeks of non-invasive conservative care. ASRA recommends that an exception to the 4-week duration be included for patients with severe pain when patients are unable to return to work or perform normal activities of daily living. See Kennedy et al. (2014). The FSIPP states in their letter, "Requiring a four-week wait in a patient with the diagnoses mentioned above, with or without a neurological deficit can lead to permanent neurological injury and or neural scaring." Comments were received in a joint letter from the FSIPP, the American Society of Interventional Pain Physicians (ASIPP), and the Society of Interventional Pain Management Surgery Centers (SIPMS), requesting a revision from four weeks to after 1-2 weeks of non-invasive conservative care. The comment was also received from the Mayo Clinic.	Thank you for the comment. Multiple studies and guidelines establish that most patients with acute back pain improve spontaneously within four weeks (Qaseem, 2017). It is not clear how the reference provided supports the requested change. The study population had a mean duration of pain of 10.1 and 8.6 weeks in the two study groups. The outcomes based on the duration of pain were not discussed in the paper. There is not sufficient evidence to provide support for the requested change. In regards to the claim that a four-week wait can lead to permanent neurological injury or scarring, there was no literature provided to support this claim, nor any literature to suggest ESIs, which are typically used for pain management, would be the appropriate treatment for patients at risk for neurological injury. If compression is so severe the patient is at risk for permanent neurological injury, referral for surgical evaluation would be expected.

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7	The requirement to use contrast (Covered Indication #2): We fully support this requirement, except for patients who have a documented contrast allergy or are pregnant. Suggested wording provided. Also, suggest rewording for limitation (#1). The ASRA also shared this comment: Under Covered Indication #2, the draft specifies that ESIs must be performed under CT or fluoroscopy image guidance with contrast. ASRA recommends that this language be updated to read, "ESIs must be performed under CT or fluoroscopy image guidance with contrast, except in patients with documented contrast allergy." In addition, we recommend that ultrasound guidance should also be considered in exceptional circumstances, for example, with positioning challenges, pregnancy, or remote settings, given its demonstrated feasibility. Evansa et al. (2015) was cited. The FSIPP, ASIPP, and SIPMS comment contrast injection requirement may be reworded with "except for patients who have a documented contrast allergy or are pregnant." A provider also submitted a comment to allow ESI without contrast in patient intolerance, typically with underlying renal impairment.	Thank you for the comment. We agree there are unique circumstances and appreciate the Evansa et al. reference. Allowance for exceptions for cases where contrast is contraindicated has been added to the finalized LCD.
8	Repeat injections (Covered Indication #6): If the patient's pain returns before three months after an initial injection, it is reasonable to attempt to reinstate relief with a repeat injection. If a 3-month threshold is required after initial injection, a significant number of patients, who would otherwise obtain relief from a second injection, will proceed to surgery. A reference was made to Mattie et al. (2020), which is referenced in the proposed LCD, and suggested wording was provided. The ASRA also submitted this comment: Under Covered Indication #6, the draft specifies that repeat ESI under certain cases may be considered medically reasonable and necessary when the medical record documents at least 50% of sustained improvement in	Thank you for the comment. The supporting reference, Mattie et al. 2020, was the Spine Intervention Society's Patient Safety Committee statement of Frequency of Epidural Steroid Injections. This statement addresses the lack of evidence for a standard interval between injections. The statement does refer to a paper by El-Yahchouchi et al. with support of a two-week assessment being superior to immediate assessment to predict long-term outcomes from a single ESI. It also references a study by Murthy et al. stating that repeat injection between two weeks and one-year results in a statistically and clinically significant decrease in pain. Clinical scenarios where the benefit does not last a full three months but a second injection sooner could

