PROPOSED | Local Coverage Determination (LCD)

Minimally Invasive Arthrodesis of the Sacroiliac Joint (SIJ) v

DL39797

PROPOSED LCD v

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Contractor Information v

Contractor Name	Contract Type	Contract Number	Jurisdiction	States
Palmetto GBA v	A and B MAC v	10111 - MAC A v	J - J v	Alabama v
Palmetto GBA v	A and B MAC v	10112 - MAC B v	J - J v	Alabama v
Palmetto GBA v	A and B MAC v	10211 - MAC A v	J - J v	Georgia v
Palmetto GBA v	A and B MAC v	10212 - MAC B v	J - J v	Georgia v
Palmetto GBA v	A and B MAC v	10311 - MAC A v	J - J v	Tennessee v
Palmetto GBA v	A and B MAC v	10312 - MAC B v	J - J v	Tennessee v
Palmetto GBA v	A and B and HHH MAC v	11201 - MAC A v	J - M v	South Carolina v
Palmetto GBA v	A and B and HHH MAC v	11202 - MAC B v	J - M v	South Carolina v
Palmetto GBA v	A and B and HHH MAC v	11301 - MAC A v	J - M v	Virginia v
Palmetto GBA v	A and B and HHH MAC v	11302 - MAC B v	J - M v	Virginia v
Palmetto GBA v	A and B and HHH MAC v	11401 - MAC A v	J - M v	West Virginia v
Palmetto GBA v	A and B and HHH MAC v	11402 - MAC B v	J - M v	West Virginia v
Palmetto GBA v	A and B and HHH MAC v	11501 - MAC A v	J - M v	North Carolina v
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Issue v

Issue Description
This LCD outlines limited coverage for this service with specific details under ***Coverage Indications, Limitations and/or Medical Necessity***. v

CMS National Coverage Policy v

Title XVIII of the Social Security Act (SSA), §1862(a)(1)(A) excludes expenses incurred for items or services which are not v reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed v body member. v

Coverage Guidance v

Coverage Indications, Limitations, and/or Medical Necessity
Covered Indications

Minimally Invasive (MI) Arthrodesis of the sacroiliac joint (SIJ) WITH placement of a transfixation device is considered v medically reasonable and necessary when ALL of the following criteria are met: v

1. Moderate to severe low back pain (LBP) primarily experienced over the anatomical location of the SIJs between the v upper level of the iliac crests and the gluteal fold AND v

2. The pain in the SIJ that causes functional impairment and pain must be measured on a pain scale. Pain assessment v must be performed and documented at baseline and after each diagnostic procedure using the same pain scale for v each assessment AND v

3. LBP duration of at least 6 months with documented failure to respond to noninvasive conservative management (CM) v (as tolerated). This CM should include medication optimization, activity modification, bracing, and active therapeutic v exercise targeted at the lumbar spine, pelvis, SIJ and hip including a home exercise program, AND v

4. LBP below L5 without radiculopathy, AND v

5. Clinical findings and/or imaging studies do not suggest any other diagnosed or obvious cause of the lumbosacral pain v (such as central spinal stenosis with neurogenic claudication/myelopathy, foraminal stenosis or disc herniation with v concordant radicular pain/radiculopathy, infection, tumor, fracture, pseudoarthrosis, or pain related to spinal v instrumentation), AND v

6. At least 3 positive findings with provocative maneuvers: flexion abduction external rotation (FABER), Gaenslen, Thigh v Thrust or Posterior Shear, SI Compression, SI Distraction and Yeoman Tests, AND v

7. Absence of generalized pain behavior (e.g., somatoform disorder) or generalized pain disorders (e.g., fibromyalgia) AND v

8. At least 75% reduction of pain for the expected duration of the injected anesthetic agent on 2 separate visits, the ability v to perform previously painful maneuvers, following an image-guided, contrast-enhanced intra-articular SIJ injection v AND v

9. A trial of at least 1 therapeutic intra-articular SIJ injection (i.e., corticosteroid injection that results in a 50% reduction of v pain for the expected duration of the injected agent AND v

