



# FSIPP

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September 27, 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: Request for Reconsideration Percutaneous Intralaminar Lumbar Decompression Laminotomy Procedure, CPT Code 0275T [HCPCS C9729]

Dear Dr. Corcoran:

In follow-up to our discussions regarding the percutaneous intralaminar lumbar decompression laminotomy (MILD) procedure – CPT Code 0275T, on behalf of the Florida Society of Interventional Pain Physicians (FSIPP), I am submitting this reconsideration request to have the MILD procedure removed from the First Coast Service Options (FCSO) non-covered LCD list. This request contains supporting materials and the three new published peer-reviewed articles that were discussed at the CAC meeting in June which support the removal of the procedure from the non-covered code list.

## **SCIENTIFIC EVIDENCE SUPPORTING THE PROCEDURE**

1. The following new published peer-reviewed articles supporting the safety and efficacy of the procedure have been published:

Basu, S, “*mild*<sup>®</sup> Procedure: Single-Site Experience with Prospective IRB Approved Clinical Outcomes Research,” *Clin J Pain*, September, 2011

Deer, et al., “Minimally Invasive Lumbar Decompression for Spinal Stenosis,” *J Neurosurgical Review*, August, 2011

Schomer, et al., “*mild*<sup>®</sup> Lumbar Decompression for the Treatment of Lumbar Spinal Stenosis,” *The Neuroradiology Journal*, 24: 620-626, 2011

Mekhail, et al., “Long-Term Results of Percutaneous Lumbar Decompression *mild*<sup>®</sup> for Spinal Stenosis,” *Pain Practice*, July, 2011\*\*

\*\*Article was previously provided to you, but was not available on PubMed. The article is now available on PubMed.

Attached are pdf copies of the above articles for your review.

2. Seven published peer-reviewed articles support the safety and efficacy of the procedure, which we argue satisfies amount of literature required to establish safety and efficacy.

The seven published articles include:

Basu, S, “*mild*<sup>®</sup> Procedure: Single-Site Experience with Prospective IRB Approved Clinical Outcomes Research,” *Clin J Pain*, September, 2011

Chopko, et al., “MiDAS I (*mild*<sup>®</sup> 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*<sup>®</sup> Procedure,” *Pain Physician* 2010; 13:35-41

Deer, et al., “Minimally Invasive Lumbar Decompression for Spinal Stenosis,” *J Neurosurgical Review*, August, 2011

Lingreen, et al., “Retrospective Review of Patient Self-Reported Improvement and Post-Procedure Findings for *mild*<sup>®</sup>,” *Pain Physician*, 13: 555-560, 2010

Mekhail, et al., “Long-Term Results of Percutaneous Lumbar Decompression *mild*<sup>®</sup> for Spinal Stenosis,” *Pain Practice*, July, 2011

Schomer, et al., “*mild*<sup>®</sup> Lumbar Decompression for the Treatment of Lumbar

Spinal Stenosis," *The Neuroradiology Journal*, 24: 620-626, 2011

Attached are pdf copies of the above articles for your review.

3. There is no published evidence to refute the safety and efficacy of the procedure. More importantly, the clinical experience establishes the procedure is safer than traditional lumbar decompression surgery and as effective.
  
4. Attached is a copy of my reconsideration letter dated June 28, 2011 which details the clinical data and published peer-reviewed literature which overwhelmingly supports the procedure's strong safety profile. The letter also details the physician support for the procedure, the specific patient selection algorithm, and the relevant skills, expertise and training required to successfully perform the procedure. The peer-reviewed literature published subsequent to my letter continues to support the clinical outcomes and safety of the procedure.

#### **REQUEST FOR RECONSIDERATION OF THE NONCOVERED LCD**

Again, on behalf of the Florida Society of Interventional Pain Physicians, I request that reconsideration for the MILD procedure to be removed it from the non-covered code list in light of the published scientific evidence that exists for this procedure. This will give interventional physicians an opportunity to appeal denials and further establish the efficacy this procedure. It is rare that a procedure such as this is developed that will save patients from suffering and the enormous expense and many failures of invasive surgical alternatives in the elderly population.

Thank you for your attention to this matter, and I look forward to hearing from you.

Sincerely,

Deborah Tracy, MD, MBA  
President  
Florida Society of Interventional Pain Physicians  
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Attachments:     -Published literature  
                      -FSIPP reconsideration letter dated June 28, 2011