angiodynamics

NANOKNIFE SYSTEM CPT BILLING CODES

CPT Coding Guidelines for Irreversible Electroporation (IRE) (Using the NanoKnife System) EFFECTIVE JANUARY 1, 2021

This is general reimbursement information only and is intended to assist you to comply with complex and changing reimbursement policies. It is not legal advice, nor is it advice about how to code, complete, or submit any particular claim for payment, nor is it intended to increase or maximize reimbursement by any third-party payor. This information has been gathered from third-party sources and was correct at the time of publication and is subject to change without notice. It is the provider's responsibility to exercise independent clinical judgment to determine appropriate coding and charges that accurately reflect all the patient's conditions and services provided. These should be recorded in the patient's medical record. The information provided here is for informational purposes only and represents no statement, promise, or guarantee by AngioDynamics concerning levels of reimbursement, payment, or charges. Payors may have their own coding and reimbursement requirements and policies. If reimbursement questions arise for a particular patient, providers should contact the payor to confirm current requirements and billing policies. All decisions related to reimbursement, including amounts to bill, are exclusively that of the provider. Providers should check and confirm coding from complete and authoritative coding sources to ensure accuracy.

This document is not intended to promote the off-label use of medical devices and physicians should use medical devices fully consistent with all government requirements. The content is not intended to instruct hospitals and/or physicians on how to use medical devices or bill for healthcare procedures.

NanoKnife 3.0
Irreversible Electroporation (IRE)

US/ON/MS/187 REV 05 03/2021

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CATEGORY III CPT BILLING CODES FOR PERCUTANEOUS AND OPEN IRE

The American Medical Association (AMA) CPT Editorial Panel approved two Category III CPT codes for reporting of percutaneous and open IRE ablation of tumors.[1] The codes are effective on January 1, 2021 and will be published in the AMA CPT 2021 book. Below are the new Category III CPT IRE codes.

Medicare 2021 National Average Payment (Not Geographically Adjusted)

SERVICE PROVIDED					
CPT® Code [1,2]	CPT® Descriptor [1,2]	Physician Fee Schedule [3]	APC [4] (Status Indicator)	Hospital OPPS Payment [4]	ASC Payment [5] (Payment Indicator)
0600T	Ablation, irreversible electroporation; 1 or more tumors per organ, including imaging guidance, when performed, percutaneous (Do not report 0600T in conjunction with 76940, 77002, 77013, 77022)	No national set payment	5362, Level 2 Laparoscopy and Related Services (J1)	$8,907.66	$4,945.20 (J8)
0601T	Ablation, irreversible electroporation; 1 or more tumors, including fluoroscopic and ultrasound guidance, when performed, open (Do not report 0601T in conjunction with 76940, 77002)	No national set payment	5362, Level 2 Laparoscopy and Related Services (J1)	$8,907.66	$4,945.20 (J8)

1. CPT® © 2021. American Medical Association (AMA). All rights reserved. CPT® is a registered trademark of the AMA. No fee schedules, basic units, relative values or related listings are included in CPT® including for Category 3 codes. Inclusion of a CPT® code does not represent AMA endorsement or imply any coverage or reimbursement policy. Reimbursement information here is from the Centers for Medicare and Medicaid Services (CMS), see sources below. Applicable FARS/DFARS restrictions apply to Government Use.
2. CPT® guidelines instruct that one must report a Category III code when available in place of an unlisted procedure code.
3. CMS, CMS 1734-F: Revisions to Payment Policies under the Medicare Physician Fee Schedule, Quality Payment Program and Other Revisions to Part B for CY 2021. Published December 28, 2020, Displayed December 2, 2020, Effective January 1, 2021. Accessed December 7, 2020
4. CMS, CMS-1736-FC: Hospital Outpatient Prospective Payment- Notice of Final Rulemaking with Comment Period (NFRM) Published December 29, 2020, Displayed December 3, 2020, Effective January 1, 2021. Accessed December 7, 2020
5. CMS, CMS-1736-FC: Ambulatory Surgical Center Payment- Notice of Final Rulemaking with Comment Period (NFRM) Published December 29, 2020, Displayed December 3, 2020, Effective January 1, 2021. Accessed December 7, 2020

2021 CPT Coding Guidelines for Ablation with IRE

The IRE procedures described by the new Category III CPT codes include the imaging guidance procedures, so those imaging guidance CPT codes are not separately billed on the CMS Form 1500 claim form.