10. Diagnostic imaging studies that include ALL the following: v

    - Imaging (plain radiographs and a computed tomography (CT) or magnetic resonance imaging (MRI)) of the SIJ v that excludes the presence of destructive lesions (e.g., tumor, infection), fracture, traumatic SIJ instability, or v inflammatory arthropathy that would not be properly addressed by percutaneous SIJ fusion (SIJF) v
    - Imaging of the pelvis (anteroposterior (AP) plain radiograph) to rule out concomitant hip pathology v
    - Imaging of the lumbar spine (CT or MRI) to rule out neural compression or other degenerative condition that can v be causing low back or buttock pain v

MI Arthrodesis of the SIJ WITHOUT placement of a transfixation device is NOT considered medically reasonable and v necessary. v

Summary of Evidence

The SIJ is a synovial or diarthrosis-amphiarthrosis joint, whose primary function is to transfer weight to and from the lower v extremities to the axial skeleton.[1] The SIJ has been implicated as a source of chronic LBP in 15% to 30% of patients.[2] The SIJ v contains both mechanoreceptors and nociceptive receptors such that SIJ pathology leads to pain in the buttocks, lower back, v groin or leg. SIJ degeneration commonly occurs, especially after lumbar fusion. The SIJ is particularly enigmatic in its ability to v mimic hip and lumbar spine pathology and also to result from the surgical treatment of hip and spine issues.[3] Patients with v SIJ pain report Oswestry Disability Index (ODI) scores in the 50s and the burden of disease associated with SIJ pain is at least v as high as that associated with other musculoskeletal conditions such as hip osteoarthritis, degenerative spondylolisthesis, or v spinal stenosis; conditions that are often treated surgically.[4] Risk factors for SIJ dysfunction may include abnormal gait, v scoliosis, degenerative and inflammatory arthritis, previous lumbar spinal surgery, trauma, and childbirth.[5] In addition, the SIJ v may be a referred site of pain, including from a degenerative disc at L5-S1, spinal stenosis, or osteoarthritis of the hip. v

Diagnosis remains problematic, with no universally accepted reference standard. Current best practice diagnostic techniques v start with pain provocation testing. A positive result on 3 or more pain provocation tests, such as Gaenslen's, FABER, v compression, distraction and thigh thrust, are used as criteria for further testing to confirm the SIJ as the primary pain v generator. Typically, diagnostic blocks and intraarticular fluoroscopically guided injections are then used for confirmation of v SIJ disorder. A standard of ≥75% relief of pain has been suggested as an indication of pain deriving from the SIJ. X-ray, CT or v MRI of the SIJ has not proven to be sensitive or specific enough to be used alone but may be helpful when used in conjunction v with other diagnostic techniques. Radiographic utility lies more in excluding the presence of other causes of pain that would v not be properly addressed by percutaneous SIJF.[3,6,7] v

The mainstay of therapy for disorders of the SIJ has been nonoperative treatment, including activity modification, NSAIDs, v physical therapy, radiofrequency neurotomy and SIJ injections (SIJIs). High quality clinical evidence corroborating the benefits v of these non-surgical therapeutic options is limited by small patient populations, lack of placebo controls, and failure to utilize v

validated outcome measures.[8] When these modalities fail, the International Society for the Advancement of Spine Surgery v (ISASS) recommends SIJ arthrodesis.[9] Surgical treatment is indicated for patients with a positive response to an SIJ injection v with >75% relief, failure of nonsurgical treatment, and continued or recurrent SIJ pain. v

Traditional open SIJF procedures are complex and invasive, involving open exposure of the joint with instrumented fixation v and/or bone graft harvesting, and are typically associated with lengthy hospital stays, large blood loss and prolonged v recovery times. Outcomes of traditional SIJF procedures were observed to be so poor with a high rate of reported non-union v that these procedures were virtually abandoned over the last few decades.[10] However, in the case of revision surgery, v nonunion, and aberrant anatomy, open arthrodesis should be performed.[11]v

To review literature on devices for SIJF, PubMed® was searched using the Boolean phrase “sacroiliac joint AND (fusion ORv arthrodesis)” since 2010. To establish a list of SIJF devices not represented in the literature, searches were performed on the v Federal Drug Administration (FDA) 510(k), premarket approval, and De Novo databases, as well as Google and LinkedIn. v Literature review yielded 11 FDA-approved devices for MI SIJF. Database query yielded an additional 22 devices for a total of v 33 devices. Twenty-one devices used the lateral transiliac approach, 6 posterior allograft approaches, 3 posterolateral v approaches, and 3 combined the lateral transiliac and posterolateral approaches. The evidence for the lateral transiliac v approach is the most robust.[12] This approach is also termed arthrodesis with placement of a transfixation device. v

