Anthem FINAL DRAFT – LOGO TO BE INSERTED UPON FINAL PRODUCTION DATE

Medical Policy

Subject:	Percutaneous Vertebral Disc and Vertebral Endplate Procedures ~~Intravertebral Disc discal Annuloplasty Procedures (Percutaneous Intradiscal Electrothermal Therapy [IDET], Percutaneous Intradiscal Radiofrequency Thermocoagulation [PIRFT] and Intradiscal Biacuplasty [IDB])~~		
Document#:	SURG.00052	**Publish Date:**	09/25/2019~~12/12/2018~~
Status:	Revised~~ewed~~	**Last Review Date:**	08~~11~~/22~~08~~/2019~~8~~

Description/Scope

This document addresses several minimally invasive surgical procedures designed to destroy nociceptive nerve fibers with or without structural changes to the intervertebral discs ~~*alter the biomechanics* of the disc annulus~~. The following percutaneous vertebral disc and vertebral endplate procedures ~~intradiscal therapies~~ have been explored as a treatment of chronic low back pain secondary to disc disease:

- intradiscal electrothermal therapy (IDET) (also referred to as intradiscal electrothermal annuloplasty)
- percutaneous intradiscal radiofrequency thermocoagulation (PIRFT)
- intraosseous basivertebral nerve ablation
-
- intradiscal biacuplasty (IDB)
-

Note: Please see the following document for percu~~u~~taneous and endoscopic spinal procedures designed to remove or ablate disc material and decompress the disc (for example, percutaneous lumbar discectomy, laser discectomy, and disc decompression using radiofrequency energy ~~[that is, disc nucleoplasty]~~):

- SURG.00071 Percutaneous and Endoscopic Spinal Surgery

Position Statement

This Medical Policy provides assistance in understanding Healthy Blue's standard Medicaid benefit plan. When evaluating coverage for a specific member benefit, reference to federal and state law, as well as contractual requirements may be necessary, since these may differ from our standard benefit plan. In the event of a conflict with standard plan benefits, federal, state and/or contractual requirements will govern. Before using this policy, please check all federal, state and/or contractual requirements applicable to the specific benefit plan coverage. Healthy Blue reserves the right to modify its Policies and Guidelines as necessary and in accordance with legal and contractual requirements. This Medical Policy is provided for informational purposes. It does not constitute medical advice. Healthy Blue may also use tools and criteria developed by third parties, to assist us in administering health benefits. Healthy Blue's Policies and Guidelines are intended to be used in accordance with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

Investigational and Not Medically Necessary:

The following procedures are considered **investigational and not medically necessary**:

1. Percutaneous intradiscal electrothermal therapy; **or**
2. Percutaneous intradiscal radiofrequency thermocoagulation; **or**
3. Intraosseous basivertebral nerve ablation; **or**
4. Intradiscal biacuplasty.

~~A. Percutaneous intradiscal electrothermal therapy (IDET) is considered **investigational and not medically necessary.**~~

~~B. Percutaneous intradiscal radiofrequency thermocoagulation (PIRFT) is considered **investigational and not medically necessary.**~~

~~C. Intradiscal biacuplasty (IDB) is considered **investigational and not medically necessary.**~~

Rationale

Intradiscal Electrothermal Therapy (IDET)

IDET with the SpineCath® IntraDiscal ElectroThermal Therapy (IDET™) System (Smith & Nephew, Inc., Andover, MA, USA) is a percutaneous intradiscal electrothermal annuloplasty procedure used to treat chronic low back pain related to degenerative disc disease. The procedure involves applying targeted thermal energy to the posterior disc annulus which causes contraction of collagen fibers and destruction of afferent nociceptors.

The intradiscal catheter system received U.S. Food and Drug Administration (FDA) 510K clearance in February 2008 as a substantially equivalent device to the predicate SpineCath Intradiscal Catheter (1998 and 1999).

Two sham-controlled randomized controlled trials (RCTs) evaluating IDET were identified. Pauza and colleagues (2004) included 64 individuals with discogenic low back pain lasting more than 6 months. Of these, 37 subjects were randomized to undergo the IDET procedure and 27 subjects to a sham procedure. Principal outcome measures included pain and disability assessed using a visual analog scale (VAS), the 36-Item Health Short Form Survey

(SF-36), and the Oswestry Disability Index (ODI) scale. A total of 56 subjects (88%) were included in the per protocol analysis. Mean change at 6 months in the VAS was significantly higher in the IDET group (2.4) than the sham group (1.1), p=0.045. However, mean change in the SF-36 bodily pain scale, the SF-36 physical functioning scale and the ODI did not differ significantly between groups.

Freeman and colleagues (2005) conducted a sham-controlled RCT study on individuals with discogenic back pain and annular tears who failed to improve despite conservative treatment. The study was carried out with 38 participants undergoing IDET and 19 receiving the sham procedure. Several subjective outcomes were measured utilizing the Low Back Outcome Score (LBOS), the ODI, and the SF-36. A successful outcome was defined as: 1) no neurological deficit; 2) improvement in the LBOS of greater than 7 points; and 3) improvement in the physical function and bodily pain section of the SF-36 form of at least greater than one standard deviation. No participant in either arm of the study met the criteria for a successful outcome. The findings of this study suggest that while IDET appears to be a safe procedure with no permanent complications, there is no significant benefit of IDET over sham treatment.

