Preauthorization is required.

The following protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient’s contract at the time the services are rendered.

RELATED PROTOCOLS

Artificial Intervertebral Disc: Cervical Spine

Artificial Intervertebral Disc: Lumbar Spine

Automated Percutaneous and Percutaneous Endoscopic Discectomy

Decompression of the Intervertebral Disc Using Laser Energy (Laser Discectomy) or Radiofrequency-Coblation (Nucleoplasty)

Percutaneous Intradiscal Electrothermal Annuloplasty, Radiofrequency Annuloplasty, and Biacuplasty

Vertebral Axial Decompression

| Populations | Interventions | Comparators | Outcomes |
|-------------|---------------|-------------|----------|
| Individuals: • With lumbar herniated disc(s) and symptoms of radiculopathy rapidly progressing or refractory to conservative care | Interventions of interest are: • Lumbar discectomy | Comparators of interest are: • Conservative, nonsurgical care | Relevant outcomes include: • Symptoms • Functional outcomes • Health status measures • Quality of life • Treatment-related mortality • Treatment-related morbidity |
| Individuals: • With cervical herniated disc(s) and symptoms of radiculopathy rapidly progressing or refractory to conservative care | Interventions of interest are: • Cervical discectomy | Comparators of interest are: • Conservative, nonsurgical care | Relevant outcomes include: • Symptoms • Functional outcomes • Health status measures • Quality of life • Treatment-related mortality |

DESCRIPTION

Discectomy is a surgical procedure in which one or more intervertebral discs are removed. Extrusion of an intervertebral disc beyond the intervertebral space can compress the spinal nerves and result in pain, numbness, and
weakness. Discectomy is intended to treat symptoms by relieving pressure on the affected nerve root(s). Discectomy can be performed by a variety of surgical approaches, with either open surgery or minimally invasive techniques.

SUMMARY OF EVIDENCE

For individuals who have lumbar herniated disc(s) and symptoms of radiculopathy rapidly progressing or refractory to conservative care who receive lumbar discectomy, the evidence includes randomized controlled trials (RCT) and systematic reviews. Relevant outcomes are symptoms, functional outcomes, health status measures, quality of life, and treatment-related mortality and morbidity. In patients with lumbar radiculopathy with disc herniation who receive discectomy, there is sufficient evidence to support the use of discectomy in patients who have not responded to “usual care” for six weeks. The evidence is limited by a lack of high-quality trials. In most trials, a high percentage of patients in the conservative care group crossed over to surgery. This high degree of crossover reduced the power to detect differences when assessed by intention-to-treat analysis. Analysis by treatment received was also flawed because of the potential noncomparability of groups resulting from the high crossover rate. Despite the methodologic limitations, the evidence has consistently demonstrated a probable short-term benefit for surgery and a more rapid resolution of pain and disability. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have cervical herniated disc(s) and symptoms of radiculopathy rapidly progressing or refractory to conservative care who receive cervical discectomy, the evidence includes two RCTs, a long-term observational study, and a systematic review. Relevant outcomes are symptoms, functional outcomes, health status measures, quality of life, and treatment-related mortality and morbidity. There is considerably less evidence on cervical discectomy than on lumbar discectomy. The best evidence on the efficacy of cervical discectomy consists of two small RCTs comparing discectomy with conservative care, and a systematic review of these trials. Although there is less evidence for this indication, it does not differ substantially from lumbar herniated disc, showing that patient-reported symptoms and disability favor surgery in the short-term, and that long-term outcomes do not differ. Because cervical discectomy closely parallels lumbar discectomy, with close similarities in anatomy and surgical procedure, it can be inferred that the benefit reported for lumbar discectomy supports a benefit for cervical discectomy. Based on the available evidence and extrapolation from studies of lumbar herniated disc, it is likely that use of discectomy for cervical herniated disc improves short-term symptoms and disability. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

POLICY

Lumbar discectomy (see Policy Guidelines section) may be considered medically necessary for the treatment of lumbar herniated disc when the following criteria are met:

• Signs and symptoms of radiculopathy on history and physical exam (see Policy Guidelines section).

• One of the following clinical presentations is present:
  o Rapidly progressing neurologic deficits; OR
  o Persistent debilitating back or leg pain that is refractory to at least six weeks of conservative therapy (see Policy Guidelines section).

• Documentation of nerve root compression on imaging (magnetic resonance imaging or computed tomography) at a level that corresponds with the patient’s symptoms (see Policy Guidelines section).
Lumbar discectomy is **not medically necessary** for the treatment of lumbar herniated disc when the above criteria are not met.

