Miscellaneous Surgical Treatments of Back Pain

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DESCRIPTION

A variety of minimally invasive techniques have been investigated over the years as a treatment of low back pain related to disc disease. Techniques can be broadly divided into techniques that are designed to remove or ablate disc material and thus decompress the disc or those that are designed to alter the biomechanics of the disc annulus which include, annular (annulus) repair/closure (Xclose™ Tissue Repair System [Anulex Technologies, Inc., Minnetonka, MN], Barricaid Annular Closure Device [Intrinsic Therapeutics, Woburn, MA]), automated percutaneous lumbar discectomy, image-guided minimally invasive decompression, laser discectomy, percutaneous laminectomy, percutaneous endoscopic discectomy (PELD), endoscopic discectomy, and most recently plasma disc decompression using radiofrequency energy, often referred to using the proprietary terms Coblation® or DISC nucleoplasty™.

Annular (Annulus) Repair/Closure

Annular closure is a surgical treatment that is performed immediately following a lumbar disc herniation (LDH) debridement surgery (e.g., lumbar discectomy, sequestrectomy, nucleotomy). The annular closure surgical procedure involves the implantation of a

device to mimic healthy annulus fibrosus at the site of the annular defect in order to aid recovery and prevent future reherniation.

Clinical Content and Therapy Purpose
The use of annular closure device (ACD) implantation as an adjunct procedure to lumbar discectomy (LD) to close sizable annular defects (usually ≥ 6 mm) with the goal of reducing the risk of recurrent lumbar disc herniation (LDH) in adult patients with LDH refractory to conservative treatment.

Populations
The population of individuals for annular closure device (ACD) is adults with symptomatic LDH and a large annular defect (between 6 to 12 mm width), refractory to ≥ 6 weeks of conservative care.

Interventions
The therapy being considered is annular closure device (ACD) implantation.

Comparators
The following therapies and practices are currently being used to treat herniated intervertebral disc(s): conservative therapy and lumbar discectomy, sequestrectomy, nucleotomy.

Outcomes
The general outcomes of interest are symptoms, functional outcomes, quality of life (QOL), and treatment-related morbidity. Specific outcomes measured by specific instruments may include improvements in functional outcomes assessed on the Oswestry Disability Index (ODI), reductions in pain using a visual analog scale (VAS), improvements in quality of life measured on the 36-Item Short-Form Health Survey (SF-36) and Euro-QOL-5D, and treatment-related morbidity including surgical success/failure and complications. To assess outcomes, follow-up at 1 year is considered appropriate.

Evidence Review

Barricaid Annular Closure Device
Hayes Inc. published a Health Technology Assessment June 2021, was reviewed and updated May 2022 on annular closure for prevention of lumbar disc reherniation. This technology assessment focused on annular closure device (ACD) for the prevention of recurrent lumbar disc herniation (LDH) after lumbar discectomy (LD). The Barricaid annular closure device (ACD) is currently the only Food and Drug Administration (FDA) approved method of annular closure that is available. The Barricaid ACD is a U-shaped bone-anchored implantable device with a jagged titanium wing and a woven polyester fabric occlusion component. The ACD is implanted so the occlusion component fills the void of the annular defect, and the titanium alloy arm anchors the ACD onto the adjacent vertebral body. Based on review of the literature, there is a low-quality body of evidence that suggests ACD may improve patient outcomes compared to lumbar discectomy. However, comparative studies found mixed results for efficacy outcomes. some studies

showed annular closure was favored over lumbar discectomy, but other studies found no statistically significant differences between treatment groups. Larger well-designed randomized controlled trials (RCTs) are needed to determine the safety and efficacy including long-term outcomes of annular closure devices with greater reliability and precision.

Kienzler et. al., (2021) In a non-comparative, single-center study analyzed the incidence of endplate changes (EPC) and outcome after LMD with additional implantation of an ACD to prevent re-herniation. This analysis included data from a RCT study-arm of patients undergoing LMD with ACD implantation as well as additional patients undergoing ACD implantation at the authors' institution. Clinical findings (VAS, ODI), radiological outcome (re-herniation, implant integrity, volume of EPC) and risk factors for EPC were assessed. A total of 72 patients (37 men, age of 47 ± 11.63 years) underwent LMD and ACD implantation between 2013 and 2016. A total of 71 (99 %) patients presented with some degree of EPC during the follow-up period (14.67 ± 4.77 months). In the multi-variate regression analysis, localization of the anchor was the only significant predictor of EPC ($p = 0.038$). The largest EPC measured 4.2 cm3. Re-herniation was documented in 17 (24 %) patients (symptomatic: n = 10; asymptomatic: n = 7); 6 (8.3 %) patients with symptomatic re-herniation underwent re-discectomy. Implant failure was documented in 19 (26.4 %) patients including anchor head breakage (n = 1, 1.3 %), dislocation of the whole device (n = 5, 6.9 %), and mesh dislocation into the spinal canal (n = 13, 18 %). Mesh subsidence within the EPC was documented in 15 (20.8 %) patients; 7 (9.7 %) patients underwent explantation of the entire, or parts of the device. The authors concluded the ACD might prevent disc re-herniation despite implant failure rates. Mechanical friction of the polymer mesh with the endplate was most likely the cause of EPC after ACD. Long-term clinical and radiological assessments is needed to examine the consequences of these findings. Limitations of this study was that it was a non-comparative, single-center study with a small patient cohort.

In 2021 Thome et. al., examined if a bone-anchored annular closure device in addition to lumbar microdiscectomy would result in lower re-herniation and re-operation rates versus lumbar microdiscectomy alone. This trial reported the 5-year follow-up for enrolled patients between December 2010 and October 2014 at 21 clinical sites. Patients in this study had a large annular defect (6 to 10 mm width) following lumbar microdiscectomy for treatment of lumbar disc herniation. Statistical analysis was performed from November to December 2020. Subjects were treated with lumbar microdiscectomy with additional bone-anchored annular closure device (device group) or lumbar microdiscectomy only (control group). Main outcomes and measures included the incidence of symptomatic re-herniation, re-operation, and AEs as well as changes in leg pain, ODI, and health-related QOL (HR-QOL) when comparing the device and control groups over 5 years of follow-up. Among 554 randomized subjects (mean [SD] age: 43 [11] years; 327 [59 %] were men), 550 were included in the modified ITT efficacy population (device group: n = 272; 270 [99 %] were White); control group: n = 278; 273 [98 %] were White) and 550 were included in the as-treated safety population (device

group: n = 267; control group: n = 283). The risk of symptomatic re-herniation (18.8 % [SE, 2.5 %] versus 31.6 % [SE, 2.9 %]; p < 0.001) and re-operation (16.0 % [SE, 2.3 %] versus 22.6 % [SE, 2.6 %]; p = 0.03) was lower in the device group. There were 53 re-operations in 40 patients in the device group and 82 re-operations in 58 patients in the control group. Scores for leg pain severity, ODI, and HR-QOL significantly improved over 5 years of follow-up with no clinically relevant differences between groups. The frequency of serious AEs was comparable between the treatment groups. Serious AEs associated with the device or procedure were less frequent in the device group (12.0 % versus 20.5 %; difference, -8.5 %; 95 % CI: -14.6 % to -2.3 %; p = 0.008).

The authors stated that this study had several limitations. First, the results were generalizable only to patients with large defects in the annulus fibrosus following lumbar discectomy. Second, most patients and all investigators were aware of treatment assignment; thus, it was possible that re-operation rates may have been influenced by performance bias. Third, patients in the trial were treated with limited lumbar discectomy with little to no removal of disc material within the intervertebral space. It was possible that lower re-herniation rates could be achieved with aggressive disc resection, although intervertebral instability and spondylosis progression were potential risks with this surgical technique. Fourth, although end-plate changes in the device group were associated with a benign clinical course through 5 years of follow-up, their natural history over longer term follow-up is currently unclear. Finally, although the 5-year follow-up visit rate of 73 % was typical of long-term clinical trials of spinal devices, the potential for bias owing to missing data must be acknowledged.

In 2020, Miller et. al., highlighted the therapeutic need and summarized the clinical results of a bone anchored ACD (Barricaid) that was designed to fill the treatment gap in patients with large post-surgical annular defects. Clinical results were summarized by means of a systematic review with meta-analysis of 2 randomized and 2 non-randomized controlled studies. The authors stated that professional societal recommendations and clinical study results support the adoption of bone-anchored annular closure for use in properly selected patients undergoing lumbar discectomy who are at high-risk for re-herniation due to a large post-surgical defect in the annulus fibrosus. The risks of symptomatic re-herniation and re-operation were approximately 50 % lower in patients treated with lumbar discectomy and the Barricaid device compared to lumbar discectomy only, representing a clinically effective treatment strategy. Furthermore, these researchers stated that as more clinical study data continue to accrue demonstrating the positive long-term results of the Barricaid device, treatment of large defects in the annulus fibrosus during the index surgery may become the standard of care to prevent future symptomatic re-herniations and associated re-operations. It should be noted that this paper was funded by Intrinsic Therapeutics. L Miller has received personal fees from Intrinsic Therapeutics. One peer reviewer was a co-investigator in a randomized-controlled trial of the Barricaid device.

Nanda et. al., (2019) examined if implanting an annular closure device (ACD) following lumbar discectomy in patients with large defects in the annulus fibrosus lowers the risk of

re-operation after 4 years. Patients with large annular defects following single-level lumbar discectomy were intra-operatively randomized to additionally receive an ACD or no treatment (controls). Clinical and imaging follow-up were performed at routine intervals over 4 years of follow-up. Main outcomes included re-operations at the treated lumbar level, leg pain scores on a visual analog scale (VAS), Oswestry Disability Index (ODI), and Physical Component Summary (PCS) and Mental Component Summary (MCS) scores from the SF-36 questionnaire. Among 550 patients (ACD 272, control 278), the risk of re-operation over 4 years was 14.4% with ACD and 21.1% with controls ($p = 0.03$). The reduction in re-operation risk with ACD was not significantly influenced by patient age ($p = 0.51$), sex ($p = 0.34$), body mass index (BMI; $p = 0.21$), smoking status ($p = 0.85$), level of herniation ($p = 0.26$), leg pain severity at baseline ($p = 0.90$), or ODI at baseline ($p = 0.54$). All patient-reported outcomes improved in each group from baseline to 4 years (all $p < 0.001$). The percentage of patients who achieved the minimal clinically important difference without a re-operation was proportionally higher in the ACD group compared to controls for leg pain ($p = 0.07$), ODI ($p = 0.10$), PCS ($p = 0.02$), and MCS ($p = 0.06$). The authors concluded that the addition of a bone anchored ACD following lumbar discectomy in patients with large post-surgical annular defects reduced the risk of re-operation and provided better long-term pain and disability relief over 4 years compared to lumbar discectomy only.

The authors stated that this study had several limitations. First, the results presented were applicable only to patients with large post-discectomy annular defects, who accounted for approximately 30% of all lumbar discectomy cases. Implantation of an ACD in patients with small annular defects cannot be justified clinically given the inherently low risk of symptom recurrence in these individuals. Additional patient characteristics that were crucial to achieving positive results included adequate disc height and non-osteoporotic bone mineral density (BMD) of the lumbar spine. Second, the decision to re-operate involved shared decision-making between the patient and surgeon and, thus, there was potential for bias in the reported re-operation rates. Finally, 5-year follow- up in this study is ongoing and these long-term outcomes are anxiously awaited to provide final comparative efficacy, safety, and cost-utility results of bone-anchored ACD implantation.

Kienzler et.al. (2019) in a randomized, multi-center study, examined the 3-year results of lumbar discectomy with a bone-anchored annular closure device (ACD) or lumbar discectomy only (controls) in patients at high-risk for re-herniation. Trial included patients with sciatica due to lumbar intervertebral disc herniation who failed conservative treatment. Patients with large annular defects after lumbar limited microdiscectomy were intra-operatively randomly assigned to receive ACD or control. Clinical and imaging follow-up was performed at routine intervals over 3 years. Main outcomes included rate of re-herniations, re-operations, and endplate changes; leg and back pain scores on a visual analog scale (VAS); Oswestry Disability Index (ODI); Physical Component Summary (PCS) and Mental Component Summary (MCS) scores from the SF-36; and adverse events (AEs) adjudicated by a data safety monitoring board. Among 554 randomized patients, the modified intent-to-treat (ITT) population consisted of 272 patients in which ACD implantation was attempted and 278 receiving control; device

implantation was not attempted in 4 patients assigned to ACD. Outcomes at 3 years favored ACD for symptomatic re-herniation (14.8 % versus 29.5 %; $p < 0.001$), re-operation (11.0 % versus 19.3 %; $p = 0.007$), leg pain (21 versus 30; $p < 0.01$), back pain (23 versus 30; $p = 0.01$), ODI (18 versus 23; $p = 0.02$), PCS (47 versus 44; $p < 0.01$), and MCS (52 versus 49; $p < 0.01$). The frequency of all-cause serious AEs was comparable between groups (42.3 % versus 44.5 %; $p = 0.61$).

The authors stated that this study had several limitations. First, these findings were not applicable to all patients undergoing lumbar discectomy, but only the approximately 30 % of cases at high-risk of re-herniation due to a large post-surgical annular defect. The ACD is not intended to be used in patients with smaller defects since treatment with a permanent implant is difficult to justify in this population due to the relatively low risk of re-herniation. Second, lack of patient and outcome-assessor blinding to treatment allocation may have biased patient-reported outcomes or the decision to re-operate. Third, while CT imaging with core laboratory reading is a strength of this trial, it may also be perceived as a limitation since the application of CT findings to routine clinical practice is unclear. Finally, longer follow-up is needed in this younger patient population to determine the durability of effect with ACD and to ensure there are no concerning late-onset safety or device-related complications. While there was no association of vertebral endplate changes (VEPC) with clinical complications over 3 years among patients who received ACD, this should be confirmed in long-term follow-up. It should also be noted that some of the investigators (P. Klassen, L. Miller, R. Assaker, and C. Thome) reported consultancy with Intrinsic Therapeutics.

Choe et. al., (2019) in a prosepective study examined the effectiveness of a novel annular closure device (ACD) for preventing lumbar disc herniation (LDH) recurrence and re-operation compared with that of conventional lumbar discectomy (CLD). These researchers compared CLD with discectomy utilizing the Barricaid ACD. Primary radiologic outcomes included disc height, percentage of pre-operative disc height maintained, and re-herniation rates. Additional clinical outcomes included visual analog scale (VAS) scores for back and leg pain, Oswestry Disability Index (ODI) scores, and 12-item short-form health survey (SF-12) quality of life (QOL) scores. Outcomes were measured at pre-operation and at 1 week, 1, 3-, 6-, 12-, and 24-months post-operation. A total of 60 patients (30 CLD, 30 ACD) were enrolled in this study. At 24-month follow-up, the disc height in the ACD group was significantly greater than that in the CLD group (11.4 ± 1.5 versus 10.2 ± 1.2 mm, $p = 0.006$). Re-herniation occurred in 1 patient in the ACD group versus 6 patients in the CLD group ($\chi 2 = 4.04$, $p = 0.044$). Back and leg VAS scores, ODI scores, and SF-12 scores improved significantly in both groups compared with pre-operative scores in the first 7 days following surgery and remained at significantly improved levels at a 24-month follow-up. However, no statistical difference was found between the 2 groups.

The authors stated that this study had 2 main limitations. First, the 2-year follow-up, in which 70 % or fewer patients were actually followed-up, was short and limited the veracity with which conclusions could be applied in the long-term. However, it provided

important early information regarding the stability and survivability of the device. These findings mirrored those of other investigators who examined this ACD and found that the device ensured maintenance of favorable clinical scores and lower rates of re-herniation. Second, the low sample size of this cohort (n = 30 in the ACD group) limited the ability to extrapolate results to larger populations.

Xclose Tissue Repair System
An annular (annulus) repair/closure may be performed following a spinal decompression (discectomy) surgery. It has been proposed that annular closure may reduce the risk of disc reherniation and the need for a fusion. Examples of devices used in an annular repair include the Xclose™ Tissue Repair System.

The Xclose™ Tissue Repair System (Anulex Technologies, Inc., Minnetonka, MN) has received 510(k) clearance for use in soft tissue approximation for procedures such as general and orthopedic surgery. It is being investigated as a method of soft tissue re-approximation of the anulus fibrosus after a lumbar discectomy procedure. However, there is insufficient evidence of the clinical effectiveness of the Xclose™ Tissue Repair System following a lumbar discectomy procedure. Randomized controlled studies are needed to determine whether closing the anulus following a lumbar discectomy procedure will result in improved clinical outcomes (i.e., decrease in re-herniation rates). To evaluate the benefits of anulus fibrosis repair utilizing the Xclose™ Tissue Repair system, Anulex is sponsoring a prospective, controlled, randomized study that will compare discectomy patients who receive annular repair using the Xclose™ Tissue Repair System to those who receive a standard discectomy without using the Xclose™. However, results from this study have not yet been published in the peer-reviewed medical literature.

Summary of Evidence
Based on review of the peer reviewed medical literature regarding annular closure devices (ACDs) (Barricade and Xclose™ Tissue Repair System) a surgical treatment performed immediately following a lumbar disc herniation (LDH) debridement surgery (e.g., lumbar discectomy, sequestrectomy, nucleotomy) to reduce the risk of recurrent lumbar disc herniation (LDH) in adult patients, there is a low-quality body of evidence that suggests ACD may improve patient outcomes compared to lumbar discectomy. However, comparative studies found mixed results for efficacy outcomes. some studies showed annular closure was favored over lumbar discectomy, but other studies found no statistically significant differences between treatment groups. Additional randomized controlled trials (RCTs) are needed to determine whether closing the anulus following a lumbar discectomy procedure will result in improved clinical outcomes (i.e., decrease in re-herniation rates). The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Automated Percutaneous and Percutaneous Endoscopic Discectomy
Automated percutaneous and endoscopic discectomy, in which the disc decompression is accomplished by the physical removal of disc material rather than its ablation.

