Percutaneous Intradiscal Electrothermal Annuloplasty, Radiofrequency Annuloplasty, and Biacuplasty

Description

Electrothermal intradiscal annuloplasty therapies use radiofrequency energy sources to treat discogenic low back pain arising from annular tears. These annuloplasty techniques are designed to decrease pain arising from the annulus by thermocoagulating nerves in the disc and tightening of annular tissue.

OBJECTIVE

The objective of this evidence review is to evaluate whether intradiscal electrothermal annuloplasty, intradiscal radiofrequency annuloplasty, and intradiscal biacuplasty improve net health outcomes in patients with discogenic back pain. This evidence review does not address disc nucleoplasty.

POLICY STATEMENT

Percutaneous annuloplasty (eg, intradiscal electrothermal annuloplasty, intradiscal radiofrequency annuloplasty, or intradiscal biacuplasty) for the treatment of chronic discogenic back pain is considered investigational.

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POLICY GUIDELINES

None.

BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

FDA REGULATORY STATUS

A variety of radiofrequency coagulation devices have been cleared for marketing by the U.S. Food and Drug Administration (FDA), some of which are designed for disc nucleotomy. In 2002, the Oratec Nucleotomy Catheter (ORATEC Interventions, Menlo Park, CA, acquired by Smith & Nephew in 2002) was cleared for marketing by FDA through the 510(k) process. The predicate device was the SpineCATH Intradiscal Catheter, which received FDA clearance for marketing in 1999. The Radionics (a division of Tyco Healthcare group) Radiofrequency Disc Catheter System received marketing clearance by FDA through the 510(k) process in 2000. FDA product code: GEI.

In 2005, the Baylis Pain Management Cooled Probe was also cleared for marketing by FDA through the 510(k) process. 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 evidence review does not address disc nucleoplasty, a technique based on the bipolar radiofrequency device (Coblation; ArthroCare, Austin, TX, acquired by Smith & Nephew, 2014). With the coblation system, a bipolar radiofrequency device is used to provide lower energy treatment 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 to provide decompression of a bulging disc. Disc nucleoplasty and laser discectomy are considered in evidence review 7.01.93.

RATIONALE

Summary of Evidence

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 the effects of the technology on health outcomes.

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 the effects of the technology on health outcomes.

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 the effects of the technology on health outcomes.

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SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

American Society of Interventional Pain Physicians

A 2013 review of the evidence informing American Society of Interventional Pain Physicians guidelines found limited-to-fair evidence for intradiscal electrothermal therapy (IDET; another term for intradiscal electrothermal annuloplasty) and biacuplasty and limited evidence for percutaneous intradiscal radiofrequency thermocoagulation.\(^1\) These guidelines updated 2007 guidelines, which concluded that the evidence was moderate for management of chronic discogenic low back pain with IDET.\(^2\) Complications included catheter breakage, nerve root injuries, post-IDET disc herniation, cauda equina syndrome, infection, epidural abscess, and spinal cord damage. The evidence for percutaneous intradiscal radiofrequency thermocoagulation was limited, with complications similar to IDET.\(^3\)

National Institute for Health and Care Excellence

A 2016 guidance update by the National Institute for Health and Care Excellence (NICE) indicated that the evidence on safety and efficacy of percutaneous intradiscal radiofrequency thermocoagulation for low back pain was "limited" and should only be used by "special arrangement".\(^4\)

In 2016, NICE guidance on electrothermal annuloplasty was also updated.\(^5\) NICE considered evidence on the efficacy of percutaneous intradiscal radiofrequency thermocoagulation for low back pain to be inconsistent and of poor quality, although no major safety concerns were identified. NICE recommended percutaneous intradiscal radiofrequency thermocoagulation only with special arrangements for clinical governance, consent, and audit or research.

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

The Centers for Medicare & Medicaid Services has determined that thermal intradiscal procedures, including IDET and percutaneous intradiscal radiofrequency thermocoagulation, are not reasonable and necessary for the treatment of low back pain. Therefore, TIPS [thermal intradiscal procedures], 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.\(^6\)

REFERENCES

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

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POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:

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<td>New policy</td>
<td>Policy statement changed to read not medically necessary. Related policies added.</td>
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<td>June 2012</td>
<td>Replace policy</td>
<td>Policy updated with literature search; references 3, 5, 16, 18, 19 and 21 added; policy statement unchanged.</td>
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<tr>
<td>September 2013</td>
<td>Replace policy</td>
<td>Policy updated with literature review, policy statement unchanged.</td>
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<tr>
<td>September 2014</td>
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<td>Policy updated with literature review; reference 17 added. Policy statement unchanged.</td>
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<td>Policy updated with literature review through November 1, 2016; references 9-10 added; reference 14 updated; some references removed. Title changed to &quot;Percutaneous intradiscal electrothermal annuloplasty, radiofrequency annuloplasty, and biacuplasty.&quot; Policy statement terminology revised to reflect the changes in the title but the intent is unchanged.</td>
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<td>Policy updated with literature review through February 11, 2020; no references added. Policy statements unchanged.</td>
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