Cervical discectomy (see Policy Guidelines section) may be considered **medically necessary** for the treatment of cervical herniated disc when the following criteria are present:

- Signs and symptoms of radiculopathy and/or myelopathy on history and physical exam (see Policy Guidelines section).
- One of the following clinical presentations is present:
  - Rapidly progressing neurologic deficits; OR
  - Persistent debilitating neck, back, or arm pain that is refractory to at least six weeks of conservative therapy (see Policy Guidelines section); OR
  - Persistent or progressive symptoms of myelopathy that are refractory to at least six weeks of conservative therapy (see Policy Guidelines section).
- Documentation of nerve root compression on imaging (magnetic resonance imaging or computed tomography) at a level that corresponds with the patient’s symptoms (see Policy Guidelines section).

Cervical discectomy is **not medically necessary** for the treatment of cervical herniated disc when the above criteria are not met.

Discectomy is considered **investigational** for all other indications.

**POLICY GUIDELINES**

**LUMBAR DISCECTOMY**

Lumbar discectomy refers to standard open discectomy or minimally invasive microdiscectomy. Microdiscectomy will be defined for the purpose of this protocol as having the following features: (1) uses a small surgical incision (as opposed to an endoscopic “port”), (2) uses a specially designed microscope to achieve direct visualization of the vertebral column (as opposed to indirect visualization with an endoscope or other type of cameras), and (3) removes disc and other surgical products by direct visualization through the surgical incision. Microdiscectomy may be done with adjunctive devices, such as tubular retractors to improve visualization, or endoscopy to localize the correct areas to operate. However, removal of the disc itself must be done under direct visualization to be considered microdiscectomy.

**CERVICAL DISCECTOMY**

Cervical discectomy refers to open anterior cervical discectomy (with or without fusion) or minimally invasive posterior cervical discectomy/foraminotomy.

There are numerous alternative procedures for performing discectomy, with uncertain efficacy compared with standard procedures. For this protocol, the following procedures, most of which are discussed in other policies, are considered **investigational**:

- Laser discectomy (Decompression of the Intervertebral Disc Using Laser Energy [Laser Discectomy] or Radiofrequency Coblation [Nucleoplasty] Protocol)
- Radiofrequency coblation (nucleoplasty) (Decompression of the Intervertebral Disc Using Laser Energy [Laser Discectomy] or Radiofrequency Coblation [Nucleoplasty] Protocol)
- Automated percutaneous discectomy (Automated Percutaneous and Percutaneous Endoscopic Discectomy Protocol)
Endoscopic discectomy (Automated Percutaneous and Percutaneous Endoscopic Discectomy Protocol)

- Intradiscal electrothermal annuloplasty (Percutaneous Intradiscal Electrothermal Annuloplasty, Radiofrequency Annuloplasty, and Biacuplasty Protocol)
- Intradiscal radiofrequency therapy (Percutaneous Intradiscal Electrothermal Annuloplasty, Radiofrequency Annuloplasty, and Biacuplasty Protocol)
- Chemonucleolysis

**RADICULOPATHY**

Radiculopathy presents with a characteristic set of signs and symptoms based on history and physical exam.

**History:**
- Pain that radiates down the back of the leg to below the knee
- Numbness and tingling in a dermatomal distribution
- Muscular weakness in a pattern associated with spinal nerve root compression.

**Physical exam:**
- Positive straight leg raise test
- Loss of deep tendon reflexes corresponding to affected nerve root level
- Loss of sensation in a dermatomal pattern.

Conservative nonsurgical therapy for the duration specified should include the following:

- Use of prescription-strength analgesics for several weeks at a dose sufficient to induce a therapeutic response
  - Analgesics should include anti-inflammatory medications with or without adjunctive medications, such as nerve membrane stabilizers or muscle relaxants, AND
- Participation in at least six weeks of physical therapy (including active exercise) or documentation of why the patient could not tolerate physical therapy, AND
- Evaluation and appropriate management of associated cognitive, behavioral, or addiction issues AND
- Documentation of patient compliance with the preceding criteria.

Persistent debilitating pain is defined as:

- Significant level of pain on a daily basis, defined on a visual analog scale score as greater than four; AND
- Pain on a daily basis that has a documented impact on activities of daily living despite optimal conservative nonsurgical therapy, as outlined above, and appropriate for the patient.

**MEDICAL NECESSITY**

Medical necessity is established by documentation of medical history, physical findings, and diagnostic imaging results that demonstrate spinal nerve compression and support the surgical treatment intervention. Documentation in the medical record must clearly support the medical necessity of the surgery and include medical history, physical examination, and diagnostic testing.
Medical History

- Assessment of comorbid physical and psychological health conditions (e.g., morbid obesity, current smoking, diabetes, renal disease, osteoporosis, and severe physical deconditioning)
- History of back surgery, including minimally invasive back procedures
- Prior trial, failure, or contraindication to conservative medical/nonoperative interventions that may include but are not limited to the following:
  - Activity modification for at least six weeks
  - Oral analgesics and/or anti-inflammatory medications
  - Physical therapy
  - Chiropractic manipulation
  - Epidural steroid injections.

Physical Examination

- Clinical findings including the patient’s stated symptoms and duration.

