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Medicare Advantage Policy Manual **Policy ID:** M-MED149

Investigational (Experimental) Services, New and Emerging Medical Technologies and Procedures, and Other Non-Covered Services

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IMPORTANT REMINDER

The Medicare Advantage Medical Policy manual is not intended to override the member Evidence of Coverage (EOC), which defines the insured's benefits, nor is it intended to dictate how providers are to practice medicine. Physicians and other health care providers are expected to exercise their medical judgment in providing the most appropriate care for the individual member.

The Medicare Advantage Medical Policies are designed to provide guidance regarding the decision-making process for the coverage or non-coverage of services or procedures in accordance with the member EOC and the Centers of Medicare and Medicaid Services (CMS) policies, when available. In the event of a conflict, applicable CMS policy or EOC language will take precedence over the Medicare Advantage Medical Policy. In the absence of CMS guidance for a requested service or procedure, the health plan may apply their Medical Policy Manual or MCG™ criteria, both of which are developed with an objective, evidence-based process using scientific evidence, current generally accepted standards of medical practice, and authoritative clinical practice guidelines.

Medicare and EOCs exclude from coverage, among other things, services or procedures considered to be investigational, cosmetic, or not medically necessary, and in some cases, providers may bill members for these non-covered services or procedures. Providers are encouraged to inform members in advance when they may be financially responsible for the cost of non-covered or excluded services.

DESCRIPTION

INVESTIGATIONAL (EXPERIMENTAL) SERVICES

Title XVIII of the Social Security Act, §1862(a)(1)(A) prohibits Medicare coverage for items and services which are not "reasonable and necessary" for the diagnosis and treatment of an injury or illness or to improve the functioning of a malformed body member. According to the *Medicare Claims Processing Manual, Chapter 23, §30.A*, if a procedure or device lacks scientific evidence regarding safety and efficacy because it is investigational or experimental, the service is noncovered because it is not reasonable and necessary to treat illness or injury.[1]

In the absence of a national coverage determination (NCD), local coverage determination (LCD), or other Medicare coverage guidance, Medicare regulations allow a Medicare Advantage Organization (MAO) to make its own coverage determination, applying an objective, evidence-based process, based on authoritative evidence.[2]

It is important to note the presence of a payment amount in the Medicare Physicians' Fee Schedule (MPFS) does not imply that Medicare has determined the service to be a "reasonable and necessary" covered service.[1] In addition, according to the Medicare Benefit Policy Manual, Chapter 14, while U.S. Food and Drug Administration (FDA) approval does not automatically guarantee coverage under Medicare, in order to even be *considered* for coverage under Medicare, devices must be either FDA- or Institutional Review Board (IRB)-approved. Therefore, any device that has not received FDA-approval would not be considered medically reasonable or necessary.[3] The FDA reviews data from well-designed studies and clinical trials in order to determine safety and effectiveness prior to approval for sale, but does not establish medical necessity of that device or drug. While Medicare may adopt FDA determinations regarding safety and effectiveness, CMS or Medicare contractors evaluate whether or not the drug or device is reasonable and necessary for the Medicare population under §1862(a)(1)(A). *(Note, not all services or procedures are subject to FDA review and approval.)*

Requests for health care services, treatments, procedures, or devices that are not addressed in an NCD, LCD, or other Medicare reference, or not specified as "covered" in Medicare benefit manuals or other transmittals may be reviewed to ensure sufficient evidence regarding safety and efficacy is available, ensuring the services are medically reasonable and necessary for members. *(See the "Policy Guidelines" below for important notes regarding Medicare and investigational services.)*

MEDICARE ADVANTAGE POLICY CRITERIA

Note: For services provided in the context of a clinical trial, or medical devices related to Category A or B Investigational Device Exemption (IDE) studies, please see Cross References

Procedures and items that are subject to Coverage with Evidence Development (CED) criteria may be addressed in separate Medicare Advantage medical policies when those services are reviewed by the health plan.[4] National coverage determinations (NCDs) that require CED can be found on the CMS web page for *Coverage with Evidence Development*. (See Cross References)

The following are new and emerging medical technologies reported with Category III CPT codes. These codes are generally created to track new, unproven therapies, devices, and tests. There are a number of reasons a service may be non-covered, including but not limited to, national coverage determination (NCD) guidance, lack of FDA approval, or the service is not considered "medically reasonable or necessary" under Title XVIII of the Social Security Act, §1862(a)(1)(A).

IMPORTANT NOTE: This list is not intended to be an all-inclusive list. Some procedures may be addressed in specific Medicare Advantage medical policies and therefore, would not be included in this Medicare medical policy, but the same rationale in this policy could apply. Other services not included in this list may also be non-covered. The absence or removal of a code from this medical policy does not imply coverage.