Traditionally, discectomy was performed manually through an open incision, using cutting forceps to remove nuclear material from within the disc annulus. This technique was modified by automated devices that involve placement of a probe within the intervertebral disc and aspiration of disc material using a suction cutting device. Endoscopic techniques may be intradiscal or may involve extraction of noncontained and sequestered disc fragments from inside the spinal canal using an interlaminar or transforaminal approach. Following insertion of the endoscope, decompression is performed under visual control.

Clinical Input
In 2018, the BlueCross BlueShield Association sought clinical input to determine whether the use of automated percutaneous discectomy or endoscopic percutaneous discectomy for individuals with herniated intervertebral discs would provide a clinically meaningful improvement in net health outcome and whether the use is consistent with generally accepted medical practice. In response to requests, clinical input was received from 3 respondents, including 2 specialty society-level response(s); no physician-level responses identified through a specialty society; 1 physician-level response identified through an academic medical center.

For individuals who have herniated intervertebral discs who receive automated percutaneous discectomy or percutaneous endoscopic discectomy, clinical input does not support a clinically meaningful improvement in net health outcome and does not indicate this use is consistent with generally accepted medical practice. Clinical input suggests that automated percutaneous discectomy may be an appropriate treatment option for the highly selected patient who has a small focal disc fragment compressing a lumbar nerve causing radiculopathy in the absence of lumbar stenosis or severe bony foraminal stenosis. Similarly, clinical input suggests that endoscopic percutaneous discectomy may be an appropriate treatment option for the highly selected patient who has a small focal disc herniation causing lumbar radiculopathy. However, respondents were mixed in the level of support for this indication, and overall, the clinical input is not generally supportive of a clinically meaningful improvement in net health outcome.

Clinical Context and Therapy Purpose
The purpose of automated percutaneous discectomy is to provide a treatment option that is an alternative to or an improvement on existing therapies for individuals with herniated intervertebral disc(s).

Populations
The relevant population of interest is individuals with herniated intervertebral disc(s).

Interventions
The therapy being considered is automated percutaneous discectomy.

Comparators
The following therapies and practices are currently being used to treat herniated intervertebral disc(s): conservative therapy and open discectomy or microdiscectomy.

Outcomes
The general outcomes of interest are symptoms, functional outcomes, quality of life (QOL), and treatment-related morbidity. Specific outcomes measured by specific instruments may include improvements in functional outcomes assessed on the Oswestry Disability Index (ODI), reductions in pain using a visual analog scale (VAS), improvements in quality of life measured on the 36-Item Short-Form Health Survey (SF-36) and Euro-QOL-5D, and treatment-related morbidity including surgical success/failure and complications. To assess outcomes, follow-up at 1 year is considered appropriate.

Review of Evidence

Systematic Reviews
Systematic reviews have assessed automated percutaneous discectomy compared to other interventions; however, the majority of these reviews contained observational studies published more than a decade ago with generally small patient populations and inconsistent results.

Randomized Controlled Trials
The Lumbar Automated Percutaneous Discectomy Outcomes Group (LAPDOG) trial is a randomized controlled trial (RCT) to compare automated percutaneous discectomy with open discectomy in patients with lumbar disc herniation. No additional RCTs have been identified since the LAPDOG trial. The trial was designed to recruit 330 patients but enrolled 36 patients for reasons not readily apparent. Twenty-seven patients were available at follow-up, with efficacy reported by 41% of those undergoing automated percutaneous discectomy and by 40% of those undergoing conventional discectomy. The trialists concluded that "It is difficult to understand the remarkable persistence of percutaneous discectomy in the face of a virtually complete lack of scientific support for its effectiveness in treated lumbar disc herniation."

All published trials have focused on lumbar disc herniation. There were no randomized controlled trials (RCTs) of automated percutaneous discectomy for cervical or thoracic disc herniation. A review of the evidence from American Society of Interventional Pain Physicians (2013) noted that "even though Dekompressor (disc removal system) may be considered a new interventional modality, the early studies were published approximately 8 years ago. Consequently, one would expect that the technique's continued use would be supported by more recent, high-quality evaluations”

Section Summary
The evidence for automated percutaneous discectomy in individuals who have herniated intervertebral disc(s) includes small randomized controlled trials (RCTs) and systematic reviews. Evidence from small RCTs does not support the use of this procedure. Well-

designed and executed RCTs are needed to determine the benefits and risks of this procedure.

Percutaneous Endoscopic Discectomy

Clinical Context and Therapy Purpose
The purpose of percutaneous endoscopic discectomy is to provide a treatment option that is an alternative to or an improvement on existing therapies for individuals with herniated intervertebral disc(s).

Populations
The relevant population of interest is individuals with herniated intervertebral disc(s).

Interventions
The therapy being considered is percutaneous endoscopic discectomy.

Comparators
The following therapies and practices are currently being used to treat herniated intervertebral disc(s): conservative therapy and open discectomy or microdiscectomy.

Outcomes
The general outcomes of interest are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Specific outcomes measured by specific instruments include improvements in functional outcomes assessed on the ODI, reductions in pain using a VAS, improvements in quality of life measured on the SF-36 and Euro-QOL-5D, and treatment-related morbidity including surgical success/failure and complications. To assess outcomes, follow-up at 1 year is considered appropriate.

Review of Evidence

Systematic Reviews
A number of systematic reviews have evaluated the efficacy and safety of percutaneous endoscopic discectomy compared to open discectomy or microendoscopic discectomy. A comparison of the trials included in more recent systematic reviews (2016 to present). Results from the systematic reviews were fairly consistent with a significantly reduced length of hospitalization observed with endoscopic discectomy and sometimes significant improvements in VAS or ODI, but only at specific time points. Overall, no consistently significant improvement in VAS, ODI, total complication rate, reoperation, or recurrence was observed with endoscopic discectomy versus other interventions. Authors of the systematic reviews noted multiple limitations including the innate flaws of included studies (i.e., observational designs, a limited number of studies meeting criteria for inclusion, small sample sizes, lack of allocation concealment and blinding), different methodologies contributing to heterogeneity in analyses, loss of usable and sufficient data resulting in difficulty performing accurate analysis of outcomes, and that a majority of

the more recently completed studies were completed in China, which may affect the generalizability of the results to other populations.

Randomized Controlled Trials

A total of 67 trials comparing percutaneous endoscopic discectomy to other discectomy procedures have been completed. Results of these trials are similar to those seen in the more comprehensive systematic reviews percutaneous endoscopic discectomy was associated with a significant reduction in length of stay with no consistent or clinically meaningful improvements in patient-reported outcome measures such as VAS and ODI. Two of the 3 RCTs evaluated treatment-related morbidities and reported a reduced incidence of intraoperative and postoperative complications and repeat surgeries with percutaneous endoscopic discectomy.

Study Design and Conduct Limitations of the Randomized Controlled Trials (RCTs) of Percutaneous Endoscopic Discectomy

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]	Power[e]	Statistical[f]
Gadjradj et al 2022	4. A proportion of patients with a strong preference for PTED who were randomised to open microdiscecto my dropped out of the study after randomization	1,2. Blinding did not occur				
Ran et al 2021	3.Allocation concealment unclear	1,2. Blinding did not appear to occur			1. Power calculations not reported	
Wang et al 2019	3.Allocation concealment unclear	1,2. Blinding did not appear to occur			1. Power calculations not reported	

PTED: percutaneous transforaminal endoscopic discectomy; RCT: randomized controlled trials.
The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a]Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias.
[b]Blinding key: 1. Not blinded to treatment assignment; 2. Not blinded outcome assessment; 3. Outcome

assessed by treating physician.
[c]Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.
[d]Data Completeness key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials).
[e]Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference.
[f]Statistical key: 1. Analysis is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Analysis is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated.

Observational Studies

A number of observational studies have also assessed the learning curveand the need for longer follow-up for endoscopic discectomy. The largest and longest follow-up to date has been reported by Choi et al (2015), who examined 10,228 patients at their institution who had had percutaneous endoscopic lumbar discectomy over a 12-year period. They found that 4.3% of cases required reoperation in the first 6 weeks due to incomplete removal of herniated discs (2.8%), recurrence (0.8%), persistent pain (0.4%), and approach-related pain (0.2%).

Yu et.al., (2021) published the results of a retrospective multicenter study that followed patients for 2 years after receipt of transforaminal percutaneous endoscopic discectomy (n=632) and microendoscopic discectomy (n=421) for lumbar disc herniation. Mean blood loss ($p<.001$) and mean duration of hospital stay ($p=.018$) were significantly reduced with transforaminal percutaneous endoscopic lumbar discectomy compared to microendoscopic discectomy. Rates of complications, recurrence, and revisions were similar in both groups. The VAS pain scores did not differ between groups after the first postoperative day. At 1 month postoperatively, there was a significant difference in ODI scores between groups ($p=.016$) in favor of transforaminal percutaneous endoscopic discectomy, but there was no significant difference at other time points.

Song et.al., (2021) published a retrospective single-center study that compared percutaneous endoscopic lumbar discectomy (n=306) and microendoscopic discectomy (n=116) in patients undergoing same day ambulatory surgery for lumbar disc herniation. Mean blood loss and mean duration of hospital stay were significantly less with percutaneous endoscopic lumbar discectomy (both $p<.001$ compared to microendoscopic discectomy). After 3 years of follow-up, e VAS pain scores for the back were also significantly lower in the percutaneous endoscopic lumbar discectomy group compared to the microendoscopic discectomy group ($p=.001$), but there was no difference between groups in pain scores for the legs ($p=.224$). Overall recurrence rates ($p=.201$) and ODI scores ($p=.220$) were also similar between groups.

Section Summary

The evidence for percutaneous endoscopic discectomy in individuals who have herniated intervertebral disc(s) includes a number of randomized controlled trials (RCTs), systematic reviews, and comparative observational studies with at least 2 years of follow

up. Many of the more recent RCTs are conducted at institutions within China. There are few reports from the United States. Overall, results from RCTs and systematic reviews reveal a significantly reduced length of hospitalization with endoscopic discectomy and occasionally significant improvements in VAS or ODI, but only at specific time points. No consistently significant improvement in VAS, ODI, total complication rate, reoperation, or recurrence was observed with percutaneous endoscopic discectomy versus other interventions.

Summary of Evidence
For individuals who have herniated intervertebral disc(s) who receive automated percutaneous discectomy, the evidence includes randomized controlled trials (RCTs) and systematic reviews of observational studies. The published evidence from small RCTs is insufficient to evaluate the impact of automated percutaneous discectomy on the net health outcome. Well-designed and executed RCTs are needed to determine the benefits and risks of this procedure. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have herniated intervertebral disc(s) who receive percutaneous endoscopic discectomy, the evidence includes a number of randomized controlled trials (RCTs), systematic reviews, and observational studies. Many of the more recent RCTs are conducted at institutions within China. There are few reports from the United States. Results do not reveal a consistently significant improvement in patient-reported outcomes and treatment-related morbidity with percutaneous endoscopic discectomy in comparison to other discectomy interventions. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Decompression of Intervertebral Disc using Laser Energy (Laser Discectomy) or Radiofrequency-Coblation (Nucleoplasty)

Laser Discectomy
A variety of different lasers have been investigated for laser discectomy, including YAG, KTP, holmium, argon, and carbon dioxide lasers. Regardless of the type of laser, the procedure involves placement of the laser within the nucleus under fluoroscopic guidance and then activated. Due to differences in absorption, the energy requirements and the rate of application differ among the lasers. In addition, it is unknown how much disc material must be removed to achieve decompression. Therefore, protocols vary according to the length of treatment, but typically the laser is activated for brief periods only.

Clinical Context and Therapy Purpose
The purpose of decompression of the intervertebral disc using laser discectomy for patients with discogenic back pain or radiculopathy is to provide a treatment option that is an alternative to or an improvement on existing therapies.

Populations
The relevant population of interest is individuals with discogenic back pain or radiculopathy.

Interventions
The therapy being considered is laser discectomy.

Comparators
The following therapies are currently being used to make decisions about laser discectomy: conservative management such as physical therapy and medication, epidural steroid injection, and the potential for conventional discectomy or surgical decompression in severe cases.

The optimal comparators are conservative therapy with a sham control, epidural steroid injection, or conventional discectomy.

Outcomes
The general outcomes of interest are symptoms, functional outcomes, and treatment-related morbidity. Laser discectomy has a fairly extensive literature describing different techniques using different lasers.

Review of Evidence

Systematic Reveiws
A systematic review completed by Singh et. al. reviewed the evidence on percutaneous laser disc decompression. The authors selected 17 observational studies due to the lack of randomized controlled trials (RCTs), meta-analysis could not be conducted, and evidence was considered limited.

A Cochran review of surgical interventions for lumbar disc prolapse included 2 comparative studies on laser discectomy that were reported as proceedings and abstracts. Reviewers concluded that clinical outcomes following automated discectomy and laser discectomy “are at best fair and certainly worse than after microdiscectomy, although the importance of patient selection is acknowledged.”

Observational Studies
A comparative study compared outcomes of 500 patients who had discogenic pain and herniated discs treated using microdiscectomy by 6 surgeons with 500 patients treated using percutaneous laser disc decompression by a single surgeon. Patients with sequestered discs were excluded. This retrospective review found that the hospital stays (6 days versus 2 days), overall recovery time (60 days versus 35 days), and repeat procedure rates (7% versus 3%), all respectively, were shorter or had lower rates in the laser group than in the microdiscectomy group. No statistical comparisons were provided. The percentage of patients with overall good/excellent outcomes (Macnab criteria measuring pain and function) was found to be similar in both groups (85.7% versus

83.8%, respectively) at the 2-year assessment; quantitative outcome measures were not reported.

Other than the comparative studies previously mentioned, the evidence for laser discectomy is limited to case series.

Section Summary
Evidence on decompression of the intervertebral disc using laser energy consists of observational studies. Given the variable natural history of back pain and the possibility of placebo effects with this treatment, observational studies are insufficient to permit conclusions concerning the effect of this technology on health outcomes.

Disc Neucleoplaty with RadiofrequencyCoblation
The Disc nucleoplasty™ procedure uses bipolar radiofrequency energy in a process referred to as Coblation technology. The technique consists of small, multiple electrodes that emit a fraction of the energy required by traditional radiofrequency energy systems. The result is that a portion of nucleus tissue is ablated not with heat, but with a low-temperature plasma field of ionized particles. These particles have sufficient energy to break organic molecular bonds within tissue, creating small channels in the disc. The proposed advantage of this Coblation technology is that the procedure provides for a controlled and highly localized ablation, resulting in minimal therapy damage to surrounding tissue.

Clinical Context and Therapy Purpose
The purpose of decompression of the intervertebral disc using radiofrequency coblation for patients with discogenic back pain or radiculopathy is to provide a treatment option that is an alternative to or an improvement on existing therapies.

Populations
The relevant population of interest is individuals with discogenic back pain or radiculopathy.

Interventions
The therapy being considered is disc nucleoplasty with radiofrequency coblation.

Comparators
The following therapies are currently being used to make decisions about laser discectomy: conservative management such as physical therapy and medication, epidural steroid injection, and the potential for conventional discectomy or surgical decompression in severe cases.

The optimal comparators are conservative therapy with a sham control, epidural steroid injection, or conventional discectomy.

Outcomes
The general outcomes of interest are symptoms, functional outcomes, and treatment-related morbidity.

Follow-up would ideally be ≥ 1 year.

Review of Evidence

Systematic Reviews
A systematic review that included a randomized controlled trial (RCT) and 14 observational studies on disc nucleoplasty (radiofrequency coblation) that met inclusion criteria the authors concluded that the evidence was limited to fair.

Randomized Controlled Trials
In 2020, De Rooij et. al., compared the effects of percutaneous cervical nuceloplasty and anterior cervical discectomy in 48 patients with cervical radicular pain due to a single-level contained soft-disc herniation. The primary outcome measure was arm pain intensity as measured by a visual analog scale (VAS). Overall, a statistically significant interaction between the groups on arm pain intensity and the secondary outcome of SF-36 item pain, in favor of anterior cervical discectomy, was noted at 3 months. There was also a trend for more improvement of arm pain in favor of anterior cervical discectomy at 12 months, with no statistical interactions on the secondary outcomes observed. Of note, the trial was discontinued before reaching the required sample size as enrollment into the trial was low.

Section Summary
The evidence includes unblinded randomized controlled trials (RCTs) and the overall interpretation of these study results is limited. In 2020 prospective study by De Rooij et.al., that compared nucleoplasty to anterior cervical discectomy in patients with cervical radicular pain. Overall, no significant differences between the groups were observed at 1 year. Additionally, the RCT was terminated early as the enrollment rate was low, resulting in the study being underpowered. Further prospective controlled trials comparing nucleoplasty with microdiscectomy are needed to evaluate efficacy and time to recovery in patients with disc protrusion.

Summary of Evidence
For individuals who have discogenic back pain or radiculopathy who receive laser discectomy, the evidence includes systematic reviews of observational studies. While numerous case series and uncontrolled studies have reported improvements in pain levels and functioning following laser discectomy, the lack of well-designed and -conducted controlled trials limits interpretation of reported data. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have discogenic back pain or radiculopathy who receive disc nucleoplasty with radiofrequency coblation, the evidence includes randomized controlled

trials (RCTs) and systematic reviews. For nucleoplasty, there are RCTs in addition to several uncontrolled studies. These RCTs are limited by the lack of blinding, an inadequate control condition in 1, inadequate data reporting in the second, and low enrollment with early study termination in the third. The available evidence is insufficient to permit conclusions concerning the effect of these procedures on health outcomes due to multiple confounding factors that may bias results. High-quality randomized trials with adequate follow-up (at least 1 year), which control for selection bias, the placebo effect, and variability in the natural history of low back pain, are needed. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Image-Guided Minimally Invasive Decompression for Spinal Stenosis
Image-guided minimally invasive spinal decompression is a percutaneous procedure for decompression of the central spinal canal in individuals with spinal stenosis and hypertrophy of the ligamentum flavum. Spinal stenosis can occur in the cervical, thoracic, or lumbar regions of the spine. In spinal stenosis, the space around the spinal cord narrows, compressing the spinal cord and its nerve roots. Narrowing is most often caused by osteophyte formation, herniated discs, or thickened ligaments (ligamentum flavum). Spinal stenosis is often linked to age-related changes in disc height and arthritis of the facet joints. The goal of surgical treatment is to "decompress" the spinal cord and/or nerve roots. Image-guided minimally invasive spinal decompression is proposed as an alternative to existing posterior decompression procedures. In this procedure, a specialized cannula, and surgical tools (mild®) are used under fluoroscopic guidance for bone and tissue sculpting near the spinal canal.

