

Appendix A

General Methodological Principles of Study Design

When making national coverage determinations, CMS evaluates relevant clinical evidence to determine whether or not the evidence is of sufficient quality to support a finding that an item or service falling within a benefit category is reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. The critical appraisal of the evidence enables us to determine whether: 1) the specific assessment questions can be answered conclusively; and 2) the intervention will improve health outcomes for patients. An improved health outcome is one of several considerations in determining whether an item or service is reasonable and necessary.

CMS divides the assessment of clinical evidence into three stages: 1) the quality of the individual studies; 2) the relevance of findings from individual studies to the Medicare population; and 3) overarching conclusions that can be drawn from the body of the evidence on the direction and magnitude of the intervention's risks and benefits.

The issues presented here represent a broad discussion of the issues we consider when reviewing clinical evidence. However, it should be noted that each coverage determination has unique methodological aspects.

1. Assessing Individual Studies

Methodologists have developed criteria to determine weaknesses and strengths of clinical research. Strength of evidence generally refers to: 1) the scientific validity underlying study findings regarding causal relationships between health care interventions and health outcomes; and 2) the reduction of bias. In general, some of the methodological attributes associated with stronger evidence include those listed below:

- Use of randomization (allocation of patients to either intervention or control group) in order to minimize bias.
- Use of contemporaneous control groups (rather than historical controls) in order to ensure comparability between the intervention and control groups.
- Prospective (rather than retrospective) studies to ensure a more thorough and systematic assessment of factors related to outcomes.
- Larger sample sizes in studies to help ensure adequate numbers of patients are enrolled to demonstrate both statistically significant as well as clinically significant outcomes that can be extrapolated to the Medicare population. Sample size should be large enough to make chance an unlikely explanation for what was found.
- Masking (blinding) to ensure patients and investigators do not know to which group patients were assigned (intervention or control). This is important especially in subjective outcomes, such as pain or quality of life, where enthusiasm and psychological factors may lead to an improved perceived outcome by either the patient or assessor.

Regardless of whether the design of a study is a randomized controlled trial, a non-randomized controlled trial, a cohort study or a case-control study, the primary criterion for methodological strength or quality is the extent to which differences between intervention and control groups can be attributed to the intervention studied. This is known as internal validity. Various types of bias can undermine internal validity. These include:

- Different characteristics between patients participating and those theoretically eligible for study but not participating (selection bias)
- Co-interventions or provision of care apart from the intervention under evaluation (confounding)
- Differential assessment of outcome (detection bias)
- Occurrence and reporting of patients who do not complete the study (attrition bias)

In principle, rankings of research design have been based on the ability of each study design category to minimize these biases. A randomized controlled trial minimizes systematic bias (in theory) by selecting a sample of participants from a particular population and allocating them randomly to the intervention and control groups. Thus, randomized controlled studies have been typically assigned the greatest strength, followed by non-randomized clinical trials and controlled observational studies. The following is a representative list of study designs (some of which have alternative names) ranked from most to least methodologically rigorous in their potential ability to minimize systematic bias:

- Randomized controlled trials
- Non-randomized controlled trials
- Prospective cohort studies
- Retrospective case control studies
- Cross-sectional studies
- Surveillance studies (e.g., using registries or surveys)
- Consecutive case series
- Single case reports

When there are merely associations but not causal relationships between a study's variables and outcomes, it is important not to draw causal inferences. Confounding refers to independent variables that systematically vary with the causal variable. This distorts measurement of the outcome of interest because its effect size is mixed with the effects of other extraneous factors. For observational, and in some cases randomized controlled trials, the method in which confounding factors are handled (either through stratification or appropriate statistical modeling) are of particular concern. For example, in order to interpret and generalize conclusions to our population of Medicare patients, it may be necessary for studies to match or stratify their intervention and control groups by patient age or co-morbidities.