Codes	Number	Description & Manufacturer Information (when applicable)	Non-Coverage Rationale
CPT	0219T	Placement of a posterior intrafacet implant(s), unilateral or bilateral, including imaging and placement of bone graft(s) or synthetic device(s), single level; cervical (e.g., NuFix [NUTECH SPINE, Inc.] or TruFUSE®)	Noridian local coverage article *Billing and Coding: Facet Joint Interventions for Pain Management* (A58405)
	0220T	; thoracic	
	0221T	; lumbar	
	0222T	; each additional vertebral segment (List separately in addition to code for primary procedure)	
	0338T	Transcatheter renal sympathetic denervation, percutaneous approach including arterial puncture, selective catheter placement(s) renal artery(ies), fluoroscopy, contrast injection(s), intraprocedural roadmapping and radiological supervision and interpretation, including pressure gradient measurements, flush aortogram and diagnostic renal angiography when performed; unilateral (e.g., Symplicity™ renal denervation device [Medtronic, Inc.], EnligHTN™ multi-electrode renal denervation system [St. Jude Medical], One-Shot Renal Denervation System™ [Covidien], V2 renal denervation system™ [Vessix Vasular), Thermocouple Catheter™ [Biosense Webster])	As of most recent review, devices designed specifically for ablation of the renal sympathetic nerves have not received FDA-approval.
	0339T	; bilateral	
	0443T	Real-time spectral analysis of prostate tissue by fluorescence spectroscopy, including imaging guidance (List separately in addition to code for primary procedure) (e.g.,	As of most recent review, this has not received FDA-approval

		Precision Biopsy ClariCore Optical Biopsy System®)	
	0444T	Initial placement of a drug-eluting ocular insert under one or more eyelids, including fitting, training, and insertion, unilateral or bilateral	As of most recent review, this has not received FDA-approval
	0445T	Subsequent placement of a drug-eluting ocular insert under one or more eyelids, including re-training, and removal of existing insert, unilateral or bilateral	
	0469T	Retinal polarization scan, ocular screening with on-site automated results, bilateral	Medicare Status “N” code; Therefore, non-covered for Medicare and Medicare Advantage
	0481T	Injection(s), autologous white blood cell concentrate (autologous protein solution), any site, including image guidance, harvesting and preparation, when performed	As of most recent review, this has not received FDA-approval
	0512T	Extracorporeal shock wave for integumentary wound healing including topical application and dressing care; initial wound	As of most recent review, this has not received FDA-approval
	0513T	Extracorporeal shock wave for integumentary wound healing including topical application and dressing care; each additional wound (List separately in addition to code for primary procedure)	
	0515T	Insertion of wireless cardiac stimulator for left ventricular pacing, including device interrogation and programming, and imaging supervision and interpretation, when performed; complete system (includes electrode and generator [transmitter and battery]) (e.g., WiSE™ CRT System [EBR Systems, Inc])	As of most recent review, this has not received FDA-approval
	0516T	; electrode only	
	0517T	Insertion of wireless cardiac stimulator for left ventricular pacing, including device interrogation and programming, and imaging supervision and interpretation, when performed; both component(s) of pulse generator (battery and transmitter) only	

	0518T	Removal of pulse generator for wireless cardiac stimulator for left ventricular pacing;battery component only	
	0519T	Removal and replacement of pulse generator for wireless cardiac stimulator for left ventricular pacing, including device interrogation and programming; both components (battery and transmitter)	
	0520T	Removal and replacement of pulse generator for wireless cardiac stimulator for left ventricular pacing, including device interrogation and programming; battery component only	
	0521T	Interrogation device evaluation (in person) with analysis, review and report, includes connection, recording, and disconnection per patient encounter, wireless cardiac stimulator for left ventricular pacing (e.g., WiSE™ CRT System [EBR Systems, Inc])	
	0522T	Programming device evaluation (in person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis, including review and report, wireless cardiac stimulator for left ventricular pacing (e.g., WiSE™ CRT System [EBR Systems, Inc])	
	0547T	Bone-material quality testing by microindentation(s) of the tibia(s), with results reported as a score (e.g., OsteoProbe® [Active Life Scientific, Inc.])	As of most recent review, this has not received FDA-approval
	0553T	Percutaneous transcatheter placement of iliac arteriovenous anastomosis implant, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention	As of most recent review, this has not received FDA-approval
	0559T	Anatomic model 3D-printed from image data set(s); first individually prepared and processed component of an anatomic structure	Not medically reasonable or necessary under Medicare and §1862(a)(1)(A). This is to

0560T	; each additional individually prepared and processed component of an anatomic structure (List separately in addition to code for primary procedure)	plan a surgery, it does not "treat or diagnosis" an illness or injury. *Codes 0559T-0562T are for services which provide a printed physical multi-dimensional model of a patient's anatomy to aid in the planning of surgical procedures.*
0561T	Anatomic guide 3D-printed and designed from image data set(s); first anatomic guide	
0562T	; each additional anatomic guide (List separately in addition to code for primary procedure)	
0567T	Permanent fallopian tube occlusion with degradable biopolymer implant, transcervical approach, including transvaginal ultrasound (e.g., FemBloc® [Femasys, Inc.])	As of most recent review, this has not received FDA-approval.
0568T	Introduction of mixture of saline and air for sonosalpingography to confirm occlusion of fallopian tubes, transcervical approach, including transvaginal ultrasound and pelvic ultrasound (e.g., FemBloc® [Femasys, Inc.])	As of most recent review, this has not received FDA-approval.
0571T	Insertion or replacement of implantable cardioverter-defibrillator system with substernal electrode(s), including all imaging guidance and electrophysiological evaluation (includes defibrillation threshold evaluation, induction of arrhythmia, evaluation of sensing for arrhythmia termination, and programming or reprogramming of sensing or therapeutic parameters), when performed	As of most recent review, this has not received FDA-approval.
0572T	Insertion of substernal implantable defibrillator electrode	
0574T	Repositioning of previously implanted substernal implantable defibrillator-pacing electrode	
0575T	Programming device evaluation (in person) of implantable cardioverter-defibrillator system with substernal electrode, with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis, review and report by a physician or other qualified health care professional	