Posterior decompression for spinal stenosis has been evolving toward increasingly minimally invasive procedures in an attempt to reduce postoperative morbidity and spinal instability. Unlike conventional surgical decompression, the percutaneous mild® decompressive procedure is performed solely under fluoroscopic guidance (eg, without endoscopic or microscopic visualization of the work area). This procedure is indicated for central stenosis only, without the capability of addressing nerve root compression or disc herniation, should either be required.

Percutaneous image-guided minimally invasive spinal decompression using a specially designed tool kit (mild®) has been proposed as an ultra-minimally invasive treatment of central lumbar spinal stenosis. In this procedure, the epidural space is filled with contrast medium under fluoroscopic guidance. Using a 6-gauge cannula clamped in place with a back plate, single-use tools (portal cannula, surgical guide, bone rongeur, tissue sculptor, trocar) are used to resect thickened ligamentum flavum and small pieces of lamina. The tissue and bone sculpting are conducted entirely under fluoroscopic guidance, with contrast media added throughout the procedure to aid visualization of the decompression. The process is repeated on the opposite side for bilateral decompression of the central canal. The devices are not intended for use near the lateral neural elements and are contraindicated for disc procedures.

Image-Guided Minimally Invasive Cervical or Thoracic Discectomy

Clinical Context and Therapy Purpose
The purpose of Image-guided minimally Invasive spinal decompression is to provide a treatment option that is an alternative to or an improvement on existing therapies for patients with cervical or thoracic spinal stenosis.

Populations
The population of interest is individuals with cervical or thoracic spinal stenosis.

In spinal stenosis, the space around the spinal cord narrows, compressing the spinal cord and its nerve roots. The goal of surgical treatment is to “decompress” the spinal cord and/or nerve roots.

The most common symptoms of cervical/thoracic spinal stenosis are neck pain and radiculopathy of the shoulder and arm. The most common cause of cervical radiculopathy is degenerative changes, including disc herniation.

Interventions
The therapy being considered is image-guided minimally invasive cervical or thoracic decompression.

Image-guided minimally invasive spinal decompression describes a percutaneous procedure for decompression of the central spinal canal in patients with spinal stenosis and hypertrophy of the ligamentum flavum. In this procedure, a specialized cannula, and surgical tools (mild®) are used under fluoroscopic guidance for bone and tissue sculpting near the spinal canal.

Comparators
The following practice is currently being used to treat cervical or thoracic spinal stenosis: conservative therapy and open decompression.

For patients with cervical or thoracic stenosis, surgical treatment includes discectomy or foraminal decompression.

Outcomes
The general outcomes of interest are symptoms, functional outcomes, health status measures, and treatment-related morbidity.

Outcome measures for spinal surgery are relatively well-established. Most studies used back and leg visual analog scores or the Zurich Claudication Questionnaire to assess pain and the ODI to assess functional limitations. Most studies also use a broader functional status index such as the SF-12 or SF-36, particularly the physical function subscale of SF-36. Determining the MCID for these measures is complex. The MCID for a given measure can depend on the baseline score or severity of illness, the method used to

calculate MCID, and the times at which the scores are measured. For these reasons, some investigators prefer to calculate a MDD.

Both short-term and long-term outcomes are important in evaluating spinal treatments. Net benefit should take into account immediate (perioperative) adverse events; improvements in pain, neurological status, and function at 12 to 24 months as measured by the ODI, SF-36, Zurich Claudication Questionnaire, or visual analog scale measures; and 5-year secondary surgery rates, which reflect longer-term complications, recurrences, and treatment failures.

Review of Evidence
No evidence assessing use of image-guided minimally invasive cervical or thoracic decompression for treatment of patients with cervical or thoracic spinal stenosis was found.

Section Summary
There is no evidence to inform conclusions about use of image-guided minimally invasive spinal decompression to treat cervical or thoracic spinal stenosis.

Image-Guided Minimally Invasive Lumbar Discectomy

Clinical Context and Therapy Purpose
The purpose of image-guided minimally invasive lumbar decompression is to provide a treatment option that is an alternative to or an improvement on existing therapies for patients with lumbar spinal stenosis.

Populations
The relevant population of interest is individuals with lumbar spinal stenosis.

In spinal stenosis, the space around the spinal cord narrows, compressing the spinal cord and its nerve roots. The goal of surgical treatment is to “decompress” the spinal cord and/or nerve roots.

The most common symptoms of lumbar spinal stenosis are back pain with neurogenic claudication (i.e., pain, numbness, weakness) in the legs that worsens with standing or walking and is alleviated by sitting or leaning forward. Compression of neural elements generally occurs from a combination of degenerative changes, including ligamentum flavum hypertrophy, bulging of the intervertebral disc, and facet thickening with arthropathy. Spinal stenosis is often linked to age-related changes in disc height and arthritis of the facet joints. Lumbar spinal stenosis is among the most common reasons for back surgery and the most common reason for lumbar spine surgery in adults over the age of 65.

Interventions
The therapy being considered is image-guided minimally invasive lumbar decompression.

Image-guided minimally invasive lumbar decompression describes a percutaneous procedure for decompression of the central spinal canal in patients with spinal stenosis and hypertrophy of the ligamentum flavum. In this procedure, a specialized cannula and surgical tools (mild®) are used under fluoroscopic guidance for bone and tissue sculpting near the spinal canal.

Comparators
The following practices are currently being used to treat lumbar spinal stenosis: Conservative therapy and open decompression.

Image-guided minimally invasive lumbar decompression is proposed as an alternative to existing posterior decompression procedures.

Outcomes
The general outcomes of interest are symptoms, functional outcomes, health status measures, and treatment-related morbidity.

Outcome measures for spinal surgery are relatively well-established. Most studies used back and leg visual analog scores or the Zurich Claudication Questionnaire to assess pain and the Oswestry Disability Index (ODI) to assess functional limitations. Most studies also use a broader functional status index such as the 36-Item Short-Form Health Survey (SF-36) or 12-Item Short-Form Health Survey (SF-12), particularly the physical function subscale of SF-36. Determining the minimal clinically important differences (MCID) for these measures is complex. The MCID for a given measure can depend on the baseline score or severity of illness, the method used to calculate MCID, and the times at which the scores are measured. For these reasons, some investigators prefer to calculate a minimum detectable difference (MDD).

Both short-term and long-term outcomes are important in evaluating spinal treatments. Net benefit should take into account immediate (perioperative) adverse events; improvements in pain, neurological status, and function at 12 to 24 months as measured by the ODI, SF-36, Zurich Claudication Questionnaire, or visual analog scale measures; and 5-year secondary surgery rates, which reflect longer-term complications, recurrences, and treatment failures.

Review of Evidence
This evidence review addresses posterior decompression of lumbar spinal stenosis with percutaneous treatment performed under fluoroscopic guidance. The primary literature on image-guided minimally invasive lumbar decompression includes a large RCT (n=302) , a small RCT (n=38), and a number of prospective and retrospective cohort studies and case series.

Randomized Controlled Trials

The protocol for the MiDAS ENCORE (Evidence-based Neurogenic Claudication Outcomes Research) trial (NCT02093520) was approved by the Centers for Medicare & Medicaid Services under coverage with evidence development. This nonblinded study, conducted at 26 interventional pain management centers in the U.S., randomized 302 patients in a 1:1 ratio to image-guided minimally invasive lumbar decompression or epidural steroid injections. This trial included Medicare beneficiaries 65 years or older who had neurogenic claudication symptoms for at least 3 months and had failed standard therapies, including physical therapy, home exercise programs, and oral analgesics. Selection criteria required radiologic evidence of lumbar spinal stenosis with ligamentum flavum greater than 2.5 mm confirmed by preoperative magnetic resonance imaging or computed tomography. Patients had several spinal stenosis cofactors in addition to ligamentum flavum hypertrophy, including bulging disc (91%), foraminal narrowing (88%), facet hypertrophy (84%), facet arthropathy (82%), and degenerative disc disease (71%), that could not be addressed by the image-guided minimally invasive lumbar decompression technique. Baseline scores were similar in both groups. However, more patients in the epidural steroid injection group withdrew prior to trial treatment (22 patients vs 6 patients) due to dissatisfaction with randomization results and decisions to have surgery or other nonstudy therapy. This unequal dropout rate would suggest risk of bias due to nonblinding of patients and assessors and patient expectations. Patients who withdrew from the trial after treatment but before the 1-year follow-up (22 image-guided minimally invasive lumbar decompression, 32 epidural steroid injections) were considered treatment failures. Six-month and 1-year results were published in 2016 Patients in the epidural steroid injection group were allowed up to 4 epidural steroid injection treatments and received a mean of 2 injections over 1 year. The primary endpoint the proportion of responders achieving the minimally important difference of at least a 10-point improvement on the ODI score was significantly higher in the image-guided minimally invasive lumbar decompression group than in the epidural steroid injection group at both 6 months and 1 year. Secondary efficacy endpoints were the proportion of responders achieving the minimally important difference on the numeric rating scale for pain and the Zurich Claudication Questionnaire. Adverse events were low (1.3% for both groups). Responder rates in patients with spinal comorbidities were reported to be similar to overall responder rates. However, it may be difficult to separate out the effect of comorbidities, because over 80% of patients had 1 or more spinal stenosis comorbidities.

Two-year follow-up data for patients treated with image-guided minimally invasive lumbar decompression in the MiDAS ENCORE trial was published in 2018 by Staats et. al., and the follow-up data was available for 69% of study participants and is summarized in below.

At 2 years, a total of 26 patients had been withdrawn because of receipt of disallowed secondary intervention or study withdrawal with the intent to receive disallowed secondary intervention. The remaining 117 MILD patients were then potentially available for 2-year follow-up. Of those patients, 8 missed the 2-year follow-up visit, 5 withdrew

for unrelated reasons, and 5 died of reasons unrelated to the MILD procedure including stroke and cardiac arrest. The remaining patients comprise the modified intent-to-treat population of 99 MILD patients who returned for 2-year follow-up. The modified intent-to-treat analysis includes all observed data for each follow-up visit reported. Subjects who missed a given follow-up, or who withdrew prior to that follow-up, were not included in the analysis for that visit.

At 2-year follow-up, all primary and secondary efficacy outcome measures showed clinically meaningful and statistically significant improvement from baseline and remained stable compared with 6-month and 1-year follow-ups. At 2 years, ODI improved by 22.7 points (95% CI, 18.5–26.9), NPRS improved by 3.6 points (95% CI, 3.1–4.2), and ZCQ symptom severity and physical function domains improved by 1.0 (95% CI, 0.8–1.2) and 0.8 (95% CI, 0.6–0.9) points, respectively.

During 2-year follow-up, no MILD patients underwent a subsequent MILD procedure at any level. Eight (5.6%) of 143 patients underwent a subsequent surgical procedure at the index level, 22 (15.4%) of 143 received an ESI or nerve block at the level of surgery, and one of these patients also received a spinal cord stimulator as a treatment for the pain at the index level. One additional patient received a rhizotomy at the index level, and 1 patient received an intrathecal infusion pump.

There was no serious device- or procedure-related adverse events reported for these patients, and there was no evidence of spinal instability at 2 years after the MILD procedure. As previously reported, 2 MILD patients (1.3%) experienced a device- or procedure-related adverse event in this study, which was the same rate as the ESI patients in the control arm during the randomized phase of this study (P = 1.00).8,9 During 1 MILD case, intraoperative oozing was observed at the decompression site, and Gelfoam was administered through the cannula into the interlaminar space. The patient was discharged on the same day as the procedure with no complications. A second patient experienced postoperative pain possibly related to MILD that resolved within 3 days of the index procedure.

Study Relevance Limitations

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Follow-up[e]
MiDAS ENCORE	4. Study population had a high proportion of patients with comorbidities that the intervention was not designed to address.		3. Delivery not similar intensity as intervention.		1-2. Follow-up data at 2 years not reported for comparator.

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Population key: 1. Intended use population unclear; 2. Clinical context is unclear; 3. Study population is unclear; 4. Study population not representative of intended use.
[b] Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4.Not the intervention of interest.
[c] Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively.
[d] Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. No CONSORT reporting of harms; 4. Not established and validated measurements; 5. Clinical significant difference not prespecified; 6. Clinical significant difference not supported.
[e] Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms.

Study Design and Conduct Limitations

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]	Power[e]	Statistical[f]
MiDAS ENCORE	3. Allocation concealment unclear.	1. Not blinded to treatment assignment.		1. High loss to follow-up or missing data.	1. Power calculations not clearly reported. 2. Power not calculated for primary outcome. 3. Not clear if power calculations were based on clinically important difference(s).	3. Confidence intervals and/or p values not reported for all outcome measures. 4. Comparative treatment effects not reported for 2 year follow-up.

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias.
[b] Blinding key: 1. Not blinded to treatment assignment; 2. Not blinded outcome assessment; 3. Outcome assessed by treating physician.
[c] Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.
[d] Data Completeness key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. No intent to treat analysis (per protocol for noninferiority trials).
[e] Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference.
[f] Statistical key: 1. Analysis is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to

event; 2. Analysis is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated.

Systematic Reviews

Prior to publication of MiDAS ENCORE trial results, the International Spine Intervention Society published a systematic review of the image-guided minimally invasive lumbar decompression literature. Included were a randomized controlled trial (RCT) with 38 patients and 12 cohort studies or series. Pain measurements, using a visual analog score or the Zurich Claudication Questionnaire, showed a weighted mean improvement of 41% in the short term (4 to 6 weeks), 46% at 3 months, 42% at 6 months, and 49% at 1 year. However, mean visual analog score exceeded 3 at all times post-treatment. Ten studies assessed function, 9 using the Oswestry Disability Index or one using the Roland-Morris Disability Questionnaire. Oswestry Disability Index scores improved by a weighted mean of 16.5 at 6 weeks, 16.2 at 12 weeks, 15.4 at 6 months, and 14.0 at 1 year, a weighted cumulative decline to 33 from 47 at baseline. The study by Chopko et. al., reporting 2-year outcomes, was of questionable validity, and data were not included. Mean final ODI scores exceeded 30 for most studies, which would not be considered in the normal range. No direct procedure-related complications were identified in the selected studies, although the possibility of damage to dura and nerve roots with this procedure was noted. Overall, the body of evidence addressing the image-guided minimally invasive lumbar decompression procedure was of low quality.

Case Series

One potential indication for image-guided minimally invasive lumbar decompression is patients with symptomatic lumbar spinal stenosis primarily caused by a hypertrophic ligamentum flavum who are considered poor candidates for traditional decompressive surgery.

Chopko et.al., also reported on image-guided minimally invasive lumbar decompression in 14 patients considered at high-risk for complications from open spine surgery and general anesthesia. Comorbidities included obesity, diabetes, hypertension, chronic obstructive pulmonary disease, chemotherapy, and coronary artery disease. Postoperatively, 9 (64%) of the 14 patients reported improvement in visual analog score pain scores of at least 3 points. Oswestry Disability Index scores did not change significantly. A retrospective review by Lingreen et. al., reported on outcomes of a consecutive series of 42 patients who underwent image-guided minimally invasive lumbar decompression by an interventional pain specialist. Most patients had not been considered surgical candidates by a spine surgeon. visual analog score pain scores averaged 9.6 at baseline and 5.8 at 30 days post procedure, with 34 (80%) of patients reporting changes in visual analog score of 3 or more points. Thirty (71%) patients reported improvements in function following image-guided minimally invasive lumbar decompression. No major adverse events were identified.

Section Summary

The evidence on the use of image-guided minimally invasive lumbar decompression to treat lumbar spinal stenosis or cervical/thoracic spinal stenosis consists of a large ongoing

randomized controlled trial (RCT) (n=302), a systematic review of a small RCT (n=38), and several prospective and retrospective cohort studies and case series. The largest RCT compared image-guided minimally invasive lumbar decompression with epidural steroid injections (control) in patients with ligamentum flavum hypertrophy and who failed conservative therapy. Results suggested reductions in pain and improvements in function scores in the image-guided minimally invasive lumbar decompression group vs the control group. The trial was unblinded and there is evidence of differing expectations and follow-up in both groups, suggesting a high-risk of bias. The available evidence is insufficient to determine the efficacy of mild® compared with placebo or to determine the efficacy of image-guided minimally invasive lumbar decompression compared with open decompression. Trials with relevant control groups could provide greater certainty on the risks and benefits of this procedure.

Summary of Evidence
For individuals who have lumbar spinal stenosis who receive image-guided minimally invasive lumbar decompression, the evidence includes a large, randomized controlled trial (RCT) (n=302), a systematic review of a small RCT (n=38), and several prospective and retrospective cohort studies and case series. The largest RCT compared image-guided minimally invasive lumbar decompression with epidural steroid injections (control) in patients who had ligamentum flavum hypertrophy and who failed conservative therapy. Results suggested reductions in pain and improvements in function scores in the image-guided minimally invasive lumbar decompression group versus the control group. The trial was unblinded and there is evidence of differing expectations and follow-up in the 2 groups, suggesting a high-risk of bias. The available evidence is insufficient to determine the efficacy of mild® compared with placebo or to determine the efficacy of image-guided minimally invasive lumbar decompression compared with open decompression. Trials with relevant control groups could provide greater certainty on the risks and benefits of this procedure. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have cervical or thoracic spinal stenosis who receive image-guided minimally invasive spinal decompression, no evidence was identified. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Percutaneous Intradiscal Electrothermal Annuloplasty, Radiofrequency Annuloplasty, Biacuplaty and Intraosseous Basivertebral Nerve Ablation
A number of electrothermal intradiscal procedures have been introduced to treat discogenic low back pain; they rely on various probe designs to introduce radiofrequency (RF) energy into the disc. 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.