Arthrodesis with Placement of Transfixation Device

More recently, MI techniques with novel implants have been developed that are designed to confer the benefits of permanent v SIJ stabilization but with a more reasonable safety profile. To date, most published data describe use of a lateral transfixing v approach. While a small number of studies describe use of hollow modular anchor screws, a larger number describe use of v triangular titanium implants (TTIs) with a porous surface. These implants serve to minimize rotation and maximize surface v area at the SIJ.[13]v

Kube and Muir[14] evaluated 1 year clinical results from a cohort of 18 patients with SIJ pain unresponsive to conservative v treatment who underwent minimally invasive surgical (MIS) SIJFs. At 12 months, the overall fusion rate was 88%. Back and v leg pain improved from 81.7 to 44.1 points on the visual analog scale (VAS) ($p<0.001$) and from 63.6 to 27.7 points ($p<0.001$), v respectively. Disability scores improved from 61.0 to 40.5 ($p<0.009$) on the ODI. No major complications were reported. v

Similar results were noted by Rainov et al.[15] in their retrospective study of 160 patients with painful SIJ dysfunction who v underwent unilateral or bilateral SIJF using TTIs. By 12 months, pain decreased from 8.0 to 2.5 (VAS) ($p<0.0001$) and v disability (ODI) from 45.3 to 16.4 ($p<0.001$). v

A prospective multicenter single arm interventional trial looking at 172 subjects with MIS for SIJ dysfunction was conducted v by Duhon et al.[16] Patients completed VAS and ODI assessments preoperatively, and at 1, 3, 6, and 12 months v postoperatively. Patient satisfaction with surgery was also assessed at 6 and 12 months. Mean VAS improved from 79.8 at v baseline to 30.0 and 30.4 at 6 and 12 months, respectively. Mean ODI improved from 55.2 at baseline to 32.5 and 31.4 at 6 v and 12 months. At 6 and 12 months, 93 and 87% of subjects, respectively, were somewhat or very satisfied and 92 and 91%, v respectively, would have the procedure again. Follow-up at 24 months demonstrated sustainability of quality-of-life scores v using EuroQol-5 Dimension (EQ5D), as well as a decrease from 76.2% at baseline of opioid usage to 55.0% at 24 months v ($p<0.0001$). CT scan at 1 year demonstrated a high rate of bone adherence (97%) to at least 2 implants on both the iliac and v sacral sides with modest bone growth across the SIJ.[17]v

Polly et al.[18] described 2-year outcomes from a Level 1 multicenter randomized controlled trial (RCT) of MIS vs non-surgical v management (NSM) for SIJ dysfunction. One hundred and forty-eight subjects with SIJ dysfunction were randomly assigned v to MI SIJF with TTIs (SIJF, n=102) or NSM, n=46). SIJ pain score utilizing VAS, disability score utilizing ODI and quality of life v EQ5D scores were collected at baseline and at scheduled visits to 24 months. In the SIJF group, mean SIJ pain improved v rapidly and was sustained (mean improvement of 55.4 points) at month 24. The 6-month mean change in the NSM group v (12.2 points) was substantially smaller than that in the SIJF group (by 38.3 points, $p<0.0001$ for superiority). By month 24, v 83.1% and 82.0% received either clinical improvement or substantial clinical benefit, respectively, in VAS SIJ pain score. v Similarly, 68.2% and 65.9% had received clinical improvement or substantial clinical benefit in ODI score at month 24. In the v NSM group, these proportions were <10%. The rate of adverse events related to SIJF was low and only 3 subjects assigned v to SIJF underwent revision surgery within the 24-month follow-up period. v

In a long-term (3-year) follow-up, MI trans-iliac SIJF with TTIs continued to be associated with improved pain, disability, and v quality of life with relatively high satisfaction rates.[19] Subjects included in this Long Term Outcomes Study (LOIS) were v enrolled at 12 centers who participated in either INSITE or SIFI. INSITE is a prospective multicenter randomized trial of SIJF vs. v

