SURGICAL TREATMENT FOR SPINE PAIN

Policy Number: 2019T0547U **Effective Date**: April 1, 2019

Instructions for Use

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COVERAGE RATIONALE

The following spinal procedures are proven and medically necessary:
- Spinal fusion using extreme lateral interbody fusion (XLIF®)
- Direct lateral interbody fusion (DLIF)

For the following spinal procedures, refer to MCG™ Care Guidelines, 23rd edition:
- Cervical Diskectomy or Microdiskectomy, Foraminotomy, Laminotomy, S-310 (ISC)
- Lumbar Diskectomy, Foraminotomy, or Laminotomy S-810 (ISC)
- Cervical Laminectomy S-340 (ISC)
- Lumbar Laminectomy S-830 (ISC)
- Cervical Fusion, Anterior S-320 (ISC)
- Cervical Fusion, Posterior S-330 (ISC)
- Lumbar Fusion S-820 (ISC)

The following spinal procedures are unproven and not medically necessary due to insufficient evidence of efficacy (this includes procedures that utilize interbody cages, screws, and pedicle screw fixation devices*):
- Laparoscopic anterior lumbar interbody fusion (LALIF)*
- Transforaminal lumbar interbody fusion (TLIF) which utilizes only endoscopy visualization (such as a percutaneous incision with video visualization)*
- Axial lumbar interbody fusion (AxiaLIF®)*
- Interlaminar lumbar instrumented fusion (ILIF) (e.g., Coflex-F®)*
- Spinal decompression and interspinous process decompression systems for the treatment of lumbar spinal stenosis (e.g., Interspinous process decompression (IPD), Minimally invasive lumbar decompression (MILD))
- Spinal stabilization systems
  - Stabilization systems for the treatment of degenerative spondylolisthesis
  - Total facet joint arthroplasty, including facetectomy, laminectomy, foraminotomy, vertebral column fixation
  - Percutaneous sacral augmentation (sacroplasty) with or without a balloon or bone cement for the treatment of back pain
- Stand-alone facet fusion without an accompanying decompressive procedure:
  - This includes procedures performed with or without bone grafting and/or the use of posterior intrafacet implants such as fixation systems, facet screw systems or anti-migration dowels

APPLICABLE CODES

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply

any right to reimbursement or guarantee claim payment. Other Policies and Coverage Determination Guidelines may apply.

Coding Clarification:

- The North American Spine Society (NASS) recommends that anterior or anterolateral approach techniques performed via an open approach should be billed with CPT codes 22554–22585. These codes should be used to report the use of extreme lateral interbody fusion (XLIF) and direct lateral interbody fusion (DLIF) procedures (NASS, 2010).
- Laparoscopic approaches should be billed with an unlisted procedure code.

CPT Code	Description
0200T	Percutaneous sacral augmentation (sacroplasty), unilateral injection(s), including the use of a balloon or mechanical device, when used, 1 or more needles, includes imaging guidance and bone biopsy, when performed
0201T	Percutaneous sacral augmentation (sacroplasty), bilateral injections, including the use of a balloon or mechanical device, when used, 2 or more needles, includes imaging guidance and bone biopsy, when performed
0202T	Posterior vertebral joint(s) arthroplasty (e.g., facet joint[s] replacement) including facetectomy, laminectomy, foraminotomy and vertebral column fixation, injection of bone cement, including fluoroscopy, single level, lumbar spine
0219T	Placement of a posterior intrafacet implant(s), unilateral or bilateral, including imaging and placement of bone graft(s) or synthetic device(s), single level; cervical
0220T	Placement of a posterior intrafacet implant(s), unilateral or bilateral, including imaging and placement of bone graft(s) or synthetic device(s), single level; thoracic
0221T	Placement of a posterior intrafacet implant(s), unilateral or bilateral, including imaging and placement of bone graft(s) or synthetic device(s), single level; lumbar
0222T	Placement of a posterior intrafacet implant(s), unilateral or bilateral, including imaging and placement of bone graft(s) or synthetic device(s), single level; each additional vertebral segment (List separately in addition to code for primary procedure)
0274T	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), 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), single or multiple levels, unilateral or bilateral; lumbar
22100	Partial excision of posterior vertebral component (e.g., spinous process, lamina or facet) for intrinsic bony lesion, single vertebral segment; cervical
22101	Partial excision of posterior vertebral component (e.g., spinous process, lamina or facet) for intrinsic bony lesion, single vertebral segment; thoracic
22102	Partial excision of posterior vertebral component (e.g., spinous process, lamina or facet) for intrinsic bony lesion, single vertebral segment; lumbar
22103	Partial excision of posterior vertebral component (e.g., spinous process, lamina or facet) for intrinsic bony lesion, single vertebral segment; each additional segment (List separately in addition to code for primary procedure)
22110	Partial excision of vertebral body, for intrinsic bony lesion, without decompression of spinal cord or nerve root(s), single vertebral segment; cervical
22112	Partial excision of vertebral body, for intrinsic bony lesion, without decompression of spinal cord or nerve root(s), single vertebral segment; thoracic
22114	Partial excision of vertebral body, for intrinsic bony lesion, without decompression of spinal cord or nerve root(s), single vertebral segment; lumbar
22116	Partial excision of vertebral body, for intrinsic bony lesion, without decompression of spinal cord or nerve root(s), single vertebral segment; each additional vertebral segment (List separately in addition to code for primary procedure)
22206	Osteotomy of spine, posterior or posterolateral approach, 3 columns, 1 vertebral segment (e.g., pedicle/vertebral body subtraction); thoracic

CPT Code	Description
22207	Osteotomy of spine, posterior or posterolateral approach, 3 columns, 1 vertebral segment (e.g., pedicle/vertebral body subtraction); lumbar
22208	Osteotomy of spine, posterior or posterolateral approach, 3 columns, 1 vertebral segment (e.g., pedicle/vertebral body subtraction); each additional vertebral segment (List separately in addition to code for primary procedure)
22210	Osteotomy of spine, posterior or posterolateral approach, 1 vertebral segment; cervical
22212	Osteotomy of spine, posterior or posterolateral approach, 1 vertebral segment; thoracic
22214	Osteotomy of spine, posterior or posterolateral approach, 1 vertebral segment; lumbar
22216	Osteotomy of spine, posterior or posterolateral approach, 1 vertebral segment; each additional vertebral segment (List separately in addition to primary procedure)
22220	Osteotomy of spine, including discectomy, anterior approach, single vertebral segment; cervical
22222	Osteotomy of spine, including discectomy, anterior approach, single vertebral segment; thoracic
22224	Osteotomy of spine, including discectomy, anterior approach, single vertebral segment; lumbar
22226	Osteotomy of spine, including discectomy, anterior approach, single vertebral segment; each additional vertebral segment (List separately in addition to code for primary procedure)
22532	Arthrodesis, lateral extracavitary technique, including minimal discectomy to prepare interspace (other than for decompression); thoracic
22533	Arthrodesis, lateral extracavitary technique, including minimal discectomy to prepare interspace (other than for decompression); lumbar
22534	Arthrodesis, lateral extracavitary technique, including minimal discectomy to prepare interspace (other than for decompression); thoracic or lumbar, each additional vertebral segment (List separately in addition to code for primary procedure)
22548	Arthrodesis, anterior transoral or extraoral technique, clivus-C1-C2 (atlas-axis), with or without excision of odontoid process
22551	Arthrodesis, anterior interbody, including disc space preparation, discectomy, osteophytectomy and decompression of spinal cord and/or nerve roots; cervical below C2
22552	Arthrodesis, anterior interbody, including disc space preparation, discectomy, osteophytectomy and decompression of spinal cord and/or nerve roots; cervical below C2, each additional interspace (List separately in addition to code for separate procedure)
22554	Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); cervical below C2
22556	Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); thoracic
22558	Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); lumbar
22585	Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); each additional interspace (List separately in addition to code for primary procedure)
22586	Arthrodesis, pre-sacral interbody technique, including disc space preparation, discectomy, with posterior instrumentation, with image guidance, includes bone graft when performed, L5-S1 interspace
22590	Arthrodesis, posterior technique, craniocervical (occiput-C2)
22595	Arthrodesis, posterior technique, atlas-axis (C1-C2)
22600	Arthrodesis, posterior or posterolateral technique, single level; cervical below C2 segment

CPT Code	Description
22610	Arthrodesis, posterior or posterolateral technique, single level; thoracic (with lateral transverse technique, when performed)
22612	Arthrodesis, posterior or posterolateral technique, single level; lumbar (with lateral transverse technique, when performed)
22614	Arthrodesis, posterior or posterolateral technique, single level; each additional vertebral segment (List separately in addition to code for primary procedure)
22630	Arthrodesis, posterior interbody technique, including laminectomy and/or discectomy to prepare interspace (other than for decompression), single interspace; lumbar
22632	Arthrodesis, posterior interbody technique, including laminectomy and/or discectomy to prepare interspace (other than for decompression), single interspace; each additional interspace (List separately in addition to code for primary procedure)
22633	Arthrodesis, combined posterior or posterolateral technique with posterior interbody technique including laminectomy and/or discectomy sufficient to prepare interspace (other than for decompression), single interspace and segment; lumbar
22634	Arthrodesis, combined posterior or posterolateral technique with posterior interbody technique including laminectomy and/or discectomy sufficient to prepare interspace (other than for decompression), single interspace and segment; each additional interspace and segment (List separately in addition to code for primary procedure)
22800	Arthrodesis, posterior, for spinal deformity, with or without cast; up to 6 vertebral segments
22802	Arthrodesis, posterior, for spinal deformity, with or without cast; 7 to 12 vertebral segments
22804	Arthrodesis, posterior, for spinal deformity, with or without cast; 13 or more vertebral segments
22808	Arthrodesis, anterior, for spinal deformity, with or without cast; 2 to 3 vertebral segments
22810	Arthrodesis, anterior, for spinal deformity, with or without cast; 4 to 7 vertebral segments
22812	Arthrodesis, anterior, for spinal deformity, with or without cast; 8 or more vertebral segments
22818	Kyphectomy, circumferential exposure of spine and resection of vertebral segment(s) (including body and posterior elements); single or 2 segments
22819	Kyphectomy, circumferential exposure of spine and resection of vertebral segment(s) (including body and posterior elements); 3 or more segments
22830	Exploration of spinal fusion
22840	Posterior non-segmental instrumentation (e.g., Harrington rod technique, pedicle fixation across 1 interspace, atlantoaxial transarticular screw fixation, sublaminar wiring at C1, facet screw fixation) (List separately in addition to code for primary procedure)
22841	Internal spinal fixation by wiring of spinous processes (List separately in addition to code for primary procedure)
22842	Posterior segmental instrumentation (e.g., pedicle fixation, dual rods with multiple hooks and sublaminar wires); 3 to 6 vertebral segments (List separately in addition to code for primary procedure)
22843	Posterior segmental instrumentation (e.g., pedicle fixation, dual rods with multiple hooks and sublaminar wires); 7 to 12 vertebral segments (List separately in addition to code for primary procedure)
22844	Posterior segmental instrumentation (e.g., pedicle fixation, dual rods with multiple hooks and sublaminar wires); 13 or more vertebral segments (List separately in addition to code for primary procedure)
22845	Anterior instrumentation; 2 to 3 vertebral segments (List separately in addition to code for primary procedure)
22846	Anterior instrumentation; 4 to 7 vertebral segments (List separately in addition to code for primary procedure)

