



FSIPP

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June 28, 2011

James J. Corcoran, MD, MPH
Medicare Contractor Medical Director – J9 MAC
First Coast Service Options, Inc.
P.O. Box 45274
Jacksonville, FL 32232

RE: Percutaneous Intralaminar Lumbar Decompression Laminotomy Procedure
CPT Code 0275T [HCPCS C9729]

Dear Dr. Corcoran:

Thank you for allowing me and other members of the CAC to discuss the percutaneous intralaminar lumbar decompression laminotomy procedure at last Saturday's CAC meeting. As follow-up to the meeting, on behalf of the Florida Society of Interventional Pain Physicians (FSIPP), I would like formally request a reconsideration of the aforementioned procedure and ask it be removed from the noncovered LCD.

To accompany this reconsideration request, I am submitting to you a brief summary of evidence in support of this procedure, which includes compelling new information not available at the time of our meeting last week. Specifically, the procedure's long-term follow-up data was published in a peer-reviewed journal on June 17, 2011.

In addition to the recently published long-term data, please also consider the following evidence supporting the procedure's removal from the noncovered LCD:

- a) The clinical data and published, peer reviewed literature overwhelmingly support the procedure's strong safety profile.***
- b) The procedure essentially represents an alternative approach to performing the well-established and routinely-reimbursed decompression laminotomy.***
- c) The interventional pain physicians who typically perform this procedure possess the relevant skills and expertise, are well-trained and have the support of many neuro and orthopedic surgeons.***
- d) The procedure's patient selection algorithm is specific, appropriate and consistent with the AMA's Typical Patient Vignette for the new CPT code, 0275T.***

DISCUSSION OF EVIDENCE SUPPORTING THE PROCEDURE

- a) The clinical data and published, peer-reviewed literature overwhelmingly supports the procedure's strong safety profile.***

In 828 study procedures, performed primarily by interventional pain physicians, there were no serious adverse events, including events such as dural tears, nerve damage, bleeding complications requiring transfusions, and hematomas. This compares to a complication rate in excess of 20% associated with open surgical decompression procedures, according to the published literature.

The procedure's strong safety profile is achieved by design of the method and is consistent with the percutaneous, image-guided and epidurogram-enabled posterior decompression approach, which limits biomechanical change and the risk of complications. In more than 10,000 procedures performed through June 2011, there have been only three reported serious adverse events—each resolved with full patient recovery and no sequelae.

Please refer to the attached poster from Timothy Deer, MD, Charleston, WV, “*mild*[®] - long term outcomes with percutaneous decompression,” which won the 2011 peer-reviewed Research Poster Award at the 27th Annual American Academy of Pain Management (AAPM) meeting. According to his data, there were no adverse events in 170 consecutive procedures.

b) The procedure essentially represents an alternative approach to perform the studied, well-established and routinely-reimbursed decompression laminotomy.

A decompression laminotomy is a well-established procedure for patients with lumbar spinal stenosis, is routinely reimbursed by FCSO and is widely-documented in peer reviewed publications. The publications include:

Castro-Menendez, et al., “Midterm Outcome After Microendoscopic Decompressive Laminotomy,” *Neurosurgery*; 2009; Jul; 65(1):100-10

Sinikallio, et al., “Lumbar Spinal Stenosis Patients are Satisfied with Short-Term Results of Surgery – Younger Age, Symptom Severity, Disability and Depression Decrease Satisfaction,” *Disabil Rehab*; 2007; Apr 15; 29(7); 537-44

Weinstein, et al, “Surgical Versus Nonsurgical Therapy for Lumbar Spinal Stenosis,” *New Engl J Med*; 2008; 358; 794-810

In the case of this procedure, the decompression result is achieved percutaneously using image-guidance, rather than by an open or endoscopic approach. It is critical to note that *decompression* is responsible for the clinical efficacy of the procedure, and the approaches differ according to access and visualization, not the mechanism of action or the clinical work. Furthermore, safety would seem to favor the percutaneous approach, which is evidenced by the data and published literature.