	0576T	Interrogation device evaluation (in person) of implantable cardioverter-defibrillator system with substernal electrode, with analysis, review and report by a physician or other qualified health care professional, includes connection, recording and disconnection per patient encounter	
	0577T	Electrophysiologic evaluation of implantable cardioverter defibrillator system with substernal electrode (includes defibrillation threshold evaluation, induction of arrhythmia, evaluation of sensing for arrhythmia termination, and programming or reprogramming of sensing or therapeutic parameters)	
	0578T	Interrogation device evaluation(s) (remote), up to 90 days, substernal lead implantable cardioverter-defibrillator system with interim analysis, review(s) and report(s) by a physician or other qualified health care professional	
	0579T	Interrogation device evaluation(s) (remote), up to 90 days, substernal lead implantable cardioverter-defibrillator system, remote data acquisition(s), receipt of transmissions and technician review, technical support and distribution of results	
	0582T	Transurethral ablation of malignant prostate tissue by high-energy water vapor thermotherapy, including intraoperative imaging and needle guidance	As of most recent review, this has not received FDA-approval.
	0602T	Glomerular filtration rate (GFR) measurement(s), transdermal, including sensor placement and administration of a single dose of fluorescent pyrazine agent (e.g., Transdermal GFR System [MediBeacon])	As of most recent review, this has not received FDA-approval.
	0603T	Glomerular filtration rate (GFR) monitoring, transdermal, including sensor placement and administration of more than one dose of fluorescent pyrazine agent, each 24 hours	
	0604T	Optical coherence tomography (OCT) of retina, remote, patient-initiated image	

		capture and transmission to a remote surveillance center unilateral or bilateral; initial device provision, set-up and patient education on use of equipment (e.g., Home OCT [Notal Vision])	As of most recent review, this has not received FDA-approval.
	0605T	Optical coherence tomography (OCT) of retina, remote, patient-initiated image capture and transmission to a remote surveillance center unilateral or bilateral; remote surveillance center technical support, data analyses and reports, with a minimum of 8 daily recordings, each 30 days	
	0606T	Optical coherence tomography (OCT) of retina, remote, patient-initiated image capture and transmission to a remote surveillance center unilateral or bilateral; review, interpretation and report by the prescribing physician or other qualified health care professional of remote surveillance center data analyses, each 30 days	
	0613T	Percutaneous transcatheter implantation of interatrial septal shunt device, including right and left heart catheterization, intracardiac echocardiography, and imaging guidance by the proceduralist, when performed (e.g., V-Wave Shunt [V-Wave Medical])	As of most recent review, this has not received FDA-approval.
	0614T	Removal and replacement of substernal implantable defibrillator pulse generator	As of most recent review, this has not received FDA-approval.
	0620T	Endovascular venous arterialization, tibial or peroneal vein, with transcatheter placement of intravascular stent graft(s) and closure by any method, including percutaneous or open vascular access, ultrasound guidance for vascular access when performed, all catheterization(s) and intraprocedural roadmapping and imaging guidance necessary to complete the intervention, all associated radiological supervision and interpretation, when performed (e.g., LimFlow Stent Graft System)	As of most recent review, this has not received FDA-approval.
	0623T	Automated quantification and characterization of coronary atherosclerotic	Not medically reasonable or necessary under

		plaque to assess severity of coronary disease, using data from coronary computed tomographic angiography; data preparation and transmission, computerized analysis of data, with review of computerized analysis output to reconcile discordant data, interpretation and report (e.g., Cleerly Cornonary* [Clearly Inc.])	Medicare and §1862(a)(1)(A). This quantifies and characterizes arterial plaque buildup. It does not “treat or diagnosis” an illness or injury.
	0624T	; data preparation and transmission	
	0625T	; computerized analysis of data from coronary computed tomographic angiography	
	0626T	; review of computerized analysis output to reconcile discordant data, interpretation and report	
	0627T	Percutaneous injection of allogeneic cellular and/or tissue-based product, intervertebral disc, unilateral or bilateral injection, with fluoroscopic guidance, lumbar; first level (e.g., Viable Allograft Supplemental Disc Regeneration [VAST] [Via Disc] [Vivex Biologics])	As of most recent review, this has not received FDA-approval.
	0628T	; each additional level (List separately in addition to code for primary procedure)	
	0629T	Percutaneous injection of allogeneic cellular and/or tissue-based product, intervertebral disc, unilateral or bilateral injection, with CT guidance, lumbar; first level	
	0630T	; each additional level (List separately in addition to code for primary procedure)	
	0631T	Transcutaneous visible light hyperspectral imaging measurement of oxyhemoglobin, deoxyhemoglobin, and tissue oxygenation, with interpretation and report, per extremity (e.g., HyperView™ [HyperMed Imaging, Inc.])	Not medically reasonable or necessary under Medicare and §1862(a)(1)(A). This is used to determine oxygenation levels in superficial tissues for patients with potential circulatory compromise, but it does not “treat or diagnosis” an illness or injury.