CPT Code	Description
22847	Anterior instrumentation; 8 or more vertebral segments (List separately in addition to code for primary procedure)
22848	Pelvic fixation (attachment of caudal end of instrumentation to pelvic bony structures) other than sacrum (List separately in addition to code for primary procedure)
22849	Reinsertion of spinal fixation device
22850	Removal of posterior nonsegmental instrumentation (e.g., Harrington rod)
22852	Removal of posterior segmental instrumentation
22853	Insertion of interbody biomechanical device(s) (e.g., synthetic cage, mesh) with integral anterior instrumentation for device anchoring (e.g., screws, flanges), when performed, to intervertebral disc space in conjunction with interbody arthrodesis, each interspace (List separately in addition to code for primary procedure)
22854	Insertion of intervertebral biomechanical device(s) (e.g., synthetic cage, mesh) with integral anterior instrumentation for device anchoring (e.g., screws, flanges), when performed, to vertebral corpectomy(ies) (vertebral body resection, partial or complete) defect, in conjunction with interbody arthrodesis, each contiguous defect (List separately in addition to code for primary procedure)
22855	Removal of anterior instrumentation
22859	Insertion of intervertebral biomechanical device(s) (e.g., synthetic cage, mesh, methylmethacrylate) to intervertebral disc space or vertebral body defect without interbody arthrodesis, each contiguous defect (List separately in addition to code for primary procedure)
22867	Insertion of interlaminar/interspinous process stabilization/distraction device, without fusion, including image guidance when performed, with open decompression, lumbar; single level
22868	Insertion of interlaminar/interspinous process stabilization/distraction device, without fusion, including image guidance when performed, with open decompression, lumbar; second level (List separately in addition to code for primary procedure)
22869	Insertion of interlaminar/interspinous process stabilization/distraction device, without open decompression or fusion, including image guidance when performed, lumbar; single level
22870	Insertion of interlaminar/interspinous process stabilization/distraction device, without open decompression or fusion, including image guidance when performed, lumbar; second level (List separately in addition to code for primary procedure)
22899	Unlisted procedure, spine
62380	Endoscopic decompression of spinal cord, nerve root(s), including laminotomy, partial facetectomy, foraminotomy, discectomy and/or excision of herniated intervertebral disc, 1 interspace, lumbar
63001	Laminectomy with exploration and/or decompression of spinal cord and/or cauda equina, without facetectomy, foraminotomy or discectomy (e.g., spinal stenosis), 1 or 2 vertebral segments; cervical
63003	Laminectomy with exploration and/or decompression of spinal cord and/or cauda equina, without facetectomy, foraminotomy or discectomy (e.g., spinal stenosis), 1 or 2 vertebral segments; thoracic
63005	Laminectomy with exploration and/or decompression of spinal cord and/or cauda equina, without facetectomy, foraminotomy or discectomy (e.g., spinal stenosis), 1 or 2 vertebral segments; lumbar, except for spondylolisthesis
63011	Laminectomy with exploration and/or decompression of spinal cord and/or cauda equina, without facetectomy, foraminotomy or discectomy (e.g., spinal stenosis), 1 or 2 vertebral segments; sacral
63012	Laminectomy with removal of abnormal facets and/or pars inter-articularis with decompression of cauda equina and nerve roots for spondylolisthesis, lumbar (Gill type procedure)
63015	Laminectomy with exploration and/or decompression of spinal cord and/or cauda equina, without facetectomy, foraminotomy or discectomy (e.g., spinal stenosis), more than 2 vertebral segments; cervical

CPT Code	Description
63016	Laminectomy with exploration and/or decompression of spinal cord and/or cauda equina, without facetectomy, foraminotomy or discectomy (e.g., spinal stenosis), more than 2 vertebral segments; thoracic
63017	Laminectomy with exploration and/or decompression of spinal cord and/or cauda equina, without facetectomy, foraminotomy or discectomy (e.g., spinal stenosis), more than 2 vertebral segments; lumbar
63020	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc; 1 interspace, cervical
63030	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc; 1 interspace, lumbar
63035	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc; each additional interspace, cervical or lumbar (List separately in addition to code for primary procedure)
63040	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc, reexploration, single interspace; cervical
63042	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc, reexploration, single interspace; lumbar
63043	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc, reexploration, single interspace; each additional cervical interspace (List separately in addition to code for primary procedure)
63044	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc, reexploration, single interspace; each additional lumbar interspace (List separately in addition to code for primary procedure)
63045	Laminectomy, facetectomy and foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s], [e.g., spinal or lateral recess stenosis]), single vertebral segment; cervical
63046	Laminectomy, facetectomy and foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s], [e.g., spinal or lateral recess stenosis]), single vertebral segment; thoracic
63047	Laminectomy, facetectomy and foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s], [e.g., spinal or lateral recess stenosis]), single vertebral segment; lumbar
63048	Laminectomy, facetectomy and foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s], [e.g., spinal or lateral recess stenosis]), single vertebral segment; each additional segment, cervical, thoracic, or lumbar (List separately in addition to code for primary procedure)
63050	Laminoplasty, cervical, with decompression of the spinal cord, 2 or more vertebral segments
63051	Laminoplasty, cervical, with decompression of the spinal cord, 2 or more vertebral segments; with reconstruction of the posterior bony elements (including the application of bridging bone graft and non-segmental fixation devices [eg, wire, suture, mini-plates], when performed)
63055	Transpedicular approach with decompression of spinal cord, equina and/or nerve root(s) (e.g., herniated intervertebral disk), single segment; thoracic
63056	Transpedicular approach with decompression of spinal cord, equina and/or nerve root(s) (e.g., herniated intervertebral disk), single segment; lumbar (including transfacet, or lateral extraforaminal approach) (e.g., far lateral herniated intervertebral disk)

CPT Code	Description
63057	Transpedicular approach with decompression of spinal cord, equina and/or nerve root(s) (e.g., herniated intervertebral disk), single segment; each additional segment, thoracic or lumbar (List separately in addition to code for primary procedure)
63064	Costovertebral approach with decompression of spinal cord or nerve root(s), (e.g., herniated intervertebral disk), thoracic; single segment
63066	Costovertebral approach with decompression of spinal cord or nerve root(s), (e.g., herniated intervertebral disk), thoracic; each additional segment (List separately in addition to code for primary procedure)
63075	Discectomy, anterior, with decompression of spinal cord and/or nerve root(s), including osteophytectomy; cervical, single interspace
63076	Discectomy, anterior, with decompression of spinal cord and/or nerve root(s), including osteophytectomy; cervical, each additional interspace (List separately in addition to code for primary procedure)
63077	Discectomy, anterior, with decompression of spinal cord and/or nerve root(s), including osteophytectomy; thoracic, single interspace
63078	Discectomy, anterior, with decompression of spinal cord and/or nerve root(s), including osteophytectomy; thoracic, each additional interspace (List separately in addition to code for primary procedure)
63081	Vertebral corpectomy (vertebral body resection), partial or complete, anterior approach with decompression of spinal cord and/or nerve root(s); cervical, single segment
63082	Vertebral corpectomy (vertebral body resection), partial or complete, anterior approach with decompression of spinal cord and/or nerve root(s); cervical, each additional segment (List separately in addition to code for primary procedure)
63085	Vertebral corpectomy (vertebral body resection), partial or complete, transthoracic approach with decompression of spinal cord and/or nerve root(s); thoracic, single segment
63086	Vertebral corpectomy (vertebral body resection), partial or complete, transthoracic approach with decompression of spinal cord and/or nerve root(s); thoracic, each additional segment (List separately in addition to code for primary procedure)
63087	Vertebral corpectomy (vertebral body resection), partial or complete, combined thoracolumbar approach with decompression of spinal cord, cauda equina or nerve root(s), lower thoracic or lumbar; single segment
63088	Vertebral corpectomy (vertebral body resection), partial or complete, combined thoracolumbar approach with decompression of spinal cord, cauda equina or nerve root(s), lower thoracic or lumbar; each additional segment (List separately in addition to code for primary procedure)
63090	Vertebral corpectomy (vertebral body resection), partial or complete, transperitoneal or retroperitoneal approach with decompression of spinal cord, cauda equina or nerve root(s), lower thoracic, lumbar, or sacral; single segment
63091	Vertebral corpectomy (vertebral body resection), partial or complete, transperitoneal or retroperitoneal approach with decompression of spinal cord, cauda equina or nerve root(s), lower thoracic, lumbar, or sacral; each additional segment (List separately in addition to code for primary procedure)
63101	Vertebral corpectomy (vertebral body resection), partial or complete, lateral extracavitary approach with decompression of spinal cord and/or nerve root(s) (e.g., for tumor or retropulsed bone fragments); thoracic, single segment
63102	Vertebral corpectomy (vertebral body resection), partial or complete, lateral extracavitary approach with decompression of spinal cord and/or nerve root(s) (e.g., for tumor or retropulsed bone fragments); lumbar, single segment
63103	Vertebral corpectomy (vertebral body resection), partial or complete, lateral extracavitary approach with decompression of spinal cord and/or nerve root(s) (e.g., for tumor or retropulsed bone fragments); thoracic or lumbar, each additional segment (List separately in addition to code for primary procedure)

CPT Code	Description
63170	Laminectomy with myelotomy (e.g., Bischof or DREZ type), cervical, thoracic, or thoracolumbar
63172	Laminectomy with drainage of intramedullary cyst/syrinx; to subarachnoid space
63173	Laminectomy with drainage of intramedullary cyst/syrinx; to peritoneal or pleural space
63180	Laminectomy and section of dentate ligaments, with or without dural graft, cervical; 1 or 2 segments
63182	Laminectomy and section of dentate ligaments, with or without dural graft, cervical; more than 2 segments
63185	Laminectomy with rhizotomy; 1 or 2 segments
63190	Laminectomy with rhizotomy; more than 2 segments
63191	Laminectomy with section of spinal accessory nerve
63194	Laminectomy with cordotomy, with section of 1 spinothalamic tract, 1 stage; cervical
63195	Laminectomy with cordotomy, with section of 1 spinothalamic tract, 1 stage; thoracic
63196	Laminectomy with cordotomy, with section of both spinothalamic tracts, 1 stage; cervical
63197	Laminectomy with cordotomy, with section of both spinothalamic tracts, 1 stage; thoracic
63198	Laminectomy with cordotomy with section of both spinothalamic tracts, 2 stages within 14 days; cervical
63199	Laminectomy with cordotomy with section of both spinothalamic tracts, 2 stages within 14 days; thoracic
63200	Laminectomy, with release of tethered spinal cord, lumbar
63250	Laminectomy for excision or occlusion of arteriovenous malformation of spinal cord; cervical
63251	Laminectomy for excision or occlusion of arteriovenous malformation of spinal cord; thoracic
63252	Laminectomy for excision or occlusion of arteriovenous malformation of spinal cord; thoracolumbar
63265	Laminectomy for excision or evacuation of intraspinal lesion other than neoplasm, extradural; cervical
63266	Laminectomy for excision or evacuation of intraspinal lesion other than neoplasm, extradural; thoracic
63267	Laminectomy for excision or evacuation of intraspinal lesion other than neoplasm, extradural; lumbar
63268	Laminectomy for excision or evacuation of intraspinal lesion other than neoplasm, extradural; sacral
63270	Laminectomy for excision of intraspinal lesion other than neoplasm, intradural; cervical
63271	Laminectomy for excision of intraspinal lesion other than neoplasm, intradural; thoracic
63272	Laminectomy for excision of intraspinal lesion other than neoplasm, intradural; lumbar
63275	Laminectomy for biopsy/excision of intraspinal neoplasm; extradural, cervical
63277	Laminectomy for biopsy/excision of intraspinal neoplasm; extradural, lumbar
63280	Laminectomy for biopsy/excision of intraspinal neoplasm; intradural, extramedullary, cervical
63282	Laminectomy for biopsy/excision of intraspinal neoplasm; intradural, extramedullary, lumbar
63285	Laminectomy for biopsy/excision of intraspinal neoplasm; intradural, intramedullary, cervical
63286	Laminectomy for biopsy/excision of intraspinal neoplasm; intradural, intramedullary, thoracic

