Medical Policy

Minimally Invasive Procedures and Associated Devices used to Treat Back Pain (Including Thermal Intradiscal Procedures, Interspinous Spacers, Interlaminar Stabilization Devices, and Minimally Invasive Surgical Procedures for Spinal Fusion and/or to Remove Disc Material)

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Product Applicability

N All Plan* Products

Well Sense Health Plan
☒ New Hampshire Medicaid
☒ NH Health Protection Program

Boston Medical Center HealthNet Plan
☒ MassHealth
☒ Qualified Health Plans/ConnectorCare/Employer Choice Direct
☒ Senior Care Options ◊

Notes:
+ Disclaimer and audit information is located at the end of this document.
◊ The guidelines included in this Plan policy are applicable to members enrolled in Senior Care Options only if there are no criteria established for the specified service in a Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) on the date of the prior authorization request. Review the member’s product-specific benefit documents at www.SeniorsGetMore.org to determine coverage guidelines for Senior Care Options.

Policy Summary

The Plan considers the use of minimally invasive procedures and associated devices at any spinal level to be experimental and investigational when used for the treatment of pain associated with disc

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Minimally invasive procedures and associated devices are proposed as a clinical alternative to (or in addition to) standard, open spinal surgery and/or conservative medical treatment. Minimally invasive techniques include but are not limited to percutaneous spinal procedures, laparoscopic and/or endoscopic spinal procedures, thermal intradiscal procedures, interspinous spacers, interlaminar stabilization devices, minimally invasive surgical procedures to remove disc material, minimally invasive spinal fusion procedures, lateral surgical approaches for spinal fusion, and/or the use of any combination of minimally invasive techniques. Prior authorization is required for all services included in this Plan policy.

The Plan uses InterQual criteria to determine the medical necessity of a standard, open spinal procedure (rather than criteria included in this Plan policy) when Plan prior authorization is required for the specified surgical procedure. Prior authorization guidelines are documented by applicable procedure code in the Plan’s Prior Authorization Code Look-up Tools (available at www.bmchp.org for BMC HealthNet Plan members and posted at www.wellsense.org for Well Sense Health Plan members). When prior authorization is necessary and applicable InterQual criteria are not met for a standard, open spinal fusion procedure, Plan Medical Director review is required. The Plan does NOT reimburse for a minimally invasive procedure (and related devices that include but are not limited to interbody cages, screws, spacers, and/or other fixation devices) when used as a stand-alone surgical treatment of pain associated with disc disease, back pain, and/or for any other indication because the clinical utility and clinical validity of these procedures have not been sufficiently established. The Plan does NOT reimburse additionally for these unproven minimally invasive procedures/techniques (and associated devices) when used with a standard, open spinal procedure and/or with established conservative, nonsurgical treatment(s) because these minimally invasive procedures and devices are considered experimental and investigational by the Plan.

It will be determined during the Plan’s prior authorization process if the service is considered experimental and investigational for the requested use. See the Plan’s policy, Experimental and Investigational Treatment (policy number OCA 3.12), for the product-specific definitions of experimental or investigational treatment.

Description of Item or Service

Currently, there is insufficient evidence to consistently support the clinical utility and clinical validity of minimally invasive procedures and associated devices at any spinal level as a clinical alternative to (or in addition to) conservative medical treatment and/or standard, open surgical procedures for the medically necessary treatment of pain associated with disc disease, back pain, and/or for any other indication. Minimally invasive spinal column surgical procedures (and associated devices) have been developed as a clinical alternative to standard, open spinal surgeries such as laminectomy or discectomy to treat herniated discs, to stabilize unstable spinal column segments, and to manage back pain. Types of minimally invasive procedures and techniques used for the treatment of back pain

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and/or disc disease include but are not limited to the following, as specified below in items 1 through 4:

1. **Thermal Intradiscal Procedures (TIPS):** Intradiscal techniques employing devices that utilize a radiofrequency energy source or electrothermal energy to apply or create heat and/or disruption within the disc for coagulation and/or decompression of disc material to treat symptomatic patients with annular disruption of contained herniated disc, to seal annular tears or fissures, or destroy nociceptors (altering the biomechanics for the purpose of relieving pain). TIPS may be identified or labeled based on the name of the catheter/probe(s) that is used (e.g., SpineCath, discTRODE, SpineWand, Accutherm, or TransDiscal electrodes). Examples include the following, as specified below in items a through e:

   a. **Disc Nucleoplasty:** Also known as percutaneous (or plasma) disc decompression (PDD) or ablation, disc nucleoplasty is a disc decompression procedure using bipolar radiofrequency energy in a process called Coblation® technology. The device (ArthroCare Perc-D SpineWand) uses multiple, small electrodes that are designed to ablate a portion of nucleus tissue with a low-temperature plasma field of ionized particles. The proposed advantage of Coblation® technology is that the procedure provides for a controlled and highly localized ablation, resulting in minimal therapy damage to surrounding tissue.

   b. **Intradiscal Biacuplasty (IDB):** A radiofrequency procedure that uses two (2) electrodes placed on the opposite posterior lateral side of the disc annulus; it is proposed as a treatment alternative to lumbar disc replacement or fusion in a patient with discogenic pain.

   c. **Intradiscal Electrothermal Therapy (IDET):** Also known as percutaneous intradiscal electrothermal annuloplasty or intradiscal thermal annuloplasty (IDTA), IDET is a minimally invasive treatment for discogenic back pain that involves the application of thermal energy percutaneously into a suspected painful disc as an alternative to disc surgery. The heating catheter is inserted through the nucleus of the disc until it penetrates the inner layers of the annulus; the effect is to destroy nociceptor nerve fibers in the annulus and change the collagen structure within the disc for the reduction of pain.

   d. **Percutaneous Intradiscal Radiofrequency Thermocoagulation (PIRFT):** A disc decompression procedure using radiofrequency energy to alter the biomechanics of the disc annulus. The radiofrequency catheter is inserted into the center of the disc nucleus to cause collagen in the disc to contract and thicken.
e. **Targeted Disc Decompression (TDD):** A minimally invasive spinal procedure that uses the ACCUTHERM Decompression Catheter (Smith & Nephew), which is a heating coil to coagulate the collagen; this causes tissue contraction designed to treat herniated discs.

