



American Society of Neuroradiology

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**RE: Final LCD: Minimally Invasive Arthrodesis of the Sacroiliac Joint**  
CGS - LCD L39802  
Noridian - LCD L39812  
Palmetto - LCD L39797

Dear Drs., Loveless, Moynihan, and Volkar,

On behalf of the many providers and Medicare beneficiaries we represent who are candidates for important sacroiliac (SI) joint arthrodesis therapy options, we appreciate the opportunity to share concerning issues related to the process for development of the aforementioned LCDs, all titled 'Minimally Invasive Arthrodesis of the Sacroiliac Joint.' Please accept our comments as applicable to all three Medicare Administrative Contractors implicated in this letter.

As we noted in comments to the proposed LCDs, the policy position stating, 'MI Arthrodesis of the SIJ WITHOUT placement of a transfixation device is NOT considered medically reasonable and necessary,' could limit access to a safe, effective, and durable treatment option, potentially exacerbating healthcare disparities among Medicare patients. As the structure of these codes evolves, we would like to offer our assistance in reviewing the changes, presenting the evidence, and suggesting a path forward that preserves access to these procedures in patients in whom the evidence has proven benefit.

**As such, we respectfully request a moratorium on the implementation of these LCDs to facilitate this discussion while avoiding patient diversion to costly and less effective alternatives in the interim. Namely, we wish to present further evidence with respect to the selection criteria for minimally invasive sacroiliac joint fusion without placement of a transfixation device.**

A summary of our major concerns is listed below with statements in the proposed final language in the Analysis of Evidence (Rationale for Determination) section highlighted.



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1. **"The level of support in the clinical literature for the non-transfixation procedure, non-cortical piercing procedure is supported by very low- and low-quality evidence.33 "**
  - a. The comment about the level of support in the clinical literature is referenced with a publication by Lorio et al from 2020, which is before the publication of all of the data that was submitted in 2023 to support the Category 1 CPT code 27278 (approved for use starting January 2024). The literature was sufficient for the Cat 1 code, and additional evidence has since been produced, including one-year follow-up of a Level 2b trial showing comparable results to existing laterally placed implants with a much lower rate of adverse events and no consistent need for general anesthesia.
2. **"There are no studies which include a control group and current evidence does not provide confidence that the reported outcomes are due to the intervention. The study investigators acknowledge the need for further investigations which must establish if this technology is at least equivalent to current standard of care treatments and provide longer term data including safety."**
  - a. Early studies on SI fusion contained control groups that had negligible clinical improvement in pain and function compared to statistically significant improvements in pain, function and quality of life (1, 2). The control groups in these groups had, by definition, chronic SI joint pain and had already failed non-surgical management. All the existing literature submitted for Cat 1 approval included patients treated with SI joint fusion who had already failed non-surgical treatment. Additionally, there are no high quality published clinical studies that evaluate the effectiveness of pain medication, chiropractic care, yoga, and massage for the treatment of SI joint dysfunction. There is also no high-level clinical evidence that manual manipulation of the SI joint does not change position of the joint. The 12-month follow-up of cortical allograft fusion patients (CPT 27278) shows only one serious adverse event compared to 30 adverse events for the studies with control groups (1 - 3).
3. **"This procedure is not recommended by the ISASS, while it does state that transiliac procedures for SIJF have become a recognized safe, predictable, and preferred surgical method for the management of intractable, debilitating primary or secondary SIJ pain disorders.33 Based on all these factors, the MIS approach that does not transfix or pierce the cortices of the ilium or sacrum, the SIJ is not considered reasonable and necessary."**
  - a. The statement that this study is not recommended by ISASS references a 2020 paper by Lorio et al. (4) The first use of the cortical allograft for fusion was in 2012, but this was **not** a minimally invasive procedure. The **first review of evidence for minimally invasive posterior SI joint was not published until 2021, the year after the ISASS paper (5)**. Additionally, the comment about piercing the cortices is not applicable to this technique, which involves distraction arthrodesis that is not designed to penetrate prominently through the cortical bone. The review of evidence for the minimally invasive posterior approach concluded that, "Preliminary evidence reports consistent pain reduction with minimal complications" and was printed in 2021 in the International Journal of Spine Surgery, which is published by ISASS.



