



April 11, 2025

Submitted via email to MedicarePhysicianFeeSchedule@cms.hhs.gov

Dr. Mehmet Oz
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

Re: Requesting a G-Code for Cryoablation Therapy to Treat Postoperative Pain in Calendar Year (CY) 2026 Medicare Physician Fee Schedule (PFS) Rulemaking

Dear Administrator Oz:

AtriCure, Inc. (AtriCure) is a leading innovator in surgical treatments and therapies for postoperative pain management, atrial fibrillation, and left atrial appendage management. Among other technologies, AtriCure is the developer of the Cryo Nerve Block Therapy (cryoNB) for postoperative pain management for patients who undergo certain cardiac, thoracic, and other surgical procedures. CryoNB therapy is delivered through AtriCure's cryoablation probes, marketed under the names cryoICE®, cryoSPHERE™, cryoSPHERE MAX™, cryoICE® cryoSPHERE™, and cryoICE® Cryo2. CryoNB therapy blocks pain signals in the affected areas for several months during a patient's recovery, which provides lasting postoperative pain relief and reduces the need for opioids.

We are writing to formally request that CMS in the CY 2026 Medicare Physician Fee Schedule (PFS) Rule establish a G-code to describe the additional intraoperative time required by the surgeon to perform adjunctive cryoablation therapy for postoperative pain management. We are grateful for CMS's continued efforts to foster access to treatment options that can replace or reduce the use of opioids for patients experiencing postoperative or postsurgical pain. This is critical for patients undergoing treatment for substance use disorders (SUDs), specifically opioid use disorder (OUD). We are especially appreciative that in the CY 2025 Hospital Outpatient Prospective Payment System (OPPS) Final Rule, CMS included CryoNB on the list of devices eligible for temporary additional payments for non-opioid postsurgical pain relief pursuant to the Non-Opioids Prevent Addition in the Nation (NOPAIN) Act.

Despite CMS's efforts to promote the use of non-opioid alternatives for pain relief, access to cryoablation therapy remains impeded. Currently, physicians lack a mechanism to bill for the additional 20-30 minutes of intraoperative time needed for a surgeon to perform cryoablation for postoperative pain management. Cryoablation in this setting is supplemental to normal analgesia used during surgery. Further, some providers incorrectly interpret Medicare's anesthesia rules as prohibiting payment for extra professional services associated with ancillary cryoablation therapy when provided by the same

surgeon, despite the 2024 Q3 AHA Coding Clinic guidance stating that cryoablation is separately reportable because it represents a separate surgical objective from the main procedure.¹ A G-code for physician work associated with intraoperative administration of cryoablation therapy for postoperative pain relief would promote patient access to these important treatments and clarify the application of existing Medicare policies to cryoablation procedures, as well as translate the relevant AHA Coding Clinic guidance for providers. Furthermore, and as noted above, a G-code would help advance provider adoption of cryoablation for postsurgical pain management, thereby ensuring that patients with OUD have a safe and reliable postsurgical pain-relief option.

Background

Intraoperative cryoablation therapy is performed as a supplemental procedure adjunctive to the primary surgical procedure (e.g., cardiac, thoracic, and other surgeries) to provide postoperative (up to ~ 60 days) pain relief. Cryoablation freezes nerves (without causing permanent nerve damage) near the surgical site, which temporarily blocks pain signals in the affected area for several months during a patient's recovery period. During recovery, the nerve endings regenerate.

During surgery, cryoablation generally requires 20 to 30 minutes of intraoperative time for the surgeon in addition to the accompanying surgical procedure. There is robust clinical evidence highlighting the use of intraoperative cryoablation to reduce the need for opioids to treat postsurgical patients, as well as recent guideline recommendations.²

The opioid crisis in the United States remains an ongoing emergency, as evidenced by the most recent renewal of the opioid public health emergency declaration.³ Congress and CMS have both taken significant steps to improve access to treatment options that can replace or reduce the use of opioids for patients experiencing postoperative or postsurgical pain—for example, enacting the NOPAIN Act through section 4135 the Consolidated Appropriations Act, 2023 (CAA, 2023) to provide temporary additional payments for non-opioid pain-management therapies furnished in the outpatient setting. For patients who are being treated for OUD and require surgery, non-opioid pain-management therapies are essential to ensure their safe recovery after invasive procedures, without the need for opioids.

In the CY 2025 OPPS Final Rule, CMS included one form of cryoablation therapy, CryoNB, on its list of devices eligible for temporary additional payments for non-opioid postsurgical pain relief pursuant to

¹ AHA Coding Clinic®, Q3 2024 vol. 11, no. 3 (effective with discharges Aug. 1, 2024).