An industry funded meta-analysis by Appleby and colleagues (2006) analyzed the peer-reviewed published literature on IDET from 1998 to 2005, both controlled and uncontrolled studies. The authors identified 17 unique publications, only 1 of which was an RCT (the Pauza, 2004 study, discussed above). While the authors concluded that the pooled results of the literature provided evidence of the safety and efficacy of the IDET procedure, 16 of the 17 studies reviewed were case series and lacked control or comparison groups.

~~The available data from RCTs do not suggest that the IDET is more effective than a sham intervention at improving clinical outcomes. Most of the studies on IDET have been case series.~~

Percutaneous Intradiscal Radiofrequency Thermocoagulation (PIRFT)

The PIRFT procedure is a minimally invasive surgical technique in which radiofrequency (RF) energy is directly applied to disc material ~~for 90 seconds at a temperature of 70°C~~. Similar to IDET, this procedure does not ablate the disc material, but alters the biomechanics of the disc or destroys the nociceptive pain fibers.

The Radionics® discTRODE™ (probe) system (Radionics, Inc., Burlington, MA) ~~-~~received 510(k) clearance from the FDA in October 2000 ~~as a substantially equivalent device for use in PIRFT~~ to reduce pain, physical impairment

This Medical Policy provides assistance in understanding Healthy Blue's standard Medicaid benefit plan. When evaluating coverage for a specific member benefit, reference to federal and state law, as well as contractual requirements may be necessary, since these may differ from our standard benefit plan. In the event of a conflict with standard plan benefits, federal, state and/or contractual requirements will govern. Before using this policy, please check all federal, state and/or contractual requirements applicable to the specific benefit plan coverage. Healthy Blue reserves the right to modify its Policies and Guidelines as necessary and in accordance with legal and contractual requirements. This Medical Policy is provided for informational purposes. It does not constitute medical advice. Healthy Blue may also use tools and criteria developed by third parties, to assist us in administering health benefits. Healthy Blue's Policies and Guidelines are intended to be used in accordance with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

and functional disability due to annular disruption of contained herniated discs. Two published double-blind sham-controlled RCTs on the Radionics device were identified. ~~-~~In 2001, Barendse and colleagues ~~in the Netherlands~~ published an RCT with 24 individuals who had chronic discogenic low back pain. Participants in the radiofrequency treatment group (n=13) received a 90-second 70°C treatment~~lesion~~ of the intervertebral disc. The subjects in the control group (n=15) underwent the same procedure, but without use of RF~~radiofrequency~~ current. Both the treating physician and the participants were blinded to the group assignment. Physical impairment, rating of pain, the degree of disability, and quality of life were assessed by a blinded investigator prior to the beginning of treatment. At the end of 8 weeks, the VAS, global perceived effect, and ODI scores did not differ significantly ~~reveal differences~~ between the 2 groups. The authors concluded that PIRFT is ineffective in reducing chronic discogenic low back pain.

Kvarstein and colleagues (2009) studied 20 subjects with chronic discogenic low back pain. ~~-~~Individuals were assigned to active treatment with the discTRODE probe or a sham control group. Both study groups underwent insertion of the ~~radiofrequency (~~RF~~)~~ probe by the treating physician while a separate operator controlled delivery of the RF therapy, thus blinding the participants as well as the treating physician to treatment or sham. The primary outcome measure was a change in pain intensity. Secondary outcome measures were subject's categorical impression of change in experienced pain, health-related quality of life, and functional ability. The primary outcome, a change in pain intensity was not statistically significant between groups and, with the exception of subject's impression of pain, other outcomes were similar between groups. ~~. However, differences in the subjects' impressions of changes in experienced pain were statistically significant. The remaining outcome measures were not statistically significant. T~~The authors found that at 12 months the mean change in pain intensity in the actively treated subjects was small and not clinically meaningful. Taking into consideration that 40% (4 of 10) of the treated subjects had increased pain 12 months later, the authors concluded that the benefit of PIRFT was inconsistent and would not recommend intra-annular thermal therapy with the discTRODE probe as a treatment for chronic low back pain.

Intraosseous Basivertebral Nerve Ablation

The Intracept® Intraosseous Nerve Ablation System (Relievant Medsystems, Inc, Redwood City, CA) received 510(k) clearance in August 2017 as a radiofrequency (RF) ablation system for use in ablation of the basivertebral nerves (BVN) of the L3 through S1 vertebrae. ~~, intended to relieve chronic low back pain of at least 6 months duration that has not responded to at least 6 months of conservative care.~~

This Medical Policy provides assistance in understanding Healthy Blue's standard Medicaid benefit plan. When evaluating coverage for a specific member benefit, reference to federal and state law, as well as contractual requirements may be necessary, since these may differ from our standard benefit plan. In the event of a conflict with standard plan benefits, federal, state and/or contractual requirements will govern. Before using this policy, please check all federal, state and/or contractual requirements applicable to the specific benefit plan coverage. Healthy Blue reserves the right to modify its Policies and Guidelines as necessary and in accordance with legal and contractual requirements. This Medical Policy is provided for informational purposes. It does not constitute medical advice. Healthy Blue may also use tools and criteria developed by third parties, to assist us in administering health benefits. Healthy Blue's Policies and Guidelines are intended to be used in accordance with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

Two RCTs have evaluated the Intracept system for treatment of chronic low back pain. Fischgrund (2018; 2019) compared Intracept treatment to sham treatment and Khalil (2019) compared it to usual care.

