Comments and Responses Regarding Draft Local Coverage Determination:

Lumbar Epidural Injections

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 Lumbar Epidural Injections LCD. The official notice period for the final LCD begins on November 01, 2014, and the final determination will become effective on December 16, 2014.

Comment: Lumbar Policy: Several commenters stated that they were disappointed that none of the proposed policy covers cervical and thoracic epidural injections and they requested clarification regarding cervical and thoracic epidural injections.

Response: The disappointment is noted. Other subsequent policies are anticipated as determined by need. The absence of an LCD does not imply specific non-coverage of a service.

Comment: Descriptive Policy: One commenter requested inclusion of a description of services as in some other policies on the same services.

Response: There are other commenters that appreciated the attempt at brevity, feeling that the scientific background presented is common knowledge to many performing these procedures. National Government Services (NGS) attempted to present the basic statements of medical necessity and coverage.

Comment: Neurogenic Claudication: One commenter stated that the draft only lists two causes of neurogenic claudication and that there are many which makes our list grossly inadequate.

Response: Neurogenic claudication is a symptom complex associated with the nerve irritation of spinal stenosis. The ICD codes for this dx. are included in the policy.

Comment: Adequate Coverage for Discogenic Pain: One commenter stated that an additional indication be added for discogenic pain after ruling out facet joint and sacroiliac joint pain, which has already been included in other policies. This is essential to provide uniform coverage policies. Patients may even be jumping from state to state if this indication is not present and if this is covered in a neighboring state.

Response: The coverage and coding of discogenic pain appears consistent with other contractors. Mechanisms to provide additional services for exceptionally affected clinical cases exist.

Comment: Imaging for Epidural Injections: One commenter questioned why we are requiring the use of contrast for steroid epidural injections, but not for plain local anesthetic epidural injections?

Response: The use of imaging is urged for epidural injections, it is required by policy with all steroid and transforaminal injections.

Comment: Ultrasound Guidance: One commenter requested clarification on whether ultrasound could be included with fluoroscopy and computed tomography for guidance.

Response: The concerns of the commenter are noted, however at the present time, it is not considered as efficacious as the other imaging modalities. Medicare will accept additional literature on this subject as it evolves.

Comment: CT radiation exposure: One commenter stated that while they support the limited use of advanced CT imaging in selected cases, it should not be routinely used for any spinal pain management injection.

Response: The commenter's concerns over increased radiation exposure are noted. Medicare expects clinicians performing these services to be trained in judicious use of imaging.

Comment: Language Correction: One commenter stated that the language in #4, under "Procedural Requirements" be corrected to state contrast instead of injection. "Contrast medium should be injected during epidural injection procedures unless patient has contraindication to the contrast."

Response: The language correction is appreciated.

Comment: Transforaminal Injections: One commenter requested that we change the language in # 8a, under "Procedural Requirements," from "may be performed" to "will be covered". They stated per policy that no more than two transforaminal injections may be performed at a single setting (e.g. single level bilaterally or two levels unilaterally.

Response: The language as it exists has a more cautionary effect. The exceptional circumstances described can be handled with submission of additional documentation, etc, and would not result in "improper billing."

Comment: Steroid Dose Prescription: One commenter questioned the need for prescriptive detail in a coverage policy.

Response: The uniqueness of dosage recommendations is noted, but Medicare has a responsibility of patient safety. The policy guidance was developed by multiple organizations of involved practitioners.

Comment: Concurrent Injections: One commenter requested allowance for transforaminal and interlaminar injections in the same setting when medically necessary.

Response: The majority of commentary submitted felt that this was not sound clinical judgment in most clinical circumstances, and Medicare will retain the policy prohibition.

Comment: Exception to Steroid Dosing: One commenter questioned the prescriptiveness of policy, and ability to handle "exceptional cases"

Response: The recommended doses were a consensus opinion of involved specialties. Exceptional clinical circumstances with additional medical documentation provided may be reviewed by the Medical Director.