CPT Code	Description
63287	Laminectomy for biopsy/excision of intraspinal neoplasm; intradural, intramedullary, thoracolumbar
63290	Laminectomy for biopsy/excision of intraspinal neoplasm; combined extradural-intradural lesion, any level
63300	Vertebral corpectomy (vertebral body resection), partial or complete, for excision of intraspinal lesion, single segment; extradural, cervical
63301	Vertebral corpectomy (vertebral body resection), partial or complete, for excision of intraspinal lesion, single segment; extradural, thoracic by transthoracic approach
63302	Vertebral corpectomy (vertebral body resection), partial or complete, for excision of intraspinal lesion, single segment; extradural, thoracic by thoracolumbar approach
63303	Vertebral corpectomy (vertebral body resection), partial or complete, for excision of intraspinal lesion, single segment; extradural, lumbar or sacral by transperitoneal or retroperitoneal approach
63304	Vertebral corpectomy (vertebral body resection), partial or complete, for excision of intraspinal lesion, single segment; intradural, cervical
63305	Vertebral corpectomy (vertebral body resection), partial or complete, for excision of intraspinal lesion, single segment; intradural, thoracic by transthoracic approach
63306	Vertebral corpectomy (vertebral body resection), partial or complete, for excision of intraspinal lesion, single segment; intradural, thoracic by thoracolumbar approach
63307	Vertebral corpectomy (vertebral body resection), partial or complete, for excision of intraspinal lesion, single segment; intradural, lumbar or sacral by transperitoneal or retroperitoneal approach
63308	Vertebral corpectomy (vertebral body resection), partial or complete, for excision of intraspinal lesion, single segment; each additional segment (List separately in addition to codes for single segment)

DESCRIPTION OF SERVICES

Lumbar spinal stenosis (LSS) is a narrowing of the spinal canal that compresses the neural elements in the lower back. It may be caused by trauma, tumor, infection, or congenital defects but is predominately caused by degenerative changes in the intervertebral discs and the ligaments and bone structures of the spine. These changes typically begin with a breakdown of the discs with consequent collapse of disc space, which leads to disc bulge and herniation, and transference of weight to the facet joints. This in turn leads to cartilage erosion and compensatory growth of new bone (bone spurs) over the facet joints as well as thickening of ligaments around the facet joints to help support the vertebrae (AAOS, 2013). Surgery may be performed if symptoms do not respond adequately to nonsurgical approaches and continue to cause poor quality of life (AANS, 2014; AAOS, 2013).

Spinal procedures with the goal of decompression and/or stabilization can be done with an open surgical approach or minimally invasively. Open procedures require larger incisions, muscle stripping, longer hospitalization and subsequent increased recovery time. There is no standard definition of minimally invasive surgical techniques. "Minimally invasive" may include the use of smaller incisions, stab incisions or portals for instrumentation. The advantages of using a smaller surgical incision are reduced postoperative pain, diminished blood loss, faster recovery and reduced hospital stays.

Spinal Fusion

Spinal fusion, also called arthrodesis, is a surgical technique that may be done as an open or minimally invasive procedure. There are many different approaches to spinal fusion, but all techniques involve removing the disc between two or more vertebrae and fusing the adjacent vertebrae together using bone grafts and/or spacers placed where the disc used to be. Spacers can be made of bone or bone substitutes, metal (titanium), carbon fiber, polymers or bioresorbable materials and are often supported by plates, screws, rods and/or cages.

Several minimally invasive spinal fusion procedures have been developed and include the following:

- **Laparoscopic anterior lumbar interbody fusion (LALIF)** is a minimally invasive alternative to an open surgical approach to spinal fusion. The vertebrae are reached through an incision in the lower abdomen or side. This method employs a laparoscope to remove the diseased disc and insert an implant (i.e., rhBMP, autogenous bone, cages or fixation devices) into the disc space intended to stabilize and promote fusion.
- **Transforaminal lumbar interbody fusion (TLIF)** is a modification of the posterior lumbar interbody fusion (PLIF) that gives unilateral access to the disc space to allow for fusion of the front and back of the lumbar spine.

The front portion of the spine is stabilized with the use of an interbody spacer and bone graft. The back portion is secured with pedicle screws, rods and additional bone graft. TLIF is performed through a posterior incision over the lumbar spine and can be done as an open or percutaneous procedure.

- **Axial lumbar interbody fusion (AxiaLIF ™)**, also called trans-sacral, transaxial or para-coccygeal interbody fusion, is a minimally invasive technique used in L5-S1 (presacral) spinal fusions. The technique provides access to the spine along the long axis of the spine, as opposed to anterior, posterior or lateral approaches. The surgeon enters the back through a very small incision next to the tailbone and the abnormal disc is taken out. Then a bone graft is placed where the abnormal disc was and is supplemented with a large metal screw. Sometimes, additional, smaller screws are placed through another small incision higher on the back for extra stability.
- **Interlaminar lumbar instrumented fusion (ILIF)** combines direct neural decompression with an allograft interspinous spacer to maintain the segmental distraction, and a spinous process fixation plate, or other fixation options such as cortical pedicle screws to maintain stability for eventual segmental fusion. (e.g., Coflex-F®)

Williams and Park (2007) address the presumed superiority of one minimally invasive approach over another as follows: "At this time, no particular approach and no particular minimally invasive technique of stabilization has been shown to be superior to others, and there are several good studies that show statistical equivalency between anterior lumbar antibody [sic] fusion (ALIF), posterior lumbar antibody [sic] fusion (PLIF), and posterolateral fusion with instrumentation."

Spinal Decompression and Interspinous Spacers

Interspinous process decompression (IPD) is a minimally invasive surgical procedure used to treat lumbar spinal stenosis when conservative treatment measures have failed to relieve symptoms. IPD involves surgically implanting a spacer between one or two affected spinous processes of the lumbar spine. After implantation the device is opened or expanded to distract (open) the neural foramen and decompress the nerves. Interlaminar spacers are implanted midline between adjacent lamina and spinous processes to provide dynamic stabilization following decompressive surgery. IPD is purported to block stenosis-related lumbar extension and, thus, relieve associated pain and allow resumption of normal posture.

The following is a list of some of the minimally invasive procedures that decompress (reduce) the pressure on the spinal or nerve root:

- The **X-STOP Interspinous Process Decompression (IPD) System** has been developed as part of a minimally invasive surgical method to treat lumbar spinal stenosis, an abnormal narrowing or constriction of spaces that provide pathways for spinal nerves. For many individuals this device can be implanted by an orthopedic surgeon under local anesthesia as an outpatient procedure, although in some circumstances, the physician may prefer to admit the patient for an inpatient stay. (Zucherman et al., 2004. Hayes Archived 2016)
- The **Coflex® Interlaminar Stabilization Device** is an implantable titanium interspinous process device (IPD) that reduces the amount of lumbar spinal extension possible while preserving range of motion in flexion, axial rotation, and lateral bending. The coflex is a U-shaped device with 2 pair of serrated wings extending from the upper and lower long arms of the U. The U portion is inserted horizontally between 2 adjacent spinous processes (bones) in the back of the spine, and the wings are crimped over bone to hold the implant in place. The device is implanted after decompression of stenosis at the affected level(s). (Paradigm Spine, 2013)
- **Image-guided minimally invasive lumbar decompression (MILD®)** is a percutaneous procedure for decompression of the central spinal canal in individuals with lumbar spinal stenosis. The mild Device Kit (Vertos Medical Inc.) is a sterile, single-use system of surgical instruments. After filling the epidural space with contrast medium, a cannula is clamped in place with a back plate and a rongeur, tissue sculpter and trocar are used to resect thickened ligamentum flavum and small pieces of lamina. The process may be repeated on the opposite side for bilateral decompression. (Vertos Medical, 2018)

Spinal Stabilization

The use of dynamic stabilization devices has been proposed as an alternative to rigid stabilization devices. Like standard frame devices, these devices are fixed in place using pedicle screws which are attached to the vertebral bodies adjacent to the intervertebral space being fused. Unlike standard frames, these devices are designed using flexible materials which purport to stabilize the joint while still providing some measure of flexibility.

- The **Dynesys® Dynamic Stabilization System** was designed as a means to provide stability during spinal fusion to stabilize the spine; however, is currently being investigated as a substitute for spinal fusion. The Dynesys Dynamic Stabilization System is intended for use in skeletally mature individuals as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the lumbar or sacral spine: degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudoarthrosis).
- **Total facet joint arthroplasty** is a non-fusion spinal implant developed to treat individuals with moderate to severe spinal stenosis.
- **Percutaneous sacroplasty** is a minimally invasive surgical treatment that attempts to repair sacral insufficiency fractures using polymethylmethacrylate (PMMA) bone cement. Sacral insufficiency fractures have traditionally

been treated with conservative measures, including bed rest, analgesics, orthoses/corsets and physical therapy. In some cases pain persists, and is refractory to these measures. These individuals are predominately elderly, and hardware implantation may not be possible in weakened bone. For this procedure, 2 thin, hollow tubes are placed in the lower back, over the left half and right half of the sacrum, guided by images from x-rays or computed tomography scans. The surgeon then advances a needle through each tube to the site of the sacral fracture and injects 2 to 5 mL of bone cement. (Hayes, 2018)

Facet Fusion

Facet syndrome as a cause of low back pain is less common than degenerative disc disease and is not a clearly identified source of back pain. Facet joints are the articulations or connections between the vertebrae. Nociceptive nerve fibers have been identified in the facet joint capsules, in synovial tissue and in pericapsular tissue. It is hypothesized that increased motion and instability of the motion segments can lead to stress on the facet joint capsule, ultimately leading to the production of pain. Pain is characterized as worsening in extension and easing with flexion; it may radiate to the lateral buttock and thigh.

Facet fusion is a procedure that uses an allograft to fuse the joint together to provide spinal column stability and pain reduction. Facet fusion has been proposed as a treatment option for individuals with facet joint pain that does not respond to conservative treatment. (Gellhorn, 2013)

CLINICAL EVIDENCE

Spinal Fusion

Lumbar spinal fusion has been shown to result in reduced pain and improved function in select patients. Minimally invasive techniques have been developed for intertransverse process, posterior lumbar interbody, and transforaminal lumbar interbody fusions. It is emphasized that while these less-invasive procedures appear promising, the clinical results of these techniques remain preliminary with few long-term studies available for critical review. The author concluded that preliminary clinical evidence suggests that minimally invasive lumbar fusion techniques will benefit patients with spinal disorders. This study has a relatively short follow-up period. More long-term studies are still indicated.

Laparoscopic Anterior Lumbar Interbody Fusion (LALIF)

Chung et al. (2003) compared perioperative parameters and minimum 2-year follow-up outcome for laparoscopic and open anterior surgical approach for L5-S1 fusion. The data of 54 consecutive patients who underwent anterior lumbar interbody fusion (ALIF) of L5-S1 from 1997 to 1999 were collected prospectively. More than 2-years' follow-up data were available for 47 of these patients. In all cases, carbon cage and autologous bone graft were used for fusion. Twenty-five patients underwent a laparoscopic procedure and 22 an open mini-ALIF. Three laparoscopic procedures were converted to open ones. For perioperative parameters only, the operative time was statistically different while length of postoperative hospital stay and blood loss were not. The incidence of operative complications was three in the laparoscopic group and two in the open mini-ALIF group. After a follow-up period of at least 2 years, the two groups showed no statistical difference in pain, measured by visual analog scale, in the Oswestry Disability Index or in the Patient Satisfaction Index. The fusion rate was 91% in both groups. The laparoscopic ALIF for L5-S1 showed similar clinical and radiological outcome when compared with open mini-ALIF, but significant advantages were not identified.

Evidence in the peer-reviewed scientific literature evaluating laparoscopic anterior lumbar interbody fusion is primarily in the form of prospective and retrospective case series, comparative trials, and nonrandomized trials. Authors have commented on the technical difficulty of this method and the associated learning curve, although as the surgeons experience increases in most studies, the operative time decreases. There is some evidence to support less blood loss and a tendency toward shorter hospital stay when LALIF is performed for single-level anterior fusion; however, there is a paucity of evidence to support improved outcomes in multilevel procedures. Currently, the published, peer-reviewed scientific literature does not allow strong conclusions regarding the overall benefit and long-term efficacy of the laparoscopic approach compared to open spinal fusion.