In 2018, Fischgrund and colleagues published a double-blind, a sham-controlled RCT evaluating the safety and efficacy of the Intracept system and RF ablation of the BVN for the treatment of chronic low back pain. A total of 225 participants with chronic (≥ 6 months) isolated lumbar pain who had not responded to at least 6 months of non-operative management were randomized to either a sham (n=78) or treatment (n=147) intervention. In the active treatment group, ~~individuals~~ the RF probe was activated and the temperature at the tip was maintained at 85°C for 15 minutes. The duration of the session in the sham group was the same but the RF treatment was only simulated. Study participants had ~~The mean age of participants was 47 years (range 25-69) with~~ a minimum ODI of 30 points (on 100 point scale) and a minimum VAS of 4 cm (10 cm scale). ~~-~~The primary efficacy endpoint was the comparative change in ODI from baseline to 3 months. Both intention-to-treat (ITT) and per protocol (PP) analysis were pre-planned. A total of 19 of 147 (13%) participants in the treatment group were excluded from the PP analysis; 16 for a targeting failure, 1 for procedural failure and 2 for protocol non-compliance. One participant in the sham group was excluded from the PP analysis and this was for protocol non-compliance.

At 3 months, in the ITT analysis, ~~In the intention to treat (ITT) analysis at 3 months,~~ there was no statistically significant difference between groups in the primary outcome, mean ODI. ~~-~~ODI improved a mean of 19.0 points in the treatment group and 15.4 points in the sham group, p=0.107. ~~-~~However, there was a difference between groups in the 3-month PP analysis~~The per protocol analysis included 205 of 225 randomized individuals (91%): . At 3 months~~ the mean ODI in the treatment arm improved 20.5 points and 15.2 points in the sham arm, ~~,~~ p=0.019~~).~~. In the 12-month PP analysis, the difference between the treatment and sham groups in mean ODI was no longer statistically significant (22.6 points versus 25.3 points, p=0.153). PP ~~Per protocol aa~~nalyses of pain severity (assessed by VAS) found no significant difference between groups in VAS improvement at 3 months (p~~-~~=0.083) but significantly greater improvement in the treatment compared with the control group at 6 and 12 months.

Eight procedure-related events (2.7%) were reported in 6 participants following the 225 procedures; 2 of these 6 participants were in the sham arm. The events included nerve root injury (n=1), lumbar radiculopathy (n=2), retroperitoneal hemorrhage (n=1), and transient motor or sensory deficits (n=4).

Fischgrund (2019) reported 24-month results from the above RCT. A total of 106 of 128 (83%) of individuals in the 3-month PP analysis of active treatment completed 24-month follow-up. In this group, the mean improvement in ODI, which was 20.8 points at 3 months, was 23.4 points at 23 months. Data were not available on ODI outcomes at 24 months in the sham-treated group as unblinding occurred after 12 months and most individuals crossed over to treatment with the Intracept system. Thus long-term comparative outcomes are not known.

A second RCT evaluating the Intracept system, known as the INTRACEPT trial, was published by Khalil and colleagues in 2019. The trial was open label and compared intraosseous RF treatment to standard care in individuals with at least 6 months of chronic low back pain who had not responded to at least 6 months of conservative care. Intervention with the Intracept system consisted of treatment of up to 4 vertebrae in non-consecutive levels from L3 to S1. Individuals in the standard care continued treatment with conservative therapy. The primary study endpoint was difference in the ODI at 3 months. A pre-planned interim analysis was undertaken when 60% of participants reached the 3-month follow-up (n=51 in the Intracept group and n=53 in the standard care group). The interim analysis found statistically significant differences between groups on all patient-reported outcomes measures, favoring the Intracept group. For the primary outcome, the mean change in the ODI at 3 months in the interim analysis was -25.3 points in the Intracept group and -4.4 points in the standard care group, p<0.001. Mean change in VAS was -3.46 points in the Intracept group and -0.01 in the standard care group, p<0.001. As specified in the study protocol, the study was halted and individuals in the standard care group were allowed to cross over to treatment with the Intracept system. ~~A limitation of the study is that, whereas the sham-controlled studies found a high response rate in the placebo group and mixed findings, the INTRACEPT study did not include a sham control and thus a placebo effect at the interim analysis cannot be ruled out.~~ Limitations of this study include the lack of a sham control and limited duration of follow-up.

~~Observational studies evaluating PIRFT have also been published. The safety and efficacy of the Intracept system was evaluated in a prospective, multicenter, single-arm, industry-sponsored study of 17 individuals with chronic low back pain of greater than 6 months duration who were unresponsive to at least 3 months of conservative care (Becker, 2017). No specific course of conservative care was mandated before study enrollment. The intraosseous BVN was ablated using the Intracept system within the vertebral bodies adjacent to the diagnosed level. Self-reported outcome measures were collected prospectively, at 6 weeks, and 3, 6, and 12 months postoperatively using the ODI, VAS score, and SF-36. The mean baseline ODI of the treated cohort was 52 ± 13, decreasing to a mean of~~

This Medical Policy provides assistance in understanding Healthy Blue's standard Medicaid benefit plan. When evaluating coverage for a specific member benefit, reference to federal and state law, as well as contractual requirements may be necessary, since these may differ from our standard benefit plan. In the event of a conflict with standard plan benefits, federal, state and/or contractual requirements will govern. Before using this policy, please check all federal, state and/or contractual requirements applicable to the specific benefit plan coverage. Healthy Blue reserves the right to modify its Policies and Guidelines as necessary and in accordance with legal and contractual requirements. This Medical Policy is provided for informational purposes. It does not constitute medical advice. Healthy Blue may also use tools and criteria developed by third parties, to assist us in administering health benefits. Healthy Blue's Policies and Guidelines are intended to be used in accordance with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

23 ± 21 at 3 months follow-up (p<0.001). The statistically significant improvement in ODI observed at 3 months was maintained through the 12-month follow-up. The mean baseline VAS score decreased from 61 ± 22 to 45 ± 35 at 3 months follow-up (p<0.05), and the mean baseline physical component summary increased from 34.5 ± 6.5 to 41.7 ± 12.4 at 3 months follow-up (p=0.03). There were no reported device- or procedure-related serious adverse events. Limitations of this study include the small sample size and the non-randomized, unblinded, single-arm study design.