Comment: Imaging Requirement

Response: There is divided opinion upon the need for imaging with all epidural injections, hence the language "urged but not required." The policy clearly supports the need for appropriate imaging, with requirement to accompany steroid injections and transforaminal injections.

Comment: Frequency Limitation: One commenter is questioning the policy statement "series of three"

Response: The statement addresses a common misperception that this type of injection needs to be scheduled consistently in a sequence of three injections, rather than by an assessment of clinical response. The medical necessity of each injection needs to be established.

Comment: Cautionary Statement: Limitation #4 "Numbness and/or weakness without paresthesiae/dysesthesiae or pain preclude coverage." One commenter stated that it is provider's opinion that new onset weakness and/or numbness with corresponding MRI findings can indicate pathology potentially amenable to steroid decompression. The procedure report should indicate the reasoning for the procedure and rule out other causes of the current symptoms (e.g. diabetes).

Response: Medicare choses to retain this cautionary statement.

Comment: Radiologic Contraindications: Clinical circumstances such as pregnancy may contraindicate use of fluoroscopy or other imaging.

Response: While not anticipated as a common event in the Medicare population, pregnancy does represent a meaningful exception and will be addressed with supplemental documentation.

Comment: Qualifications: Under "Provider Qualifications" several commenters stated that: CRNAs, PAs and NPs with weeks of intense shadowing, then hands on training, then cadaver conferences, should be able to handle MBN blocks and later, ablations. The techniques can easily be taught under the direction of experienced physicians so whoever is doing them is deemed proficient in the techniques and safety. As a PA under supervision it is the job of the

supervising physician to guide the PA's responsibilities and performance. It is clear that in PA regulations, duties include anything and everything the supervising physician feels the PA is competent in. This includes spine injections.

Response: .Reimbursement for the procedures discussed in this LCD is not linked to specific provider types. Any eligible provider receives payment for these services if both requirements for training, or experience, and credentialing are met.

Comment: Qualifications: One commenter stated that the Provider Qualifications section of the LCD states, "Patient safety and quality of care mandate that healthcare professionals who perform pain management procedures are appropriately trained and/or credentialed by a formal residency/fellowship program and/ or are certified by either an accredited and nationally recognized organization or by a post-graduate training course accredited by an established national accrediting body or accredited professional training program." We understand this section to clearly state that National Government Services, Inc. (NGS) covers all Medicare CRNA services within their state scope of practice, including the services described in this LCD.

Response: The intention of this section is correctly understood. Please see the previous statement of qualifications for reimbursement. NGS Medicare honors both state scope of practice and Medicare regulations.

Comment:Verification of Proficiency: One commenter stated that that the statement, "If the practitioner works in a hospital facility at any time and/or is credentialed by a hospital for any procedure, the practitioner must be credentialed to perform the same procedure in the outpatient setting" be changed to – "A practitioner who works in a hospital or ASC facility at any time should be credentialed by the facility for any procedure also performed in an office setting." This will insure that any provider who performs these treatments has been reviewed by a credentialing body as to their training and technical ability to perform these treatments.

Response: NGS concurs with the intent that providers who perform these treatments have been reviewed by a credentialing body to their training and technical ability. The language has been changed to incorporate credentialing in an ASC facility.

Comment: Inclusion of Dx 756.12: One commenter stated that the draft includes lumbago, but not spondylolisthesis. Thus, spondylolisthesis in post lumbar surgery syndrome should be

added. This is required to at least maintain uniformity and they also meet medical necessity criteria, specifically post lumbar surgery syndrome.

Response: NGS will consider the addition of 756.12 based on claims submission information.

Comment: References: One commenter sent a list of references to be added.

Response: Medicare appreciates the numerous comments and literature submission from practitioners in our jurisdictions. These additional references will be archived with the policy.

Numerous comments were received that were similar in content. For streamlining, the comments were consolidated topically and addressed as such.

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