2. **Minimally Invasive Treatments to Remove Disc Material:** Endoscopic discectomy, percutaneous disc decompression (PDD), or nucleoplasty procedures are surgical procedures using lasers or other cutting probes to remove or ablate disc material and thus decompress the disc, or use instrumentation via a port to decompress neural elements. Many types of lasers have been designed for laser discectomy, including YAG, KTP, holmium, argon, and carbon dioxide lasers. Several types of cutting devices have been developed to remove or ablate disc material, including the Stryker Dekompressor Percutaneous Discectomy Probe or the Endius MDS MicroDebrider System. Regardless of the type of laser or cutting probe, the procedure involves placement of the laser and probes within the nucleus under fluoroscopic guidance. The lasers are activated for short periods to ablate disc material, and cutting probes generally suction out some or all of the disc material. Examples include but are not limited to the following, as specified below in items a through e:

a. **Arthroscopic Microdiscectomy (AMD):** Also referred to as a percutaneous or posterolateral endoscopic discectomy, AMD is endoscopically guided decompression using a posterolateral (in back and away from the midline) approach bolstered by visual controls, illumination, and magnification, to remove the herniated disc fragments through cannulas placed within the disc.

b. **Automated Percutaneous Discectomy:** A minimally invasive intradiscal procedure that uses a blunt-tipped suction and cutting probe that is inserted through the skin and placed in the middle of a herniated disc under fluoroscopic guidance. The cut disc material is removed and aspirated through the side port of the device. This procedure is designed to remove or ablate disc material and thus decompress the disc. The Stryker DeKompressor® Percutaneous Discectomy Probe (Stryker) and the Nucleotome® (Clarus Medical) are examples of percutaneous discectomy devices that received clearance from the U.S. Food and Drug Administration (FDA) through the 510(k) process.

c. **Percutaneous Laminotomy/Laminectomy for Decompression of Neural Elements:** A minimally invasive procedure wherein, under indirect guidance, a port is docked on the inferior vertebral segment lamina via stab incision. Various instrumentation is utilized to remove bone, and possible other structures (including a disc), in order to decompress neural elements. Percutaneous image-guided lumbar decompression (PILD) is a posterior decompression of the lumbar spine performed percutaneously to remove a portion of the lamina and debulk the ligamentum flavum; the procedure is performed without any direct...
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Visualization of the surgical area using indirect image guidance (e.g., fluoroscopic, CT) with contrast media to identify and monitor the compressed area via epiduragram.

d. **Percutaneous Laser Discectomy, Laser Discectomy, or Laser-Assisted Disc Decompression (LADD):** A minimally invasive disc decompression technique for the treatment of symptomatic disc herniation by reducing the pressure on the spine or nerve root. This procedure uses a laser placed within the nucleus of the disc under fluoroscopic guidance to remove or ablate disc material and thus decompress the material that has herniated and is causing nerve impingement. An example of this technology includes the mild (minimally invasive lumbar decompression or MILD®) technique using the mild Device Kit (by Vertos Medical Inc.); MILD® is a percutaneous procedure using a single-use system to fill the epidural space with contrast medium, clamp a cannula in place, and then resect tissue to decompress the central spinal canal in patients with lumbar spinal stenosis, either unilaterally or bilaterally. The North American Spine Society defines an open decompression procedure as one that is done through an incision of approximately one inch or more; a minimally invasive lumbar decompression is performed through small incisions of less than 1 inch. Minimally invasive lumbar decompression procedures include those performed under direct visualization using specialized tubular retractors, and procedures performed under indirect visualization.

e. **Transforaminal Endoscopic Surgery (TES®) Including TESSYS® Stenosis and iLESSYS® Interlaminar Endoscopic Surgical System:** TES is an endoscopic surgical system using a TESSYS® method developed by joimax® for the treatment of herniated discs and sequestrations through the lateral, transforaminal access under analgesic sedation. After verifying the herniated disc with magnetic resonance imaging (MRI) and/or computer tomography (CT) and conventional x-ray images, intraoperative discography and chromography is conducted using the needle included in the TES® surgical system to make a definitive determination of the herniated disc position. The TESSYS® method and technology is designed to permit access to spinal disc sequestra and herniations along the lumbar spine, including L5-S1, regardless of their position. TESSYS® instrumentation includes guiding rods, guiding tubes, disposable reamers, and reamer ejectors. Soft tissue is gradually dilated under permanent x-ray monitoring, and direct access to the herniated disc occurs through the intervertebral foramen (which contains the nerve roots and may be anatomically narrow); in order to ensure safe access into the spinal canal and avoid irritation of the nerves in the foramen, the caudal part of the intervertebral foramen is widened millimeter by millimeter using special reamers. Once the gradual stretching of the tissue and the foramen is completed, loose tissue and prolapsed material are removed with a foraminoscope, under full endoscopic view and with gripping, cutting and punching forceps. When all spinal disc fragments are removed, an endoscopic check will be performed to verify that all affected nerve roots are free.
The TESSYS® Stenosis and iLESSYS® Program are an endoscopic treatment options also developed by joimax®. Both products provide 360 degree access and are designed to provide full pressure release of the spinal canal using endoscopic instrumentation as a clinical alternative to an open surgical procedure. The TESSYS® Stenosis instruments are used to complement the TESSYS® method. The iLESSYS® Program/ iLESSYS® Interlaminar Endoscopic Surgical System is designed for the treatment of disc herniation accessible through the lamina at level L5-S1. Examples of associated devices include but are not limited to the EndoLIF® On-Cage implant, Percusys® percutaneous screw-rod-system, and iLESSYS® Delta.