Diagnostic Testing

- Radiologically confirmed lumbar spine abnormality based on a magnetic resonance image or computerized tomography scan with myelogram of the lumbar spine within the past six months
- Report of the selective nerve root injection results, if applicable to the patient’s diagnostic workup.

BACKGROUND

DISC HERNIATION

Extrusion of an intervertebral disc beyond the intervertebral space can compress the spinal nerves and result in symptoms of pain, numbness, and weakness.

The natural history of untreated disc herniations is not well-characterized, but most herniations will decrease in size over time due to shrinking and/or regression of the disc. Clinical symptoms will also tend to improve over time in conjunction with shrinkage or regression of the herniation.

TREATMENT

Because most disc herniations improve over time, initial care is conservative, consisting of analgesics and a prescribed activity program tailored to patient considerations. Other potential nonsurgical interventions include opioid analgesics and chiropractic manipulation. Epidural steroid injections can also be used as a second-line intervention and are associated with short-term relief of symptoms.

However, some disc herniations will not improve over time with conservative care. A small proportion of patients will have rapidly progressive signs and symptoms, thus putting them at risk for irreversible neurologic deficits. These patients are considered to be surgical emergencies, and expedient surgery is intended to prevent further neurologic deterioration and allow for nerve recovery.

Other patients will not progress but will have the persistence of symptoms that require further intervention. It is estimated that up to 30% of patients with sciatica will continue to have pain for more than one year. For these patients, there is a high degree of morbidity and functional disability associated with chronic back pain, and there is a tendency for recurrent pain despite treatment. Therefore, treatments that have more uniform efficacy
for patients with a herniated disc and chronic back pain are needed. In particular, decreased chronic pain and decreased disability are the goals of treatment of chronic low back pain due to a herniated disc.

SURGICAL TREATMENT

Discectomy is a surgical procedure in which one or more intervertebral discs are removed. The primary indication for discectomy is herniation (extrusion) of an intervertebral disc. Discectomy is intended to treat symptoms by relieving pressure on the affected nerve(s).

Lumbar Discectomy

Lumbar discectomy can be performed by a variety of surgical approaches. Open discectomy is the traditional approach. In open discectomy, a 2- to 3-cm incision is made over the area to be repaired. The spinal muscles are dissected, and a portion of the lamina may be removed to allow access to the vertebral space. The extruded disc is removed either entirely or partially using direct visualization. Osteophytes that are protruding into the vertebral space can also be removed if deemed necessary.

The main alternative to open discectomy is microdiscectomy, which has gained popularity. Microdiscectomy is a minimally invasive procedure that involves a smaller incision, visualization of the disc through a special camera, and removal of disc fragments using special instruments. Because less resection can be performed in a microdiscectomy, it is usually reserved for smaller herniations, in which a smaller amount of tissue needs to be removed. A few controlled trials comparing open discectomy with microdiscectomy have been published and reported that neither procedure is clearly superior to the other, but that microdiscectomy is associated with more rapid recovery. Systematic reviews and meta-analyses have also concluded that the evidence does not support the superiority of one procedure over another.

Cervical Discectomy

The most common procedure for cervical discectomy is anterior cervical discectomy. This is an open procedure in which the cervical spine is approached through an incision in the anterior neck. Soft tissues and muscles are separated to expose the spine. The disc is removed using direct visualization. This procedure can be done with or without spinal fusion, but most commonly it is performed with fusion.

A less invasive procedure for cervical discectomy is posterior cervical discectomy and foraminotomy. This is performed through a small incision in the back of the neck. The nerves and muscles are separated using a small retractor. The spine is visualized with microscopic guidance, and a portion of the spine (the foramen) is removed to expose the spinal canal. Special instruments are used to remove a portion of the disc or the entire disc.

Adverse Events

Complications of discectomy generally include bleeding, infections, and inadvertent nerve injuries. Dural puncture occurs in a small percentage of patients, leading to leakage of cerebrospinal fluid that can be accompanied by headaches and/or neck stiffness. In a small percentage of cases, worsening of neurologic symptoms can occur postsurgery.

Other Surgical Alternatives

Other variations on discectomy include the following. These procedures do not have high-quality comparative trials versus standard discectomy, and will therefore not be considered as true alternatives to discectomy for this evidence review:

- Laser discectomy
- Radiofrequency coblation (nucleoplasty)
- Automated percutaneous discectomy
• Automated endoscopic discectomy
• Intradiscal electrothermal annuloplasty
• Intradiscal radiofrequency therapy
• Vertebral axial decompression
• Chemonucleolysis

REGULATORY STATUS
Discectomy is a surgical procedure and, as such, is not subject to regulation by the U.S. Food and Drug Administration. Some instrumentation used during laminectomy may be subject to U.S. Food and Drug Administration approval.

Services that are the subject of a clinical trial do not meet our Technology Assessment and Medically Necessary Services Protocol criteria and are considered investigational. For explanation of experimental and investigational, please refer to the Technology Assessment and Medically Necessary Services Protocol.

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. Some of this protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.

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