Zhang and colleagues (2016) evaluated the efficacy of PIRFT using single-level bipolar RF thermocoagulation (RFTC) to L4/5 or L5/S1 spinal levels in 23 subjects with discogenic low back pain. Subjects were assessed before the procedure and at 1 week, 1 month, 3 months, 6 months, and 1 year after the procedure. The primary outcome included measurement of VAS and ODI scores. Two subjects were lost to follow-up in the final analysis. VAS and ODI scores were reported as significantly decreased after bipolar RFTC treatment at all-time points of follow-up (p<0.05). A significant change was also reported in all secondary measures, such as pain relief, reduction of analgesic dose, and patient satisfaction. Three subjects experienced mild short-term post-dural puncture headache, but the symptom disappeared within 1 week. No serious complications, such as nerve injuries, discitis, and hematoma, or neurological sequelae occurred in any of the subjects. Limitations of this study include lack of a control group and the small sample size.

In summary, only a few RCTs have evaluated FDA-cleared devices for PIRFT and, in their primary analyses (ITT when available), these have not found that PIRFT provides statistically and clinically significant benefits. Studies were generally limited by small sample sizes and relatively short-term comparative follow-up.

Intradiscal Biacuplasty (IDB)

In On December 19, 2006, the TransDiscal™ System (Baylis Medical Company Inc., Montreal, QC Canada) received FDA 510(k) clearance as an IDB device proposed to reduce chronic intervertebral disc-related back pain by using cooled radiofrequency probes to ablate the neurons that generate pain sensations.

A sham-controlled RCT evaluating IBD was published by Kapural and colleagues in 2013. The study included 64 individuals with chronic discogenic low back pain (6 months duration or longer) and evaluated outcome measures of SF-36 physical functioning subscore (0-100), the numerical rating scale (NRS) for pain (0-10), and the ODI (0-100) at 1, 3, and 6 months. The investigators reported that there were no significant differences between the groups

at 1 or 3 months. At 6 months, the IDB group showed a significantly greater change from baseline for the SF-36 (15.0 vs. 2.63), NRS (-2.19 vs. -0.64) and ODI (-7.43 vs. 0.53). Mean SF-36 and NRS scores were considered to be clinically significant, but mean ODI scores did not achieve the minimally important difference of 10 points. With clinical success defined post-hoc as a 15 point increase in physical function together with a greater than 2 point decrease in pain, 30% of IDB participants and 3% of sham-treated participants were considered successful. There was no significant difference in opioid use between the 2 groups. Limitations of this study include the lack of a formal assessment of blinding effectiveness among participants, the relatively short follow-up time of 6 months, and the limited number of participants evaluated in the sample and subgroup analysis.

Participants were unblinded at 6 months, and those initially randomized to sham procedure were given the option to cross over to IDB. A total of 22 of 27 participants in the original active treatment group were followed for 12 months and reported clinically significant improvements in physical function and NRS scores; although, the magnitude of the decrease was modest and the final NRS score of 4.4 remained high (Kapural, 2015). Out of 30 participants in the sham group, 24 chose to cross over with only 20 of 24 participants followed at 6 months. In this group, improvements in physical function and pain did not differ statistically from those participants originally randomized to IDB treatment. No complications or adverse events were reported that related to the procedure.

Desai and colleagues (2016) published an open-label RCT of 63 individuals with lumbar discogenic pain diagnosed by provocation discography. Participants were randomized to IDB plus conservative medical management (IDB plus CMM; n=29) or CMM alone (n=34). At 6 months, participants in the CMM group were eligible for crossover if desired. The primary outcome measure was defined as the change in VAS from baseline to 6 months. Secondary outcome measures included treatment "responders," defined as the proportion of participants with a 2-point or 30% decrease in VAS scores. For the primary outcome measure, the mean VAS score reduction was significantly greater in the IDB plus CMM group compared to the CMM group alone (-2.4 vs. -0.56; p=0.02). For the secondary outcome measure, the proportion of responders was greater in the IDB plus CMM group compared to the CMM (50% vs. 18%); however, the rate was not statistically significant. Limitations of this industry-sponsored study include all enrolled individuals were required to fail an initial 6 months of CMM, and the lack of a sham control group and participant blinding.

Of the 29 participants originally randomized to IDB, 22 (76%) were available for 12-month follow-up (Desai, 2017). The mean 12-month change in VAS score was -2.2 (from 6.7 at baseline to 4.4 at 12 months, p=0.001). After 6 months, participants randomized to CMM alone were allowed to choose to receive IDB and were followed

for another 6 months; 25 of 34 participants crossed over to IBD plus CMM. VAS score improved from 7.0 to 4.7 ($p<0.001$) in the crossover group, and 55% were considered to be responders. However, only 27% of crossover participants achieved at least 50% improvement in pain, compared with 41% of participants in the original IDB plus CMM group. An important limitation of this study was that it was not statistically powered to evaluate reduction in opioid use, as the sample size was not adequate to detect statistically different changes between the study groups. It was reported that not every eligible participant in the IDB plus CMM and crossover study groups provided data at each respective follow-up time-point. Finally, CMM protocols were not standardized from clinic to clinic and participant to participant, and the physicians were permitted to treat study participants based on personal clinical preferences.