The intradiscal electrothermal annuloplasty (IDEA) procedure, a navigable catheter with an embedded thermal resistive coil is inserted posterolaterally into the disc annulus or nucleus. Using indirect radiofrequency energy, electrothermal heat is generated within the thermal resistive coil at a temperature of 90 degrees centigrade; the disc material is heated for up to 20 minutes. Proposed advantages of indirect electrothermal delivery of radiofrequency energy with IDEA include precise temperature feedback and control, and the ability to provide electrothermocoagulation to a broader tissue segment than would be allowed with a direct radiofrequency needle. Annuloplasty using a laser-assisted spinal endoscopy kit to coagulate the disc granulation tissue (percutaneous endoscopic laser annuloplasty) has also been described.

Percutaneous intradiscal radiofrequency thermocoagulation (PIRFT) uses direct application of radiofrequency energy. With PIRFT, the radiofrequency 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 Radiofrequency Disc Catheter System has been specifically designed for this purpose.

Intradiscal biacuplasty involves the use of two cooled radiofrequency 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.

Vertebral body endplates have been proposed as a source of lower back pain, caused by intraosseous nerves. The basivertebral nerve (BVN) enters the posterior vertebral body and sends branches to the superior and inferior endplates. Vertebrogenic pain, transmitted via the BVN, has been purported to occur with endplate damage or degeneration.

Intradiscal Electrothermal Annuloplasty

Clinical Context and Therapy Purpose
The purpose of percutaneous intradiscal electrothermal annuloplasty in patients who have discogenic back pain is to provide a treatment option that is an alternative to or an improvement on existing therapies.

Populations
The relevant population of interest is patients with discogenic back pain.

Interventions
The therapy being considered is percutaneous intradiscal electrothermal annuloplasty.

Comparators
Relevant comparators are conservative management and surgical spinal decompression.

Outcomes
The general outcomes of interest are symptoms, functional outcomes, quality of life (QOL), and treatment-related morbidity. Based on available literature, follow-up of at least 6 to 12 months is recommended.

Review of Evidence

Randomized Controlled Trials – Section Summary
Two randomized controlled trials (RCTs) on intradiscal electrothermal annuloplasty have reported conflicting results, with 1 finding a benefit for intradiscal electrothermal annuloplasty and the other no benefit. The most recent RCT identified was from 2005. No recent literature on intradiscal electrothermal annuloplasty has been identified.

Percutaneous Intradiscal Radiofrequency Annuloplasty

Clinical Context and Therapy Purpose
The purpose of percutaneous intradiscal radiofrequency annuloplasty in patients who have discogenic back pain is to provide a treatment option that is an alternative to or an improvement on existing therapies.

Populations
The relevant population of interest is patients with discogenic back pain.

Interventions
The therapy being considered is percutaneous intradiscal radiofrequency annuloplasty.

Comparators
Relevant comparators are conservative management and surgical spinal decompression.

Outcomes
The general outcomes of interest are symptoms, functional outcomes, quality of life (QOL), and treatment-related morbidity. Based on available literature, follow-up of at least 6 to 12 months is recommended.

Review of Evidence

Randomized Controlled Trials
There is relatively little published data on percutaneous intradiscal radiofrequency thermocoagulation.

Section Summary
Two sham-controlled randomized trials showed no evidence of a benefit with percutaneous intradiscal radiofrequency thermocoagulation. One found that only 1 of 14 patients was considered a treatment success. The other was terminated after a blinded interim analysis showed no trend to benefit compared with sham.

Intradiscal Radiofrequency Biacuplasty

Clinical Context and Therapy Purpose
The purpose of intradiscal radiofrequency biacuplasty in patients who have discogenic back pain is to provide a treatment option that is an alternative to or an improvement on existing therapies.

Populations
The relevant population of interest is patients with discogenic back pain.

Interventions
The therapy being considered is intradiscal radiofrequency biacuplasty.

Comparators
Relevant comparators are conservative management and surgical spinal decompression.

Outcomes
The general outcomes of interest are symptoms, functional outcomes, QOL, and treatment-related morbidity. Based on available literature, follow-up of at least 6 to 12 months is recommended.

Review of Evidence

Randomized Controlled Trials
Kapural et. al. (2013), Desai et .al., (2016), published studies on the use of transdiscal radiofrequency annuloplasty using 2 transdiscal probes (biacuplasty) in patients with discogenic lower back pain, including a 2013 industry-sponsored, phase 1, double-blind randomized controlled trial (RCT) and a 2016 RCT.

Kapural et. al., (2013) conducted the phase 1 randomized controlled trial (RCT). Of the 1894 patients screened, 1771 (94%) did not meet inclusion criteria. Sixty-four subjects consented and were enrolled. Outcome measures were the SF-36 physical functioning subscale (0-100), a numeric rating scale for pain (0-10), and the Oswestry Disability Index (0-100). There were no significant differences between the groups at 1 month or 3 months. At 6 months, the biacuplasty group showed a significantly greater change from baseline for the SF-36 (15.0 vs. 2.63), numeric rating scale (-2.19 vs. -0.64), and Oswestry Disability Index (-7.43 vs. 0.53) scores. Mean SF-36 and numeric rating scale scores were considered to be clinically significant, but mean Oswestry Disability Index 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 biacuplasty patients and 3% of sham-treated patients were considered successful. There was no significant difference in opioid use between groups.

Kapural et. al. (2015) reported on the unblinded 12-month follow-up from this phase 1 trial. Improvements continued through 12 months, with a change from baseline to posttreatment of 47.0 to 68.9 (of 100) on the SF-36 physical functioning subscale ($p<.01$) and 7.1 to 4.4 (of 10) on the numeric rating scale ($p<.01$). Although the change in numeric rating scale score was statistically significant, the magnitude of the decrease was modest, and a final numeric rating scale score (4.4) remained high. The change in Oswestry Disability Index score (from 40.37 at baseline to 32.44 at 12 months) was also modest ($p=.05$). Opioid usage did not decrease significantly (53.47 mg at baseline to 34.07 mg at follow-up, $p=.23$).

Desai et. al., (2016) randomized 63 patients with lumbar discogenic pain diagnosed by provocation discography to intradiscal biacuplasty plus conservative medical management (n=29) or medical management alone (n=34). Another 234 patients were scheduled for diagnostic discography but did not meet inclusion criteria. The primary outcome (the mean reduction in visual analog scale score for pain at 6 months) was significantly greater in the biacuplasty group (-2.4) than in the medical management group (-0.56; $p=.02$). The secondary outcomes were not statistically significant, which included the proportion of responders, defined as a 2-point or 30% decrease in visual analog scale scores, which was achieved in 50% of the biacuplasty group compared to 18% of controls ($p=.073$). Investigators did not report whether the trial was adequately powered. Other limitations of this industry-sponsored trial were the lack of a sham-control and patient blinding, which could contribute to a placebo effect in the subjective pain outcomes.

Of the 29 patients originally randomized to intradiscal biacuplasty, 22 (76%) were available for 12-month follow-up. Mean 12-month change in visual analog scale score was -2.2 (from 6.7 at baseline to 4.4 at 12 months; $p=.001$). After 6 months, patients randomized to medical management were allowed to receive intradiscal biacuplasty and were followed for another 6 months; 25 of 34 patients crossed over. The visual analog scale scores improved from 7.0 to 4.7 ($p<.001$) in the crossover group, and 55% were considered to be responders

Section Summary
Two industry-sponsored randomized controlled trials (RCTs) have assessed use of biacuplasty to treat chronic low back pain. In one, only 6% of subjects screened met the strict inclusion and exclusion criteria for the study. Significant differences in outcomes were observed at 6 months, but not at 1 month or 3 months, and the definition of successful treatment appears to have been post hoc. In the second multicenter RCT, 63 patients met inclusion criteria, which included a positive result on provocation discography. There was a significant treatment effect for the primary outcome measure, but not the secondary outcome measures. This trial was not sham-controlled, and it was not reported whether it was adequately powered. Additional sham-controlled trials in a broader population of patients are needed to determine the effect of this treatment with greater certainty.

Intraosseous Basivertebral Nerve Ablation

Clinical Context and Therapy Purpose
The purpose of intraosseous basivertebral nerve ablation in patients who have vertebrogenic back pain is to provide a treatment option that is an alternative to or an improvement on existing therapies.

Populations
The relevant population of interest is patients with vertebrogenic back pain.

Interventions
The therapy being considered is intraosseous basivertebral nerve ablation.

Comparators
Relevant comparators are conservative management and surgical spinal decompression.

Outcomes
The general outcomes of interest are symptoms, functional outcomes, QOL, and treatment-related morbidity. Based on available literature, follow-up of at least 6 to 12 months is recommended.

Review of Evidence
Hayes Inc. completed an Evolving Evidence Review July 2021 on the Intracept Intraosseous Nerve Ablation System for the treatment of adults with low back pain. Based on review of the clinical studies, systematic reviews and clinical practice guidelines and position statements, there is weak support for the Intracept Intraosseous Nerve Ablation System for the treatment of chronic low back pain (CLBP). Studies reported relief of pain and improvement of function and quality of life after treatment, but only 2 studies with a comparison group were identified which one study identified advantages over standard of care up to 6 months and the other study did not find clear benefits over sham at 1 year. The studies are considered poor or fair quality.

Randomized Controlled Trials
Fischgrund et. al. conducted a randomized, double-blind, sham-controlled study (SMART trial) of basivertebral nerve ablation using the Intracept system in 225 participants from the U.S. and Europe. Patients had chronic isolated lumbar pain that had not responded to at least 6 months of nonoperative management. Additional study inclusion criteria were a minimum Oswestry Disability Index of 30 points (on a 100-point scale), a minimum visual analog scale of 4, and Modic type 1 or 2 changes at the vertebral endplates of the levels targeted for treatment. Treatment was limited to a minimum of 2 and a maximum of 3 consecutive vertebral levels from L3 to S1. The active treatment group (n=147) received radiofrequency and the sham group (n=78) underwent the same protocol for the same overall duration as the treatment group; however, the radiofrequency treatment was simulated. Patients were blinded to the group assignment for 1 year, at which time those in the sham arm were allowed to cross over,

57 (73%) of whom elected to do so and receive the Intracept treatment. The primary endpoint of the original study was comparative change in Oswestry Disability Index from baseline to 3 months, and in the intent-to-treat analysis there was no statistically significant difference in this outcome between groups at this time point. There was a difference between groups in the 3-month per protocol analysis (mean Oswestry Disability Index improved 20.5 and 15.2 points in the treatment and sham arms, respectively; p=.019). However, at the 12 month per protocol analysis, the difference in mean Oswestry Disability Index between groups was no longer statistically significant. Pain severity, measured by visual analog scale, was not significantly different between groups at 3 months (p=.083) but there was significantly greater improvement in the treatment group at 6 and 12 months.

The 24-month follow-up results were reported for the active treatment group from the SMART trial. Of the per protocol population treated with ablation (treatment arm), 106 (83%) completed a 24-month follow-up visit. A durable Oswestry Disability Index mean improvement was observed (23.4 points). Data for Oswestry Disability Index outcomes were not available for the sham group because of the high crossover rate. Therefore, long-term comparative outcomes are not available.

Five-year results were reported for the 100 U.S. patients from the treatment arm from the original SMART trial who were available for follow-up. Mean Oswestry Disability Index scores improved from 42.8 to 16.9 at 5 years, a reduction of 25.9 points. Mean reduction in visual analog scale score was 4.4 points (baseline 6.7, p<.001).

The INTRACEPT trial was an open-label RCT conducted at 20 U.S. sites. A total of 140 patients with lower back pain of at least 6 months duration, with Modic Type 1 or 2 vertebral endplate changes between L3 and S1, were randomized to undergo radiofrequency ablation of the basivertebral nerve or continue standard care. Standard care consisted of pain medications, physical therapy, exercise, chiropractic treatment, acupuncture, and spinal injections; the specific treatment(s) administered were determined by the treating investigator in conjunction with the patient. Treatment of up to 4 vertebrae in non-consecutive levels from L3 to S1 was allowed. The primary study endpoint was change in Oswestry Disability Index at 3 months. A pre-planned interim analysis was undertaken when 60% of participants reached the 3-month follow-up (n=51 in the treatment group and n=53 in the standard care group) and reported statistically significant differences between groups on all patient-reported outcome measures, favoring the treatment group. The study was halted, and the individuals were allowed to cross over to the treatment arm. Study limitations include short term follow-up, lack of a sham group, and allowance of crossover at 3 months.

Twelve-month follow-up results were reported from the INTRACEPT trial; after a median of 175 days post randomization, 92% of patients initially randomized to the standard care arm elected to receive early treatment with basivertebral nerve ablation. Six-month results for the Oswestry Disability Index were significantly improved with basivertebral nerve ablation (n=66) compared to standard care (n=74) (least squares

mean difference between groups, -24.5; 95% CI, -29.4 to -19.6; p=.0001). Improvements in the Oswestry Disability index and mean visual analog scale that were reported among patients initially treated with basivertebral nerve ablation were maintained throughout the 12-month study period, with reported reductions of -25.7±18.5 points, and -3.8±2.6 cm, respectively (p<.001 for both comparisons to baseline). However, comparative data were not available beyond 6 months due to the high rate of crossover.

Section Summary
Two randomized controlled trials (RCTs) have been conducted to assess the efficacy of basivertebral nerve ablation for treatment of vertebrogenic back pain. One RCT did not find a difference in the Oswestry Disability Index between patients treated with basivertebral nerve ablation or sham control at 3 months using an intent-to-treat analysis. Although the per protocol analysis showed a significant difference; results for the per protocol population at 12 months were not significantly different. Additionally, 73% of patients in this trial crossed over to the active treatment group at 12 months and therefore, long-term comparative data are not available. A second RCT found a significant difference in the Oswestry Disability Index and other pain scores between patients treated with basivertebral nerve ablation and standard care at 3 months. Comparative data at 6 months post randomization showed similar results. However, 92% of patients initially assigned to standard care elected to cross over to receive early basivertebral nerve ablation, thus, long-term comparative data beyond 6 months are not available. Additional limitations to this RCT include lack of a sham control.

Summary of Evidence
For individuals who have discogenic back pain who receive intradiscal thermal annuloplasty, the evidence includes a small number of randomized controlled trials (RCTs). 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 individuals is needed. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have discogenic back pain who receive intradiscal radiofrequency annuloplasty, the evidence includes two randomized controlled trials (RCTs). Neither RCT found evidence of benefit with the treatment. More sham-controlled trials are needed. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have discogenic back pain who receive intradiscal biacuplasty, the evidence includes 2 industry sponsored randomized controlled trials (RCTs). One trial reported significant improvements at 6 months posttreatment, but not at 1 and 3 months. The other trial also showed a significant reduction in visual analog scale (VAS) 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 that the technology results in an improvement in the net health outcome.

For individuals who have vertebrogenic back pain who receive ablation of basivertebral nerves, the evidence includes 2 randomized controlled trials (RCTs) (the SMART and INTRACEPT trials). The SMART trial was unable to show a significant improvement in the Oswestry Disability Index with basivertebral nerve ablation compared to sham control at 3 months post randomization in the intent-to-treat population. The INTRACEPT trial showed a significant improvement in the Oswestry Disability Index with basivertebral nerve ablation compared to standard care at 3- and 6-months post randomization; however, the trial is limited by its lack of sham control. Both trials are further limited by the fact that the majority of patients assigned to control crossed over to receive active treatment, thus, long-term comparative data are not available. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Treatment of Sacroiliac Joint (SIJ) Pain: Sacroiliac Joint Fusion/Fixation
Sacroiliac joint fusion/fixation, whether performed as an open or minimally invasive (percutaneous) surgical procedure, with or without bone grafts and other metal implant devices, has been proposed as a treatment for individuals who are unresponsive to or cannot tolerate other therapy for chronic low back pain due to sacroiliac joint syndrome and other pain-related sacroiliac conditions.

Sacroiliac Joint Syndrome-Sacroiliac joint problems are referred to by varying terms, including sacroiliac joint dysfunction, sacroiliac joint inflammation, sacroiliac joint strain, and sacroiliac joint syndrome. Each of these terms refers to a condition that causes pain in the sacroiliac joint area from a variety of causes. Individuals often experience pain in the lower back and hips, but pain may also be present in the groin and thighs; this pain is often aggravated by any form of movement including sitting, lifting, running, or walking.

In practice, it is very difficult to diagnose patients with sacroiliitis and it is often mistaken for other types of back pain, as the studies indicate. The cause of sacroiliac joint inflammation and pain can be difficult to diagnose since the sacroiliac joint is not easily palpated or manipulated, radiographs or other imaging studies are often normal, and other conditions (for example, degenerative arthritis, lower back pain, sciatica) can cause similar symptoms. The diagnosis is frequently verified as originating from the SI joint via provocative physical exam maneuvers/tests including (*For further information on individual testing see Policy Guidelines*)

- Thigh thrust test
- Compression test
- Gaenslen maneuver
- Distraction test
- Patrick sign/Fabere

Treatment of Sacroiliac Joint Pain: Sacroiliac Joint Fusion/Fixation with a Transiliac Triangular Implant System

Clinical Context and Therapy Purpose
The purpose of sacroiliac joint (SIJ) fixation/fusion with a triangular implant is to provide a treatment option that is an alternative to or an improvement on existing therapies in patients with SIJ pain.

Populations
The relevant population of interest is individuals with SIJ pain.

Interventions
The therapy being considered is SIJ fixation/fusion with a triangular implant.

Comparators
The following therapy is currently being used to treat SIJ pain: conservative therapy.