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In addition to the comments in the Rationale for Determination section, there are other comments or statements that are concerning. These are listed in the table below:

Comment or Statement	Source/Section	Rebuttal / Concern
<b>Palmetto</b>		
<p>“More recently, MI 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. These devices are presently termed transfixation devices by the American Medical Association (AMA) and transverse devices by the American Society for Testing and Materials (ASTM)”</p>	<p><a href="https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdId=39797&amp;ver=7">https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdId=39797&amp;ver=7</a></p> <p><b>Section: Arthrodesis of the Sacroiliac Joint (SIJ) Utilizing Intra-articular and/or Transarticular Device(s) with Cortical Piercing</b></p>	<p>This is not accurate for the new, posteriorly placed implants. It is also concerning that the key concepts of what constitutes a transverse vs. an in-line SI joint implant (as defined by the ASTM) are not understood. Under the 27278 policy, there will be in-line implants per ASTM. There are no transverse implants. Using this wording, an inline implant would be reported to the MAC as a CPT 27279 (the transfixation or piercing technique).</p> <p>The MACs rely on alignment of the nomenclature between the AMA and ASTM. Because this is not currently the case, this LCD should be withdrawn to correct these inaccuracies and facilitate the appropriate use of the nomenclature (i.e. posterior allograft implants vs. transverse implants).</p>
<p>“New language to CPT®, as of 2026...the procedure itself is limited by directionality.”</p>	<p><a href="https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdId=39797&amp;ver=7">https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdId=39797&amp;ver=7</a></p> <p><b>Section: Arthrodesis of the SIJ Utilizing Intra-articular Device(s) that do not pierce the cortices of the ilium or sacrum</b></p>	<p>There is currently a proposal by multiple Specialty Spine Societies to further alter the definition of SI joint procedure coding. The January 2025 RUC meeting is likely to address this topic and may provide clarity on how to proceed. Following this meeting, the February 2025 CPT Panel will convene to discuss a CCA on this same topic. If adopted, this CCA would further change the code definitions before the 2026 book is printed.</p> <p>It is therefore premature to finalize any LCD or policy based on definitions that will not be effective until 2026 and are not yet settled by the societies. A withdrawal of these final LCDs is necessary until such time as the CPT code ambiguity and controversy are resolved. Otherwise, the MACs will not know what procedures they will be covering.</p>
<p>We will add clarifying language</p>	<p><a href="https://www.cms.gov/medicare-coverage-">https://www.cms.gov/medicare-coverage-</a></p>	<p>Adding the ASTM definitions will introduce significant problems. For example, the definition for in-line implants (typically coded</p>



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<p>citing ASTM definitions as well.</p>	<p><a href="https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleId=59948&amp;ver=7">database/view/article.aspx?articleId=59948&amp;ver=7</a></p> <p><b>Response to Comments: Minimally Invasive Arthrodesis of the Sacroiliac Joint (SIJ) A59948 (Comment #10)</b></p>	<p>as CPT 27278) includes those with integrated fixation design features that transfix or pierce the cortex (coded as CPT 27279).</p> <p>We believe that this represents a misunderstanding by the MACs of the issues involved and provides additional justification for serious concern the MACs do not have a firm understanding of what they will and will not be covering. We therefore recommend withdrawing this final LCD prior to its effective date of 2/16/25 to allow for further discussion with your experts, including the societies represented here and their CPT Advisors, who are integrally involved in the CPT code development process.</p>
<p>We recommend that MACs seek guidance from the AMA, as well as from the Spine Specialty Societies, on the definitions of transfixation and fusion as they relate to these procedures. The number of SI joint implants commercially available in the market today is continuing to expand. The CPT® code definitions have left an unfortunate gap in the interpretation of which procedures (and associated technologies) “transfix” as currently defined by CPT® 27279, and which “distract” as currently defined by 27278.</p>	<p><a href="https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleId=59948&amp;ver=7">https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleId=59948&amp;ver=7</a></p> <p><b>Response to Comments: Minimally Invasive Arthrodesis of the Sacroiliac Joint (SIJ) A59948 (Comment #12)</b></p>	<p>ISASS and other societies are recommending that the MACs seek more guidance before enacting a suboptimal policy. We believe guidance from the Spine Specialty Societies has not been effectively utilized as evidenced by the premature finalization of this LCD. Instead, we request a withdrawal of this final LCD to solicit our feedback to make the best possible policy for Medicare patients. Otherwise, we will be overly restricted by noncoverage of important therapies for Medicare patients.</p>
<p>MACs may not institute a prior authorization process</p>	<p><a href="https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleId=59948&amp;ver=7">https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleId=59948&amp;ver=7</a></p>	<p>The societies are willing and in fact are planning to work with CMS on options for prior authorization requirements for 27278</p>