~~At this time, the available published evidence is insufficient to permit conclusions regarding the safety and efficacy of IDB for any indication when compared with other treatment modalities such as conservative therapy or other minimally invasive modalities. Additional study in a broader population of participants is needed to determine if the IDB procedure improves health outcomes in the treatment of chronic or severe discogenic low back pain~~

Other Considerations

The Centers for Medicare and Medicaid Services (CMS) determined for services on or after September 29, 2008, that thermal intradiscal procedures (TIPs) are not reasonable and necessary for the treatment of low back pain.

Chou and colleagues (2009) published an evidence-based guideline for the American Pain Society (APS). Their findings for both IDET and PIRFT stated:

- There is good or fair evidence from randomized trials that PIRFT thermocoagulation is not effective.
- There is insufficient (poor) evidence from randomized trials (conflicting trials, sparse and lower quality data, or no randomized trials) to reliably evaluate other interventional therapies, which include IDET.

An American Society of Interventional Pain Physicians (ASIPP) (Manchikanti, 2013) evidence-based practice guideline in the management of chronic spinal pain for thermal annular procedures states:

- The evidence for intradiscal electrothermal therapy (IDET) and biacuplasty is limited to fair and is limited for discTRODE.
- IDET and biacuplasty may be performed in a select group of patients with discogenic pain nonresponsive to conservative modalities including epidural injections.

~~Complications include catheter breakage, nerve root injuries, post-IDET disc herniation, cauda equina syndrome, infection, epidural abscess, and spinal cord damage (Manchikanti, 2009).~~

~~Helm and colleagues (2017) conducted a systematic review of the available evidence evaluating the effectiveness of thermal annular procedures in treating discogenic low back pain lasting at least 3 months. Four RCTs met the inclusion criteria for thermal annular procedures. Also of these RCTs are included in this document: Pauza, 2004 and Freeman, 2005 on IDET and Kapural 2015 and Desai 2016 on IBD. The authors stated that there were not a sufficient number of studies to conduct a meta-analysis.~~

~~S~~Summary
Efficacy
~~The efficacy~~ and~~,~~ safety~~, and improvement in long-term outcomes~~ have not been established in the published medical literature for the use of percutaneous vertebral disc and vertebral endplate procedures ~~minimally invasive, thermo-controlled intradiscal annuloplasty procedures (IDET, PIRFT, and IDB)~~ in the treatment of individuals with chronic discogenic or vertebrogenic low back pain. In sham-controlled RCTs, the procedures were either not found to result in better outcomes or outcomes were mixed and did not clearly support the efficacy of active treatment. For intraosseous basivertebral nerve ablation, a study found better outcomes compared with standard care at 3 months; however, the sample size was small and a placebo effect cannot be ruled out. There is a lack of comparative long-term data on the efficacy and safety of percutaneous vertebral disc and vertebral endplate procedures.
~~These procedures have not been proven to achieve equivalent or improved health outcomes compared to available and established alternatives. In addition, the long-term effect of thermal coagulation of intervertebral discs has not been determined.~~

Background/Overview

This Medical Policy provides assistance in understanding Healthy Blue's standard Medicaid benefit plan. When evaluating coverage for a specific member benefit, reference to federal and state law, as well as contractual requirements may be necessary, since these may differ from our standard benefit plan. In the event of a conflict with standard plan benefits, federal, state and/or contractual requirements will govern. Before using this policy, please check all federal, state and/or contractual requirements applicable to the specific benefit plan coverage. Healthy Blue reserves the right to modify its Policies and Guidelines as necessary and in accordance with legal and contractual requirements. This Medical Policy is provided for informational purposes. It does not constitute medical advice. Healthy Blue may also use tools and criteria developed by third parties, to assist us in administering health benefits. Healthy Blue's Policies and Guidelines are intended to be used in accordance with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

The intervertebral disc is a combination of strong connective tissues which hold one vertebra to the next and acts as a cushion between the vertebrae. It is made of a tough outer layer called the annulus fibrosus and a gel-like center called the nucleus pulposus. Discs are basically shock absorbers, whose content is 70%-90% water. The center of the disc may start to lose water content, making the disc less effective as a cushion, causing displacement of the disc's center (herniation or rupture) through a crack in the outer layer. Pain may be from the disc itself (discogenic pain) or from disc herniation or prolapse resulting in pressure on nearby nerve roots. Most disc herniations occur in the bottom two discs of the lumbar spine, at and just below the waist. A herniated disc can press on a nerve root in the spine and may cause back pain or pain, numbness, tingling or weakness of the leg called sciatica (pain radiating down the leg). Disc problems may occur as a result of injury, wear and tear, or with aging.

The IDET procedure using the Smith & Nephew SpineCath System describes a minimally invasive ~~annuloplasty~~ procedure that has been proposed as an alternative to spinal fusion for the treatment of chronic low-back pain related to disc disease. In an initial step, the pathogenic disc is identified using pressure-based discography. A navigable catheter with an embedded thermal resistive coil is inserted posterolaterally into the disc annulus or nucleus. The catheter is then advanced through the disc circuitously to return posteriorly. Electrothermal heat is then generated with the thermal resistive coil; the disc material is heated for up to 20 minutes. This outpatient procedure typically requires less than 30 to 40 minutes of recovery time. The mechanism of action of pain relief is unknown, but it is thought to be related to shrinkage of the collagen fibers within the annulus, or destruction of the adjacent nociceptive pain fibers.