3. **Interspinous and Interlaminar Stabilization/Distraction Devices (Spacers):** Interspinous and interlaminar implants (spacers) stabilize or distract the adjacent lamina and/or spinous processes and restrict extension in order to reduce pain in patients with lumbar spinal stenosis and neurogenic claudication, as specified below in item a or item b.

a. **Interspinous Spacer:** Device that is implanted between vertebral spinous processes via a procedure that is less invasive than open decompression procedures. An expandable implant is inserted through a single small incision (general up to 1 inch in length) in the patient’s back during a brief procedure under local or general anesthesia. The procedure typically does not require removal of bone or soft tissue. This allows for potentially faster recovery than more invasive decompression procedures. The implants expand the neural foramen and limit lumbar extension, thereby relieving pain in patients with spinal stenosis and neurogenic claudication. Examples of this type of device that have been FDA approved include the Superion Interspinous Spacer (by VertiFlex Inc.) and the X STOP® Interspinous Spacer (by Medtronic Inc.). The manufacturer for the X STOP® Interspinous Spacer elected to voluntarily cease the sale and distribution of this device. The North American Spine Society (NASS)’s clinical guideline on the diagnosis and treatment of degenerative lumbar spondylolisthesis (dated 2014) state the following: “There is insufficient and conflicting evidence to make a recommendation for or against the efficacy of interspinous spacers versus medical/interventional treatment in the management of degenerative lumbar spondylolisthesis patients. Grade of Recommendation: I (Insufficient Evidence).” When conservative treatment does not relieve pain from lumbar spinal stenosis, surgical alternatives to interspinous spacers include laminectomy with or without spinal fusion, laminotomy, or hemilaminotomy.

b. **Interlaminar Stabilization Device:** Device is implanted after decompression of lumbar spinal stenosis at the affected level(s). The device is implanted between adjacent lamina and has two (2) sets of wings that are placed around the inferior and superior spinous processes. The devices (spacers) distract the laminar space and/or spinous processes and

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restrict painful extension while otherwise enabling normal motion. This procedure is performed by a neurosurgeon or orthopedic surgeon in a hospital setting after lumbar decompression with the patient under general or local anesthesia. An example of the device includes the Coflex® Interlaminar Stabilization Device (by Paradigm Spine LLC). Surgical alternatives to interlaminar stabilization for lumbar spinal stenosis include decompressive procedures such as laminectomy, laminotomy, foraminectomy, facetectomy, and discectomy, alone or followed by spinal fusion.

4. **Minimally Invasive Spinal Fusion (Arthrodesis) Procedures**: The standard surgical approaches to intervertebral spinal fusion include an open surgical procedure via an anterior or posterior route; it has been proposed that spinal fusion may also be performed as a minimally invasive procedure, including endoscopic procedure, laparoscopic procedure, percutaneous procedure, procedure using a combination of minimally invasive techniques (e.g., microdiscectomy with spacers), or a lateral surgical approach (with less cutting of muscle and soft tissue) as a clinical alternative to a standard, open surgical spinal fusion. The Plan considers minimally invasive procedures/techniques (and associated devices) used for spinal fusion to be experimental and investigation because the safety and impact on health outcomes have not been consistently demonstrated in clinical trials. For an endoscopic spinal fusion, a surgical device with a tiny camera and lens at one end will be inserted into the site of surgery through smaller incisions; this enables a better view of the inner area when connected to a larger screen and surgical instruments can be inserted through the other incisions for resection and implant. Currently, there is insufficient evidence to support the clinical utility or clinical validity of minimally invasive spinal fusion procedures that include but are not limited to the following methods, as specified below in items a through e:

a. **Axial Lumbar Interbody Fusion (AxiaLIF)**: Also known as trans-sacral, transaxial or paracoccygeal interbody fusion, AxiaLIF is a minimally invasive technique used in L5-S1 spinal fusions. The technique provides access to the spine along the long axis of the spine, as opposed to an anterior, posterior or lateral approach. The lumbar spine is accessed through a small, percutaneous incision adjacent to the sacral bone. The surgeon removes the abnormal disc, and a bone graft is placed where the abnormal disc was. The bone graft is stabilized with a large metal screw, and additional screws may be placed through another small incision higher on the back for extra stability. There is insufficient evidence to support the clinical utility or clinical validity of this technique.

b. **Endoscopic Anterior Lumbar Interbody Fusion (ALIF) or Laparoscopic Anterior Lumbar Interbody Fusion (LALIF)**: In an anterior lumbar interbody fusion (ALIF), an incision is made on the left side of the abdomen and the abdominal contents and muscles are pulled to the side to allow access to the front of the spine. A fixation device is used to distract the disc space and neural foramen to reduce nerve root impingement in cases of degenerative disc