Outcomes
The general outcomes of interest are symptoms (e.g., reductions in pain), functional outcomes, quality of life (QOL), reductions in medication use, and treatment-related morbidity. Follow-up from 1 to 5 years is of interest to monitor outcomes.

Review of Evidence

Investigation of Sacroiliac Fusion Treatment (INSITE)
Three-year follow-up results of the INSITE and Sacroiliac Joint Fusion with iFuse Implant System (SiFi) trials were published by Darr et al (2018). Of 103 patients with SIJ dysfunction who were treated with minimally invasive SIJ fusion with triangular titanium implants, 60 (72.3%) patients reported an improvement in ODI scores of ≥15 points from baseline to 3 years. The mean ODI score decreased from 56 to 28 for the same time frame, an improvement of 28 points ($p<.001$); similarly, the mean SIJ pain score decreased to 26.2, reflecting a decrease of 55 points ($p<.001$). Over 3 years of follow-up, 168 AEs were reported in 75 patients, although only 22 of these events involved the pelvis. The study was limited by its lack of long-term data from a control group not receiving surgical treatment.

Polly et al (2016) reported 2-year outcomes from the SIJ fusion arm of this RCT. Of 102 subjects originally assigned to SIJ fusion and treated, 89 (87%) were evaluated at 2 years. In this report, clinical outcomes were based on the amount of improvement in SIJ pain and in ODI scores. The improvement was defined as a change of 20 points in the SIJ pain score and 15 points in the ODI score. Substantial improvement was defined as a change of 25 points in SIJ pain score-or an SIJ pain score of 35 or less-and an improvement of 18.8 points in the ODI score. At 24 months, 83.1% had improvements in SIJ pain score, and 68.2% had improvements in ODI scores. By 24 months, the proportion taking opioids was reduced from 68.6% at baseline to 48.3%.

Whang et al (2015) reported an industry-sponsored nonblinded RCT, Investigation of Sacroiliac Fusion Treatment (INSITE) of the iFuse Implant System in 148 patients. The 12-month follow-up to this RCT was reported by Polly et al (2015), and a 2-year follow-up was reported by Polly et al (2016). However, by 12 months, almost all patients in the control group had crossed over to SIJ fusion, precluding a comparison between groups. Trial inclusion was based on a determination of the SIJ as a pain generator from a combination of a history of SIJ-localized pain, positive provocative testing on at least 3 of 5 established physical tests, and at least a 50% decrease in SIJ pain after image-guided local anesthetic injection into the SIJ. The duration of pain before enrollment averaged 6.4 years (range, 0.47-40.7 years). A large proportion of subjects (37%) had previously undergone lumbar fusion, SIJ steroid injections (86%), and RFA (16%).

Patients were randomized 2:1 to minimally invasive SIJ fusion (n=102) or to nonsurgical management (n=46). Nonsurgical management included a stepwise progression of nonsurgical treatments, depending on individual patient choice. During follow-up, control patients received physical therapy (97.8%), intra-articular steroid injections (73.9%), and RFA of sacral nerve roots (45.7%). The primary outcome measure was the 6-month success rate, defined as the proportion of treated subjects with a 20-mm improvement in SIJ pain in the absence of severe device-related or neurologic AEs or surgical revision. Patients in the control arm could crossover to surgery after 6 months. Baseline scores indicated that the patients were severely disabled, with VAS pain scores averaging 82.3 out of 100, and ODI scores averaging 61.9 out of 100 (0=no disability, 100=maximum disability).

At 6 months, success rates were 23.9% in the control group vs 81.4% in the surgical group (posterior probability of superiority >0.999). A clinically important (≥15-point) improvement in ODI score was found in 27.3% of controls compared with 75.0% of fusion patients. Measures of QOL (36-Item Short-Form Health Survey, EuroQol-5D) also improved to a greater extent in the surgery group. Of the 44 nonsurgical management patients still participating at 6 months, 35 (79.5%) crossed over to fusion. Compared with baseline, opioid use at 6 months decreased from 67.6% to 58% in the surgery group and increased from 63% to 70.5% in the control group (p=.082). At 12 months, opioid use was similar between groups (55% vs 52%, p=0.61).

iFuse Implant System Minimally Invasive Arthrodesis (iMIA).
Hayes Inc. completed a Health Technology Assessment which was last reviewed October 2021 for the iFuse implant system for minimally invasive sacroiliac joint (SJI) fusion in adult individuals with sacroiliac joint (SIJ) dysfunction refractory to conservative management. The literature review suggests that the use of iFuse for the treatment of SIJ dysfunction unresponsive to conservative management may lead to clinically significant reductions in pain and disability. Comparative results from randomized controlled trials, retrospective comparative and prospective studies suggest that SIJ fusion with iFuse is associated with better patient reported outcomes compared with conservative management for adult individuals with persistent, symptomatic SIJ dysfunction.

Twelve and 24-month results from the iMIA trial were reported by Dengler et al (2017, 2019). Twenty-one patients in the conservative management group had little or no improvement in symptoms and crossed over to SIJ fusion after the 6-month visit. These were analyzed with the last observation prior to crossover carried forward. At 12 months, low back pain had improved by 42 points (standard deviation [SD], 27.0) on a 100-point VAS in the SIJ fusion group compared with 14 points (SD=33.4) in the conservative management group ($p<.001$). At 24 months back pain had improved by 45 points compared to 11 points in the control group, with 79% (37 of 47) of SIJ fusion patients achieving at least a 20-point improvement compared to 24% (11 of 46) of controls. At 24 months there was an improvement of 26 points in ODI compared to 8 points in controls ($p<.001$). Improvement of at least 20 points was observed in 64% of the SIJ fusion group compared to 24% of the conservative management group.

In 2016 and 2017, the iFuse Implant System Minimally Invasive Arthrodesis (iMIA) study group reported another industry sponsored multicenter RCT of the iFuse Implant System in 103 patients. Selection criteria were similar to those of the trial by Whang et al (2015), including at least a 50% pain reduction on SIJ block. The mean pain duration was 4.5 years, and about half of the patients were not working due to lower back pain. Additionally, 33% of patients had undergone prior lumbar fusion. Nonsurgical management included physical therapy and exercises at least twice per week; interventional procedures (e.g., steroid injections, RFA) were not allowed. The primary outcome was change in the VAS pain score at 6 months.

In 2016 and 2017, the iFuse Implant System Minimally Invasive Arthrodesis (iMIA) study group reported another industry sponsored multicenter RCT of the iFuse Implant System in 103 patients. Selection criteria were similar to those of the trial by Whang et al (2015), including at least a 50% pain reduction on SIJ block. The mean pain duration was 4.5 years, and about half of the patients were not working due to lower back pain. Additionally, 33% of patients had undergone prior lumbar fusion. Nonsurgical management included physical therapy and exercises at least twice per week; interventional procedures (e.g., steroid injections, RFA) were not allowed. The primary outcome was change in the VAS pain score at 6 months.

Nonrandomized Studies
Prospective cohort studies with good follow-up rates are more likely to provide valid estimates of outcomes.

Results from a cohort of 172 patients undergoing SIJ fusion reported to 2 years were published by Duhon et al (2016). Patients were formally enrolled in a single-arm trial (SIFI NCT01640353) with planned follow-up for 24 months. Success was defined as a reduction of pain score of 20-mm on a 100-mm VAS, absence of device-related AEs, absence of neurologic worsening, and absence of surgical reintervention. Enrolled patients had a mean VAS pain score of 79.8, a mean ODI score of 55.2, and a mean pain duration of 5.1 years. At 6 months, 136 (80.5%) of 169 patients met the success endpoint, which met the prespecified Bayesian probability of success rate. Mean VAS pain scores

were 30.0 at 6 months and 30.4 at 12 months. Mean ODI scores were 32.5 at 6 months and 31.4 at 12 months. At 2 years, 149 (87%) of 172 patients were available for follow-up. The VAS pain score at 2 years was 26.0, and the ODI score was 30.9. Thus, 1-year outcomes were maintained at 2 years. Other outcomes (e.g., QOL scores) showed similar maintenance or slight improvement compared with 1-year outcomes. Use of opioid analgesics decreased from 76.2% at baseline to 55% at 2 years. Over the 2-year follow-up, 8 (4.7%) patients required revision surgery.

In general, cohort studies and case series have shown improvements in VAS pain scores and other outcomes measures consistent in magnitude to the RCTs. The Long Term Outcomes from INSITE and SIFI (LOIS) trial was a prospective single-arm study that enrolled patients who had participated in 2 of the studies described above for evaluation at 3, 4, and 5 years. The primary success outcome, a reduction in VAS of ≥20 points in the absence of a serious device-related AE, neurologic worsening, or surgical revision, was obtained in 81.7% (95% CI: 72.4 to 89.0%) of patients at 5 years. The improvements in other clinical outcomes were maintained out to 5 years. Opioid use decreased over time, although the contribution of the opioid use agreement cannot be determined. Fifteen percent of patients were not working due to back pain. Radiolucency suggesting implant failure were observed in 5% of cases and were associated with incorrect placement. Bridging bone was observed in 45% of sides at 12 months, 71% at 24 months, and 88% at 60 months.

The Study of Bone Growth in the Sacroiliac Joint after Minimally Invasive Surgery with Titanium Implants (SALLY) is a 5-year multicenter study that will assess non-inferiority of outcomes with a 3-D printed triangular implant as compared to the traditionally manufactured titanium coated implant. Twelve-month follow-up has been published for 46 of the 51 patients enrolled in the prospective cohort. The 6-month change in ODI met the non-inferiority margin, and secondary outcomes of pain, disability, and QOL were similar to those obtained in the INSITE, iMIA, and SIFI trials. Independent radiographic analysis showed bridging bone in 70% and 77% of sides imaged at 6 and 12 months, respectively, compared to 45% bridging bone in prior studies with the solid titanium coated implants. No breakage, migration, or subsidence was detected. However, there was no evidence that the increase in bridging bone led to an improvement in pain or functional outcomes compared to the milled implant at 12 months. Follow-up at 24 months was available for 84% of patients, with the stability of subjective and objective outcomes and similar efficacy for the 3D-printed implant and the milled implant from the earlier trials. Two patients had AEs related to the procedure and 2 had undergone revision. Follow-up is continuing.

Improved health outcomes are also supported by retrospective studies that compare SIJ fusion/fixation using a triangular implant with other treatments for SIJ pain. These results are consistent with the medium-term durability of the treatment. Analysis of an insurance database reported an overall incidence of complications to be 16.4% at 6 months and the cumulative revision rate at 4 years of 3.54%. Spain and Holt (2017) reported a retrospective review of surgical revision rates following SIJ fixation with either surgical

screws or the iFuse triangular implant. Revision rates were lower with the iFuse device than observed with surgical screws.

Section Summary
The evidence on SIJ fusion/fixation with a triangular implant includes 2 nonblinded randomized controlled trials (RCTs) of minimally invasive fusion, prospective cohorts with more than 85% follow-up, and a case series. Both RCTs have reported outcomes past 6 months, after which crossover was allowed. Both studies reported significantly greater reductions in VAS pain scores and ODI scores in SIJ fusion patients than in control groups. The reductions in pain and disability observed in the SIJ fusion group at 6 months were maintained out to 1 year compared with controls who had not crossed over. The RCTs were nonblinded without a placebo or an active control group. In addition, pain has a significant subjective and psychological component, and cognitive-behavioral techniques to address pain were specifically excluded from the types of treatment that control subjects could obtain. As relates to trial design, an independent assessment of pain outcomes would have been preferable. Prospective cohorts and case series with sample sizes ranging from 45 to 149 patients and low dropout rates (<15%) also showed reductions in pain and disability that persist out to 5 years. The cohort studies and case series are consistent with the durability of treatment benefits.

Treatment of Sacroiliac Joint Pain: Sacroiliac Joint Fixation/Fusion with an Implant Other Than a Transiliac Triangular Implant

Clinical Context and Therapy Purpose
The purpose of sacroiliac joint (SIJ) fixation/fusion with a SIJ implant is to provide a treatment option that is an alternative to or an improvement on existing therapies in patients with SIJ pain.

Populations
The relevant population of interest is individuals with SIJ pain.

Interventions
The therapy being considered is SIJ fixation/fusion with an implant other than a transiliac triangular implant.

Numerous cannulated screws are marketed that use iliosacral and posterolateral approaches that pass through the ilium. Up to 3 implants may be used.

The posterior approach involves inserting implants into the ligamentous recess between the sacrum and ilium. The devices are intended to be used with allograft bone or are composed entirely of allograft bone. The posterior approach may be called distraction arthrodesis as the implants increase the joint space and create tension on the ligaments, repositioning the joint surfaces.

Comparators
The following therapy is currently being used to treat SIJ pain: conservative therapy.

Outcomes
The general outcomes of interest are symptoms (e.g., reductions in pain), functional outcomes, quality of life (QOL), reductions in medication use, and treatment-related morbidity. Follow-up from 1 to 5 years is of interest to monitor outcomes.

Review of Evidence

Systematic Reviews
Hayes, Inc. Health Technology Assessment reviewed the literature on minimally invasive sacroiliac joint (SIJ) fusion using cylindrical threaded implants (CTIs) in adult patients with sacroiliac joint (SIJ) dysfunction due to SIJ disruption or degenerative sacroiliitis, which was last reviewed and updated October 2021. This technology assessment found per the peer reviewed medical literature the evidence for cylindrical threaded implants (CTIs) for sacroiliac joint (SIJ) fusion to be small in size with an overall quality to be very low. Studies may suggest that the use of CTI for the treatment of SJI dysfunction may lead to clinically meaningful reductions in pain and disability from baseline values, however, further comparative randomized controlled trials (RCTs) are needed to determine the effectiveness of CTIs compared to standard of care and with alternative treatments (i.e., open surgery or other minimally invasive approaches) for SIJ fusion. These comparative studies should also examine the long-term safety and durability for benefit of CTIs in addition to health-related quality of life (QOL).

A qualitative systematic review by Lorio et al (2020) for the International Society for the Advancement of Spine Surgery found evidence on the safety and effectiveness of distraction (posterior) SIJ fusion was limited to 1 prospective multicenter study, no comparative studies, and a small number of case series.

Tran et al (2019) published a systematic review comparing the effectiveness of minimally invasive joint fusion with a triangular implant (i.e., utilizing the iFuse device) compared to screw-type surgeries. A total of 20 studies were pooled to calculate a standardized mean difference across pain, disability, and global/QOL outcomes, including 14 studies evaluating the iFuse system and 7 studies evaluating cylindrical, threaded implants. Studies evaluating cylindrical, threaded implants consisted of case series and cohort studies. Patients receiving these implants experienced significantly worse pain outcomes (p=.03) compared to patients receiving iFuse, with a standardized mean difference of 1.28 (95% CI: 0.47 to 2.09) and 2.04 (95% CI: 1.76 to 2.33), respectively. A statistically significant difference in disability scores was reported between screw-type and iFuse implant groups (0.26 [95% CI: -1.90 to 2.41] vs 1.68 [95% CI: 1.43 to 1.94]; p=.01), with improved outcomes in the iFuse population. For global/QOL outcomes, a statistically significant difference in scores was reported between screw-type and iFuse implants groups (0.60 [95% CI: 0.33 to 0.88] vs 0.99 [95% CI: 0.75 to 1.24]; p=.04), with improved outcomes in the iFuse population.

Prospective Cohort Studies

Fuchs and Ruhl (2018) published 2-year results of a prospective multi-center cohort of the posterior approach to arthrodesis of the SIJ. A total of 171 patients from 20 hospitals in Germany were treated from 2011 to 2012 using a DIANA implant (marketed in the U.S. as the NADIA implant). The DIANA implant is a hollow, tapered dowel that comes in diameters of 13, 15, 17, or 19 mm. A distraction tool was used to determine the size of the implant, which is inserted between the ilium and sacrum under distraction. Allogeneic bone grafts were used in 66% of cases. Patients had partial weight bearing on the operated side for 6 to 8 weeks. At the 2-year follow-up, VAS had decreased from 74 to 37, ODI improved from 51% to 33%, and the McGill Pain Questionnaire decreased from 50% to 31% (all p<.001). Use of opioids decreased from 49.3% of patients to 30.3% at follow-up. In computed tomography (CT) scans, only 31% of patients showed SIJ fusion at 2 years.

Rappoport et al (2017) reported an industry-sponsored prospective study of SIJ fusion with a cylindrical threaded implant (SI-LOK). The study included 32 patients using a diagnosis of SIJ dysfunction who had failed nonoperative treatment, including medication, physical therapy, and therapeutic injections. A diagnostic injection was performed to confirm the source of pain to the SIJ. The procedure included drilling to prepare for screw insertion and implantation of 3 screws, at least 1 of which was slotted. The slotted screws were packed with an autogenous bone graft from the drill reaming's. Pain and disability scores were reduced following device implantation (see Table 18), and revisions within the first 12 months of the study were low (n=2). At the 2 year follow-up, VAS scores remained low, although 4 (12.5%) did not return for follow-up and 2 patients required revision surgery; analysis did not count these as treatment failures.

Araghi et al (2017) published interim results from an industry-sponsored prospective cohort study evaluating pain and ODI outcomes for patients treated for SIJ pain with the SImmetry system. For the 50 patients enrolled at the time of publication, the mean VAS score had decreased from 76.2 at baseline to 35.1 at 6 months after the procedure (p<.001), with 36 (72%) patients achieving minimal clinically important difference (≥20-point reduction). The mean ODI score likewise showed significant improvement from baseline to 6 months, decreasing from 55.5 to 35.3 (p<.001). Over half of the cohort (56% [n=28]) achieved the minimal clinically important difference (15-point reduction) on the ODI. Prior to surgery, 66% (n=33) of the cohort were on opioids, decreasing to 30% (n=15) at the 6-month follow-up (p<.001). QOL was assessed with the EQ-5D time trade-off index: at baseline, the mean EQ-5D was 0.51, decreasing to 0.69 after 6 months (p<0.001). Likewise, improvements in the Physical and Mental Components Summary scores of the 36-Item Short-Form Health Survey were significantly improved at 6 months, compared with baseline. The strength of findings was limited by the small sample size and short follow-up; without full enrollment of 250 patients, the trial is underpowered to detect contributing factors to fusion and pain relief. Also, the trial does not have a control group.