Please refer to the following published, peer-reviewed literature concerning the procedure, including the long-term follow-up data (attached), which was not in publication since the procedure was added to the noncovered LCD:

Mekhail, et al., “Long-Term Results of Percutaneous Lumbar Decompression *mild*[®] for Spinal Stenosis,” *Pain Practice*, June, 2011*

Basu, et al., “*mild*[®] Procedure: Single-Site Experience with Prospective IRB

Approved Clinical Outcomes Research,” *Clin J Pain* – accepted for publication

Chopko, et al., “MiDAS I (*mild*[®] Decompression Alternative to Open Surgery): A Preliminary Report of a Prospective, Multi-Center Study,” *Pain Physician*; 2010; 13:369-378

Deer, et al., “New Image-Guided Ultra-Minimally Invasive Lumbar Decompression Method: The *mild*[®] Procedure,” *Pain Physician* 2010; 13:35-41

Deer, et al., “Minimally Invasive Decompression for Lumbar Spinal Stenosis,” *J Neuro Review: Spine* – accepted for publication

Schomer, et al., “*mild*[®] Lumbar Decompression for the Treatment of Lumbar Spinal Stenosis,” *Neuro-radiology* – accepted for publication

Wong, et al., “*mild*[®] for the Treatment of Lumbar Spinal Stenosis,” *Clin J Pain* –accepted for publication

**Published June 17, 2011, subsequent to our CAC meeting*

Further demonstrating equivalence of the clinical work across these alternative decompression procedures is the following set of facts and circumstances regarding the creation of CPT Code 0275T:

The North American Spine Society (NASS) acknowledged the similarity across these decompression procedures in their CPT application, which was submitted to the American Medical Association (AMA) in December 2010. Procedural CPT Code 0275T is the result of this NASS application, which proposed an alternative to open or endoscopic decompression laminotomy (currently covered under CPT Code 63030). With guidance from NASS, the AMA established CPT Code 0275T, which describes the actual decompression component of the procedure using language identical to CPT Code 63030.

c) The interventional pain physicians who typically perform this procedure possess the relevant skills and expertise, are well-trained and have the support of many neuro and orthopedic surgeons.

Skills, Access and Training

The interventional pain physicians who typically perform this procedure have expertise in the epidural space and relevant experience with other image-guided procedures performed in that space. The procedure may even require less precision (but certainly no more) than is required for the placement of leads for a neurostimulator or placement of an intra-thecal catheter for pain pumps. Moreover, the manufacturer (Vertos

Medical) controls access to the technology that enables the procedure by requiring physician training and certification before it will sell or ship product. Vertos Medical, conducts this extensive physician-led certification program at its headquarters, and the program format includes both didactic and hands-on cadaveric sessions.

It is also important to note that the educational content for this certification program material was developed in collaboration with an interventional pain physician, Timothy R. Deer, MD, Charleston, WV, and a neurosurgeon, Bohdan Chopko, MD, PhD, Mansfield, OH, and therefore represents perspectives from both specialties.

Neurosurgeon Support and Testimony

During the recent public CAC meeting, we heard the testimony of Robert Levy, MD, the incoming Chairman of the Department of Neurosurgery at the University of Florida. Dr. Levy testified that he has reviewed the published literature and found that the clinical data clearly demonstrate the procedure's safety and efficacy. He observed that one of the procedure's core safety attributes is that decompression occurs, at all times, posterior to the thecal sac. Furthermore, Dr. Levy noted that the skills necessary to treat the patient and respond to potential complications of the procedure are those possessed by the interventional pain physicians, as well as interventionally-trained neuro and orthopedic spine surgeons.

d) The procedure's patient selection algorithm is specific, appropriate and consistent with the AMA's typical patient vignette associated with the new CPT code, 0275T.

Appropriately selected patients are those who present with the following:

- Clinically symptomatic LSS
- Neurogenic claudication triggered by axial loading activities
- Lower back pain while standing and/or walking

Further, LLS has been radiologically confirmed, including the presence of hypertrophic ligamentum flavum, and symptoms are determined to be consistent with the radiologic images. Where conservative measures have failed to adequately manage or relieve

