June 17, 2015

Dr. Olatokunbo Awodele
WPS Medicare
3333 Farnam Street
Omaha, NE 68131

RE: Comments to draft LCD DL35994 - Percutaneous minimally invasive fusion/stabilization of the sacroiliac joint for the treatment of back pain

Dear Dr. Awodele:

I am writing to submit comments to draft LCD DL35994 - Percutaneous minimally invasive fusion/stabilization of the sacroiliac joint for the treatment of back pain.

ISASS, the International Society for the Advancement of Spine Surgery, is a global, scientific and educational society organized to provide an independent venue to discuss and address the issues involved with all aspects of basic and clinical science of motion preservation, stabilization, innovative technologies, MIS procedures, biologics and other fundamental topics to restore and improve motion and function of the spine. On behalf of our more than 1,500 members, I am writing to oppose WPS Medicare's draft non-coverage determination for minimally invasive sacroiliac joint fusion (MIS SIJ fusion). ISASS supports decision-making at the physician-patient level based on medical necessity and achieving the best outcomes to address the patient's medical condition and therefore supports patient access to and coverage of MIS SIJ fusion. ISASS respectfully requests WPS Medicare develop a coverage policy based on all relevant literature and consider inclusion of the ISASS coverage criteria for MIS SIJ fusion into its coverage policy.

WPS Medicare supports its draft non-coverage determination of MIS SIJ fusion with five sources of literature and states that the sacroiliac joint (SIJ) "remains a controversial source of primary low back pain, and surgery is rarely performed for sacroiliac joint dysfunction. The anatomical location makes it difficult to examine in isolation and many provocative tests place mechanical stresses on adjacent structures. In addition, several other structures may refer pain to the sacroiliac joint. Fusion/stabilization of the sacroiliac joint for the treatment of back pain presumed to originate from the SI joint is considered investigational, including but not limited to percutaneous and minimally invasive techniques and are not eligible for coverage."

These statements do not accurately reflect the current literature on MIS SIJ fusion. An across-the-board non-coverage determination by WPS Medicare unduly restricts patient access to a procedure that is shown to be successful in reducing pain and improving quality of life for patients. ISASS disagrees with WPS Medicare's conclusions based on information we have gathered over the past several years from surgeons performing MIS SIJ fusion and from a systematic review of all available data and literature on the procedure. Based on the data and literature, in March 2014, ISASS issued a comprehensive policy statement on MIS SIJ fusion. The ISASS policy statement includes a discussion on the SIJ as a pain generator, information on diagnosing the SIJ as the primary source of pain, a discussion of non-surgical and surgical treatment options and recommended coverage criteria for MIS SIJ fusion.

The SIJ as a Pain Generator

The SI joints are paired diarthrodial articulations of the sacrum and ilium and serve as the connection between the spine and pelvis. The small amount of motion in the joint (2-4 degrees) occurs primarily through nutation and counternutation of the sacrum.(32) There are no muscles that cross solely the SI joint, thus there are no prime movers. Instead, movement is dependent on the articulations and movement within the lumbopelvic hip complex (e.g. flexion at the hip results in diminished lumbar lordosis and counternutation of the sacrum, extension of the lumbar spine results in nutation of the sacrum).(33) The subchondral bone, capsule, and surrounding ligaments of the SI joint are rich in nociceptive pain fibers.(1) Though the specific segments responsible are a subject of debate, it is generally accepted that the posterior primary rami of the lower lumbar and upper sacral segments innervate the joint.(32)

The SIJ is a well-known cause of pain in the lumbopelvic hip complex.(32, 34-36) There are many possible etiologies including, but not limited to, degenerative sacroiliitis, primary osteoarthritis, post-traumatic osteoarthritis or incongruence, adjacent joint degeneration as a result of lumbar spinal conditions and procedures, and idiopathic causes. Low back pain is a worldwide epidemic and one of the top 3 causes of health related chronic pain in developed countries.(37) Low back pain is associated with increased risk of falling,(38) which in an elderly population, can result in hip and/or spinal fractures. The annual expenditures for chronic back pain are astounding and exceed $100 billion in the United States alone.(39)

While lumbar spinal structures are important factors in to consider in patients who presented with low back pain, substantial evidence suggests that the SIJ may be the pain generator in many of these patients.(34-35, 40-41) In patients who fail to improve after successful lumbar spinal arthrodesis, SIJ pain may explain the delayed onset of postoperative pain or failure to improve as a result of possible misdiagnosis or presence of other pain generators.(42-45) Ha et

al. reported radiographic evidence of SIJ degeneration in up to 75% of patients treated with lumbar spinal fusion.(46) DePalma et al. determined the SIJ as the pain generator in 43% of patients complaining of persistent pain after lumbar spinal fusion.(47)