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disease; the ALIF device also stabilizes loose vertebrae in cases of spondylolisthesis. The devices used to promote fusion across adjacent vertebrae and maintain correct alignment include fixation devices, titanium cages or bone dowels, and bone grafts or bone-forming substrates. ALIF is a widely used open spine fusion technique that may be performed alone when there is not a lot of instability in the spine (e.g., one level degenerative disc disease where there is a lot of disc space collapse). ALIF may also be combined with a posterior approach (anterior/posterior fusions) when the patient needs more rigid fixation than an anterior approach alone provides. ALIF is a standard, open surgical technique for spinal fusion. Laparoscopic anterior lumbar interbody fusion (LALIF) is a type of back surgery used as a clinical alternative to an open ALIF to fuse the disc space of the spine by entering the front of the body. Although previously there was a lot of interest in perfecting an endoscopic approach for ALIF surgery, it has largely been abandoned because it placed the great vessels (aorta and vena cava) at too great a risk. There is insufficient evidence to support the clinical utility or clinical validity of endoscopic ALIF and/or LALIF as a surgical alternative to an open ALIF or any standard, open surgical approach to intervertebral spinal fusion.

c. **Interlaminar Lumbar Instrumented Fusion (ILIF):** ILIF combines direct neural decompression with an allograft interspinous spacer to maintain the segmental distraction. A spinous process fixation plate or other fixation device such as cortical pedicle screws is used to maintain stability for eventual segmental fusion. An example includes the coflex-F® Implant System.

d. **Lateral Interbody Fusion (Direct Lateral Interbody Fusion [DLIF] or Extreme Lateral Interbody Fusion [XLIF®]):** 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). 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 and avoiding any major nerves in the area between the incision and the column (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. The procedure is generally indicated for interbody fusion at the lower levels of the spine (e.g., L1-L5 levels), and it may be necessary to remove part of the iliac crest during the procedure. 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, but the clinical validity and clinical utility of a lateral interbody fusion (e.g., DLIF or XLIF) as a surgical alternative to posterior lumbar interbody fusion (PLIF), transforaminal lumbar interbody fusion (TLIF), or any standard, open surgical approach to intervertebral spinal fusion.

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e. **Minimally Invasive Transforaminal Lumbar Interbody Fusion (MITLIF)/Transforaminal Lumbar Interbody Fusion (TLIF) Utilizing Only Endoscopy**: With the transforaminal interbody fusion (TLIF) method, the surgeon approaches the damaged lumbar spine from the posterior of the body to place bone graft between two vertebrae. Unlike an open transforaminal spinal fusion, MITLIF (or TLIF utilizing endoscopy) employs laparoscopic surgical techniques (using only indirect, endoscopic visualization) along with muscle dilation procedures to insert bone grafts and/or medical devices between two (2) or more adjacent spinal vertebrae in order to stabilize them and initiate a biological response that will fuse the vertebrae; this provides continued support to the spinal column and reduces the pain associated with spinal disease or injury. Using a brief electrical current delivered via a wire, the muscles are dilated to allow surgical tools to pass beneath them to access the spinal column for surgery. MITLIF requires less muscle stripping and less neural traction than an open procedure, and MITLIF causes less soft tissue trauma when compared to an open transforaminal spinal fusion surgery. There is insufficient evidence to support the clinical utility or clinical validity of MITLIF (TLIF utilizing only endoscopy) as a surgical alternative to an open transforaminal spinal fusion or any standard, open surgical procedure to intervertebral spinal fusion.

### Medical Policy Statement

The Plan considers the use of minimally invasive procedures and associated devices at any spinal level to be experimental and investigational when used as **stand-alone procedures** for the treatment of pain associated with disc disease, back pain, and/or for any other indication. Minimally invasive procedures and associated devices are proposed as a clinical alternative to (or in addition to) standard, open spinal surgery and/or conservative medical treatment. Minimally invasive techniques include but are not limited to percutaneous spinal procedures, laparoscopic and/or endoscopic spinal procedures, thermal intradiscal procedures, interspinous spacers, interlaminar stabilization devices, minimally invasive surgical procedures to remove disc material, minimally invasive spinal fusion procedures, lateral surgical approaches for spinal fusion, and/or the use of any combination of minimally invasive techniques. The Plan **does NOT reimburse additionally** for these unproven minimally invasive procedures/techniques (and associated devices that include but are not limited to interbody cages, screws, spacers, and/or other fixation devices) **when used with a standard, open spinal procedure and/or with established conservative, nonsurgical treatment(s)** because these minimally invasive procedures and devices are considered experimental and investigation by the Plan. Prior authorization is required for all of these services.

The Plan uses InterQual criteria to determine the medical necessity of a standard, open spinal procedures (rather than criteria included in this Plan policy) when Plan prior authorization is required for the specified surgical procedure. Prior authorization guidelines are documented by applicable

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procedure code in the Plan’s Prior Authorization Code Look-up Tools (available at www.bmchp.org for BMC HealthNet Plan members and posted at www.wellsense.org for Well Sense Health Plan members). When prior authorization is necessary and applicable InterQual criteria are not met for a standard, open spinal procedure, Plan Medical Director review is required.