	0632T	Percutaneous transcatheter ultrasound ablation of nerves innervating the pulmonary arteries, including right heart catheterization, pulmonary artery angiography, and all imaging guidance (e.g., Therapeutic IntraVascular UltraSound [TIVUS™; SoniVie Ltd.])	As of most recent review, this has not received FDA-approval.
	0639T	Wireless skin sensor thermal anisotropy measurement(s) and assessment of flow in cerebrospinal fluid shunt, including ultrasound guidance, when performed (e.g., Flowsense™ [Rhaeos])	As of most recent review, this has not received FDA-approval.
	0640T	Noncontact near-infrared spectroscopy (eg, for measurement of deoxyhemoglobin, oxyhemoglobin, and ratio of tissue oxygenation), other than for screening for peripheral arterial disease, image acquisition, interpretation, and report; first anatomic site	Not medically reasonable or necessary under Medicare and §1862(a)(1)(A). This is used to determine oxygenation levels in superficial tissues for patients with potential circulatory compromise, but it does not "treat or diagnosis" an illness or injury.
	~~0641T~~	~~+ ; image acquisition only, each flap or wound~~ (Deleted 01/01/2024)	
	~~0642T~~	~~+ ; interpretation and report only, each flap or wound~~ (Deleted 01/01/2024)	
	0645T	Transcatheter implantation of coronary sinus reduction device including vascular access and closure, right heart catheterization, venous angiography, coronary sinus angiography, imaging guidance, and supervision and interpretation, when performed (e.g., Neovasc Reducer ™ System)	In October 2020, FDA panel summary indicating no clear evidence of effectiveness or benefit/harm ratio. *(FDA web page)* Procedures which lack scientific evidence regarding safety and efficacy are noncovered by Medicare as they are considered not reasonable or necessary *(Medicare Claims Processing Manual, Ch. 23, §30 A)* under the Social Security Act Sec.1862 (a)(1)(A).
	0660T	Implantation of anterior segment intraocular nonbiodegradable drug-eluting system, internal approach	As of most recent review, this has not received FDA-approval.

0661T	Removal and reimplantation of anterior segment intraocular nonbiodegradable drug-eluting implant	
0672T	Endovaginal cryogen-cooled, monopolar radiofrequency remodeling of the tissues surrounding the female bladder neck and proximal urethra for urinary incontinence	As of most recent review, this has not received FDA-approval.
0674T	Laparoscopic insertion of new or replacement of permanent implantable synchronized diaphragmatic stimulation system for augmentation of cardiac function, including an implantable pulse generator and diaphragmatic lead(s)	
0675T	Laparoscopic insertion of new or replacement of diaphragmatic lead(s), permanent implantable synchronized diaphragmatic stimulation system for augmentation of cardiac function, including connection to an existing pulse generator; first lead	
0676T	Laparoscopic insertion of new or replacement of diaphragmatic lead(s), permanent implantable synchronized diaphragmatic stimulation system for augmentation of cardiac function, including connection to an existing pulse generator; each additional lead	
0677T	Laparoscopic repositioning of diaphragmatic lead(s), permanent implantable synchronized diaphragmatic stimulation system for augmentation of cardiac function, including connection to an existing pulse generator; first repositioned lead	
0678T	Laparoscopic repositioning of diaphragmatic lead(s), permanent implantable synchronized diaphragmatic stimulation system for augmentation of cardiac function, including connection to an existing pulse generator; each additional repositioned lead (List separately in addition to code for primary procedure)	
0679T	Laparoscopic removal of diaphragmatic lead(s), permanent implantable synchronized diaphragmatic stimulation system for augmentation of cardiac function	
0680T	Insertion or replacement of pulse generator only, permanent implantable synchronized diaphragmatic stimulation system for augmentation of cardiac function, with connection to existing lead(s)	

	0681T	Relocation of pulse generator only, permanent implantable synchronized diaphragmatic stimulation system for augmentation of cardiac function, with connection to existing dual leads	
	0682T	Removal of pulse generator only, permanent implantable synchronized diaphragmatic stimulation system for augmentation of cardiac function	
	0683T	Programming device evaluation (in-person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis, review and report by a physician or other qualified health care professional, permanent implantable synchronized diaphragmatic stimulation system for augmentation of cardiac function	
	0684T	Peri-procedural device evaluation (in-person) and programming of device system parameters before or after a surgery, procedure, or test with analysis, review, and report by a physician or other qualified health care professional, permanent implantable synchronized diaphragmatic stimulation system for augmentation of cardiac function	
	0685T	Interrogation device evaluation (in-person) with analysis, review and report by a physician or other qualified health care professional, including connection, recording and disconnection per patient encounter, permanent implantable synchronized diaphragmatic stimulation system for augmentation of cardiac function	
	0686T	Histotripsy (ie, non-thermal ablation via acoustic energy delivery) of malignant hepatocellular tissue, including image guidance	
	0697T	Quantitative magnetic resonance for analysis of tissue composition (eg, fat, iron, water content), including multiparametric data acquisition, data preparation and transmission, interpretation and report, obtained without diagnostic MRI examination of the same anatomy (eg, organ, gland, tissue, target structure) during the same session; multiple organs	This is not a magnetic resonance procedure covered under the Medicare NCD 220.2. Not medically reasonable or necessary under Medicare and §1862(a)(1)(A). This analyzes body composition to determine if more invasive procedures (i.e., biopsies)