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	pain relief and/or improvement in function for at least three months. ASRA recommends that if a patient fails to respond to a single ESI, one additional injection prior to three months should be allowed, with the rationale documented in the medical record. Repetitive failed ESIs beyond two is not necessary. Absent an allowance for a second ESI within three months from a first, a significant number of patients who would otherwise obtain relief from a second injection will proceed to surgery. See Mattie et al. (2020). The FSIPP, ASIPP, and SIPMS also expressed concern stating the three-month wait was not standard of care or supported by guidelines. They suggest that repeating the procedure no sooner than two weeks is the current standard of care. In addition to the multi-society comments, individual providers also submitted similar comments. One commenter asked if this time duration was correct. Another commenter pointed out that some patients received relief for one to two months, did not have other options, such as surgical options, and had to cope with pain while waiting for their next injection. They thought maybe this could improve eligibility for spinal cord stimulation. Supporting literature was not provided with these comments. A letter from the Mayo Clinic also expresses similar concerns and elaborate stating that patients who fail to respond to an initial epidural steroid injection may benefit from an epidural delivered via a different approach (interlaminar vs transforaminal vs caudal), or if pain relief was less than 3 months, but meaningful, a 2nd injection combined with appropriate rehabilitation strategies may allow patients to recover without the cost and risk of surgical intervention. They provided recommended wording.	provide relief and potentially reduce the need for surgical management were presented. We agree with the commenters that if a patient's pain is not relieved or partially relieved with the initial injection, the requirement of a three-month wait between injections may reduce a patient's treatment options. The ability to administer a second injection after a failed ESI was also recommended by our subject matter experts at the CAC meeting stating repeat ESI can be performed after 14 days, using a different approach and/or medication if medically necessary. Repeating the injection if the patient does not have at least 50% improvement using the same scale, and the provider feels that they missed the pain generator, the second injection should be at a different location or use a different approach and/or medication and the rationale for this documented in the medical record. We hold that a three months wait is appropriate for chronic use and necessary to access response and to determine if a repeat injection is indicated. However, we agree there are circumstance that a repeat injection in less than three months may be appropriate after the initial injection and LCD has been modified.
9	ESI injectant (Covered Indication #7): If the injections do not include steroids, they are not epidural "steroid" injections (ESIs), so suggest replacing "ESI injectant" with "epidural injectate." The current wording is confusing and stipulates that anti-inflammatories are required, and contrast is not. Also, it should be clear that contrast is injected first to	Thank you for the comment. Clarification has been made in the finalized LCD under coverage criteria #7. We agree that the injectant will not always contain steroids as the initial injection should confirm placement with contrast. The subsequent epidural steroid injection would be expected to include corticosteroids and may be

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	confirm epidural placement. The subsequent therapeutic injection includes corticosteroids, local anesthetics, etc. In keeping with the very appropriate requirement to use contrast for most patients (Covered Indication #2). Suggested wording was provided. The ASRA comments: Under Covered Indications #7, the draft specifies that ESI injectants must include corticosteroids, anesthetics, anti-inflammatories, and/or contrast agents. If the injections do not contain steroids, they are not epidural "steroid" injections (ESIs), so we suggest replacing "ESI injectant" with "epidural injectate." Additionally, we note that ESIs may include a local anesthetic and/or saline. As such, ASRA recommends that Covered Indication #7 be updated to reflect that epidural injectate may also include local anesthetics and/or saline. Mayo Clinic Comments: This is a very succinct sentence that, when taken verbatim, states that epidurals must include all of the following (steroids, anesthetics, and anti-inflammatories), OR an epidural injection could simply contain a contrast agent. Since there are other portions of the LCD that state the necessity of performing epidural injections procedures under image guidance with contrast injection, the commentary regarding contrast can be removed from this sentence. Additionally, corticosteroids may simply be administered with sterile saline, and this should be reflected as well. It is not clear what is meant by "anti-inflammatories" above and beyond corticosteroids. They also comment that epidural injection of substances such as stem cells and platelet-rich plasma (PRP) is investigational. We understand that coverage for these substances with present data may not be considered medically appropriate. However, corticosteroids, the essential ingredient to an epidural steroid injection, are also not FDA approved for epidural administration. While this is the standard of care and certainly is the expectation of these coverage guidelines, the sentence above is problematic as investigational and recommended wording on the biologicals. They add other adjuncts, and Steroids and LA/Saline may be reasonable in unique clinical circumstances with appropriate documentation.	combined with local anesthetics or saline. While there is published literature that there may be benefits from the injection of saline alone, there is a lack of long-term efficacy data to support this. There are times when an epidural injection may include anesthetic only, typically referred to as a selective spinal nerve block. These are usually reserved for surgical management planning and are addressed in Comment #11. The lack of FDA approval for corticosteroids for use in epidural is addressed in the LCD and is an off-label use. However, no other pharmacological agents have this level of evidence for off-label use and therefore are not included in the policy. However, given the robust body of literature to support this practice which has become standard of care and set standards for doses, frequency, and the technique is established in the literature meet the requirement for reasonable and necessary ESIs are acceptable to be used for the purpose as outlined in the LCD. Biologicals, including stem cells, platelet-rich plasma, and vitamins, are considered investigational and not reasonable and necessary. Amniotic fluid injection are not permitted per FDA. The addition of these products to the injectant can result in denial of the entire claim.

