Medica Coverage Policy

<table>
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<tr>
<th>Policy Name:</th>
<th>mild® Procedure (mild® Device Kit)</th>
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<td>Effective Date:</td>
<td>1/20/2020</td>
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Important Information – Please Read Before Using This Policy

These services may or may not be covered by all Medica plans. Please refer to the member’s plan document for specific coverage information. If there is a difference between this general information and the member’s plan document, the member’s plan document will be used to determine coverage. With respect to Medicare and Minnesota Health Care Programs, this policy will apply unless those programs require different coverage. Members may contact Medica Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions about this Medica coverage policy may call the Medica Provider Service Center toll-free at 1-800-458-5512.

Medica coverage policies are not medical advice. Members should consult with appropriate health care providers to obtain needed medical advice, care and treatment.

Coverage Policy
The mild® Procedure (mild® Device Kit) is investigative and therefore NOT COVERED.

Note: See also related Medica utilization management policy: Lumbar Spinal Fusion

Description
The mild® Procedure is a percutaneous decompression technique intended to treat lumbar spinal stenosis by increasing the dimensions of the spinal canal, thereby achieving lumbar decompression. The surgical site is not directly visualized, but rather surgery is guided by fluoroscopy using a posterior approach. The procedure involves limited percutaneous laminotomy and thinning of the ligamentum flavum, an elastic tissue attached to and extending between two adjacent vertebrae. The device kit is composed of sterile, single-use surgical instruments intended for tissue resection at the central area of stenosis. The mild Procedure is not intended for nerve root decompression or for disc procedures. The procedure is typically performed in a hospital outpatient setting or ambulatory surgical center using local anesthetics and mild sedation. It takes approximately one hour, and patients are usually discharged on the same day or may be admitted overnight for observation.

FDA Approval
This technology is considered a procedure and, therefore, not subject to FDA regulation. The mild® Device Kit (Vertos Medical Inc.) initially received FDA approval in December 2006 to perform percutaneous lumbar decompression procedures for the treatment of various spinal conditions. A modification to the device kit was issued in February 2010 and included the company name change from X-Sten to Vertos Medical Inc. and the product name change from X-Sten MILD Tool Kit to Vertos Medical mild® Device Kit.

In November 2012, FDA 510(k) predicate device approval was granted to the Vertiflex Direct Decompression System (Vertiflex, Inc.) based on the mild Device Kit.
Prior Authorization
Prior authorization is not applicable. Claims for this service are subject to retrospective review and denial of coverage, as investigative services are not eligible for reimbursement.

Coding Considerations
Use the current applicable CPT/HCPCS code(s). The following codes are included below for informational purposes only, and are subject to change without notice. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement.

CPT Codes:
- 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.

Original Effective Date: 4/1/2003

Re-Review Date(s): 11/19/2014
11/20/2019