			are needed, it does not “treat or diagnosis” an illness or injury.
	0698T	Quantitative magnetic resonance for analysis of tissue composition (eg, fat, iron, water content), including multiparametric data acquisition, data preparation and transmission, interpretation and report, obtained with diagnostic MRI examination of the same anatomy (eg, organ, gland, tissue, target structure); multiple organs (List separately in addition to code for primary procedure)	This is not a magnetic resonance procedure covered under the Medicare NCD 220.2. Not medically reasonable or necessary under Medicare and §1862(a)(1)(A). This analyzes body composition to determine if more invasive procedures (i.e., biopsies) are needed, it does not “treat or diagnosis” an illness or injury.
	0714T	Transperineal laser ablation of benign prostatic hyperplasia, including imaging guidance	As of most recent review, devices designed for transperineal laser ablation of benign prostatic hyperplasihave not received FDA-approval.
	0716T	Cardiac acoustic waveform recording with automated analysis and generation of coronary artery disease risk score	Based on limited description and purpose will follow noncovered language that states: "Medicare does not cover items and services that are not reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body member."
	0719T	Posterior vertebral joint replacement, including bilateral facetectomy, laminectomy, and radical discectomy, including imaging guidance, lumbar spine, single segment	As of most recent review, has not received FDA-approval.
	0725T	Vestibular device implantation, unilateral	
	0726T	Removal of implanted vestibular device, unilateral	
	0727T	Removal and replacement of implanted vestibular device, unilateral	

	0728T	Diagnostic analysis of vestibular implant, unilateral; with initial programming	
	0729T	Diagnostic analysis of vestibular implant, unilateral; with subsequent programming	
	0732T	Immunotherapy administration with electroporation, intramuscular	As of most recent review, has not received FDA-approval.
	0738T	Treatment planning for magnetic field induction ablation of malignant prostate tissue, using data from previously performed magnetic resonance imaging (MRI) examination	
	0739T	Ablation of malignant prostate tissue by magnetic field induction, including all intraprocedural, transperineal needle/catheter placement for nanoparticle installation and intraprocedural temperature monitoring, thermal dosimetry, bladder irrigation, and magnetic field nanoparticle activation	
	0744T	Insertion of bioprosthetic valve, open, femoral vein, including duplex ultrasound imaging guidance, when performed, including autogenous or nonautogenous patch graft (eg, polyester, ePTFE, bovine pericardium), when performed	
	0745T	Cardiac focal ablation utilizing radiation therapy for arrhythmia; noninvasive arrhythmia localization and mapping of arrhythmia site (nidus), derived from anatomical image data (eg, CT, MRI, or myocardial perfusion scan) and electrical data (eg, 12-lead ECG data), and identification of areas of avoidance	
	0746T	Cardiac focal ablation utilizing radiation therapy for arrhythmia; conversion of arrhythmia localization and mapping of arrhythmia site (nidus) into a multidimensional radiation treatment plan	
	0747T	Cardiac focal ablation utilizing radiation therapy for arrhythmia; delivery of radiation therapy, arrhythmia	

0748T	Injections of stem cell product into perianal perifistular soft tissue, including fistula preparation (eg, removal of setons, fistula curettage, closure of internal openings)
0764T	Assistive algorithmic electrocardiogram risk-based assessment for cardiac dysfunction (eg, low-ejection fraction, pulmonary hypertension, hypertrophic cardiomyopathy); related to concurrently performed electrocardiogram (List separately in addition to code for primary procedure)
0765T	Assistive algorithmic electrocardiogram risk-based assessment for cardiac dysfunction (eg, low-ejection fraction, pulmonary hypertension, hypertrophic cardiomyopathy); related to previously performed electrocardiogram
0770T	Virtual reality technology to assist therapy (List separately in addition to code for primary procedure)
0776T	Therapeutic induction of intra-brain hypothermia, including placement of a mechanical temperature-controlled cooling device to the neck over carotids and head, including monitoring (eg, vital signs and sport concussion assessment tool 5 [SCAT5]), 30 minutes of treatment
0781T	Bronchoscopy, rigid or flexible, with insertion of esophageal protection device and circumferential radiofrequency destruction of the pulmonary nerves, including fluoroscopic guidance when performed; bilateral mainstem bronchi
0782T	Bronchoscopy, rigid or flexible, with insertion of esophageal protection device and circumferential radiofrequency destruction of the pulmonary nerves, including fluoroscopic guidance when performed; unilateral mainstem bronchus

	0793T	Percutaneous transcatheter thermal ablation of nerves innervating the pulmonary arteries, including right heart catheterization, pulmonary artery angiography, and all imaging guidance	As of most recent review, this has not received FDA-approval.
	0794T	Patient-specific, assistive, rules-based algorithm for ranking pharmaco-oncologic treatment options based on the patient's tumor-specific cancer marker information obtained from prior molecular pathology, immunohistochemical, or other pathology results which have been previously interpreted and reported separately	Noridian local coverage article Algorithm definition as a component of a laboratory test (A58674). Medical necessity has not been demonstrated for this algorithm.
	0811T	Remote multi-day complex uroflowmetry (eg, calibrated electronic equipment); setup and patient education on use of equipment	As of most recent review, this has not received FDA-approval.
	0812T	Remote multi-day complex uroflowmetry (eg, calibrated electronic equipment); device supply with automated report generation, up to 10 days	
	0814T	Percutaneous injection of calcium-based biodegradable osteoconductive material, proximal femur, including imaging guidance, unilateral	As of most recent review, this has not received FDA-approval.
	0859T	Noncontact near-infrared spectroscopy (eg, for measurement of deoxyhemoglobin, oxyhemoglobin, and ratio of tissue oxygenation), other than for screening for peripheral arterial disease, image acquisition, interpretation, and report; each additional anatomic site (List separately in addition to code for primary procedure)	As of most recent review, this has not received FDA-approval.
	0860T	Noncontact near-infrared spectroscopy (eg, for measurement of deoxyhemoglobin, oxyhemoglobin, and ratio of tissue oxygenation), for screening for peripheral arterial disease, including provocative maneuvers, image acquisition, interpretation, and report, one or both lower extremities	
	0861T	Removal of pulse generator for wireless cardiac stimulator for left ventricular pacing; both components (battery and transmitter)	As of most recent review, this has not received FDA-approval.
	0862T	Relocation of pulse generator for wireless cardiac stimulator for left ventricular pacing, including device interrogation and programming; battery component only	
	0863T	Relocation of pulse generator for wireless cardiac stimulator for left ventricular pacing, including device interrogation and programming; transmitter component only	

