



Effective Health Care

Minimally Invasive Lumbar Decompression (MILD) Nomination Summary Document

Results of Topic Selection Process & Next Steps

- The topic, *Minimally Invasive Lumbar Decompression (MILD)* was found to be addressed by a by a national coverage analysis (NCA) conducted by the Centers for Medicare and Medicaid Services (CMS) for percutaneous image-guided lumbar decompression for lumbar spinal stenosis. CMS also issued a proposed memo pertaining to the NCA for public comment. Given the existing NCA and decision memo, no further activity will be undertaken on this topic.
 - Proposed Decision Memo for Percutaneous Image-guided Lumbar Decompression for Lumbar Spinal Stenosis (CAG-00433N). Available at: <http://www.cms.gov/medicare-coverage-database/details/nca-proposed-decision-memo.aspx?NCAId=269>

Topic Description

Nominator(s): Organization

Nomination Summary: The nominator is interested in understanding the effectiveness of minimally invasive lumbar decompression (MILD) compared to other therapeutic interventions (pain management procedures, surgical, pharmacologic, and others) for the treatment of lumbar spinal stenosis (LSS). The nominator states that lumbar spinal stenosis is a common condition that requires a comprehensive patient assessment to diagnose and treat. The nominator is concerned that procedures, including MILD, used to treat lumbar spinal stenosis are driven by specialty physician interests and questions remain about which patients may be most appropriate for the MILD and its comparative effectiveness. The nominator considers MILD to be an investigational therapy and suggests that information regarding the comparative effectiveness of MILD can support coverage determinations.

Staff-Generated PICO

Population(s): Individuals with lumbar spinal stenosis.

Intervention(s): MILD

Comparator(s): Surgical, pharmacologic, and other therapeutic options, combinations of these, and placebo/sham.

Outcome(s): Reduction of pain, functional disability, and short-/long-term operative complications.

Key Questions from Nominator: What is the effectiveness of minimally invasive lumbar decompression compared to other therapeutic interventions (pain management procedures, surgical, pharmacologic, and other) for the treatment of lumbar spinal stenosis?

Considerations

- The topic meets all EHC Program selection criteria. (For more information, see <http://effectivehealthcare.ahrq.gov/index.cfm/submit-a-suggestion-for-research/how-are-research-topics-chosen/>.)
- Lumbar spinal stenosis (LSS) is a narrowing of the spinal canal that compresses the nerves traveling through the lower back into the legs. It is estimated that about 400,000 Americans, most over 60 years of age, are afflicted with LSS. As the “baby boomers” age, an estimated 2.4 million Americans will be affected by lumbar spinal stenosis by 2021.
- The minimally invasive lumbar decompression (MILD) procedure treats LSS by removing hypertrophic ligamentum flavum, which restores space in the spinal canal. The procedure is minimally invasive and requires no general anesthesia, no implants, no stitches, and is performed in about one hour. The mild® kit received 510(k) clearance from the Food and Drug Administration (FDA) in 2006.
- The topic was found to be addressed by national coverage analysis (NCA) and a proposed decision memo developed by the Centers for Medicare and Medicaid Services (CMS) for percutaneous image-guided lumbar decompression for LSS.
- The NCA includes a review of the evidence on whether percutaneous image-guided lumbar decompression (PILD) for LSS provides improved health outcomes in Medicare beneficiaries and whether or not it should be covered by Medicare. The procedure that most closely falls under the description of PILD is the mild® procedure.