Transforaminal Lumbar Interbody Fusion (TLIF)

Transforaminal lumbar interbody fusion utilizing endoscopy, sometimes referred to as minimally invasive transforaminal interbody fusion (MITLIF), is essentially the same as an open transforaminal interbody fusion (TLIF) except that it is performed through smaller incisions using specialized retractors that gradually open an operative corridor through the muscles rather than pulling the muscles aside as with conventional open surgery. This approach requires a percutaneous incision with video visualization of the spine to perform TLIF. Specialized instruments are advanced through a retractor resulting in fewer traumas to soft tissues, which may result in reduced operative time and hospitalization.

Although operative time, blood loss and hospitalization were lower for MITLIF compared with more traditional procedures, there was little difference between MITLIF and open TLIF. Overall the evidence is insufficient to demonstrate long-term safety and effectiveness of MITLIF, or to determine whether this technique is equivalent to open TLIF or more established surgeries such as anterior-posterior lumbar interbody fusion (APLIF) and posterior lumbar interbody fusion (PLIF).

A Hayes technology report (2018) stated that low-quality evidence from direct comparisons for MITLIF may offer benefit over OTLIF on some clinical and safety outcomes, as well as certain perioperative measures. However, due to the lack of good-quality randomized controlled trials with sufficient duration of follow-up, the balance of benefits and harms between MITLIF and OTLIF remains unclear, and the superiority or equivalence of MITLIF has not yet been definitively established.

A retrospective study by Price et al. (2017) compared clinical results and radiographic outcomes of minimally invasive surgery (MIS) versus open techniques for transforaminal lumbar interbody fusion (TLIF). A consecutive series of 452 1 or 2-level TLIF patients at a single institution between 2002 and 2008 were analyzed. A total of 148 were MIS patients and 304 were open. Oswestry disability index (ODI) and visual analog (VAS) pain scores were documented preoperatively and postoperatively. Fusion was at a minimum of 1 year follow-up. The author's concluded MIS TLIF produces comparable clinical and radiologic outcomes to open TLIF with the benefits of decreased intraoperative blood losses, shorter operative times, shorter hospital stays and fewer deep wound infections. Results are limited by study design, and lack of a control. Further prospective studies investigating long-term functional results are required to assess the definitive merits of percutaneous instrumentation of the lumbar spine.

A retrospective study by Villavicencio et al. (2010) compared minimally invasive (n=76) and open (n=63) approaches for transforaminal lumbar interbody fusion (TLIF) in patients with painful degenerative disc disease with or without disc herniation, spondylolisthesis, and/or stenosis at one or two spinal levels. Outcomes were measured using visual analog scale (VAS), patient satisfaction, and complications. Average follow-up was 37.5 months. Postoperative change in mean VAS was 5.2 in the open group and 4.1 in the minimally invasive group. Overall patient satisfaction was 72.1% in the open group versus 64.5% in the minimally invasive group. The total rate of neurological deficit was 10.5% in the minimally invasive TLIF group compared to 1.6% in the open group. The authors concluded that open and minimally invasive approaches for transforaminal lumbar interbody fusion have equivalent outcomes; however, the rate of neural injury related complications in the minimally invasive approach must be considered when selecting patients for surgery.

Park and Foley (2008) discussed their retrospective review study results in 40 consecutive patients who underwent MI-TLIF for symptomatic spondylolisthesis utilizing this approach. Thirty cases involved a degenerative spondylolisthesis while the remaining 10 were isthmic. The minimum follow-up was 24 months with a mean of 35 months. The authors conclude that MI-TLIF for symptomatic spondylolisthesis appears to be an effective surgical option with results that compare favorably to open procedures. Results are limited by study design, small patient numbers and lack of a control.

Professional Societies

American Association of Neurological Surgeons/Congress of Neurological Surgeons (AANS/CNS)

The AANS/CNS published a guideline update in 2014 on the performance of fusion procedures for degenerative disease of the lumbar spine, with part of the guideline update focused on. This guideline did not offer any specific recommendations pertaining to TLIF in general or MITLIF specifically. The authors indicated that there was no conclusive evidence of superior clinical or radiographic outcomes based on technique when performing interbody fusion. Therefore, no general recommendations were offered regarding the technique that should be used to achieve interbody fusion. The authors also noted that they did not analyze any comparisons of minimally invasive surgery (MIS) versus traditional open surgery in this report (Mummaneni et al., 2014).

North American Spine Society (NASS)

NASS published clinical guidelines for treatment of adult isthmic spondylolisthesis (Kreiner et al., 2014) and degenerative spondylolisthesis (Matz et al., 2014). These guidelines did not offer any specific recommendations pertaining to the use of MITLIF versus OTLIF procedures. However, both guidelines recommend the development of randomized controlled trials or prospective comparative studies comparing MIS versus traditional open surgical techniques in adult patients with these conditions (Kreiner et al., 2014; Matz et al., 2014). In addition, NASS recommends that future studies provide clear and consistent definitions of what MIS techniques entail (Matz et al., 2014).

Lateral Interbody Fusion (Direct Lateral [DLIF], Extreme Lateral [XLIF®])

Open lateral approaches have historically been considered a well-established method of performing spinal surgery for indications such as treatment of spinal tumors or fractures. Lateral interbody fusion differs from standard approaches in that the spine is approached from the side (lateral), rather than through the abdominal cavity (anterior) or the back

(posterior). Direct lateral interbody fusion (DLIF) uses a similar approach as XLIF. During a direct lateral or extreme lateral approach, a narrow passageway is created through the underlying tissues and the psoas muscle using tubular dilators, without cutting the muscle; which is the major difference between the open approach and lateral approach. The interbody device and bone graft are inserted via the tubular dilator. Neuromonitoring is performed for identification of spinal nerve roots. In some cases, it is necessary to remove part of the iliac crest. The procedure is generally indicated for interbody fusion at the lower levels of the spine (e.g., L1-L5 levels) and is considered a modification to the lateral retroperitoneal approach utilized for other spinal surgery and an alternative to posterior lumbar interbody fusion (PLIF), transforaminal lumbar interbody fusion (TLIF).

A 2017 Hayes literature search identified 5 comparative clinical studies that evaluated the efficacy and safety of XLIF for the treatment of chronic LBP in adults with degenerative spinal disorders. XLIF appears to be efficacious in improving pain, disability, and quality of life. Substantial uncertainty remains due to conflicting safety and reoperation data and a lack of sufficiently powered, rigorous, comparative evidence demonstrating clinical equivalence or benefit.

A 2012 study examining the clinical outcome and fusion rates of 30 XLIF procedures (Malham et al., 2012) evaluated pain, disability, and quality of life. CT assessment of fusion was also performed. Average follow up time was 11.5 months. Complications were observed: clinical subsidence, cage breakage upon insertion, new postoperative motor deficit and bowel injury. Approach side-effects were radiographic subsidence and anterior thigh sensory changes. Two patients required reoperation; microforaminotomy and pedicle screw fixation respectively. VAS back and leg pain decreased 63% and 56%, respectively. ODI improved 41.2% with 51.3% and 8.1% improvements in PCS and MCS. Complete fusion (last follow-up) was observed in 85%. The authors felt XLIF does provide superior treatment, clinical outcomes, and fusion rates compared to conventional surgical approaches. However, they caution surgical mentor supervision for early cases.

Evidence in the published scientific literature, textbooks and guidelines from professional organizations supports lumbar fusion as an established standard of treatment for a selected group of patients with low back pain. Data comparing DLIF/XLIF to other traditional or minimally invasive approaches to interbody fusion is limited therefore no conclusions can be drawn regarding efficacy compared to other standard surgical approaches. While additional clinical trials are necessary to demonstrate impact on meaningful long-term clinical outcomes, the published evidence suggests in the short- to intermediate-term lateral interbody fusion is safe and effective as an alternative to anterior or posterior fusion approaches. In addition, although there are no formal professional society statements supporting lateral interbody fusion in the form of XLIF or DLIF, the North American Spine Society (NASS, 2014) indicates these methods are a modified standard approach for lateral interbody fusion.

Professional Societies/Position Statements

American Association of Neurological Surgeons/Congress of Neurological Surgeons (AANS/CNS)

In an evidence-based guideline on interbody fusion procedures for degenerative disease of the lumbar spine, AANS/CNS states that there is insufficient evidence to recommend a treatment standard (Resnick et al., 2014). Lateral interbody fusion (including its synonyms) is not mentioned.

National Institute for Health and Care Excellence (NICE)

NICE defines lateral interbody spinal fusion as a procedure that removes all or part of the damaged disk and inserts a supporting structure, with the objective of fusing 2 vertebrae to prevent painful joint motion through an incision in the patient's side (NICE, 2017). In its evidence-based draft recommendations, NICE states that current evidence on the safety of lateral (extreme, extra, and direct lateral) interbody fusion in the lumbar spine for LBP shows that there are serious recognized complications, although evidence on efficacy is adequate in quality and quantity. The procedure may be used if arrangements are provided for clinical governance, audit, and consent.

Axial Lumbar Interbody Fusion (AxiaLIF)

Evidence from case series in one systematic review and one additional case series (not in the systematic review) is at too high a risk of bias to support conclusions on safety and effectiveness of one-level lumbar interbody fusion or L5-S1 spondylolisthesis or spondylosis with AxiaLIF. Multicenter randomized controlled trials (RCTs) comparing AxiaLIF to traditional interbody approaches are needed to assess AxiaLIF for one- and two-level interbody fusions and to compare axial lumbar interbody fusion with other surgical approaches. Improvement in net health outcomes has not been clearly demonstrated when compared to standard surgical methods, and it remains unclear whether this surgical technique results in clinical benefits that are as good as or superior to standard surgical techniques. The evidence is insufficient to allow any conclusions regarding short- or long-term clinical benefits, possible complications, failure rates, relief of symptoms, improvement in functional levels, and the need for further surgery. (ECRI, November 2018).

Schroeder et al. (2015) performed a systematic review of seventy-four articles discussing safety profile of axial interbody arthrodesis, but only 15 (13 case series and 2 retrospective cohort studies) met the study inclusion criteria. The authors concluded that review of the literature indicates that an axial interbody fusion performed at the lumbosacral junction is associated with a high fusion rate (93.15%) and an acceptable complication rate (12.90%).

However, these results are based mainly on retrospective case series by authors with a conflict of interest. The limited prospective data available indicate that the actual fusion rate may be lower and the complication rate may be higher than currently reported.

Zeilstra et al (2013) reported their 6-year single-center experience with L5-S1 axial lumbar interbody fusion (AxiaLIF). A total of 131 patients with symptomatic degenerative disc disease refractory to non-surgical treatment were treated with AxiaLIF at L5-S1, and were followed for a minimum of 1 year. Main outcomes included back and leg pain severity, Oswestry Disability Index score, working status, analgesic medication use, patient satisfaction, and complications. Back and leg pain severity decreased by 51 % and 42 %, respectively, during the follow-up period. Back function scores improved 50 % compared to baseline. The authors concluded that single-level AxiaLIF is a safe and effective means to achieve lumbosacral fusion in patients with symptomatic degenerative disc disease. Moreover, they noted that "Our study is limited by the retrospective nature of the analysis. Additionally, all patients underwent fusion at L5 to S1 and, therefore, no conclusions can be drawn regarding the effectiveness or safety of 2-level AxiaLIF from this report. Lastly, mean patient follow-up was 21 months. Although this represents one of the longest follow-up reports following AxiaLIF surgery, long-term clinical and radiographic outcomes are unknown."