Category III codes are for emerging technologies, services, and procedures. They enable physicians and outpatient facilities to report accurately and gather data on the clinical efficacy, utilization, and outcomes of emerging technologies. According to the AMA CPT, a Category III code must be used in place of an unlisted procedure code.

Importantly, the approval of these new Category III IRE codes does not:

- Guarantee coverage by third party health payors.
- Set a national or local payment level for physician services.

In fact, payors may not immediately update their claims processing systems to include new Category III codes. Payors that have implemented the new Category III IRE codes may request documentation of clinical efficacy to support coverage. AngioDynamics can assist physicians with scientific literature and information about Medicare national coverage of the DIRECT clinical trial to facilitate knowledgeable payor decision-making.

Reporting Category III codes can also initiate a dialogue between the payor and the physician on the payment level.

PAYMENT CONSIDERATIONS

Third party health payors use different payment methodologies for Category III codes. Private payors that accept and cover Category III CPT codes can pay based on physician charges, a percentage of those charges, or if available, Medicare fee schedule amounts, as examples. Medicare/CMS does not set national physician payment levels for Category III CPT codes, so these codes are "carrier/contractor-priced". Check with the payor to see if they have guidelines for pricing Category III codes and if so, follow those guidelines.

Physicians should be prepared to submit information to the payor that helps coverage and payment decisions. For example, Noridian, a Medicare contractor, requests information that includes estimates of physician and clinical staff time and intensity of physician work. For surgical procedures, Noridian asks for documentation of skin-to-skin (intra-service) surgical times.[3] Procedures performed in an office setting may also require data about office expenses, supplies and equipment. An evidence-based dialogue with the payor contributes to accurate and equitable payment levels. Payors may describe these payment methods as crosswalking or negotiated rate setting.

Crosswalk payment from a similar procedure to the Category III code

The physician may want to offer a crosswalk analysis in communicating with a payor about a new code. The crosswalk first identifies a reference procedure with an established payment level. Next, the physician suggests that payment for the new Category III CPT IRE code should be at the same rate as the reference procedure rate because both procedures require similar physician time, effort, and complexity. The payor may accept the "comparability" of the procedures and crosswalk payment from the reference procedure to the new Category III CPT IRE code.

3. Noridian Medicare, "Local Coverage Article: Additional Information Required for Coverage and Pricing for Category III CPT Codes (A55607). Effective July 26, 2019. Retrieved from: https://med.noridianmedicare.com/documents/10546/12461373/Additional+Information+Required+for+Coverage+and+Pricing+for+Category+III+CPT+Codes+Coverage+Article

Medicare has used the crosswalk process in various settings.[4] While the Medicare physician fee schedule establishes payment based on the relative values of physician work, practice expenses, and malpractice, these metrics may be part of a local contractor Category III CPT code payment crosswalk. Physician work value typically focuses on:

- Time (pre-, intra-, and post-operative time in the hospital),
- Mental effort,
- Professional judgment,
- Technical skill,
- Physical effort,
- Stress due to risk, and
- Number and complexity of follow up visits.

For example, if the time, effort, and complexity of an IRE procedure is like a standard pancreatic surgical procedure, the physician may suggest to the payor that the payment for the Category III CPT IRE code should be crosswalked from the payment for the standard pancreatic surgical procedure. There may be resource similarities as well as clinical similarities because of the unique challenges of treating pancreatic cancer. Because the Category III IRE CPT codes include imaging guidance, the reference codes should also include physician resources with imaging guidance.

Value-based Negotiated rates

Physicians may also consider a negotiated rate approach. This uses similar information from a crosswalk but with broader clinical and payment considerations, such as:

- Unique clinical value,
- Improved net health outcomes,
- Comparison of clinical impact to other treatments,
- Resource comparisons, including the relative complexity of the procedure to alternative treatment of the same condition (see discussion above on crosswalk),
- Time and professional skill to perform the procedure including pre-, intra-, and post-operative time,
- Limited number of patients who will qualify to receive the IRE treatment,
- Role of the physician in the hospital as a center of excellence.

