PROPOSED Local Coverage Determination (LCD): Minimally Invasive Surgical (MIS) Fusion of the Sacroiliac Joint (SIJ) (DL39025)

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Contractor Information

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATE(S)
Palmetto GBA	10111 - MAC A	10111 - MAC A	J - J	Alabama
Palmetto GBA	10112 - MAC B	10112 - MAC B	J - J	Alabama
Palmetto GBA	10211 - MAC A	10211 - MAC A	J - J	Georgia
Palmetto GBA	10212 - MAC B	10212 - MAC B	J - J	Georgia
Palmetto GBA	10311 - MAC A	10311 - MAC A	J - J	Tennessee
Palmetto GBA	10312 - MAC B	10312 - MAC B	J - J	Tennessee
Palmetto GBA	11201 - MAC A	11201 - MAC A	J - M	South Carolina

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATE(S)
Palmetto GBA	11202 - MAC B	11202 - MAC B	J - M	South Carolina
Palmetto GBA	11301 - MAC A	11301 - MAC A	J - M	Virginia
Palmetto GBA	11302 - MAC B	11302 - MAC B	J - M	Virginia
Palmetto GBA	11401 - MAC A	11401 - MAC A	J - M	West Virginia
Palmetto GBA	11402 - MAC B	11402 - MAC B	J - M	West Virginia
Palmetto GBA	11501 - MAC A	11501 - MAC A	J - M	North Carolina
Palmetto GBA	11502 - MAC B	11502 - MAC B	J - M	North Carolina

Proposed LCD Information

Document Information

Source LCD ID
N/A

Proposed LCD ID
DL39025

Proposed LCD Title
Minimally Invasive Surgical (MIS) Fusion of the Sacroiliac Joint (SIJ)

CMS National Coverage Policy

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

Coverage Guidance

Coverage Indications, Limitations, and/or Medical Necessity

Minimally invasive surgical (MIS) fusion of the sacroiliac joint (SIJ) is considered medically necessary when ALL of the following criteria are met:

- Have moderate to severe pain with functional impairment and pain that persists, despite a minimum 6 months of intensive nonoperative treatment that must include medication optimization, activity modification, bracing, and active therapeutic exercise targeted at the lumbar spine, pelvis, SIJ and hip including a home exercise program

- Patient's report of typically unilateral pain that is caudal to the lumbar spine (L5 vertebrae), localized over the posterior SIJ, and consistent with SIJ pain

- A thorough physical examination demonstrating localized tenderness with palpation over the sacral sulcus (Fortin's point, i.e., at the insertion of the long dorsal ligament inferior to the posterior superior iliac spine (PSIS) in the absence of tenderness of similar severity elsewhere (e.g., greater trochanter, lumbar spine, coccyx) and that other obvious sources for their pain do not exist

- Positive response to a cluster of 3 provocative tests (e.g., thigh thrust test, compression test, Gaenslen's test, distraction test, Patrick's sign, posterior provocation test)

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

- Diagnostic imaging studies that include ALL of the following:

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

- At least 75% reduction of pain for the expected duration of 2 anesthetics (on separate visits, each with a different duration of action), and the ability to perform previously painful maneuvers, following an image-guided, contrast-enhanced intra-articular SIJ injection

- A trial of at least 1 therapeutic intra-articular SIJ injection (i.e., corticosteroid injection)

Summary of Evidence

The SIJ has been implicated as a source of chronic low back pain in 15% to 30% of patients.[1] The SIJ contains both mechanoreceptors and nociceptive receptors such that SIJ pathology leads to pain in the buttocks, lower back, groin or leg. SIJ degeneration commonly occurs, especially after lumbar fusion. Patients with SIJ pain report Oswestry Disability Index (ODI) scores in the 50s, and the burden of disease associated with SIJ pain is at least as high as that associated with other musculoskeletal conditions, such as hip osteoarthritis, degenerative spondylolisthesis, or spinal stenosis; conditions that are often treated surgically.[2] Risk factors for SIJ dysfunction may include abnormal gait, scoliosis, degenerative and inflammatory arthritis, previous lumbar spinal surgery, trauma, and childbirth.[3] In addition, the SIJ may be a referred site of pain, including from a degenerative disc at L5-S1, spinal stenosis, or osteoarthritis of the hip.

