

Comments and Responses Regarding Draft Local Coverage Determination: Pain Management

As an important part of Medicare Local Coverage Determination (LCD) development, National Government Services solicits comments from the provider community and from members of the public who may be affected by or interested in our LCDs. The purpose of the advice and comment process is to gain the expertise and experience of those commenting.

We would like to thank those who suggested changes to the draft Pain Management LCD. The official notice period for the final LCD begins on November 17, 2008. The policy will become effective on January 1, 2009. Several comments were received. We will present comments specific for individual portions of the draft policy followed by those related to the policy as a whole.

ABSTRACT

Comment: We believe that the reference to *Practice Guidelines for Chronic Pain Management: A Report by the American Society of Anesthesiologists (ASA) Task Force on Pain Management*, should be removed. Also, the reference for Practice Guidelines for Chronic Pain Management in the text may also be eliminated, as this is an extremely old reference.

Response: We agree that these references were published slightly more than a decade ago. However, we do not find them to be outmoded, particularly the definition for chronic pain. Therefore, the American Society of Anesthesiology practice guideline references will remain.

TRIGGER POINT INJECTIONS

Comment: The sentence in "Limitations," "Trigger point injections used on a routine basis for patients with chronic non-malignant pain syndromes are not considered medically necessary" was considered confusing by one commenter. One asked that the sentence be deleted and that six injections per year be allowed. Another commenter stated patients with chronic myofascial pain, rheumatoid arthritis and osteoarthritis may require frequent trigger point injections to treat their pain.

Response: The statement will be clarified to read, "Trigger point injections used on a routine basis, e.g., on a regular periodic and continuous basis, for patients with chronic non-malignant pain syndromes are not considered medically necessary."

The draft LCD "Utilization Guidelines" read as follows and will remain.

Repeat **trigger point injections** may be necessary when there is evidence of persistent pain. Generally more than three injections of the same trigger point are not indicated. Evidence of partial improvements to the range of motion in any muscle area after an injection, but with persistent significant pain, would justify a repeat injection. The medical record must clearly reflect the medical necessity for repeated injections.

Six injections per year are not precluded when medically necessary. Similarly, patients with recurrent trigger points may need repeat injections. However, the efficacy of the injections and consideration of alternate therapy should be considered for those patients requiring multiple injections.

Comment: It was stated that no specific medication has been proven to be better than any other and therefore, local anesthetics, saline, steroids, and/or Sarapin should be allowed.

Response: The draft LCD currently states, "Only injections of local anesthetics and corticosteroids are covered. Injections consisting of only saline and/or botanical substances are not supported in the peer-reviewed literature and are not considered medically necessary." In the absence of convincing literature, the statement will remain.

INJECTION OF TENDON SHEATH, LIGAMENT, GANGLION CYST, CARPAL AND TARSAL TUNNEL

Comment: Addition of ICD-9-CM code 720.1 (Spinal enthesopathy) to the "ICD-9 Codes that Support Medical Necessity" was recommended.

Response: The ICD-9-CM manual lists "Disorder of peripheral ligamentous or muscular attachments of spine" as further description of ICD-9-CM code 720.1. Injuries to interspinous ligaments requiring injections would be appropriately coded with this diagnosis. Thus, ICD-9-CM code 720.1 will be added.

EPIDURAL AND INTRATHECAL INJECTIONS: INTERLAMINAR AND CAUDAL AND TREATMENT OF SPASTICITY

Comment: The first sentence, "Epidural and intrathecal (subarachnoid and subdural) injections are utilized for acute and chronic pain, cancer pain management, and treatment of spasticity" should be corrected by deleting "subdural." The parentheses should read, "(epidural and subarachnoid)."

Response: We agree.

Comment: It was requested that we change the sentence in the first paragraph of "Indications" to, "For diagnostic purposes, a transforaminal epidural injection is performed with meticulous technique and low volume of injected local anesthetic."

Response: We accept this editorial change.

Comment: It was suggested that we remove the reference to differential blockade since it is no longer or rarely used.

Response: We will remove the reference to differential blockade.

Comment: Therapeutic indications should include “surgery” as a mechanism for epidural scarring.

Response: We agree and will make the addition.

Comment: It was recommended that post-herpetic neuralgia be added as a condition for which continuous infusions or frequent injections may be allowed.