In a 5-year post-marketing surveillance study, Gundanna et al. (2011) reported complications associated with axial presacral lumbar interbody fusion in 9152 patients. A single-level L5-S1 fusion was performed in 8034 patients (88%), and a two-level L4-S1 fusion was performed in 1118 patients (12%). Complications were reported in 1.3% of patients with the most commonly reported complications being bowel injury (0.6%) and transient intraoperative hypotension (0.2%). Other complications noted include superficial wound and systemic infections, migration, subsidence, presacral hematoma, sacral fracture, vascular injury, nerve injury and ureter injury. The overall complication rate was similar between single-level (1.3%) and two-level (1.6%) fusion procedures, with no significant differences noted for any single complication. The authors concluded that the overall complication rates compare favorably with those reported in trials of open and minimally invasive lumbar fusion surgery.

Tobler and Ferrara (2011) conducted a prospective evaluation study (n=26) to determine clinical outcomes, complications and fusion rates following axial lumbar interbody fusion. Single-level (L5-S1) fusions were performed in 17 patients and two-level (L4-S1) fusions were performed in 9 patients. Significant reductions in pain and disability occurred as early as three weeks postoperatively and were maintained. Fusion was achieved in 92% of patients at 12 months and in 96% of patients at 24 months. One patient underwent successful revision. The authors reported no severe adverse events and clinical outcomes and fusion rates comparable to other methods of interbody fusion. Further results from larger, prospective studies are needed to determine long-term efficacy.

Professional Societies/Position Statements

American Association of Neurological Surgeons (AANS)/Congress of Neurological Surgeons (CNS)

AANS and CNS have jointly published a series of guidelines addressing fusion for degenerative disease of the lumbar spine (2014). Surgical decompression is recommended for patients with symptomatic neurogenic claudication due to lumbar stenosis without spondylolisthesis who elect to undergo surgical intervention. In the absence of deformity or instability, lumbar fusion has not been shown to improve outcomes in patients with isolated stenosis, and therefore it is not recommended.

National Institute for Health and Clinical Excellence (NICE)

The National Institute for Health and Clinical Excellence (NICE) states that current evidence on the efficacy of transaxial interbody lumbosacral fusion is limited in quantity but shows symptom relief in the short term in some patients. Evidence on safety shows that there is a risk of rectal perforation. Therefore this procedure should only be used with special arrangements for clinical governance, consent and audit or research. NICE encourages further research into transaxial interbody lumbosacral fusion (NICE, 2011).

North American Spine Society (NASS)

NASS published guidelines on the treatment of degenerative spondylolisthesis in 2014. This guideline did not address axial lumbosacral interbody fusion (AxiaLIF).

Australian Safety and Efficacy Register of New Interventional Procedures – Surgical (ASERNIP-S)

An assessment of the AxiaLIF procedure by the Australian Safety and Efficacy Register of New Interventional Procedures – Surgical (ASERNIP-S) (Leopardi, 2010) noted the lack of high quality studies of the AxiaLIF procedure and the need for long-term studies. The assessment concluded: "Overall, the AxiaLIF procedure appears to offer some symptom improvement in patients suffering from back pain, without major compromise to their safety. High-quality comparative studies are needed to completely assess the safety and efficacy of the AxiaLIF procedure."

Spinal Decompression and Interspinous Process Decompression Systems

Interspinous Process Decompression (IPD) Systems

The evidence for interspinous or interlaminar spacers as a stand-alone treatment in individuals who have spinal stenosis and up to grade I spondylolisthesis includes several randomized controlled trials (RCTs). Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Overall, use of interspinous or interlaminar distraction devices (spacers) used as an alternative to spinal decompression show high failure and complication rates. Greater certainty about the net health benefit of these devices may be obtained when recently completed and moderately sized RCT on decompression with and without the implants are published. The evidence at this time is insufficient to determine the effects of the technology on health outcome.

A 2015 meta-analysis by Hong et al. included 20 studies with 3,155 patients in the interspinous spacers group and 50,983 patients treated with open decompression. Results of this meta-analysis were similar to those obtained in the more selective analysis by Wu et al. There was no significant difference between the 2 procedures for improvement rate, Oswestry Disability Index (ODI), or visual analog scale (VAS) for back or leg pain. Although secondary outcomes such as operative and hospitalization time, perioperative blood loss, and postoperative complication rate were superior in the spacer group, reoperation rate was higher in that group (16.5% vs 8.7%). Because of the higher reoperation rate the authors concluded that, while the use of spacers may be a viable technique, they could not conclude that it had replaced open decompression surgery as the gold standard for treatment of lumbar spinal stenosis.

In 2014, Wu et al. conducted a meta-analysis of 2 RCTs and 3 non-randomized prospective comparative studies. There were 204 patients in the interspinous spacer group and 217 patients in the decompressive surgery group. Pooled analysis showed no significant difference at 12 and 24 months between the spacer and decompression groups for low back pain, leg pain, ODI, Roland Disability Questionnaire (RDQ) or complications. However, the traditional decompressive surgery group had a significantly lower incidence of reoperation, with 11 of 160 cases requiring reoperation compared to 31 of 161 cases in the interspinous spacer group. Several limitations to this meta-analysis were listed, with the primary concern being the small number of studies in the published literature comparing spacers and traditional decompression surgery. Although risk of bias was analyzed, no narrative critical appraisal of the included articles was provided. The authors noted the high reoperation rate associated with spacer use and stated that the indications, risks, and benefits of these devices required careful consideration before surgery.

X-STOP

In 2015, Lonne et al. reported a trial of X-STOP versus minimally invasive decompression in 96 patients with symptoms of neurogenic intermittent claudication relieved on flexion. Intention-to-treat analysis showed no significant differences between the groups in primary and secondary outcome measures at up to 2-year follow-up. However, the number of patients having secondary surgery due to persistent or recurrent symptoms was significantly higher in the X-STOP group. The study was terminated after planned mid-term analysis due to the higher reoperation rate with X-STOP.

In 2015, 2- and 3-year results were published from an FDA-regulated, multicenter randomized, investigational device exemption (IDE), non-inferiority trial comparing the Superion interspinous spacer with the X-STOP. A total of 391 patients with intermittent neurogenic claudication despite 6 months of nonsurgical management were enrolled, randomized, and implanted with either Superion or X-STOP spacers, and followed for 2 years. The primary end point was a composite of clinically significant improvement in at least 2 of 3 ZCQ domain scores compared with baseline, freedom from reoperation, revision, removal, or supplemental fixation at the index level, freedom from epidural steroid injection or nerve block within 12 weeks of the 2-year visit, freedom from rhizotomy or spinal cord stimulator at any level, and freedom from major implant or procedure-related complications. The primary noninferiority end point was met, with a Bayesian posterior probability of 0.993. However, 111 patients (28%; 54 Superion, 57 XSTOP) were withdrawn from the study during follow-up due to a protocol-defined secondary intervention.

At 3-year follow-up, there were 120 patients in the Superion ISS group and 129 in the X-STOP group remaining (64% of 391). Of these, composite clinical success was obtained in 52.5% of patients in the Superion ISS group and 38.0% of the X-STOP group (p=0.023). The 36-month clinical outcomes were reported for 82 patients in the Superior ISS group and 76 patients in the X-STOP group (40% of 391). It is not clear from the report whether the remaining patients were lost to follow-up or were considered treatment failures and censured from the results. In addition, interpretation of this study is limited by questions about the efficacy of the comparator and lack of a control group treated by surgical decompression.

Puzzilli et al (2014) prospectively evaluated patients treated for symptomatic lumbar spinal stenosis with interspinous process decompression (IPD) implants compared with a population of patients managed with conservative treatment in a multicenter study. 542 patients affected by symptomatic lumbar spine degenerative disease were enrolled in a controlled trial. 422 patients underwent surgical treatment consisting of X-STOP device implantation, whereas 120 control cases were managed conservatively. Both patient groups underwent follow-up evaluations at 6, 12, 24, and 36 months using the Zurich Claudication Questionnaire, the Visual Analog Scale score and spinal lumbar X-rays, CT scans

and MR imaging. One-year follow-up evaluation revealed positive good results in the 83.5% of patients treated with IPD with respect to 50% of the nonoperative group cases. In 24 of 422 patients, the IPD device had to be removed, and a decompression and/or pedicle screw fixation was performed because of the worsening of neurological symptoms. The authors concluded results support the effectiveness of surgery in patients with stenosis. IPD may offer an effective and less invasive alternative to classical microsurgical posterior decompression in selected patients with spinal stenosis and lumbar degenerative disk diseases.

Hartjen et al. (2013) conducted a multicenter, prospective comparative study to assess the efficacy and safety of X-STOP in 55 patients with LSS. There were 2 groups: patients who were new study participants and patients from a prior RCT (Zucherman et al., 2005) who did not respond to nonsurgical management and crossed over to treatment with the X-STOP Outcomes were pain and disability assessed by the ZCQ and SF-36. Patients were evaluated at 6 weeks, 6 months, 12 months, and 2 years.

- At 2 years, 61% of the patients had a significant improvement in the symptom severity domain and 60% had a significant improvement in the physical function domain of the ZCQ. At 2 years, there was a 24.5% improvement in the mean symptom severity domain and a 27.8% improvement in the mean physical function domain. According to the ZCQ patient satisfaction domain, 71% of the patients were at least somewhat satisfied with their surgical results.
- At 2 years, there was statistically significant improvement in the SF-36 Physical Component Summary score and the individual domains of physical function, role physical, bodily pain, vitality, and social function ($P<0.001$ for all outcomes). There was no significant improvement in the general health domain.
- The mean improvements in ZCQ and SF-36 scores were not as pronounced in the crossover group compared with the new participants.

Bjorn et al. (2013) reported the 2-year outcomes of a noninferiority randomized trial of 100 patients with symptomatic one- or two-level lumbar spinal stenosis with neurogenic claudication relieved on flexion. Patients were randomized in a 1:1 ratio to undergo either X-STOP implantation or conventional surgical decompression. At 6, 12, and 24 months follow-up, there was no significant difference in scores for symptoms and function, or for complication rates. Reoperation rates were significantly higher in the X-STOP group than in the decompression group. Long-term data is needed to determine the durability of treatment effects and to compare the long-term reoperation rates.

Nandakumar et al. (2013) reported 2-year follow up results of patients treated with the X-STOP for symptomatic spinal stenosis. 46 of 57 patients completed the ZCQ questionnaire at 2 years. Results found 70% were satisfied at 2-years with the surgery. Single level and double level insertions did not have significant difference in clinical outcome.

Miller and colleagues (2012) published the preliminary results of a multicenter randomized investigational device exemption (IDE) non-inferiority trial which was regulated by the FDA. A total of 166 individuals with moderate lumbar spinal stenosis (LSS) unresponsive to conservative care were treated randomly with the Superion (n=80) or X-STOP (n=86) interspinous spacer. Study participants were followed through 6 months post-treatment. At 6-month follow-up, the preliminary results suggest that the Superion interspinous spacer and the X-STOP each effectively alleviate pain and improve back function in individuals with moderate LSS who are unresponsive to conservative care. The complication rate was similar for both groups; 20 % for the Superion group and 20% for the X-STOP group. The FDA-mandated primary endpoint of this IDE clinical trial is 2 years, with post-market surveillance scheduled for 10 years.

Kabir et al. (2010) conducted a systematic review to evaluate the current biomechanical and clinical evidence on lumbar interspinous spacers (ISPs). The main outcome measure was clinical outcome assessment based on validated patient-related questionnaires. Biomechanical studies were analyzed to evaluate the effects of ISPs on the kinematics of the spine. The largest number of studies has been with the X-STOP device. The biomechanical studies with all the devices showed that ISPs have a beneficial effect on the kinematics of the degenerative spine. Apart from 2 randomized controlled trials, the other studies with the X-STOP device were not of high methodologic quality. Nevertheless, analysis of these studies showed that X-STOP may improve outcome when compared to nonoperative treatment in a select group of patients, aged 50 or over, with radiologically confirmed lumbar canal stenosis and neurogenic claudication. Studies on the other devices show satisfactory outcome to varying degrees. However, due to small number and poor design of the studies, it is difficult to clearly define indications for their use in lumbar degenerative disease. The authors concluded that lumbar ISPs may have a potential beneficial effect in a select group of patients with degenerative disease of the lumbar spine. However, further well-designed prospective trials are needed to clearly outline the indications for their use.