The PIRFT procedure differs from the IDET procedure in that radiofrequency energy is applied directly to the involved disc. The radiofrequency probe is placed into the center of the disc instead of around the annulus. The practitioner activates the probe and delivers radiofrequency energy into the center of the disc for 90 seconds at a temperature of 70°C. As in IDET, the mechanism of action of pain relief is not precisely understood, but is thought to be related to a reduction of the pain receptor input by destroying the pain receptor fibers.

The Intracept intraosseous nerve ablation procedure targets the basivertebral nerve with radiofrequency energy. Treatment occurs with the individual in a prone position; either general anesthesia or conscious sedation is used. For the procedure, the radiofrequency probe is inserted into a channel leading to the trunk of the basivertebral nerve. A radiofrequency generator is used to ablate the basivertebral nerve, with the temperature at the tip of the probe maintained at 85°C for 15 minutes.

This Medical Policy provides assistance in understanding Healthy Blue's standard Medicaid benefit plan. When evaluating coverage for a specific member benefit, reference to federal and state law, as well as contractual requirements may be necessary, since these may differ from our standard benefit plan. In the event of a conflict with standard plan benefits, federal, state and/or contractual requirements will govern. Before using this policy, please check all federal, state and/or contractual requirements applicable to the specific benefit plan coverage. Healthy Blue reserves the right to modify its Policies and Guidelines as necessary and in accordance with legal and contractual requirements. This Medical Policy is provided for informational purposes. It does not constitute medical advice. Healthy Blue may also use tools and criteria developed by third parties, to assist us in administering health benefits. Healthy Blue's Policies and Guidelines are intended to be used in accordance with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

The IDB procedure uses two internally cooled radiofrequency probes placed on the posterolateral sides of the intervertebral annulus fibrosus to heat nerve tissue while circulating water to cool the tissue that is adjacent to the disc. During the procedure, the individual is mildly sedated and the area to be treated anesthetized. After approximately 15 minutes, the probes and needles are removed and a bandage is placed over the treatment site. IDB is similar to PIRFT in that it uses radiofrequency energy and similar to IDET and PIRFT in that it is not designed to coagulate, burn or destroy the disc material.

Definitions

Annulus: The hard, tough outer layer of the vertebral disc surrounding the center portion called the *nucleus*, which is a softer gel-like substance.

Biomechanics: The study of the effects of internal and external forces on the human body in movement and rest.

Discogenic pain: Pain generated by the disc itself which is externally intact, as opposed to disc prolapse or herniation which put pressure on nearby nerve roots.

Intraosseous: Occurring with a bone or administered by entering a bone.

Percutaneous: Through the skin (puncture as opposed to "open" surgical incision).

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

Radiofrequency: The use of electrodes to generate heat to alter tissue structure.

Spine anatomy: The spine is divided into three major sections: the cervical (neck), the thoracic (mid-back) and lumbar spine (lower back). These sections are made up of individual bones called *vertebrae*, which are the primary

area of weight bearing and provide a resting-place for the *discs*, which act as shock absorbers between the vertebrae.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services are Investigational and Not Medically Necessary:
When the code describes a procedure indicated in the Position Statement section as investigational and not medically necessary.

CPT	
22526	Percutaneous intradiscal electrothermal annuloplasty [IDET], unilateral or bilateral including fluoroscopic guidance; single level
22527	Percutaneous intradiscal electrothermal annuloplasty [IDET], unilateral or bilateral including fluoroscopic guidance; 1 or more additional levels
22899	Unlisted procedure, spine [when specified as percutaneous intradiscal radiofrequency thermocoagulation (PIRFT), intraosseous basivertebral nerve ablation or intradiscal biacuplasty (IDB)] [CPT coding instructions specify use of 22899 Unlisted procedure, spine for percutaneous intradiscal annuloplasty, any method other than electrothermal]
64999	Unlisted procedure, nervous system [when specified as intraosseous basivertebral nerve ablation]
HCPCS	
C9752	Destruction of intraosseous basivertebral nerve, first two vertebral bodies, including imaging guidance (e.g., fluoroscopy), lumbar/sacrum
C9753	Destruction of intraosseous basivertebral nerve, each additional vertebral body, including imaging guidance (e.g., fluoroscopy), lumbar/sacrum

This Medical Policy provides assistance in understanding Healthy Blue's standard Medicaid benefit plan. When evaluating coverage for a specific member benefit, reference to federal and state law, as well as contractual requirements may be necessary, since these may differ from our standard benefit plan. In the event of a conflict with standard plan benefits, federal, state and/or contractual requirements will govern. Before using this policy, please check all federal, state and/or contractual requirements applicable to the specific benefit plan coverage. Healthy Blue reserves the right to modify its Policies and Guidelines as necessary and in accordance with legal and contractual requirements. This Medical Policy is provided for informational purposes. It does not constitute medical advice. Healthy Blue may also use tools and criteria developed by third parties, to assist us in administering health benefits. Healthy Blue's Policies and Guidelines are intended to be used in accordance with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