**Limitations**

The Plan considers percutaneous spinal procedures, laparoscopic and/or endoscopic spinal procedures, thermal intradiscal procedures, interspinous spacers, interlaminar stabilization devices, minimally invasive surgical procedures to remove disc material, minimally invasive spinal fusion procedures, lateral surgical approaches for spinal fusion, and/or the use of any combination of minimally invasive techniques to be experimental and investigational when used in the treatment of pain associated with disc disease and/or back pain. Minimally invasive procedures (and related devices that include but are not limited to interbody cages, screws, spacers, and/or other fixation devices) performed as a stand-alone treatment or used with a standard, open spinal procedure and/or with established conservative, nonsurgical treatment(s) are considered experimental and investigational at any spinal level. Minimally invasive procedures (and associated devices) include but are not limited to ANY of the following, as specified below in items 1 through 22:

1. Arthroscopic microdiscectomy (also referred to as a percutaneous or posterolateral endoscopic discectomy)

2. Automated percutaneous discectomy (e.g., The Stryker DeKompressor® Percutaneous Discectomy Probe by Stryker and the Nucleotome® by Clarus Medical)

3. Axial lumbar interbody fusion (AxiaLIF)

4. Disc nucleoplasty or percutaneous (or plasma) disc decompression (PDD) or ablation

5. Endoscopic anterior lumbar interbody fusion (ALIF)

6. Interlaminar lumbar instrumented fusion (ILIF)

7. Interlaminar stabilization device following decompressive surgery (e.g., Coflex® Interlaminar Stabilization Device)

8. Interspinous spacers (e.g., the Superion Interspinous Spacer by VertiFlex Inc. and X STOP® Interspinous Spacer by Medtronic Inc.)

9. Intradiscal biacuplasty

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10. Intradiscal electrothermal therapy (IDET)

11. Intradiscal thermal annuloplasty (IDTA)

12. Laparoscopic anterior lumbar interbody fusion (LALIF)

13. Lateral Interbody Fusion (e.g., Direct Lateral Interbody Fusion [DLIF] or Extreme Lateral Interbody Fusion [XLIF®])

14. METRx microendoscopic discectomy

15. Minimally Invasive Transforaminal Lumbar Interbody Fusion (MITLIF)

16. Percutaneous intradiscal radiofrequency thermocoagulation (PIRFT)

17. Percutaneous image-guided lumbar decompression

18. Percutaneous laminotomy/laminectomy

19. Percutaneous laser discectomy, laser discectomy, or laser-assisted disc decompression (e.g., minimally invasive lumbar decompression or MILD® by Vertos Medical Inc.)

20. Targeted disc decompression (TDD)

21. Transforaminal endoscopic surgery (TES®) including but not limited to the following products: TESSYS® Stenosis System, iLESSYS® Interlaminar Endoscopic Surgical System, EndoLIF® On-Cage implant, Percusys® percutaneous screw-rod-system, and iLESSYS® Delta

22. Transforaminal lumbar interbody fusion (TLIF) utilizing only endoscopy

Note: The Plan uses InterQual criteria to determine the medical necessity of a standard, open spinal procedure (rather than criteria included in this Plan policy) when Plan prior authorization is required for the specified surgical procedure and associated devices. Prior authorization guidelines are documented by applicable procedure code in the Plan’s Prior Authorization Code Look-up Tools (available at [www.bmchp.org](http://www.bmchp.org) for BMC HealthNet Plan members and posted at [www.wellsense.org](http://www.wellsense.org) for Well Sense Health Plan members). When prior authorization is necessary and applicable InterQual criteria are not met for a standard, open spinal procedure, Plan Medical Director review is required.

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Definitions

**Discogenic Back Pain:** Back pain that is caused by the intervertebral disc that is externally intact, as opposed to disc prolapse or herniation that applies pressure on the nearby nerve roots. Discogenic back pain is confined to the back and does not radiate down the legs.

**Neurogenic Claudication:** A clinical syndrome of intermittent gluteal pain, lower extremity pain, and/or fatigue with or without back pain caused by symptomatic lumbar spinal stenosis (LSS). LSS is a common condition in aging adults that results from degenerative changes in the spine, causing compression of nerves at the level of the lumbar vertebra. LSS symptoms are typically provoked by upright exercise such as walking, and symptoms (which can range from mild to severe) are relieved with forward flexion, sitting, or recumbency.

**Nociceptors:** Group of cells that acts as a receptor for painful stimuli and transmits information about those sensations to the central nervous system. These specialized nerve endings are responsible for nociception, one (1) of the two (2) types of persistent pain (the other, neuropathic pain, occurs when nerves in the central or peripheral nervous system are damaged). Nociceptors can become chronically activated and send persistent pain signals; the level of pain depends on the level of irritation at the nociceptor.

**Spine Anatomy:** The spine is divided into three (3) major areas: the cervical or neck area, the thoracic or mid-back area, and the lumbar or low back area. The areas are comprised of individual bones or vertebrae that are the primary target of weight bearing and provide a resting area for the disc, which act as shock absorbers between the vertebrae. Each disc is comprised of two (2) parts, the outer layer or the annulus and the center or the nucleus. The annulus is a tough outer ligament and the nucleus is a soft gel-like substance in the center of the disc.

**Spondylolisthesis:** A condition in which a defect in a part of the spine causes one vertebral body to slip forward (displacement) over another vertebrae. Typical symptoms of spondylolisthesis include back pain and/or leg pain. Most adolescents with spondylolisthesis do not actually experience any symptoms or pain. Spondylolisthesis is most likely caused by an underlying condition of spondylolysis. There are different types of spondylolisthesis, including degenerative, isthmic, dysplastic, traumatic, and pathologic.

**Applicable Coding**

The Plan uses and adopts up-to-date Current Procedural Terminology (CPT) codes from the American Medical Association (AMA), International Statistical Classification of Diseases and Related Health Problems, 10th revision (ICD-10) diagnosis codes developed by the World Health Organization and adapted in the United Stated by the National Center for Health Statistics (NCHS) of the Centers for Disease Control under the U.S. Department of Health and Human Services, and the Health Care

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Common Procedure Coding System (HCPCS) established and maintained by the Centers for Medicare & Medicaid Services (CMS). Because the AMA, NCHS, and CMS may update codes more frequently or at different intervals than Plan policy updates, the list of applicable codes included in this Plan policy is for informational purposes only, may not be all inclusive, and is subject to change without prior notification. Whether a code is listed in the Applicable Coding section of this Plan policy does not constitute or imply member coverage or provider reimbursement. Providers are responsible for reporting all services using the most up-to-date industry-standard procedure and diagnosis codes as published by the AMA, NCHS, and CMS at the time of the service.