Methodological strength is, therefore, a multidimensional concept that relates to the design, implementation and analysis of a clinical study. In addition, thorough documentation of the conduct of the research, particularly study's selection criteria, rate of attrition and process for data collection, is essential for CMS to adequately assess the evidence.

2. Generalizability of Clinical Evidence to the Medicare Population

The applicability of the results of a study to other populations, settings, treatment regimens, and outcomes assessed is known as external validity. Even well-designed and well-conducted trials may not supply the evidence needed if the results of a study are not applicable to the Medicare population. Evidence that provides accurate information about a population or setting not well represented in the Medicare program would be considered but would suffer from limited generalizability.

The extent to which the results of a trial are applicable to other circumstances is often a matter of judgment that depends on specific study characteristics, primarily the patient population studied (age, sex, severity of disease, and presence of co-morbidities) and the care setting (primary to tertiary level of care, as well as the experience and specialization of the care provider). Additional relevant variables are treatment regimens (dosage, timing, and route of administration), co-interventions or concomitant therapies, and type of outcome and length of follow-up.

The level of care and the experience of the providers in the study are other crucial elements in assessing a study's external validity. Trial participants in an academic medical center may receive more or different attention than is typically available in non-tertiary settings. For example, an investigator's lengthy and detailed explanations of the potential benefits of the intervention and/or the use of new equipment provided to the academic center by the study sponsor may raise doubts about the applicability of study findings to community practice.

Given the evidence available in the research literature, some degree of generalization about an intervention's potential benefits and harms is invariably required in making coverage decisions for the Medicare population. Conditions that assist us in making reasonable generalizations are biologic plausibility, similarities between the populations studied and Medicare patients (age, sex, ethnicity and clinical presentation), and similarities of the intervention studied to those that would be routinely available in community practice.

A study's selected outcomes are an important consideration in generalizing available clinical evidence to Medicare coverage determinations because one of the goals of our determination process is to assess health outcomes. We are interested in the results of changed patient management not just altered management. These outcomes include resultant risks and benefits such as increased or decreased morbidity and mortality. In order to make this determination, it is often necessary to evaluate whether the strength of the evidence is adequate to draw conclusions about the direction and magnitude of each individual outcome relevant to the intervention under study. In addition, it is important that an intervention's benefits are clinically significant and durable, rather than marginal or short-lived.

If key health outcomes have not been studied or the direction of clinical effect is inconclusive, we may also evaluate the strength and adequacy of indirect evidence linking intermediate or surrogate outcomes to our outcomes of interest.

3. Assessing the Relative Magnitude of Risks and Benefits

Generally, an intervention is not reasonable and necessary if its risks outweigh its benefits. Health outcomes are one of several considerations in determining whether an item or service is reasonable and necessary. For most determinations, CMS evaluates whether reported benefits translate into improved health outcomes. CMS places greater emphasis on health outcomes actually experienced by patients, such as quality of life, functional status, duration of disability, morbidity and mortality, and less emphasis on outcomes that patients do not directly experience, such as intermediate outcomes, surrogate outcomes, and laboratory or radiographic responses. The direction, magnitude, and consistency of the risks and benefits across studies are also important considerations. Based on the analysis of the strength of the evidence, CMS assesses the relative magnitude of an intervention or technology's benefits and risk of harm to Medicare beneficiaries.