ICD-10 Procedure

	For the following codes when specified as intraosseous basivertebral nerve ablation, percutaneous intradiscal electrothermal annuloplasty (IDET), percutaneous intradiscal radiofrequency thermocoagulation (PIRFT) or intradiscal biacuplasty (IDB):
015B3ZZ	Destruction of lumbar nerve, percutaneous approach
015B4ZZ	Destruction of lumbar nerve, percutaneous endoscopic approach
0RQ33ZZ	Repair cervical vertebral disc, percutaneous approach
0RQ34ZZ	Repair cervical vertebral disc, percutaneous endoscopic approach
0RQ53ZZ	Repair cervicothoracic vertebral disc, percutaneous approach
0RQ54ZZ	Repair cervicothoracic vertebral disc, percutaneous endoscopic approach
0RQ93ZZ	Repair thoracic vertebral disc, percutaneous approach
0RQ94ZZ	Repair thoracic vertebral disc, percutaneous endoscopic approach
0RQB3ZZ	Repair thoracolumbar vertebral disc, percutaneous approach
0RQB4ZZ	Repair thoracolumbar vertebral disc, percutaneous endoscopic approach
0SQ23ZZ	Repair lumbar vertebral disc, percutaneous approach
0SQ24ZZ	Repair lumbar vertebral disc, percutaneous endoscopic approach
0SQ43ZZ	Repair lumbosacral disc, percutaneous approach
0SQ44ZZ	Repair lumbosacral disc, percutaneous endoscopic approach

ICD-10 Diagnosis

All diagnoses

References

Peer Reviewed Publications:

1. Appleby D, Anderson, G, Totta, M. Meta-analysis of the efficacy and safety of intradiscal electrothermal therapy (IDET). Pain Med. 2006; 7(4):308-316.
2. Barendse GA, van Den Berg SG, Kessels AH, et al. Randomized controlled trial of percutaneous intradiscal radiofrequency thermocoagulation for chronic discogenic back pain: lack of effect from a 90-second 70 C lesion. Spine (Phila Pa 1976). 2001; 26(3):287-292.

~~3. Becker S, Hadjipavlou A, Heggeness MH. Ablation of the basivertebral nerve for treatment of back pain: a clinical study. Spine J. 2017; 17(2):218-223.~~
~~4.~~3. Desai MJ, Kapural L, Petersohn JD, et al. A prospective, randomized, multicenter, open-label clinical trial comparing intradiscal biacuplasty to conventional medical management for discogenic lumbar back pain. Spine (Phila Pa 1976). 2016; 41(13):1065-1074.
~~5.~~4. Desai MJ, Kapural L, Petersohn JD, et al. Twelve-month follow-up of a randomized clinical trial comparing intradiscal biacuplasty to conventional medical management for discogenic lumbar back pain. Pain Med. 2017; 18(4):751-763.
5. Fischgrund JS, Rhyne A, Franke J et al. Intraosseous basivertebral nerve ablation for the treatment of chronic low back pain: 2-year results from a prospective randomized double-blind sham-controlled multicenter study. Int J Spine Surg. 2019; 13(2):110-119.
6. Fischgrund JS, Rhyne A, Franke J, et al. Intraosseous basivertebral nerve ablation for the treatment of chronic low back pain: a prospective randomized double-blind sham-controlled multi-center study. Eur Spine J. 2018; 27(5):1146-1156.
7. Freedman BA, Cohen SP, Kuklo TR, et al. Intradiscal electrothermal therapy (IDET) for chronic low back pain in active-duty soldiers: 2 year follow-up. Spine J. 2003; 3(6):502-509.
~~8.~~ Freeman BJ, Fraser RD, Cain CM, et al. A randomized, double-blind, controlled trial: intradiscal electrothermal therapy versus placebo for the treatment of chronic discogenic low back pain. Spine (Phila Pa 1976). 2005; 30(21):2369-2377.
~~9.~~8. ~~Helm, S, Simopoulos TT, Stojanovic M et al. Effectiveness of thermal annular procedures in treating discogenic low back pain. Pain Physician. 2017; 20: 447-470.~~
~~10.~~9. Kapural L, Vrooman B, Sarwar S, et al. A randomized, placebo-controlled trial of transdiscal radiofrequency, biacuplasty for treatment of discogenic lower back pain. Pain Med. 2013; 14(3):362-373.
~~11.~~10. Kapural L, Vrooman B, Sarwar S, et al. Radiofrequency intradiscal biacuplasty for treatment of discogenic lower back pain: a 12-month follow-up. Pain Med. 2015; 16(3):425-431.
~~12.~~11. Karasek M, Bogduk N. Twelve-month follow-up of a controlled trial of intradiscal thermal annuloplasty for back pain due to internal disc disruption. Spine (Phila Pa 1976). 2000; 25(20):2601-2607.
12. Khalil J, Smuck M, Koreckij T et al. A prospective, randomized, multi-center study of intraosseous basivertebral nerve ablation for the treatment of chronic low back pain. Spine J. 2019 Jun 20. [Epub ahead of print].
13. Kvarstein G, Mawe L, Indahl A, et al. A randomized double-blind controlled trial of intra-annular radiofrequency thermal disc therapy-a 12-month follow-up. Pain. 2009; 145(3):279-286.