Providers are responsible for obtaining prior authorization for the services specified in the Medical Policy Statement section and Limitation section of this Plan policy, even if an applicable code appropriately describing the service that is the subject of this Plan policy is not included in the Applicable Coding section of this Plan policy. Coverage for services is subject to benefit eligibility under the member’s benefit plan. Please refer to the member’s benefits document in effect at the time of the service to determine coverage or non-coverage as it applies to an individual member. See Plan reimbursement policies for Plan billing guidelines.

The Plan considers minimally invasive procedures and associated devices at all spinal levels to be experimental and investigational when used for the treatment of pain associated with disc disease, back pain, and/or for any other indication when used as a clinical alternative to (or in addition to) standard, open spinal surgery and/or conservative medical treatment. Minimally invasive techniques include but are not limited to percutaneous spinal procedures, laparoscopic and/or endoscopic spinal procedures, thermal intradiscal procedures, interspinous spacers, interlaminar stabilization devices, minimally invasive surgical procedures to remove disc material, minimally invasive spinal fusion procedures, lateral surgical approaches for spinal fusion, and/or the use of any combination of minimally invasive techniques. The Plan does NOT reimburse for a minimally invasive procedure (and related devices that include but are not limited to interbody cages, screws, spacers, and/or other fixation devices) when used as a stand-alone surgical treatment of pain associated with disc disease, back pain, and/or for any other indication because the clinical utility and clinical validity of these procedures have not been sufficiently established. The Plan does NOT reimburse additionally for these unproven minimally invasive procedures/techniques (and associated devices) when used with a standard, open spinal procedure and/or with established conservative, nonsurgical treatment(s) because these minimally invasive procedures and devices are considered experimental and investigational by the Plan. Prior authorization is required for all of these services.

The Plan uses InterQual criteria to determine the medical necessity of a standard, open spinal procedure (rather than criteria included in this Plan policy) when Plan prior authorization is required for the specified surgical procedure. Prior authorization guidelines are documented by applicable procedure code in the Plan’s Prior Authorization Code Look-up Tools (available at www.bmchp.org for BMC HealthNet Plan members and posted at www.wellsense.org for Well Sense Health Plan.

Minimally Invasive Procedures and Associated Devices used to Treat Back Pain (Including Thermal Intrascial Procedures, Interspinous Spacers, Interlaminar Stabilization Devices, and Minimally Invasive Surgical Procedures for Spinal Fusion and/or to Remove Disc Material)

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members). When prior authorization is necessary and applicable InterQual criteria are not met for a standard, open spinal fusion procedure, Plan Medical Director review is required.

<table>
<thead>
<tr>
<th>CPT Codes</th>
<th>Description: Codes Considered Experimental and Investigational</th>
</tr>
</thead>
<tbody>
<tr>
<td>22526</td>
<td>Percutaneous intradiscal electrothermal annuloplasty, unilateral or bilateral including fluoroscopic guidance, single level</td>
</tr>
<tr>
<td></td>
<td>Plan note: An example is IDET.</td>
</tr>
<tr>
<td>22527</td>
<td>Percutaneous intradiscal electrothermal annuloplasty, unilateral or bilateral including fluoroscopic guidance, 1 or more additional levels (list separately in addition to code for primary procedure)</td>
</tr>
<tr>
<td>22869</td>
<td>Insertion of interlaminar/interspinous process stabilization/distraction device, without open decompression or fusion, including image guidance when performed, lumbar; single level</td>
</tr>
<tr>
<td>22870</td>
<td>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)</td>
</tr>
<tr>
<td>22899</td>
<td>Unlisted procedure, spine</td>
</tr>
<tr>
<td></td>
<td>Plan notes:</td>
</tr>
<tr>
<td></td>
<td>1. Use for percutaneous intradiscal annuloplasty using method other than electrothermal.</td>
</tr>
<tr>
<td></td>
<td>2. Laparoscopic procedures and procedures without an assigned procedure code should be billed with this unlisted code.</td>
</tr>
<tr>
<td>62287</td>
<td>Decompression procedure, percutaneous, of nucleus pulposus of intervertebral disc, any method utilizing needle based technique to remove disc material under fluoroscopic imaging or other form of indirect visualization, with the use of an endoscope, with discography and/or epidural injection(s) at the treated level(s), when performed, single or multiple levels, lumbar</td>
</tr>
<tr>
<td></td>
<td>Plan note: Examples include manual or automated percutaneous lumbar discectomy, percutaneous laser discectomy, disc nucleoplasty, laser-assisted disc decompression (LADD), or endoscopic transforaminal discectomy.</td>
</tr>
<tr>
<td>62380</td>
<td>Endoscopic decompression of the spinal cord, nerve root(s), including laminotomy, partial facetectomy, foraminotomy, discectomy and/or excision of herniated intervertebral disc, 1 interspace, lumbar</td>
</tr>
<tr>
<td></td>
<td>Plan note: Code used for transforaminal (TESSYS®) and/or interlaminar (iLESSYS®) procedures.</td>
</tr>
</tbody>
</table>

Minimally Invasive Procedures and Associated Devices used to Treat Back Pain (Including Thermal Intrascial Procedures, Interspinous Spacers, Interlaminar Stabilization Devices, and Minimally Invasive Surgical Procedures for Spinal Fusion and/or to Remove Disc Material)

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Clinical Background Information

Back pain is a significant health problem with social and economic impact. In most cases, low back pain is temporary and can be relieved by conservative medical management; however for some individuals, back pain becomes a chronic and disabling condition. Internal disc disruption (IDD) is one perceived cause of discogenic back pain but controversy surrounds diagnosis and management of this condition. IDD identifies the syndrome of back pain and non-radicular referred pain in the setting of degenerative disc disease. In IDD, there is no associated herniation or prolapse of disc material, and radiological findings are often inconclusive. Generally, first-line treatment for chronic discogenic back pain is conservative, consisting of pharmacotherapy and/or a multidisciplinary pain management program that may include exercises, education, and physical therapy. If the pain does not improve, patients may then choose to continue with conservative management or to undergo surgery (i.e., spinal fusion).