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<p>unless specifically instructed to do so by CMS.</p>	<p><a href="https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleId=59948&amp;ver=7">database/view/article.aspx?articleId=59948&amp;ver=7</a></p> <p><b>Response to Comments: Minimally Invasive Arthrodesis of the Sacroiliac Joint (SIJ) A59948 (Comment #14)</b></p>	<p>procedures. Until that occurs, there should be time for further discussion and withdrawal of the LCD pending the outcome of those discussions.</p>
<p>MACs should delay adoption of the proposed LCD pending clarification of the definitions for CPT® codes 27278 and 27279 by the AMA CPT® Editorial Panel.</p>	<p><a href="https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleId=59948&amp;ver=7">https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleId=59948&amp;ver=7</a></p> <p><b>Response to Comments: Minimally Invasive Arthrodesis of the Sacroiliac Joint (SIJ) A59948 (Comment #25)</b></p>	<p>As explained by many commenters, the code development work for SI joint fusion is nowhere near complete. It is premature to finalize an LCD in this environment. We therefore insist the MACs withdraw the LCD pending the outcome of CPT Panel and RUC proceedings this year.</p>
<p><b>Noridian</b></p>		
<p>The LCD has been updated to include the ASTM definitions in order to further clarify the distinction between the 2 CPT® codes. However, because the terminology utilized by the AMA is how billing and coding is submitted, until such time as the AMA updates the language, this LCD will utilize existing AMA language. The CPT® language will be updated in the 2026 book and has been included in the definitions distinguishing the 2 procedures.</p>		<p>As previously noted, there is currently a proposal by multiple Specialty Spine Societies to further alter the definition of SI joint procedure coding. The January 2025 RUC meeting is likely to address this topic and may provide clarity on how to proceed. Following this meeting, the February 2025 CPT Panel will convene to discuss a CCA on this same topic. If adopted, this CCA would further change the code definitions before the 2026 book is printed.</p> <p>It is premature to finalize any LCD or policy based on definitions that will not be effective until 2026 and are not yet settled by the societies. A withdrawal of these final LCDs is necessary until such time as the CPT code ambiguity and controversy are resolved. Otherwise, the MACs will not know what procedures they will be covering.</p>

**LCD Utilization of Societal Guidelines.**

Several guidelines are available to inform the diagnosis and treatment of sacroiliac (SI) joint dysfunction, including those from the American Society of Pain and Neuroscience (ASPN), the North American Spine Society (NASS), and the International Society for the Advancement of Spine Surgery (ISASS). Each



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organization has contributed to the understanding and management of SI joint dysfunction, emphasizing different approaches based on their respective areas of focus.

The ASPN 2024 guideline stands out for its integration of updated evidence and emphasis on minimally invasive procedures. Despite what is mentioned in the LCD, this guideline adheres to AGREE II principles. Compared to the 2020 ISASS and 2021 NASS guidelines, ASPN offers more comprehensive real-world applicability, methodological transparency, and the inclusion of the latest clinical advancements. Below, we present a comparison of the strengths of these guidelines in a tabular format:

## Comparison of SI Joint Guidelines

Aspect	ASPN 2024	NASS 2021	ISASS 2020
Evidence Base	Incorporates updated clinical data, recent studies, and real-world evidence, providing a comprehensive framework.	Based on data available as of 2021, with limited real-world integration.	Primarily uses earlier evidence, lacking integration of new studies on minimally invasive approaches.
Focus on Minimally Invasive Care	Emphasizes posterior allograft techniques (CPT 27278), offering safer, less invasive options.	Includes minimally invasive options but focuses more on traditional transfixation techniques.	Predominantly focused on surgical approaches with less attention to minimally invasive options.
Alignment with AGREE II	Adheres to AGREE II principles, ensuring methodological rigor, stakeholder inclusion, and clarity.	Partially aligns with AGREE II but lacks transparency in COI safeguards.	Limited documentation of AGREE II adherence or methodological rigor.
Real-World Data Integration	Strong emphasis on real-world evidence, broadening applicability and complementing trial data.	Minimal real-world data integration.	Focuses more on controlled clinical settings, with limited real-world applicability.
Consistency with Coding Guidance	Fully aligns with NASS 2024 coding guidance, supporting accurate use of CPT 27278 for posterior allograft techniques.	Precedes NASS 2024 coding guidance, offering less alignment with updated procedural standards.	Lacks alignment with newer coding frameworks and guidance.
Peer Review	Published in a PubMed-indexed	Published in peer-reviewed journals	Peer-reviewed but with less emphasis