Response: Post-herpetic neuralgia and herpes zoster are currently listed as indications for “therapeutic intrathecal (subarachnoid) injections and infusions of opioid, local anesthetic, clonidine, and other medications may be used for the treatment of acute or chronic pain,” In addition, ICD-9-CM codes for these conditions are listed under “ICD-9 Codes that Support Medical Necessity.”

EPIDURAL INJECTIONS – TRANSFORAMINAL

Comment: Removal of “acute post-operative or post-traumatic pain” as an indication was requested, because the commenter considered it not to be an appropriate indication. There was no request to remove post-decompressive radiculitis as an indication.

Response: Post-decompressive radiculitis is the “acute post-operative pain” indication responsible for the listing of the latter. We will remove the “acute post-operative or post-traumatic pain” indication but retain post-decompressive radiculitis as a therapeutic indication.

We will also require imaging (fluoroscopy or computed tomography) for all transforaminal epidural injections.

Comment: One commenter requested we not make a distinction between diagnostic and therapeutic transforaminal injections. In addition, for therapeutic reasons, he felt it was beneficial to use 3 cc to force the steroid along a good length of the nerve root, regardless of whether there is spillage onto another nerve.

Response: We find the first request counter to evidence-based guidelines and advice from other interventional pain management specialists. In regards to the second, the draft LCD already states, “Injections for therapeutic reasons can be of greater volume.”

PARAVERTEBRAL JOINT/NERVE BLOCKS – DIAGNOSTIC AND THERAPEUTIC and PARAVERTEBRAL JOINT/NERVE DENERVATION

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Comment: The percentages in which spinal facet joints have been implicated have remained at 15% to 45% of patients with low back pain, but changed to 36% to 67% of patients with neck pain and 34% to 48% of patients with thoracic pain. (Boswell MV, Trescott AM, Datta S, Schultz DM et al. Interventional techniques: evidence-based practice guidelines in the management of chronic spinal pain. *Pain Physician*. 2007;10:7-111.)

Response: We will update the percentages.

Comment: It was recommended that the reference for percentages of false-positive results with a single diagnostic facet joint/nerves be updated to those in Sehgal et al.'s 2007 article¹

Response: The reference will be updated and a typographical correction made for the thoracic spine false-positive rates.

Comment: Change of "double blind comparative blocks" to "double diagnostic blocks" was requested "to allow some freedom for the clinician to use various local anesthetics." Three exceptions were also requested: those traveling a long distance, those elderly people who may have difficulty obtaining rides and those individuals on anticoagulation. It was felt these three groups of patients in some situations would benefit from a single diagnostic block and could then proceed more rapidly to radiofrequency denervation.

Response: The draft LCD requires "double-comparative local anesthetic blockade of a joint." The anesthetic agents are required to have different durations of action, but the specific agents are not named. The significant percentage of false-positive results for a single injection reported in the literature is the basis for requiring double-comparative local anesthetic blockade. The requirement will remain in the final policy.

Comment: A verbal comment was received supporting the double-comparative block requirement but suggesting that a "two to four point improvement in pain is often considered a statistically significant improvement." He also favored only requiring a 50% improvement in pain.

Response: We appreciate the support of double-comparative blocks. The commenter was invited to submit literature to support the standard of 50% rather than 80-90% initial pain relief. No literature was received.

Comment: Addition of "adjacent to the" in the sentence, "After a needle is placed into the facet joint or adjacent to the target medial branch nerve under imaging guidance,...." was requested.

Response: We appreciate and accept the suggestion.

Comment: "Thoracic pain greater than chest wall pain" was requested as an additional appropriate condition for diagnostic paravertebral facet joint/nerve blocks.

Response: The indication is valid and will be added.

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Comment: We were asked to remove the sentence that states facet blocks cannot be performed in the presence of neurologic deficits. It was noted there are patients who have a failed back syndrome who have chronic root irritation and/or injury with long term chronic neurologic changes that will never improve, but might have improvement in their back pain from treatment of their facet syndrome.

Response: We were unable to find the prohibition in the draft LCD.

Comment: A change in the definition of “significant pain relief” for facet blocks was requested to read as follows.