Currently, there is insufficient clinical evidence to support the medical efficacy of minimally invasive procedures and associated devices at all spinal levels when used for the treatment of pain associated with disc disease, back pain, and/or for any other indication. Minimally invasive techniques include but are not limited to percutaneous spinal procedures, laparoscopic and/or endoscopic spinal procedures, thermal intradiscal procedures, interspinous spacers, interlaminar stabilization devices, minimally invasive surgical procedures to remove disc material, minimally invasive spinal fusion procedures, lateral surgical approaches for spinal fusion, and/or the use of any combination of minimally invasive techniques. Therefore these procedures and associated devices are considered experimental and investigational when used as used as a clinical alternative to (or in addition to) standard, open spinal surgery and/or conservative medical treatment.

At the time of the Plan’s most recent policy review, the Centers for Medicare and Medicaid Services (CMS) has concluded that the scientific evidence does not demonstrate that thermal intradiscal

Minimally Invasive Procedures and Associated Devices used to Treat Back Pain (Including Thermal Intrascial Procedures, Interspinous Spacers, Interlaminar Stabilization Devices, and Minimally Invasive Surgical Procedures for Spinal Fusion and/or to Remove Disc Material)

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procedures improve health outcomes, and therefore has issued a national non-coverage determination for thermal intradiscal procedures (TIP) under §1862(a)(1)(A) of the Social Security Act in national coverage determination (NCD) # 150.11; procedures included in this determination include but are not limited to the following: Intradiscal electrothermal therapy (IDET), intradiscal thermal annuloplasty (IDTA), percutaneous intradiscal radiofrequency thermocoagulation (PIRFT), radiofrequency annuloplasty (RA), intradiscal biacuplasty (IDB), percutaneous (or plasma) disc decompression (PDD) or coblation, or targeted disc decompression (TDD). CMS has determined that percutaneous image-guided lumbar decompression (PILD) for lumbar spinal stenosis (LSS) is not a medically necessary treatment under section 1862(a)(1)(A) of the Social Security Act with NCD #150.13; PILD may be covered by Medicare when provided in a clinical study under section 1862(a)(1)(E) for beneficiaries with LSS who are enrolled in an approved clinical study that meets CMS established criteria for clinical trials according to NCD 150.13. No CMS clinical guidelines were found for interspinous spacers, interlaminar stabilization devices, transforaminal endoscopic surgery (TES®) with TESSYS® or iLESSYS®, and/or minimally invasive spinal fusion procedures. Verify CMS criteria for the specified service in the applicable NCD or local coverage determination (LCD) on the date of the prior authorization request for a Senior Care Options member.

References


Minimally Invasiv e Procedures and Associated Devices used to Treat Back Pain (Including Thermal Intrascial Procedures, Interspinous Spacers, Interlaminar Stabilization Devices, and Minimally Invasive Surgical Procedures for Spinal Fusion and/or to Remove Disc Material)

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Minimally Invasive Procedures and Associated Devices used to Treat Back Pain (Including Thermal Intrascial Procedures, Interspinous Spacers, Interlaminar Stabilization Devices, and Minimally Invasive Surgical Procedures for Spinal Fusion and/or to Remove Disc Material)

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<table>
<thead>
<tr>
<th>Original Approval Date</th>
<th>Original Effective Date* and Version Number</th>
<th>Policy Owner</th>
<th>Approved by</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regulatory Approval: N/A Internal Approval: 05/26/09: MPCTAC 05/26/09: UMC 06/24/09: QIC</td>
<td>09/01/09 Version 1</td>
<td>Medical Policy Manager as Chair of Medical Policy, Criteria, and Technology Assessment Committee (MPCTAC) and member of Quality Improvement Committee (QIC)</td>
<td>MPCTAC, QIC, and Utilization Management Committee (UMC)</td>
</tr>
</tbody>
</table>

* Effective Date for the BMC HealthNet Plan Commercial Product(s): 01/01/12
* Effective Date for the Well Sense Health Plan New Hampshire Medicaid Product(s): 01/01/13
* Effective Date for the Senior Care Options Product(s): 01/01/16

Policy Title:
- Effective 09/01/09, this policy replaced the IDET policy. Policy title from 09/01/09 to 05/31/16 was Thermal Intradiscal and Other Minimally Invasive Surgical Treatments for Back Pain.
- Policy renamed **Minimally Invasive Procedures for Back Pain (Including Thermal Intradiscal Procedures, Interspinous Spacers, Interlaminar Stabilization Devices, and Minimally Invasive Surgical Procedures to Remove Disc Material)** as of 06/01/16.
- Policy title updated as of 03/01/17 to the following: **Minimally Invasive Procedures and Associated Devices used to Treat Back Pain (Including Thermal Intradiscal Procedures, Interspinous Spacers, Interlaminar Stabilization Devices, and Minimally Invasive Surgical Procedures for Spinal Fusion and/or to Remove Disc Material)**