Appendix B
Case Series Table
Thermal Intradiscal Procedures

Author/ Year	Procedure/ Case Series type/ study focus if enrollees are different than standard	Subject # (loss to follow- up)/ demographics	Follow-up (range)	Outcomes	Results (Mean scores unless otherwise specified)
Saal and Saal 2002	IDET prospective	62(4) Mean age 40.5 years (range 20-59 years)	28 months(24 -35)	VAS score SF-36(PF) SF-36(BP)	6.8 (+/- 1.9)→3.4 (+/- 2.0) 40.5 (+/- 25)→71.8 (+/- 23) 29.8 (+/- 16.0)→51.7 (+/- 22.6)
Derby Eek Chen O'Neill Ryan 2000	IDET prospective	32 Mean age 42	12 months	VAS score (change) Roland- Morris (change)	-1.84, SD 2.38 -4.03, SD 4.82
Gerszten Welch McGrath Willis 2002	IDET prospective	27 Mean age 41	12 months	ODI SF-36(PF) SF-36(BP)	34 → 30 32 → 47 27 → 38
Welch Gerszten McGrath 2001	IDET prospective	23(16) Mean age 39	3 months	ODI SF-36(PF) SF-36(BP)	34 → 26 31 → 47 5 → 25
Spruit and Jacobs 2002	IDET prospective	20(1) Mean age 37.6 years(range 26- 56)	6 months	VAS ODI	6.5 (SD 1.5, range 42- 96)→5.1(SD 2.7, range 2-100) 43.1(SD 7.3, range 26- 52)→36.7(SD 21.1, range 0-64)
Nunley Jawahar Brandao Wilkinson 2008	IDET Prospective/ workers comp	53 Mean age 42(range 20-61)	56 months (range 29 to 72 months)	VAS ODI	63.8 (range 0 - 100) → 19.4 24.8 (range 0 - 41) → 5.2

Author/ Year	Procedure/ Case Series type/ study focus if enrollees are different than standard	Subject # (loss to follow- up)/ demographics	Follow-up (range)	Outcomes	Results (Mean scores unless otherwise specified)
Park Moon Park Kim Choi Lee 2005	IDET prospective	25 Average age 32 years (range 18- 49)	12 months	VAS	7.3 → 4.9 32% (8 patients) had more pain 5 patients had fusion
Singh 2000	IDET Prospective	23(2) Mean age 44.6 range 24-60	6 months	Pain relief Narcotic use	67% of patients had ≥ 50% pain relief Decreased by 29% (not statistically significant)
Freedman Cohen Kuklo Lehman Larkin Guiliana 2003	IDET Retrospective/ active duty soldiers	41(10)	29.7 months(24 -46)	VAS At least 50% reduction in pain surgery	52% had ≥ 2.0 improvement 5/31 (16%) 7/31 (23%) had surgery During follow-up
Kapural, Mekhail, Korunda, Basali 2004	IDET Prospective/ One or two level IDET versus 3 or greater level IDET	34 Average age 45.3 years (multilevel) 41.6 years (single level)	12 months	VAS 1 or 2 level IDET ≥3 level IDET Pain disability index	7.7 ± 2 → 2.5 ± 2.4 7.4 ± 1.8 → 4.9 ± 2.9 Improved in both groups
Mekhail, Kapural 2004	IDET prospective	34(2) Age range 25 to 62	12 months	VAS Workers Comp (n=10) Other(n=22) Pain disability index	7.4 ± 1.5 → 4.3 ± 2.5 8.0 ± 1.6 → 1.8 ± 1.8 Improved

Author/ Year	Procedure/ Case Series type/ study focus if enrollees are different than standard	Subject # (loss to follow- up)/ demographics	Follow-up (range)	Outcomes	Results (Mean scores unless otherwise specified)
Cohen Larkin Abdi Chang Stojanovic 2003	IDET Retrospective	79 Mean age 37 (15-60)	6 months	VAS (SD) Positive Outcome Negative Outcome	38 patients 5.9 (1.8) → 2.1 (1.3) 41 patients 6.2 (1.9) → 5.1 (1.8) 8/79 (10%) complication rate
Lutz Lutz Cooke 2003	IDET prospective	33 Mean age 40 (range 20-56)	15 months	VAS Low back Lower Extremity Roland- Morris	7.5 → 3.9 5.7 → 2.0 13.9 → 6.6 2 patients had repeat IDET 5 patients had other related surgeries
Lee Cooper Lutz Lutz Hong 2003	IDET prospective	62(11) Average age 41.4 years (range 18-60)	34 months (range 6- 47)	Visual numeric pain scale Low back Lower Extremity Roland- Morris	7.9(± 1.3)→4.7(± 3.0) 5.0(± 3.6)→2.7(± 3.2) 15.4 (± 5.3)→8.8 (± 7.5) 2 patients had repeat IDET 5 patients had other related surgeries