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	FSIPP, ASIPP, and SIPMS comments under covered indications #7 describe ESIs injectants must include corticosteroids, anesthetics, anti-inflammatories, and/or contrast agents. Please reword this as Epidural injectates must include either corticosteroids, anesthetics, anti-inflammatories, contrast agents, or a combination thereof. This will avoid confusion about that corticosteroids are mandated. They also comment: The policy calls for epidural steroid injections; however, if epidurals do not include steroids, they are not epidural steroid injections, and the language may be changed to an epidural procedure or epidural injection.	
10	Requirement of other conservative treatment (Covered Indication #8): While some patients will certainly benefit from multimodal treatment, others who experience relief from an ESI may not require additional conservative treatment. We suggest rewording to indicate that ESIs may be performed in conjunction with conservative treatments. The FSIPP also commented: This is not always possible, particularly in the cognitively impaired population. ESI's are conservative treatments when spinal surgery is the next best option. The surgical literature is replete with discussions of ESI's being part of conservative care. The FSIPP, ASIPP, and SIPMS comment that while some patients benefit from multimodal treatments, others who experience relief from epidural injections may not require additional conservative management, except for a structured exercise program.	Thank you for the comment. To qualify for ESI, patients must have failed conservative treatment or documented inability to tolerate conservative care. As defined in the LCD, conservative treatment may include physical therapy, spinal manipulation therapy, and cognitive-behavioral therapy (CBT). It may also encompass a home exercise program and medications (for example, non-steroidal anti-inflammatories [NSAIDs], analgesics, etc.). It is expected that aspects of conservative therapy determined to be most beneficial for the patient would be continued in conjunction with ESIs as part of the treatment program. The patient and provider can determine the choice of conservative treatments and documented in the medical record. The LCD provides a definition section to ensure clarity throughout the document. In the LCD, conservative therapy is clearly defined and does not include interventional procedures.
11	Diagnostic spinal nerve blocks: We suggest the following be included under indications: Diagnostic spinal nerve blocks are performed by injecting local anesthetic onto a single spinal nerve to help confirm or rule out the source of the patient's pain, often to assist in surgical planning. These blocks utilize the same CPT codes as transforaminal ESIs (64479-64484). They should be allowed in patients that may have failed a therapeutic ESI when the medical necessity is documented in the medical	Thank you for the comment. There was no supporting literature to support this comment. The Billing and Coding article provides instructions for use of a KX modifier to distinguish selective nerve root blocks from therapeutic ESIs.

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	records.	
12	Limit to 4 ESIs per 12 months (Limitation #6): Suggest considering allowance of 3 ESIs per 6 months and 6 ESIs per 12 months, regardless of the number of levels involved. A CAC member from Jurisdiction JL comments: The proposed limitation to 4 epidural injections per year anywhere in the body is not evidenced-based.	Thank you for the comment. Supporting evidence of an increased number of ESIs in a rolling 12 months was not provided. We disagree with the comment that there is no evidence to support this limitation. In the existing literature, repeat injections were necessary for a minority of patients, about 20% with less than 5% receiving more than three injections. This is also consistent with national data. If supporting literature demonstrates efficacy, safety, and medical necessity for increased frequency of injections, the LCD Reconsideration Process may be followed to request a revision to the LCD once the LCD becomes effective.
13	Series of ESIs (Limitation #11): While we do not support a "series of 3", we do support repeat injections if previous injections were successful in achieving pain relief and functional improvement or only one prior injection was unsuccessful. Suggested wording was provided.	Thank you for suggested wording to make this clearer. The finalized LCD wording has been modified.
14	Steroid dose (Limitation #12): The dosages recommended are inaccurate. Data from studies looking at dosages implemented in transforaminal injections have been inappropriately extrapolated here to interlaminar injections. Suggested wording was provided. The FSIPP comments: It is a nice goal to only use the lowest dose every time but, it is not always practical. Only one citation recommended this. This should be a recommendation not a requirement. A provider shared concern for steroid limits stating that when limitation of 80mg was implemented many of his patients did not achieve same pain relief as prior treatments with higher steroid doses and questioned rationale for decision as he did not think there was a defined consensus on the dosing limits. Another provider also objected, stating dosing limits were too low.	Thank you for the comment. We agree there is little literature to support this limitation, and the expectation is for the use of the lowest possible steroid dose. Changes have been made in the finalized LCD.