A study by Nandakumar et al. (2010) evaluated the effect of the X-STOP device on the dural sac in 48 patients with spinal stenosis. MRI scans pre- and postoperatively showed a mean increase in the dural sac area that was maintained 24 months after surgery. There was also a reduction in mean anterior disc height, from 5.9 to 4.1 mm at the instrumented level in single-level cases, from 7.7 to 6.1 mm in double-level cases caudally, and from 8.54 to 7.91 mm cranially. This was thought to be a result of the natural progression of spinal stenosis with aging. The mean lumbar spine motion was 21.7 degrees preoperatively and 23 degrees at 24 months in single-level cases. In double-

level cases, this was 32.1 degrees to 31.1 degrees. While these results show that the X-STOP device is effective in decompressing spinal stenosis, it does not significantly alter the range of motion of the lumbar spine at instrumented and adjacent levels.

Studies with long-term follow-up are needed to ascertain the clinical longevity and durability of any beneficial effects of the X-STOP device, and to evaluate safety. Definitive patient selection criteria for X-STOP therapy have not been established, and it remains unclear whether the efficacy and safety of the X-STOP device are sufficient to allow patients to undergo this treatment instead of decompression laminectomy.

A Hayes health technology brief found that while the results of available studies are promising, only one randomized controlled trial has been performed to determine whether X-STOP implantation provides better outcomes than conservative therapies. None of the studies involved more than 2 years of follow-up, and no controlled trials have been performed to compare the X-STOP IPD procedure with decompressive surgery (Archived January 2016).

Coflex

The literature search of the coflex interlaminar stabilization device that evaluated the efficacy and safety of the coflex Interlaminar Stabilization device for treating symptomatic LSS. An overall low-quality body of evidence suggests that the coflex device is associated with similar improvements in pain, function, and disability compared with fusion or decompression alone with up to 5-years follow-up and without substantial unique safety concerns. Study limitations such as an inadequate follow-up time, small sample size, retrospective design, or lack of a control group. Interstudy comparisons are hampered by heterogeneous patient populations, and differences in study design, treatment protocols, and comparators. Additional, high-quality studies are needed before definitive conclusions can be reached. (Hayes, 2018).

In a prospective, randomized multicenter study, Schmidt et al. (2018) reported on the 2-year results of a study comparing treatment with decompression with interlaminar stabilization with the coflex device to decompression alone in individuals with moderate to severe lumbar spinal stenosis at one or two adjacent levels. A total of 115 individuals were randomized to each arm. A composite clinical success (CCS) measure consisting of four components: ODI improvement > 15 points, survivorship with no secondary surgeries or lumbar injections, maintenance or improvement of neurological symptoms, and no device- or procedure-related severe AEs. At 24 months, there were no significant differences between the groups in the patient reported outcomes: the ODI scores, VAS back and neck pain scores and the Zürich Claudication Questionnaire. There were no significant differences in patient-reported outcomes between the groups. There were no significant differences in the primary outcome measures between the groups. However when the secondary measure outcome of subsequent epidural injections (4.5% in the D+ILS group versus 14.8% in the DA group) was included in the CCS, the result became significant.

NASS (2018) reviewed this study and noted: Overall, the results of this study on a strict evidence-based medicine level can be summarized as not finding a significant difference in the primary outcome measure(s). However, when considering the significant difference in subsequent epidural injections, which is a secondary outcome measure, the composite clinical success score becomes different.

An updated systematic review by Machado and colleagues (2017) included three studies which compared interspinous process spacer devices to conventional decompression. The authors noted no studies directly compared spacers with decompression surgery, but were based on indirect comparisons. A total of 355 individuals were included in studies for the coflex and X-stop devices. The authors concluded that while surgery using the interspinous spacer devices resulted in less blood loss and shorter hospital stays when compared to fusion, use of the devices did not lead to improved outcomes when compared to decompression. In addition, interspinous spacer devices were associated with higher reoperation rates.

Musacchio et al. (2016) completed a prospective, randomized, controlled trial that was conducted at 21 centers. The purpose of this study was to investigate 5-year outcomes associated with an interlaminar device. Results of this 5-year follow-up study demonstrate that decompression and interlaminar stabilization with coflex is a viable alternative to traditional decompression and fusion in the treatment of patients with moderate to severe stenosis at one or two lumbar levels. Additional randomized, controlled studies are needed to clearly outline the indications for their use.

Moojen et al. (2015) completed a randomized double blind study in which interspinous process devices (IPDs) are implanted to treat patients with intermittent neurogenic claudication (INC) based on lumbar spinal stenosis. It is hypothesized that patients with lumbar spinal stenosis treated with IPD have a faster short-term recovery, an equal outcome after 2 years and less back pain compared with bony decompression. Five neurosurgical centers included participants. 211 participants were referred to the Leiden-The Hague Spine Prognostic Study Group. 159 participants with INC based on lumbar spinal stenosis at one or two levels with an indication for surgery were randomized into two groups. Patients and research nurses were blinded for the allocated treatment throughout the study period. 80 participants received an IPD and 79 participants underwent spinal bony decompression. The primary outcome at long-

term (2-year) follow-up was the score for the Zurich Claudication Questionnaire. Repeated measurement analyses were applied to compare outcomes over time. This double-blinded study could not confirm the advantage of IPD without bony decompression over conventional 'simple' decompression, two years after surgery. Moreover, in the IPD treatment arm, the reoperation rate was higher and back pain was even slightly more intense compared to the decompression treatment arm. The use of interspinous implants did not result in a better outcome than conventional decompression, and the reoperation rate was significantly higher.

2-year outcomes of double-blind RCT (the FELIX trial) comparing the use of the Coflex® spacer without bony decompression to surgical decompression were reported in 2015. Functional outcomes were measured by ZCQ and Modified Roland-Morris Disability Questionnaire (RMDS), and pain was measured with VAS and McGill Pain Questionnaire. All 159 participants had intermittent neurogenic claudication due to lumbar spinal stenosis. Surgery time was shorter, but reoperation rates due to absence of recovery were higher in the coflex group compared with the bony decompression group. For patients with 2-level surgery, the reoperation rate was 38% for coflex versus 6% for bony decompression. At 2 years, reoperations due to absence of recovery had been performed in 33% of the coflex group compared with 8% of the bony decompression group. VAS back pain at final follow-up was also higher in the coflex group. A number of methodological limitations were reported that limit interpretation and generalizability of the study findings. Differences may not have been found due to the lack of power, though the authors were not certain that a larger sample size would lead to a different study result. "To the contrary, the higher reoperation rate and the higher intensity of [low back pain] in the [spacer] group do suggest inferiority compared to classical decompression."

Richter et al. also published 2-year follow-up results for 60 patients who underwent decompressive surgery with or without implantation of the Coflex device. Though comparative, this study was not a randomized trial; treatment was allocated at the discretion of the surgeon. The authors reported no significant between-group differences in any outcome measures, and concluded that "additional placement of a Coflex™ interspinous device does not improve the already good clinical outcomes after decompression surgery for LSS in this 24-month follow up interval."

In a multicenter, randomized controlled manufacturer-funded Food and Drug Administration (FDA) Investigational Device Exemption (IDE) trial conducted in the United States, Davis et al. (2013) compared outcomes between decompression followed by coflex implantation and decompression followed by instrumented posterolateral spinal fusion in 322 patients (215 coflex and 107 fusions). Patients were stratified by site and number of vertebral levels to be treated and were randomized to treatment with the coflex, or spinal fusion group. The primary objective was to evaluate the safety and efficacy of coflex interlaminar stabilization compared with posterior spinal fusion in the treatment of 1- and 2-level spinal stenosis and degenerative spondylolisthesis. Patient follow-up at minimum 2 years was 95.3% and 97.2% in the coflex and fusion control groups, respectively. Patients taking coflex experienced significantly shorter operative times, blood loss, and length of stay. There was a trend toward greater improvement in mean Oswestry Disability Index scores in the coflex cohort. Both groups demonstrated significant improvement from baseline in all visual analogue scale back and leg parameters. The overall adverse event rate was similar between the groups, but coflex had a higher reoperation rate. At 2 years, fusions exhibited increased angulation and a trend toward increased translation at the superior adjacent level, whereas coflex maintained normal operative and adjacent level motion. While the changes with fusion were expected, longer follow-up is needed to determine whether motion preservation with coflex leads to lower reoperation rates, compared with fusion, for adjacent level disease.

Bae and colleagues (2017) performed a 3-year follow-up analysis of the Davis (2013a) RCT. At 36 months, 91% (195/215) of the coflex group and 88% (94/107) of the fusion group were included in the analysis. The initial efficacy endpoints (composite scores) were modified for use at 36 months. At 36 months. 62.2% of the individuals in the coflex group compared to 48.9% of the individuals in the 94 group reported composite clinical success scores. There are several limitations in this study including the limited follow-up period and the heterogeneous mix of individuals. The authors noted that an RCT comparing decompression and stabilization with coflex device to decompression alone will be underway in the near future.

Four year follow-up was reported in 2015 and 5 year follow-up was reported in 2016. The reported rate of follow-up at 5 years ranged from 40% to 100%, depending on the outcome measured. For example, the ODI at 6 months was reported for 56% of patients, while major device-related complications and composite clinical success were reported for 100% of patients. Interpretation of the 5-year results is limited by the variable loss to follow-up in outcomes.

Superion

Hayes (2018) clinical research response reported there is insufficient evidence in the peer-reviewed medical literature to demonstrate the long-term safety, efficacy, and durability of the Superion ISS. There is also a lack of evidence comparing the Superion ISS to the established treatment for this condition, surgical decompression. Therefore, the impact of the Superion ISS on net health outcome is not currently know and requires further investigation.

Nunley et al. (2017) reported 5-year clinical outcomes of a randomized controlled U.S. FDA noninferiority trial in individuals with moderate lumbar spinal stenosis. While the original trial compared the Superion to the X STOP device,

the analysis was restricted to the Superion trial arm. A total of 73% of the living individuals who received the spacer device participated in the 5-year clinical outcomes assessment. Outcomes were assessed using the ZCQ, leg and back pain severity by VAS, and the ODI. The authors reported success rates in all areas of assessment, 84% reported clinical success in at least two of the three ZCQ domains, 80% leg pain VAS scores, 65% back pain VAS scores and 65% for ODI scores. There remains a lack of studies which compare interspinous spacers to standard treatments, such as decompression surgery. Overall, there is a lack of evidence to support that interspinous spacer devices are as safe and effective as the gold standard of decompression. In addition, there appears to be some concerns that the devices are not as effective as surgical decompression and lead to higher rates of reoperation.

Results of the systematic reviews suggest Interspinous Process Decompression (IPD) offers greater short-term improvement in symptoms and functional status than nonsurgical therapy. Symptomatic outcomes for IDS and surgical decompression were similar, but IPD was associated with a higher reoperation rate and higher cost. One RCT comparing Superion® to the X STOP found greater durable clinical improvement with the Superion® than the X STOP after three years in the treatment of patients with moderate degenerative LSS (Patel, 2015). Long-term (i.e., more than two years) outcome data on durability of symptom relief, the need for repeat procedures, and implant survival compared to other surgical options are inadequate. Longer-term studies are in progress as part of FDA post-approval requirements.

There is a lack of large well-designed studies in the peer review scientific literature comparing stand-alone use of Superion device to established surgical decompression. Published studies do not demonstrate any long-term health outcome advantage with the use of Superion as an alternative to standard surgical treatment. Large population sufficiently powered randomized controlled trials that demonstrate long-term health outcome advantages are needed.