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	journal, ensuring rigorous external validation through peer review.	with both internal and external reviews.	on external validation.
Patient-Centered Approach	Broadly inclusive of diverse patient populations and adaptable to various clinical settings.	Focuses more narrowly on spinal specialists, reducing broader applicability.	Geared toward surgical contexts, limiting its use across non-surgical specialties.
Conflict-of-Interest Safeguards	Details COI safeguards explicitly, minimizing potential biases in evidence grading and recommendations.	Includes COI disclosures but with less comprehensive mitigation strategies than ASPN.	Limited COI documentation and safeguards.
Current Relevance	Reflects advancements through 2024, integrating the latest procedural techniques and outcomes.	Incorporates evidence and practices up to 2021, lacking the latest advancements.	Based on practices as of 2020, omitting newer minimally invasive trends.

**Conclusion**

We request that the MACs delay implementation of these LCDs to allow the undersigned societies to work with the MACs to assess the evidence and update the LCDs in order to provide safe, clinically effective, and cost-effective care to Medicare beneficiaries as the coding, regulations, and local practice patterns related to sacroiliac joint arthrodesis evolve rapidly.

Sincerely,

American Society of Neuroradiology

American Society of Spine Radiology

Society of Interventional Radiology

American College of Radiology

American Academy of Physical Medicine & Rehabilitation





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References:

1. Polly DW, Cher DJ, Wine KD, Whang PG, Frank CJ, Harvey CF, Lockstadt H, Glaser JA, Limoni RP, Sembrano JN; INSITE Study Group. Randomized Controlled Trial of Minimally Invasive Sacroiliac Joint Fusion Using Triangular Titanium Implants vs Nonsurgical Management for Sacroiliac Joint Dysfunction: 12-Month Outcomes. *Neurosurgery*. 2015 Nov;77(5):674-90; discussion 690-1. doi: 10.1227/NEU.0000000000000988. PMID: 26291338; PMCID: PMC4605280.
2. Dengler J, Stuesson B, Kools D, Prestamburgo D, Cher D, van Eeckhoven E, Erk E, Pflugmacher R, Vajkoczy P; the iMIA study group. Referred leg pain originating from the sacroiliac joint: 6-month outcomes from the prospective randomized controlled iMIA trial. *Acta Neurochir (Wien)*. 2016 Nov;158(11):2219-2224. doi: 10.1007/s00701-016-2953-7. Epub 2016 Sep 15. PMID: 27629371.
3. Calodney A, Azeem N, Buchanan P, Skaribas I, Antony A, Kim C, Girardi G, Vu C, Bovinet C, Vogel R, Li S, Jassal N, Josephson Y, Lubenow T, Lam CM, Deer TR. Safety, Efficacy, and Durability of Outcomes: Results from SECURE: A Single Arm, Multicenter, Prospective, Clinical Study on a Minimally Invasive Posterior Sacroiliac Fusion Allograft Implant. *J Pain Res*. 2024 Mar 20;17:1209-1222. doi: 10.2147/JPR.S458334. PMID: 38524688; PMCID: PMC10961068.
4. Lorio M, Kube R, Araghi A. International society for the advancement of spine surgery policy 2020 update - Minimally invasive surgical sacroiliac joint fusion (for chronic sacroiliac joint pain): Coverage indications, limitations, and medical necessity. *Int J Spine Surg*. 2020;14(6):860-895.
5. Lee DW, Patterson DG, Sayed D. Review of Current Evidence for Minimally Invasive Posterior Sacroiliac Joint Fusion. *Int J Spine Surg*. 2021 Jun;15(3):514-524. doi: 10.14444/8073. Epub 2021 May 7. PMID: 33963035; PMCID: PMC8176825.
6. Sayed D, Deer TR, Tieppo Francio V, Lam CM, Sochacki K, Hussain N, Weaver TE, Karri J, Orhurhu V, Strand NH, Weisbein JS, Hagedorn JM, D'Souza RS, Budwany RR, Chitneni A, Amirdelfan K, Dorsi MJ, Nguyen DTD, Bovinet C, Abd-Elsayed A. American Society of Pain and Neuroscience Best Practice (ASPN) Guideline for the Treatment of Sacroiliac Disorders. *J Pain Res*. 2024 May 3;17:1601-1638. doi: 10.2147/JPR.S464393. PMID: 38716038; PMCID: PMC11075694.