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	The ACIPP, SIPMS and FSIPP joint letter also recommended changing this. Mayo Clinic comments: We would point out that the manufacture for methylprednisolone has a black box warning on epidural steroid injection and we would recommend not suggesting the use of that medication for epidural administration. Betamethasone 6-9 mg or dexamethasone 10 mg may be a more appropriate corticosteroids for epidural administration due to their solubility (particularly over that of triamcinolone).	
15	Treatment exceeding 12 months (Limitation #13): This limitation is unreasonable, and the requirements add a significant documentation burden to explain that a patient does not wish to proceed to surgery. We suggest omitting. Requiring the pain physician to communicate with the primary care provider to discuss whether the patient is eligible for prolonged repeat steroid use places undue burden on physicians and should not be required. The FSIPP in response to limitation #13 state: Citations are related to low back pain and radiculopathy-not spinal stenosis and neurogenic claudication. The natural history of nonspecific LBP is to improve with time. The other conditions listed in this LCD worsen with time in most cases. Treating spinal stenosis patients with worsening symptoms over time should NOT trigger a focused review as it is the natural disease process. The FSIPP, ASIPP and SIPMS state this limitation is unreasonable and the requirements add significant documentation burden, and also affects the access. The LCD already has sufficient guardrails in place to prevent overuse or abuse of the procedure while outlining appropriate use and thus we request that this limitation #13, that limits epidurals to 12 months be removed. As long as a physician documents medical necessity as described in the LCD with appropriate improvement, that should suffice. A provider commented that in his practice, he limits ESIs to three (occasionally four) times a year. He stated limiting to one year would be a mistake and	Thank you for the comment. Most of the literature does not demonstrate efficacy of ESIs use beyond 12 months, including the various conditions addressed throughout the LCD. Supporting literature for these recommendations was not provided. Patients must meet the improvement criteria outlined in the LCD and if the condition worsens, as may be the case with spinal stenosis, given the natural disease course, a patient may no longer qualify for ESI and alternative managements must be considered. We understand there are circumstances in which the patient does not desire surgery and are benefiting from the treatments and continued ESI may be indicated. To ensure the patients primary care physicians are aware of the prolonged steroid use and treatments being received, we feel it is reasonable practice to notify the primary care provider of treatment plan and steroid dosing being administered which can have an impact on other health conditions under their care. This limitation does not require permission from the primary care provider to continue treatments but rather a notification of continued use, so they are fully informed of the treatment plan and potential side effects. Continued use beyond 12 months also requires that all four of the criteria outlined in Limitation #13 are met to be considered medically reasonable and necessary. Language in finalized LCD was modified to provide clarification.

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	increase narcotic usage and surgery. Another provider stated that the requirement for approval from a primary care provider when injections are performed for more than 12 months will result in delays in treatment.	
16	While we appreciate that all healthcare professionals have a very important role to play in team-based care within our medical system, training provided to non-physicians does not provide requisite background and experience in accurately selecting patients; safely performing technically demanding procedures; and immediately recognizing, evaluating, and addressing potentially serious, life-altering complications. Suggested language was provided. The ASRA comments: ASRA is concerned that these training and certification requirements (as outlined in LCD) are not sufficient to ensure that professionals are qualified to make determinations about the appropriateness of care; safely performing ESI; or addressing potential serious complications. ASRA recommends that the Provider Qualifications section be updated to require successful completion by an Accreditation Council for Graduate Medical Education (ACGME) accredited post-graduate program with an emphasis on pain management. A JL Jurisdiction CAC member also comments: Performance of epidural injection procedures should be restricted to licensed physicians and surgeons as there are no completely adequate training programs for mid-level providers that provide substantially equivalent training and duration of supervised practice to those existing for M.D.'s or D.O.'s.	Thank you for the comment. The scope of practice for non-physician providers are established by State laws and are not within the scope of this policy. However, we understand that ESIs carry risk and appropriate training is necessary. To ensure the safety of the Medicare beneficiaries, we require all providers meet the provider qualifications as outlined in the LCD.
17	It should be noted that the North American Spine Society revised their coverage policy recommendations in 2020 and these should be reviewed and replace the 2013 and 2011 references.	Thank you for bringing this to our attention. This has been reviewed and the finalized LCD and references updated accordingly.
18	Please correct typos on listed society names.	Thank you for bringing this to our attention. Corrections have been made in the finalized LCD.