Value based payment can be a component of negotiated rates where the new IRE procedure offers the payor's subscribers a clinical breakthrough in treatment of a fatal disease. Since the Category III IRE CPT codes encompass the imaging guidance services, physician time and effort associated with imaging guidance should be part of the negotiated rate. Documents that payors can request include the surgical/operative note, letter of medical necessity, and for pancreatic cancer: the NanoKnife designation as a breakthrough device, and national Medicare coverage under the DIRECT trial.[5] It is important to inquire if the payor has guidelines on negotiated rate setting for physician services and if so, to follow those guidelines.

4. See references to crosswalk at 84 Federal Register 62570 (November 15, 2019), and 75 Federal Register 73,183 (for practice expenses) 73328 – 73329 for physician work and addressing the AMA RUC valuation process. (November 29, 2010). The AMA RUC does not conduct surveys, calculate values, or make payment recommendations on Category III codes. Note that Medicare does not now use a conventional cross walk under the RBRVS system for national rate setting, but local Medicare contractors and private payors recognize crosswalk as an appropriate way to price new codes.
5. Note that in negotiating rates for the new Category III IRE CPT codes, physicians should address physician services and not the hospital resources.

REIMBURSEMENT TERMINOLOGY

Term[6]	Description[6]
AMA	American Medical Association
CMS	Centers for Medicare and Medicaid Services
CPT	Current Procedural Terminology
ICD-10-PCS	International Classification of Diseases, 10th Revision, Procedure Coding System
IDE	Investigational Device Exemption
IRE	Irreversible Electroporation (Procedure performed with the NanoKnife System)
LCD	Local Coverage Determination
NCD	National Coverage Determination
OPPS	Outpatient Prospective Payment System
RBRVS	Resource Based Relative Value Scale
RVU	Relative Value Unit

OTHER RESOURCES

For **NanoKnife System inpatient hospital-related reimbursement information**, please refer to the 2021 NanoKnife System IRE Reimbursement Guide.

For other reimbursement educational materials, guides, and resources, please visit: Reimbursement Resources website.

For **information about DIRECT**, a clinical study for stage III pancreatic cancer sponsored by AngioDynamics, Inc, please visit the DIRECT Study website. This comprehensive clinical study will evaluate the effects of irreversible electroporation (IRE) ablation technology on the treatment of stage III pancreatic cancer.

REIMBURSEMENT SUPPORT

For questions regarding coding, payment, coverage, and other reimbursement information, please contact us at: Reimbursement@Angiodynamics.com

6. CMS "Acronyms tool" Published May 14, 2006. U.S. Centers for Medicare & Medicaid Services. Accessed Apr 23, 2020. Retrieved from: https://www.cms.gov/apps/acronyms/

Indication For Use
US: The NanoKnife System with six outputs is indicated for surgical ablation of soft tissue.

Contraindications
Ablation procedures using the NanoKnife System are contraindicated in the following cases: • Ablation of lesions in the thoracic area in the presence of implanted cardiac pacemakers or defibrillators • Ablation of lesions in the vicinity of implanted electronic devices or implanted devices with metal parts • Ablation of lesions of the eyes, including the eyelids • Patient history of Epilepsy or Cardiac Arrhythmia • Recent history of Myocardial Infarction

Potential Adverse Effects
Adverse effects that may be associated with the use of the NanoKnife system include, but are not limited to, the following: • Arrhythmia • Atrial fibrillation or flutter • Bigeminy • Bradycardia • Heart block or atrioventricular block • Paroxysmal supraventricular tachycardia • Tachycardia o Reflex tachycardia o Ventricular tachycardia • Ventricular fibrillation • Damage to critical anatomical structure (nerve, vessel, and/or duct) • Fistula formation • Hematoma • Hemorrhage • Hemothorax • Infection • Pneumothorax • Reflex Hypertension • Unintended mechanical perforation • Vagal Stimulation, asystole • Venous Thrombosis

Refer to Directions for Use and/or User Manual provided with the product for complete Instructions, Warnings, Precautions, Possible Adverse Effects and Contraindications. Observe all instructions for use prior to use. Failure to do so may result in patient complications. CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a physician.

USA › 14 Plaza Drive, Latham, NY 12110 › Tel: 800-772-6446 or 518-798-1215 › Fax: 518-798-1360
International › Haaksbergweg 75 (Margriettoren), 1101 BR, Amsterdam Z-O › The Netherlands › Tel: +31 (0)20 753 2949 › Fax: +31 (0)20 753 2939
angiodynamics.com