NSM whose 2-year results showed high degrees of improvement in pain, disability and quality of life in the surgical group but v only modest responses in the non-surgical group. SIFI is a prospective multicenter single-arm clinical trial evaluating the v same procedure/device; the follow-up schedule and assessments were nearly identical, and 2-year results were similarly v positive. v

Study follow-up in LOIS consisted of phone calls postoperatively at years 2.5, 3.5, and 4.5 as well as in-clinic study visits at v years 3, 4, and 5. Phone calls were intended to maintain subject contact and assess for adverse events. At in-clinic visits, v subjects completed surveys to assess SIJ pain and LBP scores (VAS), ODI, quality of life (EQ5D) time trade-off (TTO) index, v and satisfaction. All questionnaires were administered by trained study research coordinators. Of 127 potentially eligible v INSITE/SIFI subjects, 103 were enrolled in LOIS. Mean preoperative SIJ pain score was 81.5 and mean preoperative ODI was v 56.3. At 3 years, mean SIJ pain score decreased to 26.2 (a 55-point improvement from baseline, p<0.0001). At 3 years, mean v ODI decreased to 28.2 (a 28-point improvement from baseline, p<0.0001). In all, 82% of subjects were very satisfied with the v procedure at 3 years. EQ5D TTO index improved by 0.30 points (p<0.0001). No adverse events definitely related to the study v device or procedure were reported. v

A comparative 6-year retrospective case series by Vanaclocha et al.[20] looked at MIS, radiofrequency denervation and CM for v SIJ pain. The study was not randomized, and some patients were unable to undergo radiofrequency ablation (RFA) or MIS v due to insurance reasons, so there was a pool of patients who had CM only. Out of the 152 patients who had a positive v response to SIJ infiltration, 74 continued with CM, 51 underwent SI denervation and 27 underwent SIJF. In the CM group, 63 v patients had 1-yr follow-up, and 2-, 3-, 4-, 5-, and 6-yr follow-up was available in 52, 43, 34, 23, and 16 patients, v respectively. In the SI denervation group, 47 had 1-yr follow-up and further follow-up (same time points) was available in 41, v 33, 23, 6, and 2 patients. In the SIJF group, 27 patients had 1-year follow-up and further follow-up was available in 24, 20, v 15, 6, and 1 patient. Pain relief was seen at 1 month after CM, SI denervation, and SIJF. However, pain returned to near v baseline levels in the CM and SI denervation groups with further follow-up. In contrast, SIJ pain remained low postoperatively v in the SIJF group. At 6 months and beyond, the mean difference in pain improvement between the CM and SIJF groups was v approximately 6 points (repeated measures analysis of variance, P<0.001), and the difference between the SI denervation v and SIJF groups was approximately 4.5 points (P<0.001). Similar findings were seen with ODI, which showed improvement v after SI infiltration but return of high scores within 6 months. ODI scores improved substantially after SIJF but returned to v baseline levels in the CM and SI denervation groups. Mean ODI differences beyond 6 months were as follows: SIJF vs CM, 24 v points (P<0.001); SIJF vs SI denervation, 17 points (P<0.001). No patient in the CM and SI denervation groups had an v improvement in ODI of at least 15 points at year 4; in contrast, all SIJF patients showed at least a 15-point improvement at v year 4 (P<0.001). v

There are other approaches in addition to the lateral approach that still result in transfixation rather than distraction. Raikar[21] v reported on a small series of 19 patients aged 44-84 years, with a median of 58 years, underwent SIJF using this technique. v The follow-up is between 7 and 30 months, with a median of 12 months. Eighteen patients had excellent pain relief. There v was no complication from the procedure, and the blood loss was minimal. All 8 patients who had follow-up radiographs v showed solid fusion. With the posterior oblique approach described in this paper, the screw entry point is on the upper outer v surface of the iliac crest. This negates the need to dissect through the gluteal fascia to reach the ileum. This decreases the v risk of injury to the superior gluteal neurovascular structures and the cuneal nerves. It also makes it a relatively bloodless v procedure, which can be performed in an outpatient setting. This contrasts with the lateral approach in which the average v blood loss has been reported to be between 31 and 42.8 cc, and with an average length of stay between 0.8 and 1.9 v days.[15,16] The posterior oblique approach also allows the surgical trajectory to remain within the ileum and sacrum, resulting v in minimal soft tissue manipulation. In the straight posterior approach in which a bone plug is inserted into the joint, there is v distraction of the joint.[19] This contrasts with the posterior oblique approach, in which the screws decrease movement in the v joint by bringing the joint surfaces together. Theoretically, bringing the joint surfaces together should be more effective in v decreasing pain because there is less room for movement within the joint. In addition, in the posterior approach, because the v joint space is expanded, the bone graft may move, if fusion does not occur. v