Minimally Invasive Lumbar Decompression (MILD®)

Staats and colleagues (2018) reported results of a prospective, multicenter, randomized controlled clinical study. This study evaluated the long-term durability of the minimally invasive lumbar decompression (MILD) procedure in terms of functional improvement and pain reduction for patients with lumbar spinal stenosis and neurogenic claudication due to hypertrophic ligamentum flavum. Follow-up occurred at 6 months and at 1 year for the randomized phase and at 2 years for MILD subjects only. Oswestry Disability Index, Numeric Pain Rating Scale, and Zurich Claudication Questionnaire were used to evaluate function and pain. Safety was evaluated by assessing incidence of device-/procedure-related adverse events. The authors concluded that MILD showed excellent long-term durability, and there was no evidence of spinal instability through 2-year follow-up. Given the minimally invasive nature of this procedure, its robust success rate, and durability of outcomes, MILD is an excellent choice for first-line therapy for select patients with central spinal stenosis suffering from neurogenic claudication symptoms with hypertrophic ligamentum flavum. Despite the above findings that study did have the following limitations, lack of a control group at 2-year follow-up. The randomized controlled portion of the study concluded at the primary end point of 1 year, and supplementary follow-up through 2 years was conducted for the MILD patient group only. This study did not compare efficacy directly with open surgical approaches, including lumbar decompression, fusion, or spacers.

In another study, Chopko (2013) evaluated the long-term effectiveness and safety of MILD as a treatment of neurogenic claudication associated with lumbar spinal stenosis. The 2-year data are reported for 45 participants that were treated with MILD at 11 US facilities. Outcome measurements included the VAS, ODI, and ZCQ. Interim data on the participants are included for 1 week, 6 months, and 1-year follow-up. The authors reported that at 2 years, the subjects demonstrated a statistically significant reduction of pain as measured by VAS, and significant improvement in physical function and mobility as measured by ZQC and ODI. The authors also reported major improvement occurred by 1-week follow-up and showed no difference between each subsequent follow-up, suggesting considerable stability and durability of the initial result over time. There were no major adverse events or complications related to the procedure. Limitations of this study include its uncontrolled design and small size.

Brown and colleagues (2012) reported the results of a double-blind, randomized, prospective study of epidural steroid injections (ESI) and the MILD procedure at a single pain management center. A total of 38 individuals with symptomatic lumbar spinal stenosis (LSS) participated in the study and were randomized into 2 treatment groups: 21 participants in the MILD arm and 17 individuals in the ESI arm. Outcome measures were reported using the visual analog scale (VAS), the Oswestry Disability Index (ODI) and Zurich Claudication Questionnaire (ZCQ) patient satisfaction score. The authors reported that at 6 weeks, the MILD participants improved from an average VAS baseline of 6.3 to a mean of 3.8). The ESI group had a mean VAS score of 6. at baseline compared with 6.3 at 6 weeks follow-up. Using the ODI, at 6 weeks follow-up, participants in the MILD group demonstrated a decrease from a baseline mean ODI from 38.8 to 27.4. In the ESI group, the initial ODI was 40.5 and at 6 weeks follow-up, the ODI was 34.8. In the MILD group, there was no significant change in the VAS and ODI scores from weeks 6 to 12. Participants in the ESI group were not measured at week 12. Participants were allowed to cross over from the ESI group to the MILD group before 12 weeks and eventually, all of the participants in the ESI group had the MILD procedure. A total of 14 of the 17 participants in the cross-over ESI group experienced an improvement in their VAS scores after the MILD procedure. Limitations of the study include its small size and short follow-up.

One-year follow-up from an industry-sponsored multicenter study by Chopko and Caraway, with patients who were treated with MILD devices, a set of specialized surgical instruments used to perform percutaneous lumbar decompressive procedures for the treatment of various spinal conditions, was reported in 2012. (10) All 78 patients had failed conservative medical management, with 75.9% of patients treated with conservative therapy for more than 6 months. Twenty-nine patients (50%) were discharged from the surgical facility on the same day as the procedure, and none of the patients stayed longer than 24 hours. There were no reports of major intraoperative or postoperative procedure-related adverse events. The primary outcome of patient success was defined as a 2-point improvement in VAS pain, but the percentage of patients who achieved success was not reported. VAS for pain improved from a mean of 7.4 at baseline to 4.5 at 1-year follow-up. The ODI improved from 48.6 to 36.7, and there was significant improvement on all domains of the Zurich Claudication Questionnaire and the SF-12 physical component score (from 27.4 to 33.5). The small number of study participants and its industry sponsorship limit the conclusions that can be drawn from this study.

A multicenter, non-blinded prospective study of 78 patients by Chopko and Caraway (2010) assessed the safety and functional outcomes of the MILD procedure in the treatment of symptomatic central canal spinal stenosis. Outcomes were measured by Visual Analog Score (VAS), Oswestry Disability Index (ODI), Zurich Claudication Questionnaire (ZCQ), and SF-12v2 Health Survey at baseline and 6 weeks post-treatment. At 6 weeks, the study showed a reduction in pain as measured by VAS, ZCQ, and SF-12v2. In addition, improvement in physical function and mobility as measured by ODI, ZCQ, and SF-12v2 was also seen. The authors concluded that the MILD procedure was safe and demonstrated efficacy in improving mobility and reducing pain associated with lumbar spinal canal stenosis. The study is limited by short term follow-up, small sample size and lack of a control group.

A retrospective review by Lingreen and Grider (2010) evaluated the efficacy of minimally invasive lumbar decompression in 42 patients with spinal stenosis and ligamentum flavum hypertrophy. Patient self-reported VAS, pre and post procedure functional assessments of activities of daily living (ADL), major and minor complication reports and need for follow-up procedures were evaluated. Patients self-reported improvement in function as assessed by ability to stand and ambulate for greater than 15 minutes, whereas prior to the procedure 98 % reported significant limitations in functioning. Visual analog pain scores were significantly decreased by 40% from baseline. No major adverse events were reported and of the minor adverse events, soreness lasting 3.8 days was most frequently reported. The authors concluded that the MILD procedure appears to be a safe and likely effective option for treatment of neurogenic claudication in patients who have failed conservative therapy and have ligamentum flavum hypertrophy as the primary distinguishing component of the stenosis. The study is limited by small sample size, reporting of subjective outcomes and comparison to other procedures for treating lumbar spinal stenosis.

Deer and Kapural (2010) conducted a retrospective survey to evaluate the safety of the MILD procedure in 90 consecutive patients with lumbar canal stenosis. Manual and electronic chart survey was conducted by 14 treating physicians located in 9 states within the United States. Complications and/or adverse events that occurred during or immediately following the procedure prior to discharge were recorded. There were no major adverse events or complications related to the devices or procedure. No incidents of dural puncture or tear, blood transfusion, nerve injury, epidural bleeding or hematoma were observed. The authors concluded that MILD appears to be a safe procedure; however, additional studies are underway to establish complication frequency and longer-term safety. The study is limited by small sample, study design and lack of information on efficacy.

Clinical evidence comparing conventional (open approach) procedures to endoscopic spinal discectomy and disc decompression as well as image-guided minimally invasive lumbar decompression are needed. High quality randomized controlled trials with sufficiently large sample sizes and longer follow-up periods are needed to determine if percutaneous and endoscopic spinal surgery procedures are more effective than conventional (open approach) procedures.

Additional Interspinous Process Decompression Devices

A large number of interspinous process devices (IPD) have been recently introduced to the lumbar spine market as an alternative to conventional decompressive surgery in managing symptomatic lumbar spinal pathology, (i.e., lumbar stenosis and/or degenerative disease), especially in the older population. Despite the fact that they are composed of a wide range of different materials including titanium, polyetheretherketone, and elastomeric compounds, the aim of these devices is to unload spine, restoring foraminal height, and stabilize the spine by distracting the spinous processes.

Professional Societies/Position Statements

American Academy of Orthopaedic Surgeons (AAOS)

At this time, there are no AAOS Clinical Practice Guidelines or AAOS Appropriate Use Criteria addressing the use of interspinous/interlaminar spacer devices.

International Society for the Advancement of Spine Surgery

In 2016, the International Society for the Advancement of Spine Surgery (ISASS) published recommendations for decompression with interlaminar stabilization. ISASS concluded, based in part on a conference presentation of a study, that an interlaminar spacer in combination with decompression can provide stabilization in patients who do not present with greater than grade 1 instability. Recommended indications and limitations were described in the article. The document did not address interspinous and interlaminar distraction devices without decompression. (Guyer et al., 2016).

National Institute for Health and Clinical Excellence

The National Institute for Health and Care Excellence states that current evidence on interspinous distraction procedures for lumbar spinal stenosis causing neurogenic claudication (such as the X-STOP prosthesis) shows that these procedures are efficacious for carefully selected patients in the short and medium term, although failure may occur and further surgery may be needed. There are no major safety concerns. Therefore these procedures may be used provided that normal arrangements are in place for clinical governance, consent and audit. Patient selection should be carried out by specialist spinal surgeons who are able to offer patients a range of surgical treatment options (NICE, 2010).

North American Spine Society (NASS)

The 2014 revised NASS clinical guideline on interspinious process spacing devices concluded that there is insufficient evidence to make a recommendation for or against the placement of an interspinous process spacing device in patients with lumbar spinal stenosis (LSS).

Spinal Stabilization

Dynamic Stabilization System

Dynamic stabilization, also known as soft stabilization or flexible stabilization has been proposed as an adjunct or alternative to spinal fusion for the treatment of severe refractory pain due to degenerative spondylolisthesis, or continued severe refractory back pain following prior fusion, sometimes referred to as failed back surgery syndrome. Dynamic stabilization uses flexible materials rather than rigid devices to stabilize the affected spinal segment(s). These flexible materials may be anchored to the vertebrae by synthetic cords or by pedicle screws. Unlike the rigid fixation of spinal fusion, dynamic stabilization is intended to preserve the mobility of the spinal segment.

Pham and colleagues (2016) conducted a review of the literature to explore complications associated with the Dynesys stabilization system. The researchers evaluated 21 studies which included a total of 1166 subjects with a mean age of 55.5 years and a mean follow-up period of 33.7 months. The data demonstrated a surgical-site infection rate of 4.3%, a pedicle screw loosening rate of 11.7%, a pedicle screw fracture rate of 1.6%, and an adjacent-segment disease (ASD) rate of 7.0%. Of studies reporting surgical revision rates, 11.3% of subjects required reoperation. Of subjects who developed ASD, 40.6% required a reoperation for treatment. The authors concluded that the Dynesys stabilization system has a similar complication rate compared with lumbar fusion studies and has a slightly lower incidence of ASD.

In a randomized controlled trial by Welch et al. (2007), the authors present the preliminary clinical outcomes of dynamic stabilization with the Dynesys spinal system as part of a multicenter randomized prospective Food and Drug Administration (FDA) investigational device exemption (IDE) clinical trial. This study included 101 patients from six IDE sites (no participants were omitted from the analysis) who underwent dynamic stabilization of the lumbar spine with the Dynesys construct. Patient participation was based on the presence of degenerative spondylolisthesis or retrolisthesis (Grade I), lateral or central spinal stenosis, and their physician's determination that the patient required decompression and instrumented fusion for one or two contiguous spinal levels between L-1 and S-1. Participants were evaluated preoperatively, postoperatively at 3 weeks, and then at 3-, 6-, and 12-month intervals. The 100-mm visual analog scale was used to score both lower limb and back pain. Patient functioning was evaluated using the Oswestry Disability Index (ODI), and the participants' general health was assessed using the Short Form-12 questionnaire. Overall patient satisfaction was also reported. One hundred one patients (53 women and 48 men) with a mean age of 56.3 years (range 27-79 years) were included. The mean pain and function scores improved significantly from the baseline to 12-month follow-up evaluation, as follows: leg pain improved from 80.3 to 25.5, back pain from 54 to 29.4, and ODI score from 55.6 to 26.3%.

The early clinical outcomes of treatment with Dynesys are promising, with lessening of pain and disability found at follow-up review. Dynesys may be preferable to fusion for surgical treatment of degenerative spondylolisthesis and stenosis because it decreases back and leg pain while avoiding the relatively greater tissue destruction and the morbidity of donor site problems encountered in fusion. However, long-term follow-up is still recommended. (Welch, 2007).