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19	Comment from provider: It seems you have changed the previous guidelines relating to ESIs for back pain. These can be extremely useful for patients with degenerative disc disease and axial back pain that does not respond to medial branch blocks. To not allow ESI for these patients will not only increase the number of unnecessary spinal fusions, it will substantially increase cost of medical care. The commentor highly recommends reconsideration of this LCD. There was no supporting literature with this comment.	Thank you for the comment. Severe degenerative disc disease is in the 'Covered Indications' section, bullet #1. The 'Limitations' section, bullet #5 indicates that ESIs to treat non-specific low back pain (LBP), axial spine pain, complex regional pain syndrome, widespread diffuse pain, pain from neuropathy from other causes, or cervicogenic headaches are considered investigational and therefore are not considered medically reasonable and necessary. Axial and nonspecific pain without radiating pain are listed under contraindications in the NASS 2020 ESI Guidelines. If supporting literature to support the requested indication of axial spine pain that does not respond to medial branch blocks is developed, the LCD Reconsideration Process may be followed to request a revision to the LCD once the LCD becomes effective.
20	The ASRA commented regarding Herpes Zoster and Postherpetic Neuralgiae (PHN). The ASRA notes that the results of high-quality studies on the efficacy of ESI in preventing postherpetic neuralgia (PHN) are not uniform: One study found less pain and allodynia at 1 year, with an average of 2.4 ESIs. Another study found no difference at 3 and 6 months, with one ESI. However, in view of the difficulty of treating PHN, coupled with side effects of the drugs usually employed, ESIs are recommended in preventing and treating PHN. Per the study of Pasqualucci et al, at least 2 - 3 ESIs should be performed.	Thank you for the comment. There is not enough evidence on the role of ESI in the management of herpes zoster and the dosing, duration, and frequency of such therapy to make specific recommendations. Due to the lack of effective alternative treatment options, ESI is allowed for acute herpes zoster refractory to conservative management. Exception of the four-week wait is allowed due to evidence to support earlier administration may result in better and longer lasting pain relief than the group where the initial injection was delayed >30 days. Once the initial ESI is given, any repeat injections must meet the criteria for repeat injections as outlined in the LCD.
21	A provider commented: As an anesthesia provider they objected to Limitation #4 *Use of General Anesthesia, Moderate Sedation and Monitored Anesthesia Care (MAC) is usually unnecessary or rarely indicated for these procedures and therefore, is not considered medically reasonable and necessary*. They did not feel this limitation was fair, stated patients have different pain tolerance and are concerned the limitation may increase narcotic use. Multiple additional comments from anesthesia providers (CRNAs and RN) were received. Several shared concerns about movement increasing the risk	Thank you for the comment. To add clarity, definitions per the American Society of Anesthesiologists Continuum of the Depth of Sedation guidelines have been added to the LCD. The limitation outlined in the LCD is for General Anesthesia, Moderate and Deep Sedation and Monitored Anesthesia Care (MAC) and does not apply to minimal sedation anxiolysis as defined in these guidelines. The term Deep sedation was added to the limitation to ensure the language aligns with the definitions provided. Based on these definitions, there is no definition of "twilight" sedation in the LCD and conscious