Author/ Year	Procedure/ Case Series type/ study focus if enrollees are different than standard	Subject # (loss to follow- up)/ demographics	Follow-up (range)	Outcomes	Results (Mean scores unless otherwise specified)
Maurer Block Squillante 2008	IDET Prospective	56 Mean age 39.5(±11.6)	20.5 months (range 12- 24)	VAS	6.1 (± 1.8) → 2.4 (± 2.6) 2 patients had surgery during follow-up
Davis Delamarter Sra Goldstein 2004	IDET Retrospective	60(16) Average age 40(25-64)	12 months	Employed Surgery Pain	16 pre IDET 11 post IDET 6/44 (14%) had surgery during follow-up 97% continued to have back pain
Webster Verma Pransky 2004	IDET Retrospective/ Workers compensation	142 Mean age 37.4 (21-57)	22 months (10-34 months)	Narcotic use Surgery Work status	Unchanged 32/142 (22.5%) had surgery during follow- up 58% not working at 24 months
Endres Fiedler Larson 2002	IDET Retrospective	54 Mean age 40 (17-63)	12-108 weeks post IDET	Return to work VAS	66% of patients(35) ≥ 2 change in 31 patients (65%)
Derby Eek Lee Seo Kim 2004	IDET Retrospective/ IDET comparison to intradiscal injection	74 IDET 35 intradiscal injection Mean age 42 (17-62)	IDET 15.5 months Intradiscal injection 7.7 months (overall range 6-18 months)	VAS change IDET Intradiscal injections	1.3 2.2 47.8% of IDET patients reported that they felt better 65.6% of injection patients felt better

Author/ Year	Procedure/ Case Series type/ study focus if enrollees are different than standard	Subject # (loss to follow- up)/ demographics	Follow-up (range)	Outcomes	Results (Mean scores unless otherwise specified)
Derby Lee Seo Kazala Kim Kim 2004	IDET Retrospective/ Included patients with referred leg pain from disc (no nerve compression)	129(30) Mean age 43 (17-62)	18 months average	VAS 5 point scale	Back pain: 3.37 +/-0.82 → 2.59 +/- 1.08 Leg pain: 2.36 +/-1.25 → 1.79 +/- 1.35 30/129 underwent subsequent back surgery
Cohen Shockey Carragee 2007	IDET Retrospective/ Repeat IDET	9 Mean age 46 Age range 32-56	6 months	VAS	Single level:7.2 (SD1.1) → 4.4 (SD 2.4) Two level: 7.0 (SD 1.4) → 4.8 (SD 2.8)
Bryce Nelson Glurich Berg 2005	IDET unspecified	51(21) Male median age 40.5 (range 25-73) Female median 37.3(range 21 - 55)	18 months	VAS Current day Last week Roland Morris	-1.5 (SD 2.9) for n= 23 -2.4 (SD 3.2) for n= 23 Change of -26.7 (SD 36.0) for n=30
Kapural Ng Dalton Mascha Kapural de La Garza Mekhail 2008	Biacuplasty prospective	15(2) Age range 22-55	6 months	VAS ODI SF-36 PF SF-36 BP	7 (95% CI 6,8) → 3 (95% CI 2,5) 23.3 (SD 7.0) → 17.1 (SD 8.1) 51 (SD 18) → 70 (SD 16) 38 (SD 15) → 54 (SD 23)
Sharps Isaac 2002	Nucleoplasty prospective	49 (36) Mean age 38 Range 30-61 years	12 months	VAS	7.9 (+/- 1.3) → 4.3 (+/- 2.8)

