This Protocol considers this test or procedure investigational. If the physician feels this service is medically necessary, preauthorization is recommended.

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.

<table>
<thead>
<tr>
<th>Populations</th>
<th>Interventions</th>
<th>Comparators</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients/individuals with:</td>
<td>Interventions of interest are:</td>
<td>Comparators of interest are:</td>
<td>Relevant outcomes include:</td>
</tr>
<tr>
<td>• Discogenic back pain</td>
<td>• Intradiscal electrothermal annuloplasty</td>
<td>• Conservative care</td>
<td>• Functional outcomes</td>
</tr>
<tr>
<td></td>
<td>• Intradiscal radiofrequency annuloplasty/biacuplasty</td>
<td>• Alternative surgical procedures for discogenic back pain</td>
<td>• Treatment-related morbidity</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Symptoms</td>
</tr>
</tbody>
</table>

Description

Intradiscal annuloplasty therapies use energy sources to treat discogenic low back pain arising from annular tears. Thermal and radiofrequency annuloplasty techniques are designed to decrease pain arising from the annulus and enhance its structural integrity.

Summary of Evidence

There is limited evidence on the efficacy of intradiscal thermal annuloplasty, consisting of a small number of randomized controlled trials (RCTs) and case series. The two RCTs on intradiscal electrothermal annuloplasty have conflicting results, with one reporting benefit for intradiscal electrothermal annuloplasty (IDET™) and the other reporting no benefit.

There is a lack of evidence to support a role for radiofrequency annuloplasty with a single probe. One recent RCT on biacuplasty suggests that this procedure may provide modest benefit in a proportion of highly selected patients; confirmation of these results in a broader population is needed. Overall, evidence is insufficient to permit conclusions regarding the effect of these procedures on health outcomes.

Policy

Percutaneous annuloplasty (e.g., intradiscal electrothermal annuloplasty, percutaneous intradiscal radiofrequency thermocoagulation, or intradiscal biacuplasty) for the treatment of chronic discogenic back pain is considered investigational.
Background

It has been proposed that heat-induced denaturation of collagen fibers in the annular lamellae may stabilize the disc and potentially seal annular fissures and that pain reduction may occur through the thermal coagulation of nociceptors in the outer annulus.

With the intradiscal electrothermal annuloplasty procedure (IDET™; Oratec SpineCATH System), a navigable catheter with an embedded thermal resistive coil is inserted posterolaterally into the disc annulus or nucleus. The catheter is then snaked through the disc circuitously to return posteriorly. Using indirect radiofrequency (RF) energy, electrothermal heat is generated within the thermal resistive coil at a temperature of 90° C; the disc material is heated for up to 20 minutes. Proposed advantages of indirect electrothermal delivery of RF energy with IDET™ include precise temperature feedback and control, and the ability to provide electrothermocoagulation to a broader tissue segment than would be allowed with a direct RF needle.

Another procedure, referred to as percutaneous intradiscal radiofrequency thermocoagulation (PIRFT), uses direct application of RF energy. With PIRFT, the RF probe is placed into the center of the disc, and the device is activated for only 90 seconds at a temperature of 70° C. The procedure is not designed to coagulate, burn, or ablate tissue. The Radionics RF Disc Catheter System has been specifically designed for this purpose.

A more recently developed annuloplasty procedure, referred to as intradiscal biacuplasty (Baylis Medical, Montreal, Canada) involves use of two cooled RF electrodes placed on the posterolateral sides of the intervertebral annulus fibrosus. It is believed that, by cooling the probes, a larger area may be treated than could occur with a regular needle probe.

Annuloplasty using a laser-assisted spinal endoscopy kit to coagulate the disc granulation tissue (percutaneous endoscopic laser annuloplasty) has also been described.

Regulatory Status

IDET™, Oratec Nucleotomy Catheter, received marketing clearance through FDA’s 510(k) process in 2002. The predicate device was the SpineCATH® Intradiscal Catheter, which received FDA clearance for marketing in 1999. Radionics (Burlington, MA; a division of Tyco Healthcare group) RF (Radiofrequency) Disc Catheter System received marketing clearance through FDA’s 510(k) process in 2000. Valleylab (Covidien) is marketing the discTRODE™ RF catheter electrode system for use with the RFG-3CPlus™ RF lesion generator in the United States. FDA product code: GEI.

The Baylis Pain Management Cooled Probe received marketing clearance through FDA’s 510(k) process in 2005. It is intended for use “in conjunction with the Radio Frequency Generator to create radiofrequency lesions in nervous tissue.” FDA product code: GXI.

Note: This Protocol does not address DISC Nucleoplasty™, a technique based on a device offered by ArthroCare (Austin, TX). With the ArthroCare system, a bipolar RF device is used to provide lower energy treatment (Coblation®) to the intervertebral disc, which is designed to provide tissue removal with minimal thermal damage to collateral tissue. DISC Nucleoplasty is closer in concept to a laser discectomy in that tissue is removed or ablated in an effort to provide decompression of a bulging disc. DISC Nucleoplasty and laser discectomy are considered separately in the Decompression of the Intervertebral Disc Using Laser Energy (Laser Discectomy) or Radiofrequency Coblation (Nucleoplasty) Protocol.

Related Protocols

Automated Percutaneous and Endoscopic Discectomy
Decompression of Intervertebral Discs Using Laser Energy (Laser Discectomy) or Radiofrequency Coblation (Nucleoplasty)

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

References

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

1. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Intradiscal electrothermal therapy for chronic low back pain. TEC Assessments Apr 2002; Volume 17, Tab 11. PMID 11010675

2. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Percutaneous intradiscal radiofrequency thermocoagulation for chronic discogenic low back pain. TEC Assessments. Nov 6 2003; Volume 18, Tab 19. PMID 15043079