Arthrodesis without Placement of Transfixation Device

The aforementioned transfixation procedure is typically performed from a lateral approach. The procedures that are non- v transfixation approaches are usually performed from a dorsal (posterior) approach though at times are combined into dorsa- v lateral approach. Rather than transfixing the SIJ, these procedures utilize distraction arthrodesis. v

MI posterior SIJF was first introduced as a procedure in 2008 for the treatment of SIJ dysfunction. This procedure attempts to v stabilize the SIJs by fusing the sacrum to the ilium with allograft material, limiting movement of the joint.[22] The posterior v (dorsal) SIJF procedure is distinct from lateral trans-iliac MIS SIJF using transfixing devices in several ways[9]: v

- The surgeon's work effort is distinct with the dorsal procedure requiring less surgical dissection, and the procedure v generally takes less time. v
- Initial stabilization is not achieved via transfixation with a laterally placed device, but rather by tensioning of the v ligaments supporting the SIJ via placement of a bone graft or allograft implant. v
- Long-term stabilization or fusion is achieved via distraction arthrodesis rather than by integration of the surrounding v bone of the ilium and sacrum. v
- Distraction arthrodesis of the SIJ consists of placement of an implant or bone allograft into the ligamentous portion of v the SIJ, this places the supporting ligaments under tension. v
- Bone graft and/or recombinant human bone morphogenetic protein are utilized to achieve bone fusion. v

Placement of SIJF allograft implants via a posterior approach is intended to be less invasive and avoid risks associated with v encountering the neurovascular bundle.[23] Examples of posterior SIJ stabilization devices are CornerLoc™ (Foundation v Fusion Solutions, LLC.), TransFasten™v (Captiva Spine®), and LinQ™(PainTEQ. v

Based on the FDA's criteria for determining whether a structural allograft averts regulatory oversight and classification as a v drug/device/biologic, mineralized bone allografts were judged to meet the Agency's definitional descriptions for minimal v manipulation and homologous use when complying with the American Association of Tissue Banks' (AATB) accredited v guidelines for bone allograft harvesting, processing, storing and transplanting. Thus, these products do not require FDA v medical device clearance. Radiographic fusion rates achieved with mineralized bone allografts were uniformly high (>85%) v across 3 published systematic reviews. Little variation was found in the fusion rates irrespective of anatomical location, v allograft geometry, dimensions or indication, and in most cases, the rates were similar to those for autologous bone alone.[24]v

This posterior fusion approach aims to reduce neurological complications by avoiding the sacral foramen, passes through v and manipulating less soft tissue, avoiding nervous and arterial structures, and decreasing post-op recovery time. Unlike the v lateral approach which typically requires patients to undergo general anesthesia, the posterior approach can be performed v under conscious sedation with local anesthetic and is typically an outpatient day surgery procedure.[25]v

Initial research of this method was first conducted on cadavers. Six cadaveric SIJ specimens were tested under intact, v unilateral fixation, and bilateral fixation conditions. The total range of motion (ROM) of the SIJ in flexion-extension, lateral v bending, and axial rotation were evaluated by an optical tracking system, in a multidirectional flexibility pure moment model, v between +/- 7.5 Nm applied moment loads. The centers of the instantaneous axis of rotation (cIAR) of the SIJ were evaluated v during flexion-extension loading. A correlation analysis was performed between the ROM reduction in flexion-extension upon v implantation and shift of the cIAR to the graft implantation site. RESULTS: Unilateral and bilateral fixations generated SIJ v ROM reductions in flexion-extension, lateral bending, and axial rotation motions. Fixation shifted the cIAR to the graft v implantation site. Reduction in the total ROM had a moderate correlation with the shift of the cIAR. The conclusion was that v the novel posterior approach presented a multifaceted mechanism for stabilizing the joint: first, by the reduction of the total v ROM in all planes of motion; second, by shifting the centers of the cIAR towards the implant's location in the predominant v plane of motion, ensuring little to no motion at the implantation site, thus promoting fusion in this region.[26] During flexion– v extension, the posterior approach is equivalent to the lateral approach, while producing superior stabilization during lateral v bend and axial rotation.[27]v