80% of the pain that is deemed facet related or 50% of the overall pain in that region (neck/back) or alternatively we would agree with the language: A diagnostic facet block must achieve dramatic relief in order to proceed to therapeutic facet blocks and/or radiofrequency denervation treatments. In addition strike the sentence that requires six weeks of at least 50% pain relief in order to proceed to facet denervation. There is no evidence in the literature to support that statement (6 weeks).

One commenter wrote that requiring initial pain relief of 80% to 90% in order to justify continued treatment was an unrealistically high target. He supported pain relief in the order of 50% as appropriate for many patients to obtain an increase in lifestyle and activity level.

A third commenter suggested the presence of “joint tenderness may lead to the first facet joint injection, which is usually therapeutic.” He felt the double blind diagnostic blocks without steroids were an unnecessary waste of time for the patient. Two references were sent^{2,3}. The first proposed support of response rate of 50% to one diagnostic block prior to denervation. The second supported the use of paraspinal tenderness as a predictor of successful cervical facet radiofrequency denervation.

Response: Based on extensive literature, 80% (or higher) relief with controlled comparative local anesthetic blocks with anesthetics of different durations of action has been utilized as the standard to increase appropriateness of interventions. Some reports describe three comparative blocks with a placebo serving as the third injection. Lowering the requirement for immediate pain relief to 50% would potentially increase the number of false-positive responses to injections and thus lower the success rate for those patients progressing to radiofrequency neurotomy. In addition, the literature does not currently support using clinical examination alone to diagnosis facet joint pain. The requirement will not be changed.

The draft policy states, “Facet joint denervation may be considered if double-comparative paravertebral facet joint/nerve blocks do provide significant pain relief, but the pain relief is **not** long-lasting.” We will clarify the policy not to require six weeks pain relief prior to denervation, but continue to require an 80-90% positive response to double-comparative blocks as well as the ability to perform previously painful maneuvers.

Comment: One physician stated, “It was common to use 2 cc into a lumbar joint, not the 0.3 – 0.5 cc recommended for the ‘diagnostic phase.’”

Response: The finalized policy states, “After a needle is placed into the facet joint or adjacent to the target medial branch nerve under imaging guidance, a small volume (0.5 to 1.0 ml) of a short or long-acting local anesthetic agent with or without steroid is injected.” The commenter did not provide literature to support the appropriateness if a larger injected volume for diagnostic injections. Therefore, there will be no change.

Comment: The inclusion of ICD-9-CM codes 716.98, 721.1, 721.41, 721.42 and 733.82 as “ICD-9 Codes that Support Medical Necessity” was questioned.

Response: ICD-9-CM code 716.98 (Unspecified arthropathy involving other specified sites) is included as the appropriate code for face arthropathy. The spondylosis ICD-9-CM codes without myelopathy (721.0, 721.2, and 721.3) are included as appropriate diagnoses. The 721.1 (Cervical spondylosis with myelopathy), 721.41 (Spondylosis with myelopathy thoracic region), and 721.42 (Spondylosis with myelopathy lumbar region) have also been included. Nonunion of fracture (733.82) is included for patients with pseudoarthrosis.

Comment: It was stated that the LCD should address the “multitude of issues raised by the OIG” within its report.

Response: The Department of Health and Human Services, Office of Inspector General (OIG)’s “Medicare Payments for Facet Joint Injection Services” published in September 2008 was thoroughly reviewed. The OIG made the following recommendations to the Centers for Medicare and Medicaid Services (CMS).

- Strengthen Program Safeguards to Prevent Improper Payment for Facet Joint Injection Services
 - Assist carriers in developing ways to scrutinize claims for facet joint injection services provided in an office setting
 - Encourage carriers that require radiographic imaging guidance in their LCDs to implement automated edits for imaging guidance
 - Direct carriers to revisit frequency limits in their LCDs for facet joint injections
- Clarify Billing Instructions for Bilateral Services
- Take Appropriate Action Regarding the Undocumented, Medically Unnecessary, and Miscalculated Services Identified in Our Sample

In concert with CMS, the contractor will work to implement these recommendations.

SACROILIAC (SI) JOINT INJECTIONS

Comment: It was felt that the draft LCD needed clarification that diagnostic blocks can be performed with or without steroid. In addition, further language was felt necessary to distinguish between diagnostic and therapeutic blocks and their specific indications.