Author/ Year	Procedure/ Case Series type/ study focus if enrollees are different than standard	Subject # (loss to follow- up)/ demographics	Follow-up (range)	Outcomes	Results (Mean scores unless otherwise specified)
Singh Piryani Liao Nieschulz 2002	Nucleoplasty	67 (26) Mean age 44 Range 15-62	12 months	VAS	6.8 (+/- 1.1) → 4.1 (+/- 2.5)
Singh Piryani Liao 2003	Nucleoplasty Prospective (Chronic back pain with or without leg pain)	80(11) Mean 44.8 years Range 15-62 years	12 months	VAS	6.83 → 4.5
Singh Piryani Liao 2004	Nucleoplasty prospective	47(10) Mean 44years Range 15-62 years	12 months	VAS	6.7 (+/- 1.14) → 4.4 (+/- 2.34)
Yakovlev Tamimi Liang Eristavi 2007	Nucleoplasty retrospective	22 Mean age 39 Range 22-51 years	12 months	VAS Reduction in opioids intake	7.6 (SD 1.2) → 3.3 (SD 3.6) 72.7% of patients
Masala Massari Fabiano Ursone Fiori Pastore Simonetti 2007	Nucleoplasty	72(2) Mean age 48 Range 32-64 years	12 months	VAS	8.2 → 4.1
Mirzai Tekin Yaman Bursali 2007	Nucleoplasty Prospective One and two level	52 (3) Mean age 44.8	10 to 15 months	VAS ODI Analgesic intake (not defined)	7.5 (+/- 1.3) → 2.1 (+/- 1.6) 42.2 (+/-5.5) → 20.5 (+/- 8.9) 94% of patients stopped or reduced analgesics

Author/ Year	Procedure/ Case Series type/ study focus if enrollees are different than standard	Subject # (loss to follow- up)/ demographics	Follow-up (range)	Outcomes	Results (Mean scores unless otherwise specified)
Cohen Williams Kurihara Griffith Larkin 2005	Nucleoplasty with or without IDET	16 Mean age 36 7 Nucleoplasty only	Average 9 months	VAS	6.7 → 5.6

Appendix C
CMS Evidence Table for Thermal Intradiscal Procedures

Author/ Year	Study Design	Demographics	outcome measures	Results	
			outcome measure time endpoint	Intervention group	Control group
	Study, inclusion/exclusion	N age			
Pauza 2004	RCT Multiple inclusion/exclusion, includes only less than 20% disc height narrowing on x-ray, No workers comp	32 IDET 24 sham Mean age 40	VAS SF-36 Bodily Pain SF-36 Physical - Functioning ODI 6 months	6.6 (SD 1.4) → 4.2 (SD 2.6) 36 (SD 12) → 53 (SD 19) 56 (SD 24) → 71 (SD 22) 31 (SD 10) → 20 (SD 12)	6.5 (SD 1.9) → 5.4 (SD 2.7) 35 (SD 12) → 44 (SD 20) 49 (SD 21) → 60 (SD 24) 33 (SD 11) → 28 (SD 15)
Freeman 2005	RCT Multiple inclusion/exclusion, includes only less than 50% disc height narrowing	36 IDET 19 sham Mean age 40	LBOS SF-36 Bodily Pain SF-36 Physical - Functioning ODI 6 months	39.5 (SD 5.2) → 38.3 (SD 3.6) 33.1 (SD 16.0) → 38.3 (SD 21.4) 41.9 (SD 23.0) → 44.7 (SD 24.2) 41.4 (SD 14.8) → 39.8 (SD 16.3)	36.7 (SD 3.0) → 37.4 (SD 1.6) 24.4 (SD 13.5) → 31.5 (SD 15.2) 35.0 (SD 15.3) → 36.6 (SD 20.1) 40.7 (SD 11.8) → 41.6 (SD 11.2)