Policy Revisions History

<table>
<thead>
<tr>
<th>Review Date</th>
<th>Summary of Revisions</th>
<th>Revision Effective Date and Version Number</th>
<th>Approved by</th>
</tr>
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<tbody>
<tr>
<td>04/01/10</td>
<td>Annual review. Updated references.</td>
<td>Version 2</td>
<td>04/27/10: MPCTAC 05/26/10: QIC</td>
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</tbody>
</table>

* Minimally Invasive Procedures and Associated Devices used to Treat Back Pain (Including Thermal Intradiscal Procedures, Interspinous Spacers, Interlaminar Stabilization Devices, and Minimally Invasive Surgical Procedures for Spinal Fusion and/or to Remove Disc Material)

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### Policy Revisions History

<table>
<thead>
<tr>
<th>Date</th>
<th>Revision Details</th>
<th>Version</th>
<th>Date/Revision Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>04/01/11</td>
<td>Annual review. No changes to criteria. Updated references.</td>
<td>Version 3</td>
<td>04/20/11: MPCTAC 05/25/11: QIC</td>
</tr>
<tr>
<td>04/01/12</td>
<td>Annual review. Updated criteria, updated coding, updated references.</td>
<td>Version 4</td>
<td>04/18/12: MPCTAC 06/27/12: QIC</td>
</tr>
<tr>
<td>07/29/12</td>
<td>Off cycle review for Well Sense Health Plan. Revised Summary statement, revised Medical Policy Statement, revised language in Applicable Coding section, revised Limitations.</td>
<td>Version 5</td>
<td>08/03/12: MPCTAC 09/05/12: QIC</td>
</tr>
<tr>
<td>02/01/13</td>
<td>Annual review for effective date 06/01/13. References updated, updated code definitions, revised introductory paragraph in Applicable Coding section, revised Summary section and referenced Experimental and Investigational Treatment policy, reformatted Description of Item or Service section, revised the Medical Policy Statement section (formerly named the Clinical Guideline Statement section) and Limitations section, moved list of experimental and investigation procedures from the Medical Policy Statement section to the Limitations section and added procedures, added definition for nociceptors, changed name of policy category from “Clinical Coverage Guidelines” to “Medical Policy.”</td>
<td>Version 6</td>
<td>02/20/13: MPCTAC 03/21/13: QIC</td>
</tr>
<tr>
<td>08/14/13 and 08/15/13</td>
<td>Off cycle review for Well Sense Health Plan and merged policy format. Incorporate policy revisions dated 02/01/13 (as specified above) for the Well Sense Health Plan product; these policy revisions were approved by MPCTAC on 02/20/13 and QIC on 03/21/13 for applicable Plan products.</td>
<td>Version 7</td>
<td>08/14/13: MPCTAC (electronic vote) 08/15/13: QIC</td>
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<tr>
<td>02/01/14</td>
<td>Annual review for effective 03/01/14. Added arthroscopic microdiscectomy (AMD) and examples of percutaneous discectomy devices to the Description of Item or Service section. Updated references.</td>
<td>Version 8</td>
<td>02/19/14: MPCTAC 02/26/14: QIC</td>
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<tr>
<td>02/01/15</td>
<td>Annual review for effective date 04/01/15. Updated references. Removed Commonwealth Care, Commonwealth</td>
<td>Version 9</td>
<td>02/18/15: MPCTAC 03/11/15: QIC</td>
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*Minimally Invasive Procedures and Associated Devices used to Treat Back Pain (Including Thermal Intrascial Procedures, Interspinous Spacers, Interlaminar Stabilization Devices, and Minimally Invasive Surgical Procedures for Spinal Fusion and/or to Remove Disc Material)*

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Policy Revisions History

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<tbody>
<tr>
<td>11/25/15</td>
<td>Review for effective date 01/01/16. Updated template with list of applicable products and notes. Revised language in the Applicable Coding section.</td>
<td>01/01/16 Version 10</td>
<td>11/18/15: MPCTAC 11/25/15: MPCTAC (electronic vote) 12/09/15: QIC</td>
</tr>
<tr>
<td>02/01/16</td>
<td>Review for effective date 06/01/16. Updated Summary, Description of Item or Service, Limitations, Definitions, Clinical Background Information, References, and Reference to Applicable Laws and Regulations sections. Added experimental and investigational codes to the applicable code list and revised the policy title.</td>
<td>06/01/16 Version 11</td>
<td>02/17/16: MPCTAC 03/09/16: QIC</td>
</tr>
<tr>
<td>12/01/16</td>
<td>Review for effective date 04/01/17. Revised title. Updated Summary, Description of Item or Service, Definitions, Clinical Background Information, and References sections. Revised criteria in the Medical Policy Statement and Limitations sections. Revised the language and code list in the Applicable Coding section.</td>
<td>03/01/17 Version 12</td>
<td>12/21/16: MPCTAC 01/11/17: QIC</td>
</tr>
</tbody>
</table>

Last Review Date

12/01/16

Next Review Date

03/01/17

Authorizing Entity

QIC

Other Applicable Policies

Medical Policy - Experimental and Investigational Treatment, policy number OCA 3.12

Minimally Invasive Procedures and Associated Devices used to Treat Back Pain (Including Thermal Intrascial Procedures, Interspinous Spacers, Interlaminar Stabilization Devices, and Minimally Invasive Surgical Procedures for Spinal Fusion and/or to Remove Disc Material)

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Reference to Applicable Laws and Regulations


Disclaimer Information: +

Medical Policies are the Plan’s guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other Plan Policies, as well as the Member’s benefit document, and when appropriate, coordinates with the Member’s health care Providers to consider the individual Member’s health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan’s service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member’s benefit document, take precedence over these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.

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