Policy: MP263
Section: Medical Benefit Policy
Subject: Minimally Invasive Lumbar Decompression (MILD) and Percutaneous Image-guided Lumbar Decompression (PILD)

I. Policy: Minimally Invasive Lumbar Decompression (MILD) and Percutaneous Image-guided Lumbar Decompression (PILD)

II. Purpose/Objective:
To provide a policy of coverage regarding Minimally Invasive Lumbar Decompression (MILD) and Percutaneous Image-guided Lumbar Decompression (PILD)

III. Responsibility:
A. Medical Directors
B. Medical Management

IV. Required Definitions
1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions
Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

a. appropriate for the symptoms and diagnosis or treatment of the Member’s condition, illness, disease or injury;
b. provided for the diagnosis, and the direct care and treatment of the Member’s condition, illness disease or injury;
c. in accordance with current standards of good medical treatment practiced by the general medical community.
d. not primarily for the convenience of the Member, or the Member’s Health Care Provider; and
e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member’s condition, and the Member cannot receive safe or adequate care as an outpatient.

Medicaid Business Segment
Medical Necessity shall mean a service or benefit that is compensable under the Medical Assistance Program and if it meets any one of the following standards:
The service or benefit will, or is reasonably expected to, prevent the onset of an illness, condition or disability.

The service or benefit will, or is reasonably expected to, reduce or ameliorate the physical, mental or development effects of an illness, condition, injury or disability.

The service or benefit will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for members of the same age.

DESCRIPTION: Minimally Invasive Lumbar Decompression (MILD) and Percutaneous Image-guided Lumbar Decompression (PILD) utilizes a set of specialized surgical instruments to perform percutaneous lumbar decompressive procedures for the treatment of spinal stenosis. During the percutaneous MILD procedure, the epidural space is filled with contrast medium under fluoroscopic guidance. Using a 6- gauge cannula that is clamped in place with a back plate, single-use tools are used to resect thickened ligamentum flavum and small pieces of lamina. The tissue and bone sculpting is conducted entirely under fluoroscopic guidance, with additional contrast media added throughout the procedure to aid visualization of the decompression. The process is repeated on the opposite side for bilateral decompression of the central canal.

FOR MEDICARE and MEDICAID BUSINESS SEGMENT:
The Centers for Medicare & Medicaid Services (CMS) has determined that PILD will be covered by Medicare when provided in a clinical study under section 1862(a)(1)(E) through Coverage with Evidence Development (CED) for beneficiaries with lumbar spinal stenosis who are enrolled in an approved clinical study that meets the criteria outlined in the National Coverage Determination (NCD) for Percutaneous image-guided lumbar decompression for lumbar SPINAL STENOSIS (150.13)

The list of CMS approved clinical trials/clinical research studies for PILD can be found at: Percutaneous Image-guided Lumbar Decompression (PILD) for Lumbar Spinal Stenosis (LSS) http://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/PILD.html

EXCLUSIONS:
Although the US Food and Drug Administration has approved devices for image-guided minimally invasive lumbar decompression for spinal stenosis, the Plan has determined that the available published peer-reviewed literature is insufficient to establish the safety and efficacy of this procedure compared to available alternatives. Therefore, unless coverage is mandated, minimally invasive lumbar decompression (MILD and PILD) for spinal stenosis is considered experimental/investigational and is not covered.

Note: A complete description of the process by which a given technology or service is evaluated and determined to be experimental, investigational or unproven is outlined in MP 15 - Experimental Investigational or Unproven Services or Treatment.

CODING ASSOCIATED WITH: Minimally Invasive Lumbar Decompression (MILD) and Percutaneous Image-guided Lumbar Decompression (PILD)

The following codes are included below for informational purposes and may not be all inclusive. Inclusion of a procedure or device code(s) does not constitute or imply coverage nor does it imply or guarantee provider reimbursement. Coverage is determined by the member specific benefit plan document and any applicable laws regarding coverage of specific services. Please note that per Medicare coverage rules, only specific CPT/HCPCS Codes may be covered for the Medicare Business Segment. Please consult the CMS website at www.cms.gov or the local Medicare Administrative Carrier (MAC) for more information on Medicare coverage and coding requirements

0274T percutaneous laminotomy/laminectomy (interlaminar approach) for decompression of neural elements, (with or without ligamentous resection, discectomy, facetectomy and/or foraminotomy), any method, under indirect image guidance (eg, fluoroscopic, CT), single or multiple levels, unilateral or bilateral; cervical or thoracic

0275T Percutaneous laminotomy/laminectomy (intralaminar approach) for decompression of neural elements, (with or without ligamentous resection, discectomy, facetectomy and/or foraminotomy) any method under indirect image guidance (e.g., fluoroscopic, CT), with or without the use of an endoscope, single or multiple levels, unilateral or bilateral; lumbar

G0276 Blinded procedure for lumbar stenosis, percutaneous image-guided lumbar decompression (PILD) or placebo-control, performed in an approved coverage with evidence development (CED) clinical trial


LINE OF BUSINESS:
Eligibility and contract specific benefits, limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy. For Medicare, applicable LCD’s and NCD’s will supercede this policy. For PA Medicaid Business segment, this policy applies as written.

REFERENCES:


National Coverage Determination (NCD) for Percutaneous image-guided lumbar decompression for lumbar SPINAL STENOSIS (150.13) http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCID=358&ncdver=1&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=All&KeyWord=Spinal+stenosis&KeyWordLookUp=Title&KeyWordSearchType=And&from2=search.asp&bc=gAAAABAAAAAAAA%3d%3d&


Staats PS, Benyamin RM; MiDAS ENCORE Investigators. MiDAS ENCORE: Randomized Controlled Clinical Trial Report of 6 Month Results. Pain Physician 2016 Feb;19(2):25-38


Novitas Solutions. Medicare Local carrier policy. Services That Are Not Reasonable and Necessary (L35094)

This policy will be revised as necessary and reviewed no less than annually.

Devised: 4/12

Revised: 4/15 (Add CMS clinical trial coverage)
Reviewed: 4/13, 4/14; 4/16, 3/17, 3/18