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	of the procedure. Another commented that patients should have the choice if they are sedated or not. Another stated sedation is essential to achieve best results and commented on additional challenges with staffing due to nursing shortages. Another shared their unpublished experience with over 20,000 cases of anesthesia stating that not a single incidence of nerve damage challenges the accuracy of the published guidelines. None of the comments included published literature or societal guidance to support their opinions. One provider requested clarification of the documentation requirements for exceptional cases. From the same group, one patient comments with concerns about limiting her access to care and anesthesia that is essential for her care. A provider comments: Some patients require sedation because they will vagal otherwise, which can lead to the cancellation of the injection. A bilateral RFTC can take up to 20 minutes and be painful, twilight sedation in this case is reasonable. People can trigger a seizure during anxiety/pain during an injection without sedation. This would lead to the case being cancelled. Having to do a ton of documentation for something as simple as a little versed or fentanyl is inefficient and impractical.	sedation will be considered moderate sedation in the policy. Supporting literature for the medical necessity of these levels of anesthetic was not provided. Major risk of epidural anesthetics includes direct nerve trauma or spinal cord injury. To reduce the risk of direct nerve trauma or spinal cord injury, current guidelines (referenced in LCD) recommend avoidance of deeper levels of sedation so the patient can alert the provider to any paresthesia during the procedure. The evidence of safety of ESIs without anesthesia is robust including the obstetrical population. To reconsider this position, evidence to document the safety and medical necessity of deep levels of anesthetic for ESIs will need to be submitted through the LCD Reconsideration Process to request a revision to the LCD once the LCD becomes effective. There is not a set criterion established in the literature or through societal guidelines to determine patient's that may require General Anesthesia, Moderate or Deep Sedation and Monitored Anesthesia Care (MAC). A provider cannot predict certain adverse reactions such as a vagal reaction which can be related to almost any procedure including routine blood draw or shots which would not necessitate anesthesia. It would be unlikely for a patient without an underlying seizure disorder to have a seizure induced by anxiety/pain. There is no supporting data that movement increases risk for ESIs and even sedated patients are at risk for movement. The policy does not limit access to care in patients who meet the evidence-based criteria for ESIs and the level of anesthesia discussed are not a requirement to perform the procedures safely. Based on the published societal guidance, the use of anesthetic may increase the risk associated with the procedures in addition to subjecting the patient to the inherent risk of anesthesia.
22	A comment on use of ESIs for palliative measures for cancer patients such as spinal metastasis with epidural extension was submitted with a case series.	Thank you for submitting Rispoli (2019), a case series with 13 patients with metastatic disease who achieve palliative benefit from ESIs. In this report one patient achieved pain relief from ESI,

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		while the others had a variety of different pain management interventions. The 2020 NASS Guidelines include cancer or suspected cancer as a contraindication to ESI.
23	The FSIPP requests that neurogenic claudication be added after radicular pain for Covered Indication #1 for second bullet. Pain from Neurogenic Claudication is not radicular as can cover multiple dermatomes.	Thank you for the comment. This change has been made in the finalized LCD.
24	The FSIPP asks for clarification on the pain/disability scales requirements. Are we measuring pain, function or both? The wording is not clear. When is baseline determined? At initial office visit? Immediately before the injection? Please clarify.	Thank you for the comment. The provider can determine what acceptable scale for pain or function or both they wish to use. At baseline, a standardized pain or functional scale must be used to measure pain prior to intervention. This can be done at the initial office visit or immediately before the injection. Clarifications in wording have been made in the finalized LCD.
25	The FSIPP commented: The majority of the citations in the bibliography of this proposed LCD use 30% as a marker of pain relief, some as low as 20%. The 50% threshold is not the standard of research or the standard of care in the community. There are many other pain generators that can contribute to a patient's pain complex and ability to function (facet, discogenic, pain from other structures) that can severely complicate a patient's subjective response to an intervention. Patients have difficulty differentiating these overlapping sources of pain. The 50% threshold is too high. 30% is the standard in the pain literature.	Thank you for the comment. Supporting literature using the lower pain scales mentioned in the comments was not submitted. In the extensive literature review conducted for the LCD which included >175 references, the vast majority, including meta-analysis and systematic reviews, used the 50% threshold.
26	The FSIPP asked for clarification regarding Covered Indication bullet #7 regarding what is in the ESI injectant. They state: What anti-inflammatories are you recommending? Later in the LCD it states that no anti-inflammatories are approved by the FDA and therefore not approved.	Thank you for the comment. Anti-inflammatory was removed from the finalized LCD as there are no anti-inflammatories approved for use in the spine or with sufficient evidence to support use.
27	The FSIPP comments regarding Coverage Indication #9: Active rehabilitation programs are not always possible in the Medicare population. Most of the cited studies that discuss rehabilitation and functional restoration are done on a younger population for disc pain and LBP in general. In the population in question	Active rehabilitation programs, home exercise programs or functional restoration programs are established components of care for chronic back pain and included in published guidelines. Literature to exclude the Medicare population was not provided. The heterogenicity among the