Section Summary
The evidence on the fusion of the SIJ with devices other than the triangular implant includes 3 prospective cohort studies, 2 were conducted with transiliac screws, and the third with a posterior approach. No controlled studies were identified. Meta-analyses of the available prospective and retrospective studies indicate improvement in subjective outcomes from before surgery to follow-up in these unblinded studies. The meta-analyses comparing outcomes from these cohorts with non-concurrent studies suggest a possible difference in outcomes between the more well-studied triangular transiliac implant and other implant designs and approaches. There is uncertainty in the health benefit of SIJ fusion/fixation with these various implant designs. Controlled studies with the different implant designs and approaches are needed to evaluate these devices.

Summary of Evidence
For individuals who have sacroiliac joint (SIJ) pain who receive SIJ fixation/fusion with a transiliac triangular implant (iFuse triangular implant), the evidence includes 2 nonblinded randomized controlled trials (RCTs) of minimally invasive fusion, prospective cohorts with more than 85% follow-up, and case series. Relevant outcomes are symptoms, functional outcomes, quality of life (QOL), medication use, and treatment-related morbidity. Both RCTs have reported outcomes past 6 months, after which crossover was allowed. Both studies reported significantly greater reductions in VAS pain scores and ODI scores in SIJ fusion patients than in control groups. The reductions in pain and disability observed in the SIJ fusion group at 6 months were maintained out to 1 year compared with controls who had not crossed over. The RCTs were nonblinded without a placebo or an active control group. Prospective cohorts and case series with sample sizes ranging from 45 to 149 patients and low dropout rates (<15%) also showed reductions in pain and disability out to 5 years. The cohort studies and case series are consistent with the durability of treatment benefit. A Health Technology Assessment by Hayes, Inc., which was last reviewed October 2021 found based on a literature review the use of iFuse for the treatment of SIJ dysfunction unresponsive to conservative management may lead to clinically significant reductions in pain and disability. The evidence is sufficient to determine that the technology (i.e., iFuse triangular implant) results in an improvement in the net health outcome.

For individuals who have sacroiliac joint (SIJ) pain who receive SIJ fusion/fixation with an implant other than a transiliac triangular implant (i.e., iFuse triangular implant), the evidence includes 3 prospective cohort studies and retrospective case series. Relevant outcomes are symptoms, functional outcomes, quality of life (QOL), medication use, and treatment-related morbidity. Two prospective cohorts were conducted with transiliac screws and the third with a device inserted through a posterior approach. No controlled studies were identified. Meta-analyses of the available prospective and retrospective studies indicate improvement in subjective outcomes from before surgery to follow-up, but with a possible difference in outcomes between the more well studied triangular transiliac implant and other implant designs and approaches. There is uncertainty in the health benefit of SIJ fusion/fixation with these implant designs. Therefore, controlled studies with a larger number of patients and longer follow-up are needed to evaluate these

devices. A Hayes Inc., health technology assessment last reviewed October 2021 regarding minimally invasive sacroiliac joint fusion using cylindrical threaded implants (CTIs) found the quality of evidence to be low and further comparative randomized controlled trials are needed to determine the effectiveness of CTIs compared to standard of care and with alternative treatments (i.e., open surgery or other minimally invasive approaches) for SIJ fusion and these comparative studies should also examine the long-term safety and durability for benefit of CTIs in addition to health-related quality of life (QOL). The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Vertebral Body Tethering/Vertebral Body Stapling
Scoliosis is an abnormal lateral and rotational curvature of the vertebral column. Adolescent idiopathic scoliosis is the most common form of idiopathic scoliosis, defined by the U.S. Preventive Services Task Force as "a lateral curvature of the spine with onset at ≥10 years of age, no underlying etiology, and risk for progression during puberty." Progression of the curvature during periods of rapid growth can result in deformity, accompanied by cardiopulmonary complications. Diagnosis is made clinically and radiographically. The curve is measured by the Cobb angle, which is the angle formed between intersecting lines drawn perpendicular to the top of the vertebrae of the curve and the bottom vertebrae of the curve. Patients with adolescent idiopathic scoliosis are also assessed for skeletal maturity, using the Risser sign, which describes the level of ossification of the iliac apophysis.

The Risser sign measures remaining spinal growth by progressive anterolateral to posteromedial ossification. Risser sign ranges from 0 (no ossification) to 5 (full bony fusion of the apophysis). Immature patients will have 0% to 25% ossification (Risser grade 0 or 1), while 100% ossification (Risser grade 5) indicates maturity with no spinal growth remaining. Children may progress from a Risser grade 1 to grade 5 over a brief (e.g., 2-year), period.

Males and females are equally affected by scoliosis, but curve progression is up to 10 times more common in females than males. Patients who are overweight or obese have a greater risk of presenting with larger Cobb angles and more advanced skeletal maturity, possibly due to delayed detection.

Treatment of scoliosis currently depends on 3 factors: the cause of the condition (idiopathic, congenital, secondary), the severity of the condition (degrees of the curve), and the growth of the patient remaining at the time of presentation. Children who have vertebral curves measuring between 25° and 40° with at least 2 years of growth remaining are considered to be at high risk of curve progression. Genetic markers to evaluate the risk of progression are also being evaluated. Because severe deformity may lead to compromised respiratory function and is associated with back pain in adulthood, surgical intervention with spinal fusion is typically recommended for curves that progress to 45° or more.

Bracing is used to reduce the need for spinal fusion by slowing or preventing further progression of the curve during rapid growth. Commonly used brace designs include the Milwaukee, Wilmington, Boston, Charleston, and Providence orthoses. The longest clinical experience is with the Milwaukee cervical-thoracic-lumbar-sacral orthosis. Thoracic-lumbar-sacral orthoses, such as the Wilmington and Boston braces, are intended to improve tolerability and compliance for extended (>18-hour) wear and are composed of lighter weight plastics with a low profile (underarm) design. The design of the nighttime Charleston and Providence braces is based on the theory that increased corrective forces will reduce the needed wear time (i.e., daytime), thereby lessening social anxiety and improving compliance. The smart brace consists of a standard rigid brace with a microcomputer system, a force transducer, and an air-bladder control system to control the interface pressure. Braces that are more flexible than thoracic-lumbar-sacral orthoses or nighttime braces, such as the SpineCor® Scoliosis System, are also being evaluated. The SpineCor® is composed of a thermoplastic pelvic base with stabilizing and corrective bands across the upper body.

Fusionless surgical procedures, such as vertebral body stapling and vertebral body tethering, are being evaluated as alternatives to bracing. Both procedures use orthopedic devices off-label. The goal of these procedures is to reduce the rate of spine growth unilaterally, thus allowing the other side of the spine to "catch up." The mechanism of action is believed to be down-regulation of the growth plate on the convex (outer) side by compression and stimulation of growth on the endplate of the concave side by distraction. In the current stapling procedure, nickel-titanium alloy staples with shape memory are applied to the convex side of the curve. The shape memory allows the prongs to be straight when cooled and clamp down into the bone when the staple returns to body temperature. Anterolateral tethering uses polyethylene ligaments that are attached to the convex side of the vertebral bodies by pedicle screws or staples. The ligament can be tightened to provide greater tension than the staple. The optimum degree of tension is not known. The polyethylene ligaments are more flexible than staples and are predicted to allow more spinal mobility. The goal of a fusionless growth modulating procedure is to reduce the curve and prevent progression, maintain spine mobility following correction, and provide an effective treatment option for patients who are noncompliant or who have a large curve, but substantial growth is remaining. Observational data suggest that overweight patients may be at higher risk for scoliosis progression after surgery.

Clinical Context and Therapy Purpose
The purpose of vertebral body stapling (VBS) is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as observation, in patients with juvenile or adolescent idiopathic scoliosis at high risk of progression.

Populations
The relevant population of interest is individuals with juvenile or adolescent idiopathic scoliosis at high risk of progression.

Interventions
The therapy being considered is vertebral body stapling (VBS).

This is a fusionless surgical procedure intended to replace the use of traditional braces.

Comparators
Comparators of interest include observation conducted by orthopedists and primary care providers in an outpatient clinical setting. Self-treatment includes physical exercise and stretching.

Outcomes
The general outcomes of interest are change in disease status, morbid events, quality of life, and treatment-related morbidity. The existing literature evaluating VBS as a treatment for juvenile or adolescent idiopathic scoliosis at high risk of progression has varying lengths of follow-up, ranging from 2 to 4 years. While studies described below all reported at least 1 outcome of interest, longer follow-up was necessary to fully observe outcomes. Therefore, 4 years of follow-up is considered necessary to demonstrate efficacy.

Review of Evidence

Nonrandomized Comparative Study
Cuddihy et. al., (2015) in a multicenter study reported on a matched comparison of vertebral body stapling (VBS) and bracing for immature patients with moderate (25° to 44°) idiopathic scoliosis. Forty-two consecutive patients in the VBS group (57 curves) met inclusion criteria, and 52 patients in the bracing group (66 curves) were matched by initial Cobb angle, age at the start of treatment, follow-up of at least 2 years, and sex. The average curve size was 31°, and the average follow-up was 40.8 months in the VBS group and 105 months in the bracing group (maturity). For smaller thoracic curves (25° to34°), there was a non-statistically significant trend for stapling to be more effective (progression <10°, 81%) compared with bracing (61%; p=.16). For larger thoracic curves (>35°), VBS did not halt curve progression, with a success rate of 18% compared with 50% for bracing. For lumbar curves (25° to 34°), results were comparable for VBS and bracing. There were insufficient numbers of patients with lumbar curves of 35° or greater to compare results.

Observational Studies
There are several case series and 1 case-control study evaluating vertebral body stapling (VBS).

Murray et. al., (2020) described vertebral body stapling (VBS) in 7 patients with a mean age of 9.3 years (range, 7.8 to11.1 years) and an average preoperative Cobb angle of 30° (standard deviation [SD], 6°); the mean follow-up was 83 months (range, 72 to 95 months). At the first postoperative visit and most recent follow-up visit, the average Cobb angle was 20° (SD, 7°) and 37° (SD, 22°), respectively. One patient showed

improvement of greater than 10° from preoperative to final postoperative Cobb angle, 4 patients showed no change in their curve, and 2 showed progression of their curves by greater than 10° compared with preoperative imaging.

Section Summary
Evidence of the use of vertebral body stapling (VBS) for individuals with idiopathic scoliosis consists of a nonrandomized comparative study, a case-control study, and several small case series. Results from the nonrandomized comparative study and case-control study have indicated that VBS might slow curve progression in children with thoracic curves less than 35° and is at least as effective as bracing, but VBS appears to be less effective than bracing in patients with Cobb angles of 35° or more. Results from these studies are considered preliminary because few patients have been followed to skeletal maturity. Studies from other centers are consistent with results from those of the inventor of the procedure. Complications can include broken staples, staple dislodgement, curve overcorrection, congenital diaphragmatic hernia rupture, contralateral pleural effusion, pneumothoraxes, and superior mesenteric artery syndrome. Investigators have commented that their approach is almost always to recommend bracing first and offer stapling only if the child or adolescent has difficulty wearing the brace. Notably, for patients with thoracic curves of 35° or greater, Cuddihy et. al. (2015) now perform vertebral body tethering (see next section) instead of VBS.

Vertebral Body Tethering

Clinical Context and Therapy Purpose
The purpose of vertebral body tethering is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as observation, in patients with juvenile or adolescent idiopathic scoliosis at high risk of progression.

Population
The relevant population of interest is individuals with juvenile or adolescent idiopathic scoliosis at high risk of progression.

Interventions
The therapy being considered is vertebral body tethering.

This is a fusionless surgical procedure intended to replace the use of traditional braces.

Comparators
Comparators of interest include observation conducted by orthopedists and primary care providers in an outpatient clinical setting. Self-treatment includes physical exercise and stretching.

Outcomes
The general outcomes of interest are change in disease status, morbid events, quality of life, and treatment-related morbidity. The existing literature evaluating vertebral body

tethering as a treatment for juvenile or adolescent idiopathic scoliosis at high risk of progression has varying lengths of follow-up, ranging from 1 to 15 years. While studies described below all reported at least 1 outcome of interest, longer follow-up was necessary to fully observe outcomes.

Review of Evidence
Hayes Inc. completed and Evolving Evidence Review April 2022 on the Tether (Zimmer Biomet) for skeletally immature patients with progressive idiopathic scoliosis. The Tether vertebral body tethering (VBT) system is the only anterior VBT allowed for use in the United State outside of a clinical trial setting. Based on the review of systematic reviews, only one systematic review with meta-analysis was identified, most studies were retrospective or case series and did not mention surgical systems used, and VBT had a much higher incidence of complications. A review of clinical studies suggests minimal support for the use of vertebral body tethering (VBT) with the Tether (Zimmer Biomet Spine Inc), however, the studies show patients experienced high rates of complications, all studies were of poor quality and retrospective in design and only one of the studies had comparison groups, the other studies only compared metrics for pretest-posttest placement.

Observational Studies
As noted in the Regulatory Status section below on 6/4/2019, the U.S. Food and Drug Administration (FDA) granted a Humanitarian Device Exemption to a new vertebral body tethering device called The Tether (Zimmer Biomet Spine, HDE #H190005, product code QHP). Available evidence for The Tether includes only 1 small retrospective cohort study of 57 pediatric patients that is yet unpublished and is only summarized in the FDA's Humanitarian Device Exemption Summary of Safety and Probable Benefit report. In this study, pediatric patients who had failed brace treatment (e.g., greater than 5° of progression and/or intolerance to brace wear) received vertebral body tethering with Dynesys vertebral body screws, which are similar to those of the marketed version of The Tether™, but that have a slightly higher screw profile. Study participants were 86.4% female, with a mean age of 12.4 years. At baseline, mean Cobb angles were 30° to 44° in 75.4% of participants and 45° to 65° in 24.6% of participants. After 2 years, among the 44 subjects with 24-month data (out of the original 57), 43 met the probable benefit success criteria of achievement of a Cobb angle of 40°or less. Overall, the mean Cobb angles improved from 40.4° to 14.3° (+65%). Although assessment of quality of life at the last follow-up visits were described as "positive" based on the Pediatric Quality of Life Inventory, the clinical importance of this data is unclear as no baseline assessments were completed for comparison. A total of 8 participants had serious adverse events (14%), including overcorrection of the instrumented curve (8.8%), definite cord break (1.8%), development of a new curve (1.8%), and spondylolisthesis (1.8%). Other common adverse events were back pain (24.6%), overcorrection of the instrumented curve (21.1%), nausea/vomiting (21.1%), and extremity pain (21.1%). A total of 8 patients (6%) required surgical revision due to adverse events.

Other devices used vertebral body tethering are under development, and the optimum tension for vertebral body tethering is currently unknown.

Pehlivanoglu et. al., (2021) conducted a prospective cohort study of 13 skeletally immature patients (mean age, 11.8 years) who underwent vertebral body tethering (VBT) with the Dynesys system for adolescent idiopathic scoliosis with double curves. At baseline, the mean thoracic/thoracolumbar and lumbar curve magnitudes were 48.2° and 45.3°, respectively. An average of 11.8 levels of tethering were undertaken. Postoperatively, mean thoracic/thoracolumbar curve magnitudes were 14.3° to 17.3°. At the last follow-up (mean, 36.4 months), the mean thoracic/thoracolumbar curve magnitudes were 8.2° to 9.7°. No major complications were reported.

Pehlivanoglu et. al., (2020) published a prospective evaluation on the use of the Dynesys system for anterior vertebral body tethering for idiopathic scoliosis. Included patients had skeletal immaturity (N=21; average age, 11.1 years) with curve progression (curve >40°) despite the use of a brace; the average follow-up was 27.4 months. Results demonstrated that an average of 7.1 levels of tethering was undertaken. The average thoracic curve magnitudes improved from 48.2° to 16° and 10° at the first postoperative and last follow-up, respectively ($p<.001$). There were no major complications reported.

Section Summary
There is limited published evidence on vertebral body tethering (VBT). The available evidence for vertebral body tethering (VBT) is limited to a small, single-center, uncontrolled, unpublished retrospective cohort study of 57 pediatric patients. Although reported Cobb angle corrections are promising, serious adverse events occurred, data are lacking on other important health outcomes, and there are important study design limitations, including lack of a control group. Additional early reports of a correction in Cobb angle from published reports on the Dynesys system are also promising, but little is known about longer-term outcomes with this procedure. Larger, controlled studies are needed to verify these findings.

Summary of Evidence
For individuals who have juvenile or adolescent idiopathic scoliosis at high-risk of progression who receive vertebral body stapling (VBS), the evidence includes a comparative cohort study, a case-control study, and case series. There is a small body of published evidence on surgical interventions for preventing curve progression in juvenile and adolescent idiopathic scoliosis. Vertebral body stapling with memory shape staples may control some thoracic curves between 20° and 35°, but it is less effective than bracing for larger curves. The evidence is composed primarily from a center that developed the technique, along with a few case series from other institutions. Additional studies with larger sample sizes and longer follow-up are needed to evaluate the safety and efficacy of this procedure. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have juvenile or adolescent idiopathic scoliosis at high-risk of progression who receive vertebral body tethering (VBT), the evidence is limited. Vertebral body tethering (VBT) has been evaluated for thoracic curves at high-risk of progression. Currently, there is very limited evidence on this technique, with published case series on the Dynesys system reporting 1-year follow-up in 32 patients, 2-year follow-up in 11 patients, 3-year follow-up in 13 patients, and an additional prospective study reporting approximately 2-year follow-up in 21 patients. Available evidence for The Tether is limited to a small, single-center, uncontrolled, unpublished retrospective cohort study of 57 pediatric patients. Although reported Cobb angle corrections are promising, serious adverse events occurred, data is lacking on other important health outcomes, and there are important study design limitations including lack of a control group. Additional studies, with a larger number of total subjects and longer follow-up, are needed to evaluate the safety and efficacy of this surgical procedure. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Practice Guidelines and Position Statements

American Society of Interventional Pain Physicians
In 2013, the American Society of Interventional Pain Physicians published a guideline update titled "An Update of Comprehensive Evidence-based Guidelines for Interventional Techniques in Chronic Spinal Pain. Part II: Guidance and Recommendations" in the journal Pain Physician.