	0865T	Quantitative magnetic resonance image (MRI) analysis of the brain with comparison to prior magnetic resonance (MR) study(ies), including lesion identification, characterization, and quantification, with brain volume(s) quantification and/or severity score, when performed, data preparation and transmission, interpretation and report, obtained without diagnostic MRI examination of the brain during the same session	Not medically reasonable or necessary under Medicare and §1862(a)(1)(A). This quantifies procedure and characterizes brain lesions. It does not "treat or diagnosis" an illness or injury.
	0866T	Quantitative magnetic resonance image (MRI) analysis of the brain with comparison to prior magnetic resonance (MR) study(ies), including lesion detection, characterization, and quantification, with brain volume(s) quantification and/or severity score, when performed, data preparation and transmission, interpretation and report, obtained with diagnostic MRI examination of the brain (List separately in addition to code for primary procedure)	Not medically reasonable or necessary under Medicare and §1862(a)(1)(A). This quantifies procedure and characterizes brain lesions. It does not "treat or diagnosis" an illness or injury.
HCPCS	C9783	Blinded procedure for transcatheter implantation of coronary sinus reduction device or placebo control, including vascular access and closure, right heart catheterization, venous and coronary sinus angiography, imaging guidance and supervision and interpretation when performed in an approved investigational device exemption (ide) study	Comparable code to 0645T
	C9790	Histotripsy (ie, non-thermal ablation via acoustic energy delivery) of malignant renal tissue, including image guidance	

Proprietary Laboratory Analysis (PLA) and Multianalyte Assay Codes

The following laboratory tests are considered "not medically reasonable or necessary" under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). Jurisdiction of claims for laboratory services furnished by an independent laboratory normally lies with the carrier serving the area in which the laboratory test is performed.[5] Specific Medicare guidance for each test is noted below:

IMPORTANT NOTE: This list is updated routinely with codes as they are released. **It is not intended to be an all-inclusive list.** The absence of a test code from this medical policy does not imply coverage, as some tests may be addressed in other Medicare Advantage medical policies.

Codes	Number	Description and Non-coverage Rationale	Test Information
CPT	0015M	Adrenal cortical tumor, biochemical assay of 25 steroid markers, utilizing 24-hour urine specimen	*Adrenal Mass Panel, 24 Hour, Urine*

		and clinical parameters, prognostic algorithm reported as a clinical risk and integrated clinical steroid risk for adrenal cortical carcinoma, adenoma, or other adrenal malignancy ✓ Not medically reasonable or necessary under Medicare and §1862(a)(1)(A). This test provides a risk score, it does not "treat or diagnosis" an illness or injury.	Mayo Clinic (MN)
	0052U	Lipoprotein, blood, high resolution fractionation and quantitation of lipoproteins, including all five major lipoprotein classes and subclasses of HDL, LDL, and VLDL by vertical auto profile ultracentrifugation ✓ MolDX: Biomarkers in Cardiovascular Risk Assessment (L36129) *(Medicare has coverage for defined cholesterol tests. Non-coverage of lipoprotein subclasses from this LCD is applied to this test.)*	*VAP Cholesterol Test* VAP Diagnostics Laboratory, Inc. (AL)
	0058U	Oncology (Merkel cell carcinoma), detection of antibodies to the Merkel cell polyoma virus oncoprotein (small T antigen), serum, quantitative • The MolDX Program requires labs to submit a technology assessment (TA) to provide evidence of analytical and clinical validity (AV/CV), and clinical utility (CU). *(Noridian article A54554)* • The Noridian LCD L36256 states reimbursement is only allowed for "approved tests… for dates of service consistent with the effective date of the coverage determination" after MolDX review. • If a test does not have a coverage determination, then coverage is not allowed because evidence of clinical validity or utility has not been established via the TA review process. • This test is not considered medically reasonable and necessary under SSA §1862(a)(1)(A) until a MolDX review is complete and coverage is indicated by MolDX or Noridian.	*Merkel SmT Oncoprotein Antibody Titer test* University of Washington, Department of Laboratory Medicine (WA)
	0059U	Oncology (Merkel cell carcinoma), detection of antibodies to the Merkel cell polyoma virus capsid protein (VP1), serum, reported as positive or negative • The MolDX Program requires labs to submit a technology assessment (TA) to provide evidence of analytical and clinical validity (AV/CV), and clinical utility (CU). *(Noridian article A54554)*	*Merkel Virus VP1 Capsid Antibody test* University of Washington, Department of Laboratory Medicine (WA)