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	this is not always possible, and the patients should not be required to participate in this if not medically indicated.	studies regarding age is one of the challenges within the epidural literature, therefore studies focusing on the Medicare age group were prioritized in the LCD development. Due to the special needs and increased risk of this population including fall risk strategies to provide rehabilitation and full function, in addition to pain management, are almost always medically indicated. In extenuating circumstances when the patient is unable to participate in an active rehabilitation program, home exercise program or functional restoration program, these circumstances should be documented in the medical record.
28	A CAC member from Jurisdiction JL comments: The proposed restriction to 1 level bilaterally or 2 levels unilaterally is anatomically unreasonable. I have performed contrast injections into the posterior epidural space using an interlaminar technique with expectedly inferior clinical outcomes in these cases and the injectate never reaches the anterolateral epidural space where the nerves are anatomically impinged. Foraminal stenosis cannot be adequately addressed with interlaminar injections. I recommend reinstitution of the two-level bilateral transforaminal restriction that is more appropriate for clinical care of Medicare beneficiaries.	Thank you for your comment, however this comment was not accompanied by supporting literature. The 2020 NASS guidelines for ESI, one of the only published guidelines regarding levels, states no more than 2 TFESIs should be performed at a single setting (e.g., single level bilaterally or two levels) and for caudal or ILESIs, only one level per session may be performed per session.
29	Comments were received in a joint letter from the from the Florida Society of Interventional Pain Physicians, the American Society of Interventional Pain Physicians (ASIPP), and the Society of Interventional Pain Management Surgery Centers (SIPMS), which are addressed in comments #29-35 and throughout the comments above. They recommend addition of percutaneous adhesiolysis within the policy.	Thank you for the comment. We determined not to include percutaneous adhesiolysis in the epidural injection policy for pain management policy. ESIs are performed to treat an inflamed nerve root, while adhesiolyis is an attempt to break up adhesions. While percutaneous adhesiolysis uses a similar procedure as epidurals, it is not an injection and does not share literature with ESIs but rather has a different body of literature, therefore we felt it was not within the scope of this policy. The determination for coverage of percutaneous adhesiolysis will remain under the discretion of individual MACs.
30	Please revise the coverage indications with the replacement of radiculopathy with radicular pain and limiting these indications for transforaminal epidural injections with addition of disc herniation to present	Thank you for the comment. Please see Comment #3. Severe degenerative disc disease, spinal stenosis, and post-surgical syndrome are included as covered indications in the policy. Discogenic

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	indications. In addition, the covered indications must include degenerative disc disease, spinal stenosis, post-surgery syndrome, and discogenic pain without evidence of facet joint or sacroiliac joint pain as they have been covered in the previous LCDs with an abundance of evidence. References were cited with this comment.	pain is non-specific and the more specific code indicating the qualifying etiology should be used. Non-specific back pain is not considered medically reasonable and necessary as outlined in the LCD. Discogenic pain was added to the 'Definitions' section in the finalized LCD.
31	Please revise procedural limitations and outcomes assessment in reference to the duration of relief, with expansion, similar to the previous LCD, with 2 procedures in the diagnostic or initial phase with 4 and 6 weeks apart after first and second procedures per spinal region, followed by 4 epidural injections per spinal region in a rolling year, initiated with a third procedure. If the patients' condition includes an acute lumbar herniated nucleus pulposus, then the patient should wait no longer than 2 weeks for the first epidural steroid injection and no longer than 2 weeks for a second and or third epidural steroid injection, if indicated. Additionally, to provide a second epidural after 3 months of sustained 50% pain relief is not supported by the literature. An overwhelming evidence in the literature shows the first procedure providing 5.69 ± 8.23 in 1,510 patients assessed and the second procedure providing 10.02 ± 12.57 weeks assessed in 1,402 patients (references cited). In addition, multiple other studies, including the study by Friedly et al., also shows 6 weeks of relief rather than 3 months of relief.	Thank you for the comment. Please see Comments #8 and #12. We did divide into diagnostic and therapeutic phases because it is expected to have a diagnosis based on history, physical exam and imaging prior to performance of ESI for treatment (therapeutic).
32	Regarding Limitation #9, the commenters request this limitation be revised to caudal epidural injections and interlaminar epidural injections involving a maximum of one level per region are considered medically reasonable and necessary. Request coverage for multiple procedures in separate regions in the same session when reasonable and necessary (Limitation #3). The policy states multiple treatments cannot be performed. We can understand that in a single region there may not be multiple procedures; however, when these are performed in different regions there is no basis for this. In general, literature shows that 60% of the patients with spinal pain have more than one region involved. Consequently, this will significantly restrict the access. It also causes patient inconvenience, provider increased workload and costs.	Thank you for the comments. Two separate issues were brought up in these comments: 1. Multiple procedures in same session: While we understand a single patient may have multiple pain sources, if multiple blocks of different types are given in the same session it is not possible to determine which treatment has proven effective for pain relief. The policy requires at least a 50% improvement in pain and/or function from the ESI. If other procedures are performed simultaneously that cannot be adequately accessed. The exception is for a facet synovial cyst and ESI performed in the same session. There is no supporting literature for the safety of performing