Author/ Year	Study Design	Demographics	outcome measures	Results	
			outcome measure time endpoint	Intervention group	Control group
Barendse 2001	RCT Diagnostic block and positive discography/multiple exclusion listed	15 PIRFT 13 sham Mean age 45 years sham group, 41 PIRFT group	At least VAS 2 point reduction and 50% pain reduction on global perceived effect 8 weeks	One patient judged as success	Two patients judged as success
Ercelen 2003	Randomized Comparative Trial MRI changes and positive discography/multiple exclusion listed	20 PIRFT, 80°C for 120 seconds 19 PIRFT, 80°C for 360 seconds	VAS and ODI 6 months	No statistical difference between the 6 mo and pretreatment VAS and ODI	No statistical difference between the 6 mo and pretreatment VAS and ODI

Author/ Year	Study Design	Demographics	outcome measures	Results	
			outcome measure time endpoint	Intervention group	Control group
Bogduk 2002	Case Control Positive discography and radial fissure/ Several exclusion including less than 80% of expected disc height (greater than 20% narrowing)	36 IDET 17 other treatments Median age for IDET was 39 years, 45 years for the comparison group	VAS, return to work, opioids use Success defined as at least 50% reduction in pain, at work, no longer using opioids (small quantities of codeine acceptable) 24 months	19 of 35 patients successful by authors definition	1 patient successful, though this patient attributed the resolution of back pain to a hysterectomy
Kapural 2005	Prospective matched control Several inclusion/ excluded those with less than 50% of expected disc height And workers comp	21 PIRFT 28 IDET Mean age 42	VAS Mean PDI* difference (IDET – PIRFT) at one year One year *Pain Disability Index	IDET: 7.4 +/- 1.9 → 1.4 +/- 1.9 -21.8	PIRFT: 6.6 +/- 2.0 → 4.4 +/- 2.4

Appendix D

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Appendix E

DRAFT

**Medicare National Coverage Determinations
Manual**

Chapter 1, Part 2 (Sections 90 – 160.25)

Coverage Determinations

Table of Contents

(Rev.)

XXX.XX – Thermal Intradiscal Procedures (Effective October XX, 2008)

**XXX.XX – Thermal Intradiscal Procedures (TIPs) (Effective October 13, 2008)
(Rev.)**

A. General

Percutaneous thermocoagulation intradiscal procedures involve the insertion and heating of a catheter/probe(s) in the spinal disc under fluoroscopic guidance. The reported purpose of TIPs is to remove unwanted tissue such as herniated discs, create a seal to limit expression of matrix components, shrink collagen tissue, and/or destroy nociceptors. Intradiscal heating can be accomplished through a variety of means, including electrocautery, thermal cautery, laser, and radiofrequency energy (RFE); most current TIPs are performed using RFE.

The scope of this national coverage policy on TIPs includes percutaneous intradiscal techniques that employ the use of an energy source, usually RFE, to apply or create heat within the disc for coagulation and/or decompression of disc material to treat symptomatic patients with annular disruption of 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 probes/catheters, which utilize a resistance coil or other thermal intradiscal 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 targeted disc decompression (TDD). At times, TIPs are identified or labeled based on the name of the catheter/probe(s) that is used (e.g., SpineCath, discTRODE, Accutherm, or TransDiscal electrodes). Each technique or device has its own protocol for application of the therapy. Disc decompression or nucleoplasty procedures that involve the physical removal of disc tissue without the use of thermal energy source (such as the disc decompressor procedure), as opposed to the vaporization of disc tissue, are not within the scope of this NCA.

B. Nationally Covered Indications

N/A

C. Nationally Non-Covered Indications

*Effective for services performed on or after October XX, 2008, CMS has determined the evidence is adequate to conclude that TIPs are not reasonable and necessary for the treatment of low back pain; therefore, TIPs are **noncovered**.*

D. Other

N/A

(This NCD last reviewed XXXX)