Diagnosis remains problematic, with no universally accepted reference standard. Current best practice diagnostic techniques start with pain provocation testing. A positive result on 3 or more pain provocation tests, such as Gaenslen's, flexion abduction external rotation (FABER), compression, distraction and thigh thrust, are used as criteria for further testing to confirm the SIJ as the primary pain generator. Typically, diagnostic blocks and intraarticular fluoroscopically guided injections are then used for confirmation of 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 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 with other diagnostic techniques. Radiographic utility lies more in excluding the presence of other causes of pain that would not be properly addressed by percutaneous SIJF.[4]

The mainstay of therapy for disorders of the SIJ has been nonoperative treatment, including activity modification, NSAIDs, physical therapy, radiofrequency neurotomy and SIJ injections. High quality clinical evidence corroborating the benefits of these non-surgical therapeutic options is limited by small patient populations, lack of placebo controls, and failure to utilize validated outcome measures.[5] When these modalities fail, the International Society for the Advancement of Spine Surgery (ISASS) recommends SIJ arthrodesis.[6]

Traditional open SIJF procedures are complex and invasive, involving open exposure of the joint with instrumented fixation and/or bone graft harvesting, and are typically associated with lengthy hospital stays, large blood loss and prolonged recovery times. Outcomes of traditional SIJF procedures were observed to be so poor with a high rate of reported non-union that these procedures were virtually abandoned over the last few decades.[7] More recently, minimally invasive techniques with novel implants have been developed that are designed to confer the benefits of permanent SIJ stabilization, but with a more reasonable safety profile. To date, most published data describe use of a lateral transfixing approach. While a small number of studies describe use of hollow modular anchor screws, a larger number describe use of triangular titanium implants (TTI) with a porous surface. These implants serve to minimize rotation and maximize surface area at the SIJ.[8]

Kube and Muir[9] evaluated 1-year clinical results from a cohort of 18 patients with SIJ pain unresponsive to conservative treatment who underwent MIS SIJFs. At 12 months, the overall fusion rate was 88%. Back and 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 ($p<0.001$), respectively. Disability scores improved from 61.0 to 40.5 ($p<0.009$) on the ODI. No major complications were reported.

Similar results were noted by Rainov et al.[10] in their retrospective study of 160 patients with painful SIJ dysfunction who underwent unilateral or bilateral SIJF using TTI. By 12 months, pain decreased from 8.0 to 2.5 (VAS) ($p<0.0001$) and disability (ODI) from 45.3 to 16.4 ($p<0.001$).

A prospective multicenter single arm interventional trial looking at 172 subjects with MIS for SIJ dysfunction was conducted by Duhon et al.[11] Patients completed VAS and ODI assessments preoperatively and at 1, 3, 6, and 12 months postoperatively. Patient satisfaction with surgery was also assessed at 6 and 12 months. Mean VAS improved

from 79.8 at 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 and 12 months. At 6 and 12 months, 93 and 87% of subjects, respectively, were somewhat or very satisfied and 92 and 91%, respectively, would have the procedure again. Follow-up at 24 months demonstrated sustainability of quality of life scores using EuroQol-5D (EQ-5D) as well as a decrease from 76.2% at baseline of opioid usage to 55.0% at 24 months ($p<0.0001$). CT scan at 1 year demonstrated a high rate of bone adherence (97%) to at least 2 implants on both the iliac and sacral sides with modest bone growth across the SIJ.[12]

Polly et al.[13] described 2-year outcomes from a Level 1 multicenter randomized controlled trial of MIS vs non-surgical management (NSM) for SIJ dysfunction. One hundred and forty-eight subjects with SIJ dysfunction were randomly assigned to minimally invasive SIJF with TTI (n=102) or NSM (n=46). SIJ pain score utilizing VAS, disability score utilizing ODI and quality of life EQ-5D scores were collected at baseline and at scheduled visits to 24 months. In the SIJF group, mean SIJ pain improved rapidly and was sustained (mean improvement of 55.4 points) at month 24. The 6-month mean change in the NSM group (12.2 points) was substantially smaller than that in the SIJF group (by 38.3 points, $p<0.0001$ for superiority). By month 24, 83.1% and 82.0% received either clinical improvement or substantial clinical benefit, respectively, in VAS SIJ pain score. Similarly, 68.2% and 65.9% had received clinical improvement or substantial clinical benefit in ODI score at month 24. In the NSM group, these proportions were <10%. The rate of adverse events related to SIJF was low and only 3 subjects assigned to SIJF underwent revision surgery within the 24-month follow-up period.