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		multiple procedures within the same session. There is not literature on the impact of the additional the steroids used in the session. 2. While degenerative disease will likely impact more than one region, it is clinically unlikely to have two separate regions with radiculopathy at the same time. It is common to have this in non-specific or widespread pain conditions. Therefore, the policy remains as one region per session.
33	We request that approved codes should be revised with addition of degenerative disc disease codes and disc herniation codes as follows: Further, approved codes do not include degenerative disc disease and disc herniation. Consequently, please add the following: M50.21 Other cervical disc displacement, high cervical region M50.221 Other cervical disc displacement at C4-C5 level M50.222 Other cervical disc displacement at C5-C6 level M50.223 Other cervical disc displacement at C6-C7 level M50.23 Other cervical disc displacement, cervicothoracic region M50.31 Other cervical disc degeneration, high cervical region M50.321 Other cervical disc degeneration at C4-C5 level M50.322 Other cervical disc degeneration at C5-C6 level M50.323 Other cervical disc degeneration at C6-C7	Thank you for the comment. The policy allows coverage for lumbar, cervical or thoracic radicular pain and/or neurogenic claudication due to disc herniation. While disc degeneration is a coverable condition, we require the use of the more specific codes that specify the presence of radiculopathy which is a requirement for coverage.

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	level M50.33 Other cervical disc degeneration, cervicothoracic region M51.24 Other intervertebral disc displacement, thoracic region M51.25 Other intervertebral disc displacement, thoracolumbar region M51.34 Other thoracic disc degeneration, thoracic region M51.35 Other thoracic disc degeneration, thoracolumbar region M51.26 Other intervertebral disc displacement, lumbar region M51.27 Other intervertebral disc displacement, lumbosacral region M51.36 Other intervertebral disc degeneration, lumbar region M51.37 Other intervertebral disc degeneration, lumbosacral region	
34	Request coverage be added for axial spine pain without facet joint or sacroiliac joint pain, complex regional pain syndrome, neuropathy from other causes, and cervicogenic headaches. States these are responsive to epidural injections. These are performed in a minority of cases. There is no reason to restrict patient access in these areas.	As outlined in the LCD there is not sufficient evidence to support coverage of these diagnoses. If new evidence provides additional support, submission of supportive literature may be submitted as part of the LCD Reconsideration Process to request a revision to the LCD once the LCD becomes effective.
35	There are a multitude of errors in the references. Even though summary is extensive, it does not include appropriate references.	Thank you for the comment. References have been verified in the finalized LCD. While additional literature was reviewed it was not cited in bibliography unless it was specifically referenced in the document.

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36	A CAC member comments: In many patients, especially with spondylolisthesis, 3 or 4 nerves are involved in pain production or producing weakness and may cause tripping and falls. He cautions this is a risk of non-treatment.	Thank you for the comment. Spondylolisthesis is not considered a medically reasonable and necessary indication for ESI as outlined in policy. See Comment #5. For multiple levels, see Comment #28.
37	The same CAC member comments and expresses concern that not allowing multiple procedures within same visit increases the risk to medically fragile patients due to unstable diabetes or those on anticoagulants by potential hyperglycemic episodes due to steroid and the known inherent thromboembolic hazards of interruption of anticoagulants must be encountered more frequently. As well, the separation of injections produces longer periods of potential adrenal and immune suppression by extending the effective period of steroid action by weeks or months. He also comments that for patients on hemodialysis and with cardiovascular disease the policy prolongs patients' pain and agony from non-treatment by LCD policy.	Thank you for the comment. Supporting literature for safety of multiple injections or risk of harm as described above was not submitted with comments. As discussed in Comment #32, the goal is accurate diagnosis and limiting procedures to those that are medically reasonable and necessary and effective which requires the ability to access response to treatment. The commenter does not mention the risk of multiple procedures, repetitive procedures, and spinal injections inherent risk.
38	A letter from the Mayo Clinic commented the wording for the second requirement "to cause a significant degree of functional disability or vocational disability" was confusing and offered alternative wording.	Thank you for your comment and suggested wording. The LCD has been revised to clarify this requirement.

Associated Documents

Related Local Coverage Documents

LCDs

L39015 - Epidural Steroid Injections for Pain Management

Related National Coverage Documents

N/A

Public Versions

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