Response: The policy as written does not preclude the administration of steroids at the time of diagnostic blocks. “Steroids may be injected in addition to the local anesthetic” was added to the paragraph addressing

diagnostic blocks. We have rearranged the information under “Indications for Sacroiliac (SI) Joint Injections” to clarify the distinction between diagnostic and therapeutic blocks.

Comment: One commenter disagreed with requiring double comparative blocks and stated it was common to inject 5 – 8 cc with a total of 3 – 5 cc into the joint. He also requested omission of the statement, “Only sacroiliac joints for which there has been a positive response (to diagnostic block) should be injected for therapeutic reasons.”

Response: As stated elsewhere in this document, the double comparative blocks are required to decrease the incidence of false-positive responses. The policy currently states 2 – 3 cc may be injected for diagnostic studies. No literature was provided to support the use of a larger injectate for diagnostic blocks. The policy was not changed.

Comment: It was suggested that correct coding for sacroiliac joint denervation be included.

Response: We will add information to the Supplemental Instruction Article (SIA) that states CPT code 64999 (Unlisted procedure, nervous system) should be used for sacroiliac joint denervation.

ACUTE POST-OPERATIVE PAIN MANAGEMENT

Comment: Patients with major abdominal or thoracic surgery procedures often need more than three (3) days of epidural analgesia. It was recommended a time limit not be included in the document.

Response: The draft LCD states, “Catheters are usually left in place for three (3) days or less as the patients have usually recovered sufficiently to allow for removal.” We will add, “Patients with major abdominal or thoracic procedures may require a longer period.”

Comment: Allowance of chronic pain specialist assistance with the post-operative pain management of continuous intravenous morphine was requested.

Response: Routine management of patient-controlled analgesia (PCA) is not reimbursable to another physician or provider, and may not be billed as an anesthesia or evaluation and management (E&M) service. The PCA prescription and management are part of the surgeon’s post-operative management and included in the global surgery fee. Only non-routine management requiring skill beyond that of the operating surgeon should require consultation or assistance from another physician.

LIMITATIONS FOR ALL DIAGNOSTIC AND THERAPEUTIC PAIN MANAGEMENT SERVICES

Comment: One commenter agreed with our policy statements regarding performing multiple interventional pain procedures on the same day. However, he also suggested that physicians should not bill for procedures

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that resulted in no pain relief, if a procedure of another type was then subsequently performed on the same day.

Response: We have not altered the language in our policy regarding performing multiple interventional pain procedures on the same day.

Comment: The draft LCD states, "Epidural steroids should be used only in the presence of radiculopathy." We were asked to include "discogenic pain with or without radiculopathy." Another physician also asked that spinal stenosis and degenerative disc disease also be added as diagnoses.

Response: The statement will be revised to read, "Epidural steroids should only be used in the presence of radiculopathy unless the pain is discogenic in origin."

Comment: We were requested to mandate radiologic guidance for all interventional pain procedures involving the spine. It was also suggested that we note computerized tomography (CT) usage should be rare and the indications for its use rather than fluoroscopy should be noted in the record.

Response: As noted above, we will require radiologic guidance for all transforaminal epidural injections. We will retain the requirement for imaging for all listed interventions except interlaminar or caudal epidural injections. Subsequent interlaminar or caudal epidural injections after a failed or inadequate response to a blind procedure, if performed, should be under fluoroscopic visualization.

We will also add a requirement that the rationale for medically necessary use of CT rather than fluoroscopy must be documented in the record.

Comment: It was suggested, "if ever" be removed from the statement, "General anesthesia or monitored anesthesia are (MAC) is rarely, if ever required for injections address in this policy."

Response: "If ever" will be removed, but the remainder of the statement will remain.

Comment: A physician's ability to report moderate (conscious) sedation was not addressed in the policy.

Response: Physicians may report moderate (conscious) sedation when it is medically necessary. It should be noted that moderate (conscious) sedation may increase the false positive response to injections.

Comment: Epidurography is only reasonable and medically necessary when performed either with a caudal or interlaminar approach. An epidurogram should not be performed with a transforaminal approach.

Response: We will add this restriction.

Comment: The CMS and/or the contractor should consider credentialing physicians who perform interventional pain procedures.

Response: The following language in the draft LCD will be retained.