A recent study by Cher et al. reported the significance of the burden created by SIJ pain.(48) The impact of SIJ pain on pain and function is commensurate with other common orthopedic conditions, such as hip and knee osteoarthritis, spinal stenosis and degenerative spondylolisthesis, all of which are treated surgically. The cost of conservative care in the patients diagnosed with SIJ disorders is substantial. Ackerman et al., using the MarketScan Commercial Claims and Encounters database, estimated an approximate cost of $1.6 billion per 100,000 covered lives (including Medicare and private insurance) for conservative treatment.(50) Furthermore, if we assume that 15% of the $100 billion spent on low back pain should be directed at treating SIJ pain, a conservative estimate of the cost of SIJ pain is upwards of $15 billion in the United States alone. It is paramount that correctly elucidating the primary pain generator in patients presenting with low back pain is crucial for adequate treatment and return to function.

Diagnosing the SIJ as a Primary Source of Pain

Because SIJ pain can be confused with lumbar and hip pain, proper diagnosis of SIJ pain is key to appropriate patient management. Patients with SIJ pain typically report pain in the buttocks, with possible radiation into the groin or upper legs. Specific physical examination tests that stress the SIJ (e.g., distraction test, compression test, thigh thrust, FABER (Patrick's) test, Gaenslen's maneuver, sacral sulcus tenderness) are typically performed in the physician's office; in combination, these tests are thought to be predictive of SIJ pain.(2) Apart from ankylosing spondylitis, in which MRI can show edema consistent with inflammation, imaging of the SIJ typically does not provide valuable diagnostic information. Rather, imaging is used to ensure that the patient does not have alternative diagnoses that could mimic SIJ pain (e.g., hip osteoarthritis, occasionally L5/S1 spine degeneration).

The diagnosis of SIJ pain is confirmed by performing a fluoroscopy guided percutaneous SIJ block with local anesthetic (e.g., lidocaine). An acute reduction in pain of 75%(3,4) (using visual analog scale) or more compared to immediately prior to the block is diagnostic as a positive test and indicates that the injected joint is the pain generator based on published studies. A study of patients undergoing blinded injection of saline or local anesthetic showed markedly high responses to the latter, validating the test.(5) Because other pathologic processes can coexist with SIJ pain, in order to assure that SIJ pain is the primary (or only) diagnosis, the physician should ensure that non-SIJ causes of pelvic or lower back pain are ruled out on the basis of history, physical exam and/or imaging; examples of alternative diagnoses include pelvic fracture, tumor, infection, skeletal deformity, hip arthritis, and degeneration of the L5/S1 disc or other base-of-spine pathologies.

Occasionally, bilateral SIJ pain can occur. Diagnosis of bilateral SIJ pain must be made on the basis of typical history, physical examination showing bilateral SIJ pain with maneuvers (listed above) that stress the SIJ, and bilateral acute pain relief upon bilateral, fluoroscopy-guided SIJ block.

Surgical vs. Non-Surgical Treatment Options and Prevalence of Surgery

Multiple non-surgical treatments for SIJ pain are available, including pain medications (e.g., non-steroid anti-inflammatory agents, opioids), physical therapy, steroid injections into the SIJ and radiofrequency ablation of the SIJ. Most patients respond adequately to conservative treatment. However, a small number of patients do not have satisfactory pain relief and may be functionally disabled (e.g., cannot sit or stand for more than five minutes, cannot perform normal activities of daily living cannot walk up or down stairs, may require a wheelchair, may require chronic opioid treatment). Patients with a diagnosis of SIJ pain who experience pain for a minimum of six months and who do not respond to an adequate course of non-surgical treatment may be considered for SIJ fusion.

Ackerman et al. observed that the total number of estimated SIJ fusion procedures increased from 189 in 2001 to 3,900 in 2012. MIS SIJ fusions accounted for an increasing percentage of the total, ranging from 0% in 2008 to 76% in 2011, with an estimate of 85% for 2012.(50) ISASS and the Society for Minimally Invasive Spine Surgery (SMISS) conducted a survey of its 2,200 members in 2013 on the utilization of MIS SIJ fusion. The survey yielded 212 responses and the results showed that the percentage of MIS SIJ fusion procedures increased from 39% in 2009 to over 87% in 2012.Total MIS SIJ fusion procedures increased from 99 to 889 in the period from 2009 to 2012. Conversely, open procedures decreased from 152 in 2009 to 123 in 2012.(51) It is expected that the number of MIS SIJ fusion procedures will continue to increase as more surgeons learn the procedure and the clinical outcomes show patient improvement.

