



February 9, 2024

Submitted to: MedicarePhysicianFeeSchedule@cms.hhs.gov

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244
Attention: Gift Tee, Director of Division of Practitioner Services

RE: Potentially Misvalued Codes: 27279 / Establishment of Nonfacility/Office Payment

Dear Administrator Brooks-LaSure:

On behalf of the American College of Radiology (ACR), the Outpatient Endovascular and Interventional Society (OEIS), and the Society for Interventional Radiology (SIR), we appreciate the opportunity to submit to you our request for review and consideration of the potentially misvalued CPT® code 27279, Arthrodesis, sacroiliac joint, percutaneous or minimally invasive (indirect visualization), with image guidance, includes obtaining bone graft when performed, and placement of transfixing device.¹²³⁴ Specifically, the collective request of ACR, OEIS, and SIR (“the societies”) in this letter is to establish nonfacility/office payment for CPT code 27279 and review the patient safety and typical practice considerations for the code.

In the 2024 final rule, CMS expressed concern about whether 27279 “could be safely and effectively furnished in the nonfacility / office setting” and further stated “such services as described (27279) would benefit from review by other interested parties, such as the AMA RUC and private payers even as we consider our policies for such services.” To obtain further clarity around these comments the societies queried CMS as to next steps to provide safety data. This ultimately led to a presentation to CMS regarding safety data relative to 27279.

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² The ACR represents more than 41,000 diagnostic radiologists, interventional radiologists, radiation oncologists, nuclear medicine physicians, and medical physicists.

³ OEIS is a society of over 700 vascular surgeons, interventional cardiologists and interventional radiologists, all dedicated to promoting safe, appropriate, effective, and accessible outpatient care.

⁴ The Society of Interventional Radiology (SIR) is a nonprofit, professional medical society representing approximately 8,000 practicing interventional radiology physicians, trainees, students, scientists, and clinical associates dedicated to improving patient care through the limitless potential of image-guided therapies.

In that presentation several studies including three post market surveillance publications as well as two independent reviews of minimally invasive sacroiliac (SI) joint fusion procedures were discussed. These included:

- **Post-market surveillance publications**
 - Miller LE, Reckling WC, Block JE. Analysis of postmarket complaints database for the iFuse SI Joint Fusion System(R): a minimally invasive treatment for degenerative sacroiliitis and sacroiliac joint disruption. *Med Devices Auckl NZ* 2013;6:77–84.
 - Cher D, Wroe K, Reckling WC, Yerby S. Postmarket surveillance of 3D-printed implants for sacroiliac joint fusion. *Med Devices Auckl NZ* 2018;11:337–43.
 - Cher D.J., Reckling W.C., Capobianco R.A. Implant survivorship analysis after minimally invasive sacroiliac joint fusion using the iFuse Implant System [Internet]. *Med. Devices Evid. Res.* 2015; Available from: <https://www.dovepress.com/getfile.php?fileID=28113>

- **Independent reviews**
 - Whang PG, Patel V, Duhon B, Stureson B, Cher D, Carlton Reckling W, Capobianco R, Polly D. Minimally Invasive SI Joint Fusion Procedures for Chronic SI Joint Pain: Systematic Review and Meta-Analysis of Safety and Efficacy. *Int J Spine Surg.* 2023 Oct 5:8543. doi: 10.14444/8543. Epub ahead of print. PMID: 37798076.
 - Level 1 evidence
 - Chang E, Rains C, Ali R, Wines RC, Kahwati LC. Minimally invasive sacroiliac joint fusion for chronic sacroiliac joint pain: a systematic review. *Spine J* 2022;22(8):1240–53.

During this presentation the post market surveillance publication by Miller LE et al demonstrated a nerve impingement rate of 0.9%, recurrent SI pain at 0.8% and all other complaints being very rare at less than 0.2%. Similarly, Cher D et al demonstrated pain related complaints of less than 0.5% and a 1.3% issue with instruments.