- "The evidence for various modes of percutaneous disc decompression is limited to fair for nucleoplasty and limited for [automated percutaneous lumbar discectomy] APLD, percutaneous lumbar disc decompression, and decompressor."
- "The evidence 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."

International Society for the Advancement of Spine Surgery (ISASS)
In 2020, the International Society for the Advancement of Spine Surgery (ISASS) published guidelines on intraosseous ablation of the basivertebral nerve for relief of chronic low back pain. The guidelines suggest that basivertebral nerve ablation is an appropriate treatment for chronic low back pain in select patients who meet the following additional criteria:

- "CLBP (chronic low back pain) of at least 6 months duration,
- Failure to respond to at least 6 months of nonsurgical management; and
- MRI (magnetic resonance imaging) demonstrated MCI or MC2 in at least 1 vertebral endplate at 1 or more levels from L3-S1."

In 2016, the International Society for the Advancement of Spine Surgery (ISASS) updated their policy statement on minimally invasive SIJ fusion. Patients who have all the following criteria may be eligible for minimally invasive SIJ fusion:

- Significant SIJ pain (e.g., pain rating at least 5 on the 0-10 numeric rating scale where 0 represents no pain and 10 represents worst imaginable pain) or significant limitations in activities of daily living.
- SIJ pain confirmed with at least 3 physical examination maneuvers that stress the SIJ and cause the patient's typical pain.
- Confirmation of the SIJ as a pain generator with ≥ 75% acute decrease in pain upon fluoroscopically guided diagnostic intra-articular SIJ block using local anesthetic.
- Failure to respond to at least 6 months of non-surgical treatment consisting of non-steroidal anti-inflammatory drugs and/or opioids (if not contraindicated) and one or more of the following: rest, physical therapy, SIJ steroid injection. Failure to respond means continued pain that interferes with activities of daily living and/or results in functional disability.
- Additional or alternative diagnoses that could be responsible for the patient's ongoing pain or disability have been ruled out (e.g., L5/S1 compression, hip osteoarthritis).

The ISASS goes on to suggest that minimally invasive SIJ fusion is NOT indicated for patients with the following:

- Less than 6 months of back pain
- Failure to pursue conservative treatment of the SIJ (unless contra-indicated)
- Pain not confirmed with a diagnostic SIJ block
- Existence of other pathology that could explain the patient's pain.

In rare instances, bilateral SIJ pain can occur. Diagnosis of bilateral SI joint pain must be made based on a history of bilateral pain, bilateral elicitation of pain on physical examination maneuvers that stress each SIJ, and acute bilateral decrease in pain upon fluoroscopically guided intra-articular SI joint block with local anesthetic.

Bilateral SIJ fusion is probably best performed serially to ensure that fusion of both joints is necessary (i.e., pain/disability continues after the first fusion in spite of conservative treatment and a nerve block of the unfused joint results in more than 75% reduction in pain). If bilateral fusion is performed at the same operative session, the surgeon must document both medical necessity and why serial fusion is not indicated in the patient.

It is expected that a person would not undergo more than one SIJ fusion per side per lifetime except in the rare case that a revision is needed.

North American Spine Society (NASS)

In 2022, the North American Spine Society (NASS) updated the clinical practice guideline on the diagnosis and treatment of low back pain that noted there is insufficient evidence to make a recommendation for or against SIJ fusion compared with medical treatment of low back pain due to SIJ dysfunction.

In 2014, the North American Spine Society (NASS) published clinical guidelines on the diagnosis and treatment of lumbar disc herniation which included the following recommendations specific to percutaneous endoscopic discectomy and automated percutaneous discectomy:

Recommendations	**Grade or Level of Evidence (LOE)[a]**
Endoscopic percutaneous discectomy is suggested for carefully selected patients to reduce early postoperative disability and reduce opioid use compared with open discectomy.	B
There is insufficient evidence to make a recommendation for or against the use of automated percutaneous discectomy compared with open discectomy.	I
Endoscopic percutaneous discectomy may be considered for treatment.	C
Automated percutaneous discectomy may be considered for treatment.	C
Patients undergoing percutaneous endoscopic discectomy experience better outcomes if <40 years and symptom duration <3 months.	II

[a] Grade B: fair evidence (level II or III studies with consistent findings; grade C: poor quality evidence (level IV or V studies). Level of evidence II: lesser quality randomized controlled trial (e.g., <80% follow-up, no blinding, or improper randomization), prospective comparative study, systematic review of level II studies or level I studies with inconsistent results; level of evidence III: case control, retrospective, systematic review of level III studies; level of evidence IV: case series; level of evidence V: expert opinion.

In 2011, the North American Spine Society (NASS) revised clinical practice guidelines on the diagnosis and treatment of degenerative lumbar spinal stenosis. The treatment recommendations include the following:

- Interlaminar epidural steroid injection for short-term (6-weeks to 6-months) symptom relief in patients with neurogenic claudication or radiculopathy; however, there is conflicting evidence regarding long-term efficacy. (Grade of Recommendation: B)
- A multiple injection regimen of radiographically guided transforaminal epidural steroid injection or caudal injection for medium-term relief of pain. (Grade of Recommendation: C)
- Decompressive surgery to improve outcomes in patients with moderate to severe symptoms of lumbar spinal stenosis. (Grade of Recommendation: B)

No specific recommendations on percutaneous image-guided lumbar decompression were provided.

National Institute for Health and Care Excellence (NICE)
National Institute for Health and Clinical Excellence's guideline on "Minimally invasive sacroiliac joint fusion surgery for chronic sacroiliac pain" (NICE, 2018) provides the following recommendations:

- Current evidence on the safety and efficacy of minimally invasive sacroiliac (SI) joint fusion surgery for chronic SI pain is adequate to support the use of this procedure provided that standard arrangements are in place for clinical governance, consent, and audit.
- Patients having this procedure should have a confirmed diagnosis of unilateral or bilateral SI joint dysfunction due to degenerative sacroiliitis or SI joint disruption.
- Conservative treatments for SI joint pain include analgesics, non-steroidal anti-inflammatory drugs, physiotherapy, manipulative therapy, intra-articular SI joint corticosteroid injections, periarticular injections, botulinum toxin injections and radiofrequency denervation. Surgical treatment is considered for persistent chronic symptoms that are unresponsive to conservative treatment. Surgical techniques include open SI joint fusion surgery or minimally invasive SI joint fusion using percutaneous implants to stabilize the joint and treat joint pain.

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".

A 2016 guidance by the National Institute for Health and Care Excellence (NICE) on electrothermal annuloplasty was also updated. 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.

Society on Scoliosis Orthpaedic and Rehabilitation Treatment
In 2016, the guidelines from the Society on Scoliosis Orthpaedic and Rehabilitation Treatment included recommendations on the following conservative treatments for idiopathic scoliosis: assessment, bracing, physiotherapy, physiotherapeutic scoliosis-specific exercises and other conservative treatments for idiopathic scoliosis, exercises, special inpatient rehabilitation, and bracing (nighttime rigid bracing, soft bracing, part-time rigid bracing, full-time bracing). The guidelines did not address vertebral body stapling or vertebral body tethering. Treatment decisions should be individualized based on the probability of progression, curve magnitude, skeletal maturity, patient age, and sexual maturity.

Scoliosis Research Society (SRS)

The Scoliosis Research Society (SRS) has indicated that the treatment of adolescent idiopathic scoliosis falls into 3 main categories (observation, bracing, surgery) and is based on the risk of curve progression. In general, adolescent idiopathic scoliosis curves

progress in 2 ways: first, during the rapid growth period of the patient and, second, into adulthood if the curves are relatively large. Because scoliosis gets larger during rapid growth, the potential for growth is evaluated taking into consideration the patient's age, the status of whether females have had their first menstrual period, as well as radiographic parameters. The Risser grading system rates a child's skeletal maturity on a scale of 0 to 5. Patients who are Risser grade 0 and 1 are growing rapidly, while patients who are 4 and 5 have stopped growing. The Society made the following recommendations:

- "Observation is generally for patients whose curves are less than 25° who are still growing, or for curves less than 50° in patients who have completed their growth."
- "Bracing is for patients with curves that measure between 25° and 40° during their growth phase. The goal of the brace is to prevent the curve from getting bigger."
- "Surgical treatment is used for patients whose curves are greater than 45° while still growing or greater than 50° when growth has stopped. The goal of surgical treatment is two-fold: First, to prevent curve progression and secondly to obtain some curve correction…. Implants are used to correct the spine and hold the spine in the corrected position until the spine segments which have been operated on are fused as one bone."
- "Alternative treatments to prevent curve progression or prevent further curve progression such as chiropractic medicine, physical therapy, yoga, etc. have not demonstrated any scientific value in the treatment of scoliosis."

Vertebral body stapling (VBS) was not addressed on the Society's website. (*Accessed August 2022*)

Scoliosis Research Society (SRS) and Pediatric Orthopaedic Society of North America (POSNA)

A joint Scoliosis Research Society (SRS)/Pediatric Orthopaedic Society of North America (POSNA) position statement (2020) on payor coverage for anterior fusionless scoliosis technologies for immature patients with idiopathic scoliosis drew the following conclusions after a review of scientific evidence on anterior vertebral growth modulation:[35,]

- "Payors should provide coverage for any FDA approved devices under FDA stated clinical indications and requirements (limited to surgeons with active IRB approval) at the same level as traditional spinal instrumentation/fusion and growing rod procedures for management of skeletally immature patients (Risser ≤ 2 or Sanders ≤ 5) with idiopathic scoliosis (as defined above, 30 to 65 degrees Cobb angle)."
- "For those patients who meet criteria for use of The Tether™ or other similarly FDA approved growth modulation systems, the decision for fusion versus growth modulation is best made between the patient, guardians, and treating physician accounting for individual needs, values, and perspectives."

- "The SRS and POSNA do not support the use or reimbursement for anterior nonfusion instrumentation in skeletally mature individuals for the management of scoliosis or other spinal deformities."

Regulatory Status

Annular (Annulus) Repair/Closure
On February 8, 2019, the FDA granted approval for the Barricaid implantable annular closure device (ACD) (Intrinsic Therapeutics Inc.) through the FDA premarket approval (PMA) process. This device is indicated for reducing the incidence of reherniation, and reoperation in skeletally mature patients with radiculopathy (w/ or w/o back pain) attributed to a posterior or posterolateral herniation, and confirmed by history, physical examination and imaging studies which demonstrate neural compression using MRI to treat a large annular defect (between 4-6 mm tall and between 6-10 mm wide) following a primary discectomy procedure (excision of herniated intervertebral disc) at a single level between L4 and S1.

The Xclose™ Tissue Repair System (Anulex Technologies, Inc., Minnetonka, MN) has received FDA 510(k) clearance for use in soft tissue approximation for procedures such as general and orthopedic surgery. It is being investigated as a method of soft tissue re-approximation of the anulus fibrosus after a lumbar discectomy procedure.

Automated Percutaneous and Percutaneous Endoscopic Discectomy
The Dekompressor® Percutaneous Discectomy Probe (Stryker), Herniatome Percutaneous Discectomy Device (Gallini Medical Devices), and the Nucleotome® (Clarus Medical) are examples of percutaneous discectomy devices that have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. The FDA indication for these products is for "aspiration of disc material during percutaneous discectomies in the lumbar, thoracic and cervical regions of the spine."

iFuse Sacroiliac Fusion Devices for Sacroiliac Joint (SIJ) Dysfunction

Device	Manufacturer	Notice Date	Indication
SI Joint Fusion System™		11/26/2008	Fracture fixation of large bones and large bone fragments of the pelvis, including SIJ disruption and degenerative sacroiliitis.
iFuse ® SI Joint Fusion System	SI-Bone	04/21/2011	SIJ disruption and degenerative sacroiliitis.

iFuse ® Implant System	SI-Bone	10/12/2012	SIJ disruption and degenerative sacroiliitis.
iFuse ® Implant System	SI-Bone	04/01/2013	SIJ disruption and degenerative sacroiliitis.
iFuse ® Implant System	SI-Bone	10/16/2013	SIJ disruption and degenerative sacroiliitis.
iFuse ® Implant System	SI-Bone	07/23/2014	SIJ dysfunction resulting from SIJ disruption and degenerative sacroiliitis.
iFuse ® Implant System	SI-Bone	04/17/2015	SIJ dysfunction resulting from SIJ disruption and degenerative sacroiliitis.
iFuse ® Implant System	SI-Bone	07/22/2015	SIJ dysfunction resulting from SIJ disruption and degenerative sacroiliitis, including symptoms beginning during pregnancy or peripartum period and persisted postpartum for >6 months.
iFuse ® Implant System	SI-Bone	10/29/2015	SIJ dysfunction resulting from SIJ disruption and degenerative sacroiliitis, including symptoms beginning during

			pregnancy or peripartum period and persisted postpartum for >6 months.
iFuse ® Implant System	SI-Bone	03/01/2016	SIJ dysfunction resulting from SIJ disruption and degenerative sacroiliitis, including symptoms beginning during pregnancy or peripartum period and persisted postpartum for >6 months.
iFuse ® Implant System	SI-Bone	06/03/2016	SIJ dysfunction resulting from SIJ disruption and degenerative sacroiliitis, including symptoms beginning during pregnancy or peripartum period and persisted postpartum for >6 months.
iFuse ® 3D Implant System	SI-Bone	03/10/2017	SIJ dysfunction resulting from SIJ disruption and degenerative sacroiliitis, including symptoms beginning during pregnancy or peripartum period and persisted

			postpartum for >6 months.
iFuse ® Implant System-IFuse Navigation Instrument Set	SI-Bone	10/31/2017	For use with the iFuse Implant System to assist the surgeon in the identification of anatomical structures for which stereotactic surgery may be required and where reference to an anatomic structure can be identified from imaging studies. The system is intended to be used with the Medtronic StealthStation System
iFuse ® Implant System	SI-Bone	11/27/2018	SIJ dysfunction that is a direct result of SIJ disruption and degenerative sacroiliitis. This includes conditions whose symptoms began during pregnancy or in the peripartum period and have persisted postpartum for more than 6 months.
iFuse ® Implant System	SI-Bone	04/03/2019	SIJ dysfunction resulting from SIJ disruption and degenerative sacroiliitis, including symptoms

			beginning during pregnancy or peripartum period and persisted postpartum for >6 months; to augment immobilization and stabilization of the SIJ in skeletally mature patients undergoing sacropelvic fixation as part of a lumbar or thoracolumbar fusion.
iFuse ® Implant System	SI-Bone	03/31/2020	SIJ dysfunction resulting from SIJ disruption and degenerative sacroiliitis, including symptoms beginning during pregnancy or peripartum period and persisted postpartum for >6 months; to augment immobilization and stabilization of the SIJ in skeletally mature patients undergoing sacropelvic fixation as part of a lumbar or thoracolumbar fusion; acute, non-acute, and non-traumatic fractures involving the SIJ.

Cylindrical Threaded Implants for Sacroiliac Joint (SIJ) Dysfunction

Device	Manufacturer	Notice Date	Indication
FIREBIRD SI Fusion System™	Orthofix	2020	Intended for sacroiliac joint fusion for conditions including sacroiliac joint disruptions and degenerative sacroiliitis.
SambaScrew®	Orthofix	2012	Intended for fixation of sacroiliac joint disruptions. This fixation device is to only be used in skeletally mature individuals
Simmetry® Sacroiliac Joint Fusion System	Zyga Technology Inc.	12/14/2010	Intended for fixation of large bones, including bones of the pelvis, for conditions including SIJ disruption and degenerative sacroiliitis.
Simmetry® Sacroiliac Joint Fusion System	Zyga Technology Inc.	03/23/2011	Intended for fixation of large bones, including bones of the pelvis, for conditions including SIJ disruption and degenerative sacroiliitis.
Simmetry® Sacroiliac Joint Fusion System	Zyga Technology Inc.	07/21/2011	Intended for SIJ fusion for conditions including SIJ disruption and degenerative sacroiliitis.
SI-LOK ®Sacroiliac Joint Fixation System	Globus Medical Inc.	12/09/2011	Intended for SIJ fusion for conditions including SIJ disruption and degenerative sacroiliitis.
SImmetry® Sacroiliac Joint Fusion System	Zyga Technology Inc.	02/27/2013	Intended for SIJ fusion for conditions including SIJ disruption and degenerative sacroiliitis.

Silex Sacroiliac Joint Fusion®	X-Spine Systems	2014	Allows for fusion and stabilization of the SI joint in eligible individuals whom appropriate non-surgical treatment has failed.
SImmetry® Sacroiliac Joint Fusion System	Zyga Technology Inc.	01/15/2015	Intended for SIJ fusion for conditions including SIJ disruption and degenerative sacroiliitis.
SImmetry® Sacroiliac Joint Fusion System	Zyga Technology Inc.	08/05/2015	Intended for SIJ fusion for conditions including SIJ disruption and degenerative sacroiliitis.
Rialto™ SI Fusion System	Medtronic Sofamor Danek	08/12/2016	Intended for SIJ fusion for conditions including SIJ disruption and degenerative sacroiliitis.
SI-LOK® Sacroiliac Joint Fixation System, Navigation Instruments, ExcelsiusGPS Instruments	Globus Medical Inc.	02/06/2019	Intended for SIJ fusion for conditions including SIJ disruption and degenerative sacroiliitis.