Coverage Rationale for Open and MIS SIJ Fusion

Open fusion of the SIJ can provide pain relief but recovery times are long and the complication rate is high.(6-10) Patients can experience significant intraoperative bleeding and require prolonged postoperative rehabilitation. Therefore, open fusion of the SIJ is best performed on patients who are not candidates for MIS SIJ fusion.(11)

In 2008, the FDA approved the first MIS device for SIJ fusion. MIS SIJ fusion surgery obtained a Category I CPT code beginning January 1, 2015. The procedure has been performed with several types of implants, including triangular, porous, titanium coated implants,(8–16) hollow modular screws,(17–19) titanium cages,(18) and allograft dowels(6). These devices are placed either inside or across the SIJ using a minimally invasive surgical approach. MIS SIJ fusion provides pain relief by acutely stabilizing the painful SIJ with subsequent fusion.

In addition to outcomes published of multiple retrospective case series,(8–10,15,21,22) published results from a prospective multi-center randomized controlled trial (RCT) of MIS SIJ fusion vs. non-surgical management(14) and a multi-center prospective single arm trial(13) have substantiated high rates of pain relief, improvement in functional measures (SF-36, ODI and EQ-5D) and a low rate of both revisions (<5%) and serious adverse events. Furthermore, these improvements are significantly greater in patients treated with MIS SIJ fusion compared to non-surgical management:

- VAS scores improved by 53 points in the fusion group vs. 12 points for patients treated by non-surgical management;

- ODI improved 30 points in the surgery group vs. 4.9 points in patients treated by non-surgical management;
- EQ-5D scores improved by 0.29 in the fusion group ($p<.0001$) vs. 0.05 points in the non-surgical management group;
- Mean scores for all SF-36 domains improved significantly in the surgery group while no improvement was seen for any domain in the non-surgical management group; and
- Mean SF-36 Physical Component Summary (PCS) improved by 12.7 points in the surgery group vs. 1.2 points in the non-surgical management group.

All values were highly statistically significant ($p<.0001$). In a multi-center retrospective review of 263 patients undergoing either open or MIS SIJ fusion, the latter was associated with statistically significant and clinically marked decreases in operating room time (mean 163 minutes for open vs. 70 minutes for minimally invasive), decreased blood loss (mean 288 cc vs. 33 cc), and decreased length of stay (5.1 vs. 1.3 days) as well as improved relief of pain at 1 (-2.7 points on 0-10 scale vs. -6.2 points) and 2-year (-2.0 vs. -5.6 points) follow-up (all differences are statistically significant.).(11) Two published studies report that favorable outcomes achieved at one year are sustained long term (up to 5-years).(12,16)

The complication rate for MIS SIJ fusion is low. Importantly, the rate of removal or revision is less than 2%.(13,14,23) Revisions can be required in the immediate postoperative period or after many months. Early revisions may include the need to reposition an implant that is impinging on a sacral nerve or removal of an implant due to infection.

In cases of bilateral SIJ pain, bilateral SIJ fusion may occasionally be indicated and is usually performed serially to minimize the impact on rehabilitation (i.e., patients who undergo simultaneous bilateral fusion procedures may be wheelchair or bed bound for several weeks, possible slowing overall recovery).

Recommended Coverage Criteria

ISASS developed and supports the following indications and limitations for coverage:

Indications for coverage include:

- Significant SI joint 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 because of pain from the SI joint(s);

- SI joint pain confirmed with typical pain reproduction on at least 3 positive physical provocative examination maneuvers that stress the SI joint;

- Confirmation of the SI joint as a pain generator with ≥ 75% acute decrease in pain immediately following fluoroscopically guided diagnostic intra-articular SI joint block using local anesthetic. This improvement is specifically accomplished in the immediate post-injection period when the anesthetic agent is active (i.e., 4 hours dependent on the agent, dose level, and concentration;

- 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, SI joint steroid injection or rhizotomy. 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 clearly considered, investigated and ruled out.

Limitations to coverage include:

- 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.

For your reference, I have included the ISASS policy statement as an attachment to this letter and respectfully request that WPS Medicare review and incorporate the ISASS coverage criteria into its coverage policy.

Additionally, it is vitally important that WPS Medicare has access to all available data and literature on MIS SIJ fusion before issuing a final coverage determination and corresponding coverage policy. After reviewing the articles cited in the draft Local Coverage Determination, ISASS noticed several articles of importance missing from the section titled "Sources of Information and Basis for Decision". For your reference and review, I have included a list of articles referenced in our MIS SIJ fusion policy statement and respectfully request WPS Medicare review these articles prior to issuing a final coverage determination and corresponding coverage policy.

Thank you for your time and consideration of our comments and policy statement. ISASS supports patient access to and coverage of MIS SIJ fusion and respectfully requests WPS Medicare develop a coverage policy based on all relevant literature and consider inclusion of the ISASS coverage criteria into its coverage policy. Please feel free to contact us with questions or requests for discussion.

Sincerely,

Gunnar B.J. Andersson, MD, PhD
Co-President, ISASS

Enclosure: ISASS Policy Statement – MIS SIJ Fusion

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