Due to the lack of data from well-designed, long-term, randomized controlled clinical trials, current evidence is insufficient to permit conclusions about whether any beneficial effect from dynamic stabilization provides a significant advantage over conventional fusion techniques The published evidence is not robust; a majority of the studies are retrospective or prospective case series and lack controls. In addition, the complication rates and reoperation rates for dynamic stabilization compared with conventional fusion are unknown.

Professional Societies/Position Statements

North American Spine Society (NASS)

NASS published updated clinical practice guidelines in 2014 which addressed "flexible fusion," defined as dynamic stabilization without arthrodesis, for the treatment of degenerative lumbar spondylolisthesis. Due to the paucity of literature addressing the outcomes of these procedures, the workgroup was unable to make a recommendation. For future research, the workgroup recommended development of a large multicenter registry database, as well as prospective studies, with long-term follow-up comparing flexible fusion to medical or interventional treatment of this condition.

Percutaneous Sacroplasty

There continues to be a paucity of published peer-reviewed studies in medical literature to allow for adequate evaluation of sacroplasty. Small numbers of individuals treated leaves uncertainty regarding the impact of sacroplasty on health outcomes. No randomized controlled trials evaluating percutaneous sacroplasty for sacral insufficiency were identified. Additional controlled studies with long-term assessment of the results of percutaneous sacroplasty are needed to confirm that it is a safe and effective procedure for sacral insufficiency fractures.

The literature search identified a nonrandomized controlled study and a few uncontrolled studies of percutaneous sacroplasty. Results of these studies provide preliminary evidence that percutaneous sacroplasty improves outcomes for patients who have sacral insufficiency fractures. The best evidence supporting use of this treatment was obtained in the nonrandomized controlled study and the largest available uncontrolled trial. Both of these studies enrolled patients who could not tolerate or failed to respond to conservative nonsurgical therapy. Comparing presurgery with postsurgery, percutaneous sacroplasty provided statistically significant reductions in pain and improvements in mobility and activities of daily living. Two smaller uncontrolled studies of percutaneous sacroplasty do not provide reliable evidence of efficacy since the investigators did not report whether patients underwent nonsurgical treatments for sacral insufficiency fractures before sacroplasty. Further controlled studies with long-term assessment of the results of percutaneous sacroplasty are needed to confirm that it is a safe and effective procedure for sacral insufficiency fractures (Hayes, 2018).

Frey et al. (2017) reported on patients treated with percutaneous sacroplasty, particularly the long-term efficacy of sacroplasty vs nonsurgical management. This prospective, observational cohort study spanned ten years and comprised 240 patients with sacral insufficiency fractures. Thirty-four patients were treated with nonsurgical methods, and 210 patients were treated with sacroplasty. Pain, as measured by VAS, was recorded before treatment and at several follow-ups. Mean pretreatment VAS for the sacroplasty group was 8.29; for the nonsurgical treatment group, it was 7.47. Both forms of treatment resulted in significant VAS improvement from pretreatment to the 2-year follow-up. However, the sacroplasty treatment group experienced significant VAS score improvement consistently at many of the follow-up points (pretreatment to post; posttreatment through 2 weeks; 12 weeks through 24 weeks; 24 weeks through 1 year. Meanwhile, the group with nonsurgical treatment only experienced one significant pain improvement score—at the 2-week follow-up posttreatment. One major limitation of this study was that the nonsurgical treatment group was not followed up with at the 10-year mark whereas the sacroplasty group did receive follow-up.

Dougherty et al. (2014) retrospectively evaluated outcomes of consecutive patients with SIF treated by percutaneous sacroplasty in an electronic database. The study included 57 patients (75% women; age 61 to 85 years, median 74 for men or 75 for women; duration of pain 2 to 5 weeks. Pain was measured at rest and, sometimes, during activity on an 11-point NRS (higher values = greater pain) or described by patients, opioid use was also evaluated before and at 1 to 5 weeks (median, 2.5) after sacroplasty. The study is limited by retrospective design, small sample size, lack of a control group, subjective outcome measures, inconsistent evaluation of pain, and short follow-up.

Kortman et al. (2013) retrospectively examined outcomes of patients with painful SIF or symptomatic sacral lesions treated by percutaneous sacroplasty at any of 6 participating U.S. centers. Patients were included in the study if they had severe sacral pain refractory to standard conservative management (defined as any combination of bed rest, analgesics, partial weight bearing, and orthosis), imaging evidence of bilateral or unilateral SIF or focal or infiltrating sacral lesions, and symptoms attributable to sacral pathology. The SIF group consisted of 204 patients. The group with sacral lesions (SL group) included 39 patients. Sacroplasty entailed the long- or short-axis approach and PMMA or bioceramic cement, but the rate of each approach and the trade names for cement and other devices were not reported. Pain was evaluated by self-report, a VAS, and analgesic use before and at 1 month after sacroplasty. All patients with SIF were followed for ≥ 1 year. Compared with pretreatment values, mean VAS scores improved significantly after sacroplasty in patients with bilateral SIF, patients with unilateral SIF, and patients with sacral

lesions. In the entire group with SIF and the group with sacral lesions, respectively, 31% and 18% experienced complete pain relief and 3.0% and 10% experienced no significant pain relief. Use of narcotic, non-narcotic, and over-the-counter analgesics decreased markedly after versus before sacroplasty in both groups but data for analgesic use were not reported. The study is limited by retrospective design, lack of a control group, and use of subjective outcome measures.

Professional Societies

No position or policy statements or guidelines addressing the use of sacroplasty were identified in available literature or in websites of relevant professional organizations.

Facet Fusion

Facet fusion is a minimally invasive back procedure that uses specially designed bone dowels made from allograft material (donated cortical bone) that are inserted into the facet joints. The procedure is designed to stop facet joints from moving and is intended to eliminate or reduce back pain caused by facet joint dysfunction.

For individuals who have lumbar spinal stenosis who receive spinal decompression with facet arthroplasty, the evidence includes a preliminary report of a randomized controlled trial. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Interim results from a pivotal trial of the ACADIA Facet Replacement System (Meyer et al.) were reported in 2012. No additional publications from this trial, which was expected to be completed October 2015, have been identified to date. In addition to the lack of evidence on clinical outcomes with facet arthroplasty, no device has received U.S. Food and Drug Administration approval. The evidence is insufficient to determine the effects of the technology on health outcomes.

Gavaskar and Achimuthu (2010) conducted a prospective study of 30 patients with low-grade degenerative spondylolisthesis of the lumbar and lumbosacral spine who underwent facet fusion using 2 cortical screws and local cancellous bone grafts. Visual analog scale and Oswestry disability assessment were used to measure outcomes which showed significant improvement at 1-year follow-up. The authors found that patients with degenerative spondylolisthesis with lower grade slips and normal anterior structures represent an ideal indication for facet fusion. The study is limited by short term follow-up, subjective outcomes and lack of comparison to other treatment modalities.

Evidence is limited to small, uncontrolled trials with lack of blinding or long-term follow-up. Randomized, controlled trials comparing these allograft materials to standardized autograft materials are needed to determine long-term efficacy and impact on health outcomes. No studies were found that discussed facet fusion when done alone without an accompanying decompressive procedure. The current published evidence is insufficient to determine whether facet arthroplasty is as effective or as safe as spinal fusion, the current standard for surgical treatment of degenerative disc disease.

Professional Societies

American Association of Neurological Surgeons (AANS)

AANS published a technical assessment of TruFUSE and Nufix in 2009. The report concluded that there is insufficient objective information to evaluate the safety and utility of this device or to make recommendations regarding clinical usage. The AANS has no additional information on TruFUSE since 2009. The manufacturer has been contacted by AANS requesting any possible scientific data not identified in a literature search.

Lumbar fusion for facet syndrome is no longer generally accepted (International Society for the Advancement of Spine Surgery, [ISASS], 2011). According to the ISASS (2011) the surgery should only be performed in the context of a clinical trial.

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

Interspinous Fixation Devices

Products used for interspinous fixation devices are extensive. See the following website for more information and search by product name in device name section: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm.

Spinal Fusion Devices

Products used for spinal fusion and decompression devices are extensive. See the following website for more information and search by product name in device name section: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm.

Spinal Stabilization Devices

Products used for spinal stabilization devices are extensive. See the following website for more information and search by product name in device name section: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm.

Facet Arthroplasty

No facet arthroplasty devices have been approved by the U.S. Food and Drug Administration (FDA) at this time.

Percutaneous Sacroplasty

Sacroplasty is a procedure and, as such, is not regulated by the FDA. However, devices used in medical procedures do require FDA approval. The FDA has cleared an extensive variety of devices for use in sacroplasty. Products used for sacroplasty are extensive. See the following website for more information and search by product name in device name section: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm.
(Accessed October 24, 2018)

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Medicare does not have a National Coverage Determination (NCD) for spinal procedures using the following methods: extreme lateral interbody fusion (XLIF®), Direct Lateral Interbody Fusion (DLIF), Laparoscopic Anterior Lumbar Interbody Fusion (LALIF), Transforaminal Lumbar Interbody Fusion (TLIF), Axial lumbar interbody fusion (AxiaLIF), Interlaminar Lumbar Instrumented Fusion (ILIF) (e.g., Coflex-F®). Local Coverage Determinations (LCDs) exist; see the LCDs for Category III CPT Codes, Lumbar Spinal Fusion for Instability and Degenerative Disc Conditions, Non-Covered Services and Services That Are Not Reasonable and Necessary.

Medicare does not have an NCD for spinal decompression and interspinous process decompression systems (e.g., Interspinous Process Decompression (IPD) and Minimally Invasive Lumbar Decompression (MILD)) for the treatment of lumbar spinal stenosis. LCDs exist; see the LCDs for Interspinous Process Decompression, Category III CPT Codes and Services That Are Not Reasonable and Necessary.

Medicare does not have an NCD for spinal stabilization systems, total facet joint arthroplasty, facetectomy, laminectomy, foraminotomy, vertebral column fixation and percutaneous sacral augmentation (sacroplasty) with or without a balloon or bone cement for the treatment of back pain. LCDs exist; see the LCDs for Category III CPT Codes, Non-Covered Services, Percutaneous Vertebral Augmentation, Services That Are Not Reasonable and Necessary, Vertebroplasty, Vertebral Augmentation (Kyphoplasty) Percutaneous and Vertebroplasty, Vertebral Augmentation; Percutaneous.

Medicare does not have an NCD for stand-alone facet fusion without accompanying decompressive procedures. LCDs exist; see the LCDs for Category III CPT Codes and Non-Covered Services.
(Accessed November 9, 2018)

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POLICY HISTORY/REVISION INFORMATION

Date	Action/Description
04/01/2019	• Revised coverage rationale and supporting information: ○ Replaced references to "MCG™ Care Guidelines, *22nd* edition*, 2018*" with "MCG™ Care Guidelines, *23rd* edition*, 2019*"; refer to 23rd edition for complete details on applicable updates to the MCG™ Care Guidelines • Archived previous policy version 2019T0547T

INSTRUCTIONS FOR USE

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the member specific benefit plan document must be referenced as the terms of the member specific benefit plan may differ from the standard plan. In the event of a conflict, the member specific benefit plan document governs. Before using this policy, please check the member specific benefit plan document and any applicable federal or state mandates. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

This Medical Policy may also be applied to Medicare Advantage plans in certain instances. In the absence of a Medicare National Coverage Determination (NCD), Local Coverage Determination (LCD), or other Medicare coverage guidance, CMS allows a Medicare Advantage Organization (MAO) to create its own coverage determinations, using objective evidence-based rationale relying on authoritative evidence (Medicare IOM Pub. No. 100-16, Ch. 4, §90.5).

UnitedHealthcare may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. UnitedHealthcare Medical Policies are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.