In a long-term (3-year) follow-up, minimally invasive trans-iliac SIJF with TTI continued to be associated with improved pain, disability, and quality of life with relatively high satisfaction rates.[14] Subjects included in this Long Term Outcomes Study (LOIS) were enrolled at 12 centers who participated in either INSITE or SIFI. INSITE is a prospective multicenter randomized trial of SIJF vs NSM, whose 2-year results showed high degrees of improvement in pain, disability and quality of life in the surgical group but only modest responses in the non-surgical group. SIFI is a prospective multicenter single-arm clinical trial evaluating the same procedure/device; the follow-up schedule and assessments were nearly identical, and 2-year results were similarly positive.

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

A comparative 6-year retrospective case series by Vanaclocha et al.[15] looked at MIS, radiofrequency denervation and conservative management (CM) for SIJ pain. The study was not randomized, and some patients were unable to undergo radiofrequency ablation (RFA) or MIS due to insurance reasons, so there was a pool of patients who had CM only. Out of the 152 patients who had a positive response to SIJ infiltration, 74 continued with CM, 51 underwent SI denervation and 27 underwent SIJF. In the CM group, 63 patients had 1-year follow-up, and 2-, 3-, 4-, 5-, and 6-yr follow-up was available in 52, 43, 34, 23, and 16 patients, respectively. In the SI denervation group, 47 had 1-year follow-up and further follow-up (same time points) was available in 41, 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, 15, 6, and 1 patients. Pain relief was seen at 1 month after CM, SI denervation, and SIJF. However, pain returned to near baseline levels in the CM and SI denervation groups with further follow-up. In contrast, SIJ pain remained low postoperatively in the SIJF group. At 6 months and beyond, the mean difference in pain improvement between the CM and SIJF groups was approximately 6 points (repeated measures analysis of variance, $p<0.001$), and the difference between the SI denervation and SIJF

groups was approximately 4.5 points (p<0.001). Similar findings were seen with ODI, which showed improvement after SI infiltration, but return of high scores within 6 months. ODI scores improved substantially after SIJF, but returned to baseline levels in the CM and SI denervation groups. Mean ODI differences beyond 6 months were as follows: SIJF vs CM, 24 points (p<0.001); SIJF vs SI denervation, 17 points (p<0.001). No patient in the CM and SI denervation groups had an improvement in ODI of at least 15 points at year 4; in contrast, all SIJF patients showed at least a 15-point improvement at year 4 (p<0.001).

Analysis of Evidence
(Rationale for Determination)

There is moderate quality evidence that minimally invasive SIJF is an acceptable option for patients with chronic SIJ dysfunction due to degenerative sacroiliitis and sacroiliac joint disruptions unresponsive to non-surgical treatments. Implants are consistently associated with improved pain and disability from baseline without substantial safety concerns. This improvement appears to be sustained in the long term. Because diagnostic techniques for SIJ dysfunction can be unreliable, this may be a potential confounding factor in analysis of treatment protocols.

Proposed Process Information

Synopsis of Changes

CHANGES	FIELDS CHANGED
Not Applicable	N/A

Associated Information

N/A

Sources of Information

N/A

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Open Meetings

MEETING DATE	MEETING STATE(S)	MEETING INFORMATION
08/02/2021	**South Carolina**	Columbia

Contractor Advisory Committee (CAC) Meetings

N/A

MAC Meeting Information URL(s)

Open Meeting Information

Proposed LCD Posting Date

N/A

Comment Period Start Date

07/22/2021

Comment Period End Date

09/04/2021

Released to Final LCD Date

Not yet released.

Reason for Proposed LCD

- Provider Education/Guidance

Contact for Comments on Proposed LCD

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Associated Documents

Attachments

N/A

Related Local Coverage Documents

N/A

Related National Coverage Documents

N/A

Public Version(s)

N/A

Keywords

- SIJ
- SIJF
- MIS