		• The Noridian LCD L36256 states reimbursement is only allowed for “approved tests… for dates of service consistent with the effective date of the coverage determination” after MolDX review. • If a test does not have a coverage determination, then coverage is not allowed because evidence of clinical validity or utility has not been established via the TA review process. • This test is not considered medically reasonable and necessary under SSA §1862(a)(1)(A) until a MolDX review is complete and coverage is indicated by MolDX or Noridian.	
	0061U	Transcutaneous measurement of five biomarkers (tissue oxygenation [StO2], oxyhemoglobin [ctHbO2], deoxyhemoglobin [ctHbR], papillary and reticular dermal hemoglobin concentrations [ctHb1 and ctHb2]), using spatial frequency domain imaging (SFDI) and multi-spectral analysis • The MolDX Program requires labs to submit a technology assessment (TA) to provide evidence of analytical and clinical validity (AV/CV), and clinical utility (CU). *(Noridian article A54552)* • The Noridian LCD L35160 states reimbursement is only allowed for “approved tests… for dates of service consistent with the effective date of the coverage determination” after MolDX review. • If a test does not have a coverage determination, then coverage is not allowed because evidence of clinical validity or utility has not been established via the TA review process. • This test is not considered medically reasonable and necessary under SSA §1862(a)(1)(A) until a MolDX review is complete and coverage is indicated by MolDX or Noridian.	*Transcutaneous multispectral measurement of tissue oxygenation and hemoglobin using Spatial Frequency Domain Imaging (SFDI) test* Modulated Imaging, Inc. (CA)
	0062U	Autoimmune (systemic lupus erythematosus), IgG and IgM analysis of 80 biomarkers, utilizing serum, algorithm reported with a risk score • With limited exceptions (such as single gene tests), the MolDX Program requires labs to submit a technology assessment (TA) to provide evidence of analytical and clinical validity (AV/CV), and clinical utility (CU). This is especially applicable to new tests (e.g., tests with multiple genes with or without algorithmic analysis with diagnostic and/or prognostic purposes that have not received FDA companion diagnostic status or been universally recognized by recognized authorities such as	*SLE-key Rule Out* Veracis (VA)

		NCCN, ASCO or other professional societies). *(Palmetto LCD L35025)* • The Palmetto LCD L35025 states reimbursement is only allowed for "approved tests… for dates of service consistent with the effective date of the coverage determination" after MolDX review. • If a test does not have a coverage determination, then coverage is not allowed because evidence of clinical validity or utility has not been established via the TA review process. • This test is not considered medically reasonable and necessary under SSA §1862(a)(1)(A) until a MolDX review is complete and coverage is indicated by MolDX.	
	0063U	Neurology (autism), 32 amines by LC-MS/MS, using plasma, algorithm reported as metabolic signature associated with autism spectrum disorder Molecular Pathology Procedures (L35000) *(Specifically see the language in the LCD that reads, "Molecular pathology tests for diseases or conditions that manifest severe signs or symptoms in newborns and in early childhood or that result in early death… could be subject to automatic denials since these tests are not usually relevant to a Medicare beneficiary.")*	*NPDX ASD ADM Panel I* Stemina Biomarker Discovery, Inc d/b/a NeuroPointDX (WI)
	0096U	Human Papillomavirus (HPV), high-risk types (ie, 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, 68), male urine Most men who get HPV do not develop symptoms and the infection usually resolves by itself. This test is a screening test, and HPV screening testing used outside of NCD 210.2.1 is non-covered under Medicare. In addition, diagnostic tests that are **not** ordered by a physician for diagnostic or clinical decision-making are also non-covered under Medicare. Therefore, this test is non-covered under Medicare. Coverage exceptions may be made on appeal if this test is used for *diagnostic* purposes **if** a patient has signs or symptoms of disease, and the ordering physician will use these test results to make a diagnosis or make treatment decisions for a relevant illness or condition.	*HPV, High Risk Male Urine* Molecular Testing Labs (WA)
	0117U	Pain management, analysis of 11 endogenous analytes (methylmalonic acid, xanthurenic acid,	*Foundation PISM*

		homocysteine, pyroglutamic acid, vanilmandelate, 5- hydroxyindoleacetic acid, hydroxymethylglutarate, ethylmalonate, 3-hydroxypropyl mercapturic acid (3-HPMA), quinolinic acid, kynurenic acid), LCMS/MS, urine, algorithm reported as a pain-index score with likelihood of atypical biochemical function associated with pain While this test may provide information during work-up, the test results do not provide data used to diagnose a condition or make treatment decisions. Decisions are not made based on this testing that would not otherwise have been made *without* this test. Therefore, this test is considered not medically reasonable or necessary under SSA §1862(a)(1)(A).	Ethos Laboratories
	0119U	Cardiology, ceramides by liquid chromatography–tandem mass spectrometry, plasma, quantitative report with risk score for major cardiovascular events **Minnesota**: According to the article for *Molecular Pathology Procedures- Related to Molecular Policy Procedures LCD (L35000)* (A56199) Screening services such as pre-symptomatic genetic tests and services used to detect an undiagnosed disease or disease predisposition are not a Medicare benefit and are not covered. Similarly, Medicare may not reimburse the costs of tests/examinations that assess the risk of a condition unless the risk assessment clearly and directly effects the management of the patient." **Florida**: The LCD for *Molecular Pathology Procedures* L34519 includes the same notes as those mentioned above.	*MI-HEART Ceramides, Plasma* Mayo Clinic Laboratory (MN and FL)
	0251U	Hepcidin-25, enzyme-linked immunosorbent assay (ELISA), serum or plasma For asymptomatic individuals, this testing would be considered non-covered, as a screening test. For symptomatic individuals, the NCD for *Serum Iron Studies* (190.18) provides coverage for iron deficiency tests, but does not include hepcidin as a covered test. Non-coverage of this test is not considered restrictive under Medicare because	*Intrinsic Hepcidin IDx™ Test* IntrinsicDx, Intrinsic LifeSciences™ LLC. (CA and FL)