14. Pauza KJ, Howell S, Dreyfuss P, et al. A randomized, placebo controlled trial of intradiscal electro-thermal therapy for the treatment of discogenic low back pain. Spine J. 2004; 4(1):27-35.
~~15. Zhang L, Ding XL, Zhao XL, et al. Fluoroscopy-guided bipolar radiofrequency thermocoagulation treatment for discogenic low back pain. Chin Med J (Engl). 2016; 129(19):2313-2318.~~

Government Agency, Medical Society, and Other Authoritative Publications:

1. Centers for Medicare and Medicaid Services (CMS). National Coverage Determination (NCD): Thermal Intradiscal Procedures (TIPs). NCD #150.11. Effective September 29, 2008. Available at: https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=324&ncdver=1&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=All&KeyWord=Thermal&KeyWordLookUp=Title&KeyWordSearchType=And&bc=gAAAACAAAAAA&. Accessed on ~~October 5, 2018~~June 25, 2019.
2. Chou R, Atlas SJ, Stanos SP, Rosenquist RW. Nonsurgical interventional therapies for low back pain: a review of the evidence for an American Pain Society clinical practice guideline. Spine (Phila Pa 1976). 2009; 34(10):1078-1093.
3. Manchikanti L, Abdi S, Atluri S, et al. An update of comprehensive evidence-based guidelines for interventional techniques in chronic spinal pain. Part II: Guidance and recommendations. Pain Physician. 2013; 16(2 Suppl):S49-S283.
~~4. Manchikanti L, Boswell MV, Singh V, et al. The American Society of Interventional Pain Physicians-Interventional Pain Management (ASIPP-IPM). Comprehensive evidence-based guidelines for interventional techniques in the management of chronic spinal pain. Pain Physician. 2009; 12(4):699-802.~~

Index

Baylis TransDiscal System
Intracept Intraosseous Nerve Ablation System
Radionics DiscTRODE
Radionics RF Disc Catheter System
SpineCath IntraDiscal ElectroThermal Therapy (IDET) System

The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

This Medical Policy provides assistance in understanding Healthy Blue's standard Medicaid benefit plan. When evaluating coverage for a specific member benefit, reference to federal and state law, as well as contractual requirements may be necessary, since these may differ from our standard benefit plan. In the event of a conflict with standard plan benefits, federal, state and/or contractual requirements will govern. Before using this policy, please check all federal, state and/or contractual requirements applicable to the specific benefit plan coverage. Healthy Blue reserves the right to modify its Policies and Guidelines as necessary and in accordance with legal and contractual requirements. This Medical Policy is provided for informational purposes. It does not constitute medical advice. Healthy Blue may also use tools and criteria developed by third parties, to assist us in administering health benefits. Healthy Blue's Policies and Guidelines are intended to be used in accordance with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

Document History

Status	Date	Action
Revised	08/22/2019	Medical Policy & Technology Assessment Committee (MPTAC) review. Title changed to Percutaneous Vertebral Disc and Vertebral Endplate Procedures. The three investigational and not medically necessary statements combined into single statement with bullet points. Intraosseous basivertebral nerve ablation added to the investigational and not medically necessary statement. Updated Description, Rationale, Background, Definitions and References sections. Updated Coding section; added 64999, C9752, C9753, 015B3ZZ, 015B4ZZ.
Reviewed	11/08/2018	~~Medical Policy & Technology Assessment Committee (~~MPTAC ~~)~~ review. Updated Rationale and References sections.
Reviewed	02/27/2018	MPTAC review. The document header wording updated from "Current Effective Date" to "Publish Date." Updated Rationale, References, and Index sections.
Reviewed	02/02/2017	MPTAC review. Updated formatting in Position Statement section. Updated Rationale and References sections.
Reviewed	02/04/2016	MPTAC review. Updated Rationale and References sections. Removed ICD-9 codes from Coding section.
Reviewed	02/05/2015	MPTAC review. Format changes throughout document. Updated Rationale, Background, and Reference sections.
Reviewed	02/13/2014	MPTAC review. Updated Rationale, Background, and References sections.
Revised	02/14/2013	MPTAC review. Added IDB acronym to the Subject. Clarified Position Statements. Clarified and updated the Description, Rationale, Background, Definitions, References, and Index sections.
Reviewed	02/16/2012	MPTAC review. References updated.
Reviewed	02/17/2011	MPTAC review. References updated.
Reviewed	02/25/2010	MPTAC review. References updated.
	01/01/2010	Updated Coding section with 01/01/2010 CPT changes; removed CPT 0062T, 0063T deleted 12/31/2009.

Revised	02/26/2009	MPTAC review. Scope of document expanded to address intradiscal biacuplasty. Title, position statement, rationale and background/overview section revised to address intradiscal biacuplasty. Updated review date, coding, index, history sections and references.
Reviewed	02/21/2008	MPTAC review. Updated review date, rationale, references and history sections. No change to position statement. The phrase "investigational/not medically necessary" was clarified to read "investigational and not medically necessary." This change was approved at the November 29, 2007 MPTAC meeting.
Revised	03/08/2007	MPTAC review. Updated the Description, Position Statement, Rationale, Coding and Reference sections of the document to address percutaneous intradiscal radiofrequency thermocoagulation. Document formerly titled Percutaneous Intradiscal Electrothermal Coagulation (IDET Procedure).
	01/01/2007	Updated Coding section with 01/01/2007 CPT/HCPCS changes; removed HCPCS codes S2370, S2371 deleted 09/30/2004.
Reviewed	03/23/2006	MPTAC review. Updated the Rationale, Coding and Reference sections of the document.
Revised	07/14/2005	MPTAC review. Revision based on Pre-merger Anthem and Pre-merger WellPoint Harmonization.

Pre-Merger Organizations	**Last Review Date**	**Document Number**	**Title**
Anthem, Inc.	07/27/2004	SURG.00052	Chronic Spine Pain Treatments/Procedures (Minimally Invasive)
WellPoint Health Networks, Inc.	09/23/2004	3.07.06	Percutaneous Intradiscal Electrothermal Coagulation (IDET Procedure)