

Clinical Policy: Unproven Procedures

Reference Number: CP.MP.253

Date of Last Revision: 9/26

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Description

This policy establishes the criteria for identifying and managing codes associated with services, procedures, and treatments that are not supported by current research and guidelines and considered to be unproven. The purpose of this policy is to support consistent coverage determinations by applying clear, evidence-based standards for safety, efficacy, and impact on health outcomes. Codes designated as unproven under this policy are identified through review of the available evidence, including the quantity and quality of supporting research and the reported safety and effectiveness of the service, procedure, or treatment.

Note:

- Please see CP.MP.36 Experimental Technologies for general guidelines to use in determining medical necessity of experimental or investigational, or potentially experimental or investigational medical and behavioral health technologies (i.e., drugs, procedures, devices, services, or supplies) not listed in this policy.
- Exclusion of a code from this policy does not imply that the code has a medically necessary indication. Additional unproven codes may be found in topic-specific medical necessity criteria.

Policy/Criteria

- I. Current evidence does not support the efficacy and/or safety of the procedures and technologies represented by the codes in Tables 1, 2, and 3.

Background

Services billed with Current Procedural Terminology (CPT[®]), Healthcare Common Procedure Coding System (HCPCS), and International Classification of Disease, Tenth Revision, Procedure Coding System (ICD-10) codes may be designated as unproven when sufficient evidence in the peer-reviewed medical literature is lacking to demonstrate that the service has a beneficial effect on health outcomes, improves clinical outcomes compared with established alternatives, or has not achieved general acceptance within the relevant medical community. This classification may also apply to emerging technologies, procedures, devices, diagnostic tests, pharmaceuticals, or therapeutic interventions that are undergoing clinical evaluation or have not received appropriate regulatory approval for the requested indication.

- *0238T - Transluminal peripheral atherectomy*
Current evidence does not support the use of this code. There is insufficient evidence for the medical necessity of this code, and the guidelines and recommendations are generally conflicting or inconsistent. Additional studies with larger populations and long-term follow-up are needed.¹
- *0598T and 0599T - Real-time florescence wound imaging*

Current evidence and studies lack support and sufficient evidence. Current studies looking at florescence wound imaging are small and additional studies are needed looking at a larger group of participants and wounds.²

- *0608T - Remote monitoring of external continuous pulmonary fluid monitoring system*
Insufficient amount of published peer reviewed literature to evaluate medical necessity. Guidance shows no/unclear support for use of code.³
- *0686T - Histotripsy of malignant hepatocellular tissue*
Based on a review of clinical practice guidelines and position statements, guidance indicates no/unclear support for the use of histotripsy for treatment of primary and metastatic liver tumors.⁴ There is limited evidence on long-term outcomes with histotripsy.⁵
- *0913T and 0914T - Percutaneous transcatheter drug delivery by intracoronary drug-delivery balloon and XW0J3HA, XW0J3JA, XW0J3KA, and XW0J3LA - Introduction of Paclitaxel-Coated Balloon Technology, One through Four Balloons into Coronary Artery, One Artery, Percutaneous Approach, New Technology Group 10*
Literature review of code shows no/unclear support for procedure.⁶ Other therapies, such as drug-eluting stents, provide more benefit for treatment of restenosis over drug-delivery balloons.⁷
- *36837 - Percutaneous arteriovenous fistula creation*
Literature review of code shows no/unclear support for the procedure.⁸ Additional studies are needed to establish safety and efficacy.⁹
- *55880 - Ablation of malignant prostate tissue, transrectal, with HIFU*
Current guidance confers no/unclear support for high intensity-focused ultrasound (HIFU) for salvage therapy.¹⁰ The long-term effectiveness of HIFU compared to surgery or radiation therapy has not been studied.¹¹
- *83704 - Quantitation of lipoprotein particle numbers*
Current evidence and studies lack supporting and sufficient evidence. More studies are needed on the benefit of nuclear magnetic resonance testing over traditional lipid profile tests.¹²
- *C1601 - Endoscope, single use*
Guidelines show weak support for use of disposable bronchoscopes.¹³ In circumstances where there is increased risk of spreading infection or when there is no support available for immediate reprocessing of a reusable bronchoscope (i.e. during the Covid pandemic) the FDA recommends using a single-use bronchoscope.¹⁴
- *C9772 - Revascularization, endovascular, tibial/peroneal arteries with intravascular lithotripsy*
Clinical studies and reviews showed no/unclear support. Guidelines suggest some patient-oriented benefits of intravascular lithotripsy (IVL) for treatment of coronary artery

calcification (CAC) but do not recommend it as preferable technology.^{15,16,17} Additional studies are needed to determine the safety and efficacy of the procedure.^{16,18}

- *C9777 - Esophageal mucosal integrity testing by electrical impedance*
Minimal support for use of code with current studies and reviews as well as weak support for guidelines. Identified guidelines suggest there is “promise” in the diagnostic technology as an adjunctive metric but do not recommend it as a preferable method to current standard methods.¹⁹
- *C9781 - Arthroscopy, shoulder with implantation of subacromial spacer*
Minimal level of support for code based on clinical studies and reviews. Current guidance confers no/unclear support for use of subacromial spacers.²⁰
- *S9090 - Vertebral axial decompression*
No position statements or guidelines were identified, indicating no/unclear support for use of this code in patients with lower back pain.²¹

