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OVERVIEW

This policy addresses a variety of minimally invasive techniques that have been investigated over the years as treatment of low back pain related to disc disease. Techniques can be broadly divided into techniques that are designed to remove or ablate disc material, and thus decompress the disc, and those designed to alter the biomechanics of the disc annulus.

MEDICAL CRITERIA

Not applicable

PRIOR AUTHORIZATION

Not applicable

POLICY STATEMENT

Medicare Advantage Plans

Percutaneous annuloplasty (e.g., intradiscal electrothermal annuloplasty, intradiscal radiofrequency annuloplasty, or intradiscal biacuplasty), Laser discectomy and radiofrequency coblation (disc nucleoplasty) and automated percutaneous discectomy are not covered as the evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Commercial Products

Percutaneous annuloplasty (e.g., intradiscal electrothermal annuloplasty, intradiscal radiofrequency annuloplasty, or intradiscal biacuplasty), Laser discectomy and radiofrequency coblation (disc nucleoplasty) and automated percutaneous discectomy are considered not medically necessary as the evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

COVERAGE

Benefits may vary between groups and contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage or Subscriber Agreement for applicable not medically necessary/not covered benefits/coverage.

BACKGROUND

Percutaneous thermal intradiscal procedures (TIPs) involve the insertion of a catheter(s)/probe(s) in the spinal disc under fluoroscopic guidance for the purpose of producing or applying heat and/or disruption within the disc to relieve low back pain.

The scope of the Centers for Medicare and Medicaid Services national coverage determination on TIPs includes percutaneous intradiscal techniques that employ the use of 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 a contained herniated disc, to seal annular tears or fissures, or destroy nociceptors for the purpose of relieving pain. This includes techniques that use single or multiple probe(s)/catheter(s), which utilize a resistance coil or other delivery system technology, are flexible or rigid, and are placed within the nucleus, the nuclear-annular junction, or the annulus.

Although not intended to be an all-inclusive list, TIPs are commonly identified as 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). At times, TIPs are identified or labeled based on the name of the catheter/probe that is used (e.g., SpineCath, discTRODE, SpineWand, Accutherm, or TransDiscal electrodes). Each technique or device has its own protocol for application of the therapy.

The Centers for Medicare and Medicaid Services has determined that TIPs are not reasonable and necessary for the treatment of low back pain. Therefore, TIPs, which include procedures that employ the use of a radiofrequency energy source or electrothermal energy to apply or create heat and/or disruption within the disc for the treatment of low back pain, are noncovered. Therefore, these services are not covered for Medicare Advantage Plans.

Percutaneous Intradiscal Electrothermal Annuloplasty, Radiofrequency Annuloplasty, and Biacuplasty

For individuals who have discogenic back pain who receive intradiscal electrothermal annuloplasty, the evidence includes a small number of randomized controlled trials (RCTs). Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Two RCTs on intradiscal electrothermal annuloplasty reported conflicting results, with one reporting benefit for intradiscal electrothermal annuloplasty and the other reporting no benefit. Further study in a sham-controlled trial with a representative population of patients is needed. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have discogenic back pain who receive intradiscal radiofrequency annuloplasty, the evidence includes 2 RCTs. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Neither RCT found evidence of benefit with the treatment. More sham-controlled trials are needed. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have discogenic back pain who receive intradiscal biacuplasty, the evidence includes 2 industry-sponsored RCTs. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. One trial reported significant improvements at 6 months post-treatment, but not at 1 and 3 months. The other trial also showed a significant reduction in visual analog scale scores at 6 months that appeared to continue to the 12-month follow-up; however, it is unclear whether this trial was sufficiently powered. More sham-controlled trials are needed. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

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

For individuals who have discogenic back pain or radiculopathy who receive laser discectomy, the evidence includes systematic reviews of observational studies. Relevant outcomes are symptoms, functional outcomes, and treatment-related morbidity. While numerous case series and uncontrolled studies have reported improvements in pain levels and functioning following laser discectomy, the lack of well-designed and conducted controlled trials limits interpretation of reported data. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have discogenic back pain or radiculopathy who receive disc nucleoplasty with radiofrequency coblation, the evidence includes RCT s and systematic reviews. Relevant outcomes are symptoms, functional outcomes, and treatment-related morbidity. For nucleoplasty, there are 3 RCT s in addition to several uncontrolled studies. These RCT s are limited by the lack of blinding, an inadequate control condition in 1, inadequate data reporting in the second, and low enrollment with early study termination in the third. The available evidence is insufficient to permit conclusions concerning the effect of these procedures on health outcomes due to multiple confounding factors that may bias results. High-quality randomized trials with adequate follow-up (at least 1 year), which control for selection bias, the placebo effect, and variability in the natural history of low back pain, are needed. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Automated Percutaneous Discectomy

For individuals who have herniated intervertebral disc(s) who receive automated percutaneous discectomy, the evidence includes randomized controlled trials (RCTs) and systematic reviews of observational studies. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The published evidence from small RCTs is insufficient to evaluate the impact of automated percutaneous discectomy on the net health outcome. Well-designed and executed RCTs are needed to determine the benefits and risks of this procedure. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

CODING

The following codes are not covered for Medicare Advantage Plans when identified as Percutaneous thermal intradiscal procedures (TIPs) and not medically necessary for Commercial products:

- 22526** Percutaneous intradiscal electrothermal annuloplasty, unilateral or bilateral including fluoroscopic guidance; single level
- 22527** Percutaneous intradiscal electrothermal annuloplasty, unilateral or bilateral including fluoroscopic guidance; one or more additional levels (List separately in addition to code for primary procedure)
- S2348** Decompression procedure, percutaneous, of nucleus pulposus of intervertebral disc, using radiofrequency energy, single or multiple levels, lumbar
- 62287** 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 discography and/or epidural injection(s) at the treated level(s), when performed, single or multiple levels, lumbar

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