		there are other test options available to test for iron deficiency. Therefore, this test is considered not medically reasonable or necessary under SSA §1862(a)(1)(A).	
	0342U	Oncology (pancreatic cancer), multiplex immunoassay of C5, C4, cystatin C, factor B, osteoprotegerin (OPG), gelsolin, IGFBP3, CA125 and multiplex electrochemiluminescent immunoassay (ECLIA) for CA19-9, serum, diagnostic algorithm reported qualitatively as positive, negative, or borderline • According to the article for Molecular Pathology Procedures- Related to Molecular Policy Procedures LCD *(L35000)* (A56199), screening services such as pre-symptomatic genetic tests and services used to detect an undiagnosed disease or disease predisposition are not a Medicare benefit and are not covered. Similarly, Medicare may not reimburse the costs of tests/examinations that assess the risk of a condition unless the risk assessment clearly and directly effects the management of the patient."	*IMMray® PanCan-d* Immunovia, Inc. (MA)
	0344U	Hepatology (nonalcoholic fatty liver disease [NAFLD]), semiquantitative evaluation of 28 lipid markers by liquid chromatography with tandem mass spectrometry (LC-MS/MS), serum, reported as at-risk for nonalcoholic steatohepatitis (NASH) or not NASH According to Billing and Coding: Molecular Pathology and Genetic Testing (A58917), screening services such as pre-symptomatic genetic tests and services used to detect an undiagnosed disease or disease predisposition are not a Medicare benefit and are not covered. Similarly, Medicare may not reimburse the costs of tests/examinations that assess the risk of a condition unless the risk assessment clearly and directly effects the management of the patient."	*OWLiver* Cima Sciencies (TX)
	0361U	Neurofilament light chain, digital immunoassay, plasma, quantitative	

	Not medically reasonable or necessary under Medicare and §1862(a)(1)(A). This is a marker associated with disease severity, it is not used in the diagnosis or treatment of any disorder.
0443U	Neurofilament light chain (NfL), ultra-sensitive immunoassay, serum or cerebrospinal fluid Not medically reasonable or necessary under Medicare and §1862(a)(1)(A). This is a marker associated with disease severity, it is not used in the diagnosis or treatment of any disorder.

POLICY GUIDELINES

To determine whether a medical technology is a proven, medically necessary service, device, or procedure, the MAO conducts literature searches and evaluates the published scientific evidence related to each technology. The published evidence is reviewed against five (5) technology assessment criteria. In order for a technology to be considered medically necessary, all five (5) criteria must be met. If any one or more of the following criteria are not met, then the technology is considered investigational:

1. The technology must have final approval from the appropriate government regulatory bodies (i.e., Food and Drug Administration [FDA]). An approval granted as an interim step (i.e., Treatment IND) in the governmental body's regulatory process is not sufficient.
2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes, and consist of well-designed and well-conducted investigations published in peer-reviewed journals. The quality of the studies and the consistency of the results are considered when evaluating the evidence.
3. The technology must improve the net health outcome (the technology's beneficial effects on health outcomes should outweigh any harmful effects on health outcomes).
4. The technology must be as beneficial as any established alternatives. This means the technology should improve the net health outcome as much as or more than established alternatives.
5. The improvement must be attainable outside the investigational settings. When used under the usual conditions of medical practice, the technology should be reasonably expected to satisfy technology evaluation criteria #3 and #4.

In addition to the above criteria, the following additional criteria apply to new diagnostic technologies (e.g., imaging studies, laboratory procedures, home monitoring devices):

1. Technical feasibility is demonstrated, including reproducibility and precision. For comparison among studies, a common standardized protocol for the new diagnostic technology is established.
2. For accurate interpretation of study results, sensitivities, specificities, and positive and negative predictive values compared to standards are established.
3. The clinical utility of a diagnostic technique, i.e., how the results of the study can be used to benefit patient management, is established. The clinical utility of both positive and negative tests must be established.

CROSS REFERENCES

Medicare Advantage Medical Policy Development and Review, Introduction, Policy No. M-01

Clinical Trials and Investigational Device Exemption (IDE) Studies, Medicine, Policy No. M-150

Coverage with Evidence Development (CED) Studies and Registries, Medicine, Policy No. M-156

Various Medicare Advantage medical policies for specific procedures, services, or devices

REFERENCES

1. Medicare Claims Processing Manual, Chapter 23 - Fee Schedule Administration and Coding Requirements, §30 - Services Paid Under the Medicare Physician's Fee Schedule, A. Physician's Services
2. Medicare Managed Care Manual, Chapter 4 - Benefits and Beneficiary Protections, §90.5 – Creating New Guidance
3. Medicare Benefit Policy Manual, Chapter 14 - Medical Devices, §10 - Coverage of Medical Devices
4. Medicare Managed Care Manual, Chapter 4 - Benefits and Beneficiary Protections, §10.7.3 – Payment for Clinical Studies Approved Under Coverage with Evidence Development (CED)
5. Medicare Claims Processing Manual, Chapter 1 - General Billing Requirements, §10.1.5.4 - Independent Laboratories

***IMPORTANT NOTE:** Medicare Advantage medical policies use the most current Medicare references available at the time the policy was developed. Links to Medicare references will take viewers to external websites outside of the health plan's web control as these sites are not maintained by the health plan.*