Clinical Review Criteria
Intradiscal Electrothermal Therapy (IDET)

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Criteria
For Medicare Members

<table>
<thead>
<tr>
<th>Source</th>
<th>Policy</th>
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<tr>
<td>CMS Coverage Manuals</td>
<td>None</td>
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<tr>
<td>National Coverage Determinations (NCD)</td>
<td>Thermal Intradiscal Procedures (150.11)</td>
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<tr>
<td>Local Coverage Determinations (LCD)</td>
<td>None</td>
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<td>Local Coverage Article</td>
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For Non-Medicare Members

Kaiser Permanente has elected to use the Thermal Intradiscal Procedures (A-0217) MCG* for medical necessity determinations.

*MCG are proprietary and cannot be published and/or distributed. However, on an individual member basis, Kaiser Permanente can share a copy of the specific criteria document used to make a utilization management decision. If one of your patients is being reviewed using these criteria, you may request a copy of the criteria by calling the Kaiser Permanente Clinical Review staff at 1-800-289-1363.

If requesting this service, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist (Neurosurgeon, neurologist, physiatrist, pain specialists, orthopedic spine surgeon)

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, KPWA will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Intradiscal Electrothermal Therapy (IDET) is a minimally invasive procedure that was developed as a treatment for lumbar discogenic pain. It aims to reduce the symptoms of the disrupted disc by thermocoagulating annular tissue and contracting collagen fibrils. The SpineCATH™ Intradiscal Catheter delivers thermal energy to the posterior annulus via a resistive heater coil. The annulus is comprised of Type I and II collagen fibers, which are held together by hydrogen bonds in a triple helix formation. It has been shown that these bonds break when heated to 60°C to 75°C is applied to the tissue. After being heated to the optimum temperature the collagen fibers contract and thicken. Following thermal contraction, collagen tissue undergoes a remodeling or regeneration process. Remodeling includes fibroblast in-growth and proliferation as well as new collagen formation in the treatment areas. The treatment is performed on an outpatient basis, under fluoroscopy.

IDET (SpineCath, Smith and Nephew) received FDA approval for the “coagulation and decompression of disc material to treat symptomatic patients with annular disruption of contained herniated discs” (DHHS, letter 8/17/2001). It does not appear to be approved for other types of low back pain.

Medical Technology Assessment Committee (MTAC)

Intradiscal Electrothermal Therapy (IDET)
10/11/2000: MTAC REVIEW

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Evidence Conclusion: The study reviewed has a number of limitations including a small sample size, lack of a control group, potential selection bias, potential placebo effects, and the absence of significant improvements in outcomes after 6 months. Given the lack of peer-review studies and the limitation of this case series, the effectiveness of IDET for chronic back pain cannot be determined at this time.

Articles: Articles were selected based on study type. The only article found was a case series. A review article was reviewed, but no evidence table was created. The articles selected for critical appraisal include: Saal et al. Management of chronic discogenic low back pain with a thermal intradiscal catheter: A Preliminary Report. Spine 2000;25:382-388. See Evidence Table

The use of Intradiscal Electrothermal Therapy (IDET) in the treatment of back pain does not meet the Kaiser Permanente Medical Technology Assessment Criteria (fails criteria 2 for effectiveness).

07/14/2004: MTAC REVIEW

Intradiscal Electrothermal Therapy (IDET)

Evidence Conclusion: The only published RCT on the effectiveness of IDET for discogenic low back pain (Pauza) does not provide strong evidence that IDET provides a clear clinical benefit to patients. In the per protocol analysis of 6 month follow-up data, the difference in the pain scores between the IDET and sham treatment groups just reached statistical significance (p=.045). Physical functioning measured by the SF-36 did not differ significantly between groups and the difference in the Oswestry disability scale did not attain statistical significance (p=.050). In the intention to treat analysis, there was a significant difference between groups in the proportion of patients who experienced >75% pain relief. The NNT=7 with a wide confidence interval, 95% CI=3 to 138 and there was no significant difference in the proportion of patients experiencing >50% pain relief. The sample size and length of follow-up were insufficient for quantifying any adverse effects of the treatment.

Articles: The search yielded 29 articles. There was one randomized controlled trial (Pauza) and this was critically appraised. There were also three case series with longer follow-up than the RCT and a cohort study. The other studies were not critically appraised because higher-grade evidence was available. The RCT reference was: Pauza KJ, Howell S, Dreyfuss P et al. A randomized placebo-controlled trial of intradiscal electrothermal therapy for the treatment of discogenic low back pain. The Spine Journal 2004; 4: 27-35. See Evidence Table.

The use of Intradiscal Electrothermal Therapy (IDET) in the treatment of back pain does not meet the Kaiser Permanente Medical Technology Assessment Criteria (fails criteria 2 for effectiveness).

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<thead>
<tr>
<th>Date Created</th>
<th>Date Reviewed</th>
<th>Date Last Revised</th>
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<td>11/17/2000</td>
<td>05/3/2011 MDCRPC, 09/06/2011 MDCRPC, 07/03/2012 MDCRPC, 05/07/2013 MDCRPC, 03/04/2014 MPC, 01/06/2015 MPC, 11/03/2015 MPC, 09/06/2016 MPC, 07/11/2017 MPC, 05/01/2018 MPC</td>
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MDCRPC Medical Director Clinical Review and Policy Committee
MPC Medical Policy Committee

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<tr>
<th>Revision History</th>
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<tr>
<td>04/17/2016</td>
<td>Added NCD</td>
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<tr>
<td>09/08/2015</td>
<td>Revised LCD L34886 and L35008 Non-Covered Services.</td>
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Codes
CPT: 22526, 22527, S2348