Services will be considered medically reasonable and necessary only if performed by appropriately trained providers. Training and expertise must have been acquired within the framework of an accredited residency and/or fellowship program in the applicable specialty/subspecialty. If this skill has been acquired as continuing medical education, the courses must be comprehensive, offered, sponsored or endorsed by an academic institution in the United States and/or by the applicable specialty/subspecialty society in the United States, and designated by the American Medical Association (AMA) as Category 1 Credit. Documentation of training must be available upon request.

Non-physician practitioners (NPs) may only perform procedures requiring radiologic imaging if their respective states allow such in their practice act and license the practitioner to use radiation.

DOCUMENTATION REQUIREMENTS

Comment: Clarification of the following sentence was requested.

Subjective and objective responses from the patient regarding pain, including provocative maneuvers documented by pre- and post-procedure measurement four (4) to eight (8) hours after the procedure.

Response: Assessment of the patient's pain level and ability to perform previously painful maneuvers after receiving an injection is required at time intervals appropriate to the duration of action of the substances injected. We will clarify the statement.

Comment: For paravertebral joint/nerve blocks, the volume for therapeutic injections may be larger but not exceed 2 ml.

Response: We will add, "For therapeutic injections, the volume may be larger but should not exceed 2 ml.

Comment: The draft LCD states, "It is expected that only a few patients will present with pain in both anatomical regions (cervicothoracic and lumbosacral). Therefore, the routine performance of facet joint/nerve blocks (both diagnostic and therapeutic) to both regions may prompt medical review." Two commenters felt this was not accurate and one noted 60% of patients may have involvement of multiple regions. References were provided.^{4,5,6,7}

Response: Review of the submitted references showed that musculoskeletal symptoms for multiple body parts (two or more) were prevalent in 64% of the workers studied.² However, in the references addressing paravertebral joint/nerve blocks, approximately three-fourths of the patients had a positive response to double blocks only in one region; one-fifth to one-fourth had a positive response to double blocks in two regions and very few had this level of response in three regions. The policy will be revised as follows.

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The routine performance of facet joint/nerve blocks (both diagnostic and therapeutic) to both anatomic regions (cervicothoracic and lumbosacral) regions may prompt medical review. It is expected that the vast majority of patients will have positive responses in only one anatomic region.

Comment: We were asked to provide specific documentation requirements within the LCD, such as medical necessity, operative note, indications, and saved fluoroscopic images. One commenter protested the need for maintenance of fluoroscopic and CT images.

Response: We reviewed the “Documentation Requirements” in the draft LCD. Information related to each group of procedures is included as well as the need to save fluoroscopic or CT images. The latter requirement was not removed. A few additions or clarifications were made as noted.

UTILIZATION GUIDELINES

Comment: It was suggested that we limit the number of levels in a given session and limit the number of injections per year. We were also requested to, “Allow no more than six injections sessions/year of any one type, as defined by a CPT code, with continued injections allowed for relief of at least 50% lasting at least one month.” The same commenter also stated, “With regard to the number of facet/sacroiliac joint levels, it would be reasonable to allow three/visit, for instance, three facet joint/levels or two facet joints and one sacroiliac joint. The exception would be patients on Coumadin, which can be coded with V58.61 to indicate that anticoagulant therapy needed to be discontinued.”

A second commenter asked that the statement “no more than four therapeutic injections of any type..... per region per patient per year are anticipated for the majority of patients.” He asked consideration be given to patients with separate pain syndromes of axial and branch pain.

Response: The draft LCD contains utilization guidelines for each of the procedures included in the policy. Establishing absolute limits has the potential to harm the occasional patient for whom more rather than fewer procedures are medically necessary. Utilization guidelines for patients on anti-coagulants are specifically addressed. Medical review of individual claims on a pre- or post-pay basis may occur when there is concern utilization may be inappropriate or excessive.

Comment: A verbal comment was received requesting that the cervical region be separated from the thoracic region for purposes of utilization. In addition, the commenter would suggest allowing therapeutic paravertebral joint/nerve injections in the cervical, thoracic, and lumbosacral regions. The commenter also thought he might need to exceed the utilization guidelines for these injections 50% of the time for his older patients.

A written comment also requested the cervical and thoracic regions for paravertebral facet joint/nerve blocks be separated because the syndromes which cause pain in these areas may be entirely distinct.