Independent reviews by Whang PG et al, provided level one evidence via a meta-analysis of the lateral trans-iliac (LTI), posterolateral trans-iliac (PLTI) and posterior interpositional (PI) SI fusion procedures. 57 cohorts of 2851 patients were evaluated for efficacy while 63 cohorts of 3162 patients were evaluated for safety. Of these, 47 safety cohorts (2,348 patients) were of the LTI approach (CPT 27279), 8 cohorts (317 patients) were the PLTI approach (CPT 27279) and eight cohorts (497 patients) were PI approach (CPT 27278). This paper demonstrated an acute symptomatic implant malposition in 0.43% for LTI, 0% for PLTI and 0.2% for PI. Wound infection which was a late complication was seen in 0.15% of LTI and not reported in PLTI and PI. Bleeding requiring surgery was reported at 0.04% for LTI and 0% for PLTI and PI. Finally, device removal for pain (another late complication) was 0.06% for LTI, 1.1% for PLTI and 0.48% for PI. It was concluded by the authors that “the adverse event rate for all procedures was low,” and that among appropriately selected patients minimally invasive SI joint fusion is probably more effective than conservative management for reducing pain and opioid use and improving physical function and quality of life.

To provide a frame of reference for complication rates for various procedures performed in the office-based lab (OBL) setting, it was discussed that the risk of iliac perforation during angioplasty (a very common procedure in the OBL) is 0.8%. Further, the risk of death during diagnostic cardiac catheterization which was recently approved for OBL performance was 0.05%, the risk of MI during diagnostic cardiac catheterization is 0.1% and the risk of stroke during diagnostic cardiac catheterization is between 0.05 and 0.1%. All of these procedures carry a higher major risk profile than the lateral trans iliac (LTI) SI joint fusion procedure (CPT code 27279) which was demonstrated to be 0.04% for bleeding requiring surgery.

OBLs are highly sophisticated venues employing specialized equipment and personnel to provide safe and effective procedures for patients. Procedures are typically performed with moderate sedation and as of February 2024 the OEIS registry has recorded 42,900 complex vascular procedures performed in the OBL with a total complication rate of 2.16% and a major complication rate of 0.54%

All this data supports the fact that CPT code 27279 - arthrodesis, SI joint, **percutaneous or minimally invasive** can be safely performed in the OBL setting with acceptable complication rates. Additionally, the acute complications associated with 27279 (which is currently performed and reimbursed in the ambulatory surgical center – or “ASC” – setting) are managed similarly in both the ASC and OBL setting. Namely, acute symptomatic malposition (most common acute complication) is managed in both the ASC and OBL by returning to the procedure suite and removing/repositioning the implant. Bleeding requiring surgical intervention is exceedingly rare (with a published rate of 0.04%) and is treated in both the OBL and ASC with fluid support, stabilization and expeditious transport to the hospital for surgical repair.

In our comments to CMS on February 10, 2023, as part of the 2024 PFS rulemaking process, we noted that establishing valuation of the PE in the non-facility setting for 27279 will work to ensure no disparity or lack of equal access to care in various settings and allow procedure selection for sacroiliac arthrodesis not to be influenced by site of service reimbursement policy. To that end, please find attached to this letter the same invoices submitted to CMS on February 10, 2023, for implants used during performance of 27279. Note the quantity of implants used for a typical patient is three.⁵ Other supplies utilized would be similar to 27278 (previously identified as 2X000) (dorsal SI arthrodesis).

Conclusion

We feel the existing medical literature supports the conclusion that percutaneous or minimally invasive SI joint arthrodesis (27279) carries an acceptably low complication rate similar to procedures currently performed in the OBL and therefore can be safely performed in the OBL. We look forward to continuing to work with CMS to establish nonfacility/office payment for CPT code 27279. If you have additional questions regarding these matters and the views of the

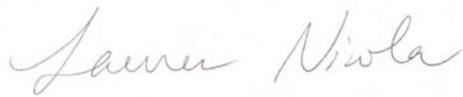
⁵ Please note that the price information contained on these invoices should be treated confidentially under the Trade Secrets Act. We have redacted all customer names.

societies, please contact Jason McKittrick at (202) 465-8711 or by email at jmckittrick@libertypartnersgroup.com.

Sincerely,

Handwritten signature of Gerald Niedzwiecki MD in black ink.

Gerald Niedzwiecki, MD, OEIS RUC Advisor

Handwritten signature of Lauren Nicola in grey ink.

Lauren Nicola, MD, FACR, ACR RUC Advisor

Handwritten signature of Minhaj S. Khaja in blue ink.

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