Deer et al.[25] conducted a multicenter retrospective observational study of patients with refractory SIJ pain treated by v interventional pain physicians at 1 of the 8 different pain management centers. A total of 111 patients were included in the v study and underwent posterior SIJF via the LinQ™ SIJF procedure for refractory SIJ-related pain following the use of spinal v cord stimulation (SCS), interspinous spacer (ISS), intrathecal drug delivery (IDDS), and/or minimally invasive lumbar v decompression (MILD). Overall, the mean patient reported pain relief following posterior SIJF was 67.6%. In patients with a v history of failed back surgery syndrome, the mean patient reported pain relief was 76.5%. In this retrospective case series of v patients with continued intolerable pain following SCS, ISS, IDDS, or MILD, the posterior SIJF device provided significant pain v relief in a salvage manner.[25]v

Caheuque et al.[28] conducted a retrospective cohort study that analyzed data from 45 patients who underwent SIJF. Included v patients were >/=50 years old, nonresponsive to conservative treatment. Subjects were divided into 2 cohorts based on the v SIJF technique. Primary outcomes were pain relief, measured by VAS, and functional improvement, determined by the ODI; v both were recorded and assessed at baseline, postoperative, and the change from pre- to postoperative. Additionally, data v regarding patient demographics, previous lumbar fusion, operative time, and duration of hospital stay were collected and v analyzed. Baseline demographic and clinical variables exhibited no significant differences in distribution between groups. The v posterior oblique cohort demonstrated a substantial reduction in operative time (over 50%) and duration of hospital stay v compared to lateral cohort. Pain relief (postoperative VAS: lateral 3.5+/-1.7 vs. posterior oblique 2.4+/-1.5 [p=0.02]) and v

functional improvement (postoperative ODI: lateral 29.6+/-7.3 vs. posterior oblique 21+/-5.7 [p</=0.001]) were significantly v better in the posterior oblique group. Pre- to postoperative improvement analysis indicated greater reduction in pain (VAS: v lateral -4.4+/-1.9 vs. posterior oblique -6.1+/-1.5 [p=0.002]) in the posterior oblique group. Their conclusion was that v compared to the lateral technique group, patients undergoing MI SIJF through the posterior oblique technique experienced v greater pain relief and demonstrated a trend toward better functional improvement, with shorter operative times and v duration of hospital stay. They suggested that the posterior oblique technique may be more efficient and beneficial to v manage patients suffering from chronic SIJ pain through joint fusion and suggested further studies. v

Sayed et al.[29] conducted a multicenter 12-month retrospective analysis of the long-term efficacy and safety of the device, v with sub-analysis of patients with prior lumbar fusions. Patients with sacroiliitis refractory to conservative care with short- v term benefit from diagnostic local anesthetic SIJIs receiving MI posterior approach SIJF with allograft were included from v different centers including both academic and private practice. Numeric rating scale (NRS) scores at baseline (pre- v procedural) and most recent follow-up were reviewed across 3 institutions. Of 110 patients who received MI SIJF, 50 patients v had sufficient data for evaluation of outcomes at least 12 months post-implant. The average time out from implant at follow- v up was 612.2 days for all unique patients. The average NRS was 6.98 pre-fusion and 3.06 at last follow-up. Twenty-four v patients had prior lumbar surgery of which 17 had prior lumbar fusions. Average NRS for this subset was 6.85 at baseline v and 2.86 at last follow-up with an average follow-up of 613.2 days out from implant. No major adverse events or v complications were associated with any of the 50 implants. This study concluded that the evidence suggested that MI v posterior SIJF is a viable approach for medically refractory sacroiliitis management with long-term efficacy and safety. v However, further prospective studies are needed to fully evaluate this technique. v