Coding Implications

This clinical policy references Current Procedural Terminology (CPT[®]). CPT[®] is a registered trademark of the American Medical Association. All CPT codes and descriptions are copyrighted 2025, American Medical Association. All rights reserved. CPT codes and CPT descriptions are from the current manuals and those included herein are not intended to be all-inclusive and are included for informational purposes only. Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

Table 1

CPT[®] Codes	Description
0238T	Transluminal peripheral atherectomy, open or percutaneous, including radiological supervision and interpretation; iliac artery, each vessel
0598T	Real-time fluorescence wound imaging with clinical darkness, to identify location of bacterial wound pathogens and measure wound size, per session; first anatomic site (eg, lower extremity, right leg)
0599T	Real-time fluorescence wound imaging with clinical darkness, to identify location of bacterial wound pathogens and measure wound size, per session; each additional anatomic site (eg, upper extremity, left leg) (List separately in addition to code for primary procedure)
0608T	Remote monitoring of an external continuous pulmonary fluid monitoring system, including measurement of radiofrequency-derived pulmonary fluid levels, heart rate, respiration rate, activity, posture, and cardiovascular rhythm (eg, ECG data), transmitted to a remote 24-hour attended surveillance center; analysis of data received and transmission of reports to the physician or other qualified health care professional

CPT[®] Codes	Description
0686T	Histotripsy (ie, non-thermal ablation via acoustic energy delivery) of malignant hepatocellular tissue, including image guidance
0913T	Percutaneous transcatheter therapeutic drug delivery by intracoronary drug-delivery balloon (eg, drug-coated, drug-eluting), including mechanical dilation by nondrug-delivery balloon angioplasty, endoluminal imaging using intravascular ultrasound (IVUS) or optical coherence tomography (OCT) when performed, imaging supervision, interpretation, and report, single major coronary artery or branch
0914T	Percutaneous transcatheter therapeutic drug delivery by intracoronary drug-delivery balloon (eg, drug-coated, drug-eluting) performed on a separate target lesion from the target lesion treated with balloon angioplasty, coronary stent placement or coronary atherectomy, including mechanical dilation by nondrug-delivery balloon angioplasty, endoluminal imaging using intravascular ultrasound (IVUS) or optical coherence tomography (OCT) when performed, imaging supervision, interpretation, and report, single major coronary artery or branch (List separately in addition to code for percutaneous coronary stent or atherectomy intervention)
36837	Percutaneous arteriovenous fistula creation, upper extremity, separate access sites of the peripheral artery and peripheral vein, including fistula maturation procedures (eg, transluminal balloon angioplasty, coil embolization) when performed, including all vascular access, imaging guidance and radiologic supervision and interpretation
55880	Ablation of malignant prostate tissue, transrectal, with high intensity-focused ultrasound (HIFU), including ultrasound guidance
83704	Lipoprotein, blood; quantitation of lipoprotein particle number(s) (eg, by nuclear magnetic resonance spectroscopy), includes lipoprotein particle subclass(es), when performed

Table 2

HCPCS Codes	Description
C1601	Endoscope, single-use (i.e., disposable), pulmonary, imaging/illumination device (insertable)
C9772	Revascularization, endovascular, open or percutaneous, tibial/peroneal artery(ies), with intravascular lithotripsy, includes angioplasty within the same vessel(s), when performed
C9777	Esophageal mucosal integrity testing by electrical impedance, transoral, includes esophagoscopy or esophagogastrroduodenoscopy
C9781	Arthroscopy, shoulder, surgical; with implantation of subacromial spacer (e.g., balloon), includes debridement (e.g., limited or extensive), subacromial decompression, acromioplasty, and biceps tenodesis when performed
S9090	Vertebral axial decompression, per session

Table 3

ICD-10 Procedure Codes	Description
XW0J3HA	Introduction of Paclitaxel-Coated Balloon Technology, One Balloon into Coronary Artery, One Artery, Percutaneous Approach, New Technology Group 10
XW0J3JA	Introduction of Paclitaxel-Coated Balloon Technology, Two Balloons into Coronary Artery, One Artery, Percutaneous Approach, New Technology Group 10
XW0J3KA	Introduction of Paclitaxel-Coated Balloon Technology, Three Balloons into Coronary Artery, One Artery, Percutaneous Approach, New Technology Group 10
XW0J3LA	Introduction of Paclitaxel-Coated Balloon Technology, Four or More Balloons into Coronary Artery, One Artery, Percutaneous Approach, New Technology Group 10

Reviews, Revisions, and Approvals	Revision Date	Approval Date
Policy developed.	08/26	08/26
Removed CPT Code 0722T from Table 1. References updated.	09/26	09/26

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Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care and are solely responsible for the medical advice and treatment of members/enrollees. This clinical policy is not intended to recommend treatment for members/enrollees. Members/enrollees should consult with their treating physician in connection with diagnosis and treatment decisions.

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members/enrollees and their representatives agree to be bound by such terms and conditions by providing services to members/enrollees and/or submitting claims for payment for such services.

Note: For Medicaid members/enrollees, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

Note: For Medicare members/enrollees, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs, and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at <http://www.cms.gov> for additional information.

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