Other Select Fusion Devices for Sacroiliac Joint (SIJ) Dysfunction

Device	Manufacturer	Date	Indication
Lateral Transiliac Approach			
Triton SI Joint Fixation System™	Choice Spine	2021	3D printed screw that facilitates sacroiliac joint fixation for conditions such as degenerative sacroiliitis as well as sacroiliac joint dysfunction.
Posterolateral Approach			

SacroFuse®/ SIJFuse™	SpineFrontier	2015	Intended for SIJ fusion for conditions including SIJ disruption and degenerative sacroiliitis.
Posterior Approach			
Catamaran™	Tenon Medical	2018	Intended for SIJ fusion for conditions including SIJ disruption and degenerative sacroiliitis.
CornerLoc™	Fusion Foundation Solutions	Not applicable: human cell and tissue product; bone allograft	Intended for SIJ fusion for conditions including SIJ disruption and degenerative sacroiliitis.
LinQ™ SI Joint Stabilization	PainTEQ	Not applicable: human cell and tissue product; bone allograft	Intended for SIJ fusion for conditions including SIJ disruption and degenerative sacroiliitis.
NADIA™ SI Fusion System (DIANA)	Ilion Medical	2020	Intended for SIJ fusion for conditions including SIJ disruption and degenerative sacroiliitis.
PsiF™ Posterior Sacroiliac Fusion	Omnia Medical	Not applicable: human cell and tissue product; bone allograft	Intended for SIJ fusion for conditions including SIJ disruption and degenerative sacroiliitis.
SIFix System®	NuTech	Not applicable: human cell and tissue product; bone allograft	Intended for SIJ fusion for conditions including SIJ disruption and degenerative sacroiliitis.
TransFasten™	Captiva Spine	Not applicable: human cell and tissue product; bone allograft	Intended for SIJ fusion for conditions including SIJ disruption and degenerative sacroiliitis.

Laser Devices
A number of laser devices have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process for incision, excision, resection, ablation, vaporization, and coagulation of tissue. Intended uses described in FDA summaries include a wide variety of procedures, including percutaneous discectomy. Trimedyne received 510(k) clearance in 2002 for the Trimedyne® Holmium Laser System Holmium: Yttrium, Aluminum Garnet (Holmium:YAG), in 2007 RevoLix Duo™ Laser System, and in 2009 Quanta System LITHO Laser System. All were cleared, based on equivalence with predicate devices for percutaneous laser disc decompression/discectomy, including foraminoplasty, percutaneous cervical disc decompression/discectomy, and percutaneous thoracic disc decompression/discectomy. The summary for the Trimedyne® system states that indications for cervical and thoracic decompression/discectomy include uncomplicated ruptured or herniated discs, sensory changes, imaging consistent with findings, and symptoms unresponsive to 12 weeks of conservative treatment. Indications for treatment of cervical discs also include positive nerve conduction studies.

In 2001, the Perc-D SpineWand™ (ArthroCare) was cleared for marketing by FDA through the 510(k) process. FDA determined that this device was substantially equivalent to predicate devices. It is used in conjunction with the ArthroCare Coblation® System 2000 for ablation, coagulation, and decompression of disc material to treat symptomatic patients with contained herniated discs. Smith & Nephew acquired ArthroCare in 2014; as of 2017, Smith & Nephew has not provided any information about coblation devices specific to spine surgeries on its website.

Mild® Tool Kit
The mild® tool kit (Vertos Medical Inc., San Jose, CA) initially received 510(k) marketing clearance as the X-Sten MILD Tool Kit (X-Sten Corp.) from the US Food and Drug Administration (FDA) on December 19, 2006, as a class II device with intended use as a set of specialized surgical instruments to be used to perform percutaneous lumbar decompressive procedures for the treatment of various spinal conditions. A subsequent approval for the Vertos Medical mild® Device Kit (Vertos Medical Inc.) was given by the FDA on February 4, 2010.

Radiofrequency (RF) Coagulation Devices
A variety of radiofrequency (RF) coagulation devices are 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 the U.S. Food and Drug Administration (FDA) through the 510(k) process. The predicate device was the SpineCATH® Intradiscal Catheter, which received FDA clearance for marketing in 1999. Radionics (a division of Tyco Healthcare group) RF (Radiofrequency) Disc Catheter System received marketing clearance through FDA's 510(k) process in 2000.

The Baylis Pain Management Cooled Probe received marketing clearance through the 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."

The Intracept Intraosseous Nerve Ablation System "is intended to be used in conjunction with radiofrequency (RF) generators for the ablation of basivertebral nerves of the L3 through S1 vertebrae for the relief of chronic low back pain of at least six months duration that has not responded to at least six months of conservative care". FDA reviewed the device and issued a substantially equivalent designation in August 2017 (K170827).

Vertebral Body Stapling
Staples, using a shape memory nickel-titanium alloy, have been cleared for marketing by the FDA through the 510(k) process for various bone fixation indications. For example, nitinol staples (Sofamor Danek) are indicated for fixation with spinal systems. Other memory shape staples cleared for marketing by the FDA through the 510(k) process for bone fixation include the OSStaple™ (BioMedical Enterprises) and the reVERTO™ Dynamic Compression Device. FDA product code: JDR. Vertebral body stapling in scoliosis is considered off-label use.

PRIOR APPROVAL

Not applicable.

POLICY

Medically Necessary
Sacroiliac Joint (SIJ) Fusion Surgery
Open Sacroiliac joint (SIJ) fusion (27280) is considered **medically necessary** for any of the following indications:

1. As an adjunct to sacrectomy or partial sacrectomy related to tumors involving the sacrum; **or**
2. As an adjunct to the medical treatment of sacroiliac joint infection/sepsis; **or**
3. Severe traumatic injuries associated with pelvic ring fracture; **or**
4. During multisegment spinal constructs (for example, correction of deformity in scoliosis or kyphosis surgery) extending to the ilium.

Investigational
Open sacroiliac joint fusion (SIJ) is considered **investigational** when the above criteria is not met and including, but not limited to the following because the evidence is insufficient to determine the effects of this technology on net health outcomes:

- mechanical low back pain
- sacroiliac joint syndrome
- degenerative sacroiliac joint

- radicular pain syndromes

Medically Necessary
Minimally Invasive Sacroiliac Joint (SIJ) Fusion (27279)
Unilateral percutaneous or minimally invasive fusion or stabilization of the sacroiliac joint, with a maximum of 3 titanium triangular implant (i.e., iFuse® Implant System (SI Bone), may be considered **medically necessary** when **ALL** the following criteria is met:

1. Individual is at least 18 years old; **and**
2. Individual has undergone and failed a minimum 6 months of intensive nonoperative treatment that must include medication optimization, activity modification, bracing, and active therapeutic exercise (physical therapy*) targeted at the lumbar spine, pelvis, sacroiliac joint, and hip, including a home exercise program; **and**
3. Pain is consistently at least a 5 on a 0 to 10 rating scale, that impacts quality of life (QOL) and limits activities of daily living (ADLs); **and**
4. There is an absence of generalized pain behavior (e.g., somatoform disorder) or generalized pain disorders (e.g., fibromyalgia); **and**
5. Individual's pain is reported as non-radiating, unilateral pain that is caudal to the lumbar spine (L5 vertebrae), localized over the posterior SIJ, and consistent with SIJ pain; **and**
6. On physical examination documented in the individual's medical records demonstrate localized tenderness with palpation over sacral sulcus (Fortin's point) in the absence of tenderness of similar severity elsewhere (e.g., greater trochanter, lumbar spine, coccyx); **and**
7. There is a positive response to 3 provocative tests:
   a. Thigh thrust test
   b. Compression test
   c. Gaenslen sign
   d. Distraction test
   e. Patrick test; **and**
8. Diagnostic imaging studies include **ALL** the following:
   a. Imaging (plain radiographs and computed tomography or magnetic resonance imaging) of the sacroiliac joint excludes the presence of destructive lesions (e.g., tumor, infection) or inflammatory arthropathy of the sacroiliac joint; **and**
   b. Imaging of the pelvis (anteroposterior plain radiograph) rules out concomitant hip pathology; **and**
   c. Imaging of the lumbar spine (computed tomography or magnetic resonance imaging) is performed to rule out neural compression or other degenerative condition that can be causing low back or buttock pain; **and**
   d. Imaging of the sacroiliac joint indicates evidence of injury and/or degeneration; **and**
9. There is at least a 75% reduction in pain following an image-guided intra-articular sacroiliac joint injection on 2 separate occasions within the last 12 months; and

10. A trial of therapeutic sacroiliac joint injection (i.e., corticosteroid injection) has been performed on at least once within the last 12 months.

Note: *Formal physical therapy, at least six visits over a six-week course, including active muscle conditioning is required. The requirement for physical therapy will not be met if there is a failure to complete prescribed physical therapy for non-clinical reasons. Documentation of formal physical therapy would be the therapist's notes.*

Investigational
Unilateral percutaneous or minimally invasive fusion or stabilization of the sacroiliac joint not meeting the above criteria and for all other indications is considered **investigational** to include any other devices not listed in the above medical necessity criteria**.**

Required Documentation for Minimally Invasive Sacroiliac Fusions ONLY:
Medical records submitted for review need to include **ALL** the following:

1. Specific device to be implanted; **and**
2. History of moderate to severe pain of at least 6 months duration including date of onset; **and**
3. Location and description of pain, and at least 3 provocative tests and results indicating pain arising from the sacroiliac joint; **and**
4. Documentation of the absence of generalized pain behavior or generalized pain disorders; **and**
5. Procedure report describing at least TWO SI joint anesthetic injections and follow-up reports on the percent change in the level of pain, for the duration of the specific local anesthetic used; **and**
6. Trial of therapeutic injection (e.g., corticosteroid) including response; and
7. Conservative non-surgical therapy:
    - Medical management with NSAIDs or other analgesics; **and**
    - Physical therapy (PT) or documentation must include clinical notes from the physical therapist describing the individual's inability to complete PT; **and**
8. Radiology reports (plain radiographs and a CT OR MRI) of the following:
    - Hip/pelvis
    - Lumbar spine
    - Sacroiliac joint

Investigational
The following procedures are considered **investigational** for all indications**,** because the evidence is insufficient to determine the effects of this technology on net health outcomes:

- Devices for annulus repair or closure (Xclose™ Tissue Repair System, Barricaid) (C9757)
- Discectomy

    - Automated percutaneous lumbar, thoracic, and cervical endoscopic discectomy or percutaneous endoscopic discectomy (PELD) (62287, 62380, 0274T, 0275T, C2614)
    - Laser discectomy and intervertebral disc decompression using radiofrequency energy, including but not limited to Coblation® and DISC nucleoplasty (62287, S2348)
- Image-guided minimally invasive decompression for the treatment of spinal stenosis (0274T, 0275T, G0276)
- Intradiscal annuloplasty including but not limited to the following: (22526, 22527)
    - Intradiscal electrothermal annuloplasty (IDEA)
    - Percutaneous intradiscal radiofrequency thermocoagulation (PIRFT)
    - Intradiscal biacuplasty
- Intraosseous radiofrequency ablation of the basivertebral nerve (e.g., Intracept system) (64628, 64629)
- Percutaneous lysis of epidural adhesions, with or without endoscopic guidance (62263, 62264)
- Vertebral body stapling (VBS) and vertebral body tethering (VBT) **(***0656T, 0657T)*

Policy Guidelines

Provocative tests of the sacroiliac region may indicate sacroiliac joint dysfunction when at least 3 different tests reproduce the individual's typical pain in the SI region, including:

- **Thigh thrust:** Test involves the examiner applying downward pressure along the femur with the individual supine. Pain at the ilium or SI joint suggests SI joint dysfunction.

- **Compression test:** Also called the approximation test, stresses the SI joint structures, in particular the posterior SI joint ligament, to attempt to replicate the individual's symptoms.

- **Gaenslen sign:** Is accomplished with the individual supine. One hip is flexed by pushing the individual's knee to their chest, while simultaneously extending the opposite hip joint. This maneuver stresses both sacroiliac joints. Posterior pelvic pain indicates a positive test.

- **Distraction test:** Also known as the gaping test, is positive for pain sacroiliac joint dysfunction or other pelvic abnormalities when downward pressure is applied simultaneously to the iliac crest when the individual is in supine position.

- **Patrick sign is also referred to as the Fabere test:** The examiner Flexes, Abducts, Externally Rotates, and Extends the affected leg so that the ankle of that leg is on top of the opposite knee (a figure of 4 configuration). The affected leg is then slowly lowered toward the examining table. A negative result occurs when

the test leg falls at least parallel to the opposite leg. A positive test result occurs when the affected leg remains above the opposite leg and pain arises unilaterally in the active hip.

PROCEDURE CODES AND BILLING GUIDELINES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnosis codes.

- 0274T Percutaneous laminotomy/laminectomy (intralaminar approach) for decompression of neural elements, (with or without ligamentous resection, discectomy, facetectomy and/or foraminotomy) any method under indirect image guidance (e.g., fluoroscopic, CT), with or without the use of an endoscope, single or multiple levels, unilateral or bilateral; cervical or thoracic
- 0275T Percutaneous laminotomy/laminectomy (intralaminar approach) for decompression of neural elements, (with or without ligamentous resection, discectomy, facetectomy and/or foraminotomy) any method under indirect image guidance (e.g., fluoroscopic, CT), with or without the use of an endoscope, single or multiple levels, unilateral or bilateral; lumbar
- 0775T Arthrodesis, sacroiliac joint, open, includes obtaining bone graft, including instrumentation, when performed
- 22526 Percutaneous intradiscal electrotherapy annuloplasty, unilateral or bilateral including fluoroscopic guidance; single level
- 22527 Percutaneous intradiscal electrotherapy annuloplasty, unilateral or bilateral including fluoroscopic guidance; 1 or more additional levels (list separately in addition to code for primary procedure)
- 22899 Unlisted procedure, spine
- 27279 Arthrodesis, sacroiliac joint, percutaneous or minimally invasive (indirect visualization), with image guidance, includes obtaining bone graft when performed, and placement of transfixing device
- 27280 Arthrodesis, sacroiliac joint, open, includes obtaining bone graft, including instrumentation, when performed
- 27299 Unlisted procedure, pelvis, or hip joint
- 62263 Percutaneous lysis of epidural adhesions using solution injection (e.g., hypertonic saline, enzyme) or mechanical means (e.g., catheter) including radiologic localization (includes contrast when administered), multiple adhesiolysis sessions; 2 or more days
- 62264 Percutaneous lysis of epidural adhesions using solution injection (e.g., hypertonic saline, enzyme) or mechanical means (e.g., catheter) including radiologic localization (includes contrast when administered), multiple adhesiolysis sessions; 1 day
- 62287 Aspiration or decompression procedure, percutaneous, of nucleus pulposus of intervertebral disc, ant method, single or multiple levels, lumbar (e.g., manual or automated percutaneous discectomy, percutaneous laser discectomy)

- 62380 Endoscopic decompression of spinal cord, nerve root(s), including laminotomy, partial facetectomy, foraminotomy, discectomy and/or excision of herniated intervertebral disc, 1 interspace, lumbar
- 64628 Thermal destruction of intraosseous basivertebral nerve, including all imaging guidance; first 2 vertebral bodies, lumbar or sacral (Intracept System)
- 64629 Thermal destruction of intraosseous basivertebral nerve, including all imaging guidance; each additional vertebral body, lumbar or sacral (List separately in addition to code for primary procedure) (Intracept System)
- 0656T Vertebral body tethering, anterior; up to 7 vertebral segments
- 0657T Vertebral body tethering, anterior; 8 or more vertebral segments
- C2614 Probe, percutaneous lumbar discectomy
- C9757 Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and excision of herniated intervertebral disc, and repair of annular defect with implantation of bone anchored annular closure device, including annular defect measurement, alignment and sizing assessment, and image guidance; 1 interspace, lumbar
- G0276 Blinded procedure for lumbar stenosis, percutaneous image-guided lumbar decompression (PILD) or placebo-control, performed in an approved coverage with evidence development (CED) clinical trial
- S2348 Decompression procedure, percutaneous, of nucleus pulposus of intervertebral disc, using radiofrequency energy, single or multiple levels, lumbar

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- Hayes Inc. Health Technology Assessment Annual Review March 16, 2022. Percutaneous Laser Disc Decompressoin for Lumbar Disc Herniation

- Hayes Inc. Emerging Technology Report May 7, 2022. LimiFlex Dynamic Sagittal Tether for Spondylolisthesis
- Hayes Inc. Minimally Invasive Lumbar Decompression (mild; Vertos Medical Inc.) Device Kit for Treatment of Lumbar Spinal Stenosis
- Hayes Inc. Hayes Technology Assessment Annual Review October 28, 2021. Minimally Invasive Sacroiliac Joint Fusion using Cylindrical Threaded Implants
- Hays Inc. Health Technology Asssessment Annual Review October 5, 2021. Minimally Invasive Sacroiliac Joint Fusion usin Triangular Titanium Implants (iFuse Implant System, SI-Bone Inc.)
- Hayes Inc. Health Technology Assessment Annual Review May 31, 2022. Annular Closure for Prevention of Lumbar Disc Reherniation

POLICY HISTORY		
Date	**Reason**	**Action**
July 2022	Annual Review	Policy Revised
January 2022	Interim Review	Policy Revised
July 2021	Annual Review	Policy Revised
July 2020	Annual Review	Policy Revised
October 2019	Interim Review	Policy Revised
July 2019	Annual Review	Policy Revised
July 2018	Annual Review	Policy Revised
July 2017	Annual Review	Policy Revised
July 2016	Annual Review	Policy Revised
October 2015	Interim Review	Policy Revised
August 2015	Annual Review	Policy Revised
September 2014	Annual Review	Policy Revised
October 2013	Annual Review	Policy Revised
November 2012	Annual Review	Policy Renewed
November 2011	Annual Review	Policy Renewed
October 2010	Annual Review	Policy Renewed

New information or technology that would be relevant for Wellmark to consider when this policy is next reviewed may be submitted to:

Wellmark Blue Cross and Blue Shield
Medical Policy Analyst
PO Box 9232
Des Moines, IA 50306-9232

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