Calodney et al.[30] is presently conducting a prospective safety and efficacy trial of this approach in the SECURE trial. This is a v multicenter, prospective, single arm study which was performed after patient identification and treatment with the novel v posterior fusion, single point transfixation system and followed for 24 months. Target enrollment is 100 patients. Interim v results on the first 69 consecutive patients at 6 months has been presented. Primary endpoint at 6-month analysis was pain v intensity reduction by VAS and functional improvement by ODI. Adverse events were assessed for safety analysis. RESULTS: v In total, 69 patients were identified for this analysis. At 6 months, a mean improvement of 34.9 was identified by a reduction v in VAS and functional improvement was demonstrated by a mean reduction in ODI of 17.7. There were 3 adverse events, all v unrelated to the device. The conclusion by Calodney was that the posterior single point transfixation is safe and efficacious v for the treatment of SIJ dysfunction with statistical improvements in pain and function. The results from the 12-month follow- v up have yet to be published. v

Analysis of Evidence (Rationale for Determination)

There is moderate quality evidence that MI arthrodesis with placement of transfixation device for SIJF is an acceptable option v for patients with chronic SIJ dysfunction due to degenerative sacroiliitis and SIJ disruptions unresponsive to non-surgical v treatments. Implants are consistently associated with improved pain and disability from baseline without substantial safety v concerns. This improvement appears to be sustained in the long term. Because diagnostic techniques for SIJ dysfunction can v be unreliable, this may be a potential confounding factor in analysis of treatment protocols. Because of these issues, the v North American Spine Society (NASS) reports there is insufficient evidence to make a recommendation for or against SIJF v compared with medical treatment for the treatment of LBP due to SIJ dysfunction. v

The level of support in the clinical literature for the non-transfixation procedure is far lower than for the transfixation v procedure.[31] There were no systematic reviews, with or without meta-analysis, or RCTs found in the literature search. The v evidence that exists is of low quality and is entirely industry supported. The longest observation period published has been v for 6 months. This procedure is not recommended by the ISASS, while it does state that transiliac procedures for SIJF have v become a recognized safe, predictable, and preferred surgical method for the management of intractable, debilitating v primary or secondary SIJ pain disorders.[31] Query of other payer LCDs reveals that for those that have an LCD on MIS of SIJ, v MI posterior dorsal approach to access the SIJ, including use of implants other than those which are placed across the joint v (i.e., transfixing) to promote fusion (e.g., allograft , nonmetallic implants), is considered experimental, investigation, or v unproven. Based on all these factors, the MIS approach that does not transfix the SIJ is not considered reasonable and v necessary. v

Proposed Process Information v

Synopsis of Changes

Changes	Fields Changed
Not Applicable v	N/A v

Associated Information

N/A v

Sources of Information

Cigna: Lumbar Fusion for Spinal Instability and Degenerative Disc Conditions, Including Sacroiliac Fusion (cigna.com) v

United Healthcare: Sacroiliac Joint Interventions v

BCBS of Massachusetts: Diagnosis and Treatment of Sacroiliac Joint Pain v

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Open Meetings

Meeting Date	Meeting States	Meeting Information
04/11/2024 v	Alabama v Georgia v North Carolina v South Carolina v Tennessee v Virginia v West Virginia v	Web Conference v

Contractor Advisory Committee (CAC) Meetings

N/A v

MAC Meeting Information URLs
Open Meeting Information 9

Proposed LCD Posting Date
N/A 9

Comment Period Start Date
03/28/2024 9

Comment Period End Date
05/11/2024 9

Reason for Proposed LCD
- Provider Education/Guidance 9

Requestor Information
This request was MAC initiated. 9

Contact for Comments on Proposed LCD
Part B Policy 9
PO Box 100238 (JM) or PO Box 100305 (JJ) 9
AG-275 9
Columbia, South Carolina 29202- 9
B.Policy@PalmettoGBA.com 9

Associated Documents 9

Attachments
There are no attachments for this LCD. 9

Related Local Coverage Documents
This LCD version has no Related Local Coverage Documents. 9

Related National Coverage Documents
This LCD version has no Related National Coverage Documents. 9

Keywords 9

- MIS 9
- SIJ 9
- SIJF 9
- transfixation 9
- non-transfixation 9