Response: The cervical and thoracic regions are combined in concert with the CPT coding descriptions. In regards to frequency of therapeutic injections, please see the policy and above comments.

CODING GUIDELINES

Comment: Billing guidelines “with specific instructions for the physicians as it relates to billing diagnostic or therapeutic facet blocks vs. radiofrequency denervation treatments, and guidance on the use of a 50 modifier for bilateral procedures” was requested. Instructions for the use of the left, right, and bilateral modifiers were requested by another commenter who also stated there was a preference for elimination of the need to use these modifiers.

Response: We would ask that the Supplemental Instructions Article (SIA) be reviewed to find this information.

Comment: It was requested we remind hospital-based physicians they may only bill for the professional component of imaging.

Response: The statement, “Physicians may only bill for the professional component when imaging is performed in a hospital or non-office facility” was added to the SIA.

Comment: Several recommendations by one commenter were made regarding coding guidelines.

Response: Each of the suggested items was present in the SIA except for the following.

The phrase, “and the 150% payment adjustment for bilateral procedures applies” was added to those sentences beginning with “Thus, they are considered ‘unilateral’ procedures.”

Comment: A recommendation was made to perform interlaminar or caudal epidural injections rather than transforaminal epidural injections for patients with bilateral radicular pain or radicular pain involving multiple nerve roots.

Response: The recommendation was considered a policy change rather than a coding guideline. There are varying recommendations in the literature regarding epidural injections. The above recommendation was not included in the policy.

GENERAL COMMENTS

Comment: One commenter was concerned that the current draft LCD, compared to previous Connecticut Part B LCDs developed by First Coast Service Options (FSCO), “is somewhat confusing and tends to micromanage the practice of interventional pain management.” Copies of applicable Connecticut Part B LCDs were provided, although the most recent revision was not always included.

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Response: The applicable Connecticut Part B LCDs were reviewed during the J13 Transition period and again in preparation of the current draft LCD. Some features of those LCDs were incorporated into the current draft. The requirement for double comparative blocks with initial pain relief of 80 – 90% and the ability to perform previously painful maneuvers was not present. However, as stated elsewhere in this document, the requirement will be maintained to limit the number of false-positive responses and potential inappropriate treatments based on a false-positive response.

Comment: Thirteen references were provided by one commenter in addition to three references specific to one comment.

Response: We thank the submitter and have listed those references in the policy under “Sources of Information and Basis for Decision.”

¹Sehgal N, Dunbar E, Shah R, Colson J. Systematic review of diagnostic utility of facet (zygapophysial) joint injections in chronic spinal pain: an update. *Pain Physician*. 2007;10:213-228.

²Cohen SP, Stojanovic MP, Crooks M, Kim P, Schmidt RK, Shields CH, Croll S, Hurley RW. Lumbar zygapophysial (facet) joint radiofrequency denervation success as a function of pain relief during diagnostic medial branch blocks: a multicenter analysis. *Spine J*. 2008;8:498-504.

³Cohen SP, Bajwa ZH, Kraemer JJ, Dragovich A, Williams KA, Stream J, Sireci A, McKnight G, Hurley RW. Factors predicting success and failure for cervical facet radiofrequency denervation: a multi-center analysis. *Reg Anesth Pain Med*. 2007;32(6):495-50.

⁴Yeung SS, Genaidy A, Deddens J, Alhemoood A, Leung PC. Prevalence of musculoskeletal symptoms in single and multiple body regions and effects of perceived risk of injury among manual handling workers. *Spine*. 2002;27:2166-2172.

⁵Manchikanti L, Boswell MV, Singh V, Pampati V, Damron KS, Beyer CD. Prevalence of facet joint pain in chronic spinal pain of cervical, thoracic, and lumbar regions. *BMC Musculoskelet Disord*. 2004;5:15.

⁶Manchukonda R, Manchikanti KN, Cash KA, Pampati V, Manchikanti L. Facet joint pain in chronic spinal pain: An evaluation of prevalence and false-positive rate of diagnostic blocks. *J Spinal Disord Tech*. 2007;20:539-545.

⁷Jacob T, Zeev A. Are localized low back pain and generalized back pain similar entities? Results of a longitudinal community based study. *Disabil Rehabil*. 2006;28:369-377.