² Miller DL, Hutchins J, Ferguson MA, Barhoush Y, Achter E, Kuckelman JP. Intercostal Nerve Cryoablation During Lobectomy for Postsurgical Pain: A Safe and Cost-Effective Intervention. *Pain Ther.* 2025 Feb;14(1):317-328. doi: 10.1007/s40122-024-00694-3.; *see also* Dunning J, Burdett C, Child A, Davies C, Eastwood D, Goodacre T, Haecker FM, Kendall S, Kolvekar S, MacMahon L, Marven S, Murray S, Naidu B, Pandya B, Redmond K, Coonar A. The pectus care guidelines: best practice consensus guidelines from the joint specialist societies SCTS/MF/CWIG/BOA/BAPS for the treatment of patients with pectus abnormalities. *Eur J Cardiothorac Surg.* 2024 66(1):ezae166.

³ HHS, Administration for Strategic Preparedness & Response (ASPR), Renewal of Determination That a Public Health Emergency Exists (Mar. 18, 2025).

the NOPAIN Act.⁴ By including CryoNB on the list of devices eligible for payments under the NOPAIN Act, CMS recognized that CryoNB's use is supported by peer-reviewed data demonstrating "the ability to replace, reduce, or avoid intraoperative or postoperative opioid use or the quantity of opioids prescribed." We thank CMS for taking this significant step to improve patient access to this important non-opioid alternative for pain relief.

Despite this critical step to improve access to intraoperative cryoablation therapy, there continue to be financial and policy barriers against physician adoption of intraoperative cryoablation therapy. Most importantly, there is currently no code to account for the 20-30 additional minutes of physician work associated with the intraoperative administration and delivery of cryoablation therapy, which hinders physician adoption of, and limits patient access to, these procedures.

Further, many providers incorrectly interpret Medicare's anesthesia rules as prohibiting payment for extra professional services associated with ancillary cryoablation therapy when provided by the same surgeon.⁵ CMS typically does not allow separate payment for anesthesia services provided by the same physician performing a surgical procedure, with limited exceptions. However, the prohibition does not apply to cryoablation for postoperative pain management because the cryoablation has a separate surgical objective during the surgery and is not an anesthesia service.⁶ Nevertheless, confusion about the application of this policy is posing an unnecessary barrier to cryoablation procedures that can reduce or replace opioid use for Medicare beneficiaries.

Recommendation: Establish a G-Code for Intraoperative Cryoablation for Postoperative Pain

CMS has authority to clarify this issue by creating a G-code to describe the additional time required for this procedure, which would facilitate greater access for patients who require or prefer non-opioid alternatives to pain relief. AtriCure respectfully requests that CMS, in the upcoming CY 2026 Medicare PFS rulemaking, establish a G-code for the physician work associated with intraoperative cryoablation therapy for postoperative pain. Establishment of a G-code will help promote patient access to this important alternative to opioids by making clear that Medicare anesthesia rules do not apply to cryoablation for postoperative pain when furnished by the same surgeon.

In addition to establishing a G-code for cryoablation therapy, CMS can include language in the upcoming CY 2026 PFS Proposed Rule, the CY 2026 OPPI Proposed Rule, or in other guidance or memoranda clarifying that the prohibitions under Medicare's anesthesia rules do not apply to intraoperative cryoablation for postoperative pain. By issuing clarifying language, and reducing provider

⁴ CY 2025 OPPI Final Rule, 89 Fed. Reg. 93912, 94354 (Nov. 27, 2024) (CMS specifically affirmed that "the CryoNB System meets the statutory requirements and should be paid separately under this provision.").

⁵ See Medicare NCCI 2024 Coding Policy Manual, Chapter 13, pgs. 6-7 (revised Jan. 1, 2025), available at: <https://www.cms.gov/files/document/13-chapter13-ncci-medicare-policy-manual-2025finalcleanpdf.pdf>.

⁶ *Supra* Note 1.



confusion, CMS will accelerate provider adoption of—and expand patient access to—non-opioid therapies for postoperative pain management.

Thank you for your consideration of this proposal. We look forward to working with you on this matter. In the interim, please do not hesitate to reach out with any questions.

Sincerely,

A handwritten signature in black ink that reads "Michael Ferguson". The signature is written in a cursive, flowing style.

Michael Ferguson, PhD
Vice President, Healthcare Economics and Reimbursement
AtriCure, Inc.