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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
	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 (LCA) for *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	
	~~0356T~~	~~Insertion of drug-eluting implant (including punctal dilation and implant removal when performed) into lacrimal canaliculus, each~~	~~As of most recent review, this has not received FDA-approval.~~ Deleted code 01/01/2022

	0378T	Visual field assessment, with concurrent real time data analysis and accessible data storage with patient initiated data transmitted to a remote surveillance center for up to 30 days; review and interpretation with report by a physician or other qualified health care professional (ForeseeHome™ AMD Monitoring Program [Notal Vision™])	Not medically reasonable or necessary under Medicare and §1862(a)(1)(A). This device is a monitoring system, it does not "treat or diagnosis" an illness or injury.
	0379T	; technical support and patient instructions, surveillance, analysis, and transmission of daily and emergent data reports as prescribed by a physician or other qualified health care professional	
	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., Precision Biopsy ClariCore Optical Biopsy System®)	As of most recent review, this has not received FDA-approval
	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
	0493T	Contact near-infrared spectroscopy studies of lower extremity wounds (eg, for oxyhemoglobin measurement)	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	; pulse generator component(s) (battery and/or transmitter) only	
	0518T	Removal of only pulse generator component(s) (battery and/or transmitter) of wireless cardiac stimulator for left ventricular pacing (e.g., WiSE™ CRT System [EBR Systems, Inc])	
	0519T	Removal and replacement of wireless cardiac stimulator for left ventricular pacing; pulse generator component(s) (battery and/or transmitter) (e.g., WiSE™ CRT System [EBR Systems, Inc])	
	0520T	; pulse generator component(s) (battery and/or transmitter), including placement of a new electrode	
	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	As of most recent review, this has not received FDA-approval

		Life Scientific, Inc.])	
	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 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.*
	0560T	; each additional individually prepared and processed component of an anatomic structure (List separately in addition to code for primary procedure)	
	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	
	0609T	Magnetic resonance spectroscopy, determination and localization of discogenic pain (cervical, thoracic, or lumbar); acquisition of single voxel data, per disc, on biomarkers (ie, lactic acid, carbohydrate, alanine, laal, propionic acid, proteoglycan, and collagen) in at least 3 discs	NCD 220.2.1
	0610T	Magnetic resonance spectroscopy, determination and localization of discogenic pain (cervical, thoracic, or lumbar); transmission of biomarker data for software analysis	
	0611T	Magnetic resonance spectroscopy, determination and localization of discogenic pain (cervical, thoracic, or lumbar); postprocessing for algorithmic analysis of	

		biomarker data for determination of relative chemical differences between discs	
	0612T	Magnetic resonance spectroscopy, determination and localization of discogenic pain (cervical, thoracic, or lumbar); interpretation and report	
	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.
	0621T	Trabeculostomy ab interno by laser; (e.g., ExTra ELT)	As of most recent review, this has not received FDA-approval.
	0622T	; with use of ophthalmic endoscope	
	0623T	Automated quantification and characterization of coronary atherosclerotic 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.])	Not medically reasonable or necessary under 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 studies of flap or wound (eg, for measurement of deoxyhemoglobin, oxyhemoglobin, and ratio of	Not medically reasonable or necessary under Medicare and §1862(a)(1)(A). This is

		tissue oxygenation [StO2]); image acquisition, interpretation and report, each flap or wound (SnapshotNIR)	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	
	0642T	; interpretation and report only, each flap or wound	
	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).
	0648T	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; single organ	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.
	0649T	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); single organ (List separately in addition to code for primary procedure)	
	0656T	Vertebral body tethering, anterior; up to 7 vertebral segments (e.g., Tether Vertebral Body Tethering System [Zimmer Biomet])	This system received FDA humanitarian device exemption (HDE) approval in August 2019 as a treatment of skeletally *immature* patients. The majority of the Medicare
	0657T	; 8 or more vertebral segments	

			population would not be “skeletally immature,” making the use of this system on these individuals outside of the HUD intended use.
	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	
	0664T	Donor hysterectomy (including cold preservation); open, from cadaver donor	No transplant programs are CMS-approved for uterine transplantation. In addition, medically reasonable and necessary infertility treatment is covered under Medicare (*Medicare Benefit Policy Manual, Ch. 15, §20.1 – Physician Expense for Surgery, Childbirth, and Treatment for Infertility*); However, procedures must still have established evidence of safety and efficacy. Procedures which lack scientific evidence of safety and efficacy are investigational (experimental) and noncovered as they are considered not reasonable and necessary to treat illness or injury under Medicare *(Medicare Claims Processing Manual, Ch. 23, §30 A)*. Uterine transplantation does not have proven safety and efficacy and therefore is not medically reasonable or necessary under the Social Security Act Sec.1862 (a)(1)(A).
	0665T	; open, from living donor	
	0666T	; laparoscopic or robotic, from living donor	
	0667T	; recipient uterus allograft transplantation from cadaver or living donor	
	0668T	Backbench standard preparation of cadaver or living donor uterine allograft prior to transplantation, including dissection and removal of surrounding soft tissues and preparation of uterine vein(s) and uterine artery(ies), as necessary	
	0669T	Backbench reconstruction of cadaver or living donor uterus allograft prior to transplantation; venous anastomosis, each	
	0670T	; arterial anastomosis, each	

	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,	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

		organ, gland, tissue, target structure) during the same session; multiple organs	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.

Proprietary Laboratory Analyses (PLA) 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 PLA codes as they are released. **It is not intended to be an all-inclusive list.** The absence of a PLA test code from this medical policy does not imply coverage, as some PLA tests may be addressed in other Medicare Advantage medical policies.

Codes	Number	Description	Test Information
	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-*	*VAP Cholesterol Test* VAP Diagnostics Laboratory, Inc. (Birmingham, AL)

		coverage of lipoprotein subclasses from this LCD is applied to this test.)	
	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 LCA 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 (Seattle, 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 LCA 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 Virus VP1 Capsid Antibody test* University of Washington, Department of Laboratory Medicine (Seattle, WA)
	0061U	Transcutaneous measurement of five biomarkers (tissue oxygenation [StO2], oxyhemoglobin [ctHbO2], deoxyhemoglobin [ctHbR], papillary and reticular dermal hemoglobin concentrations [ctHb1	*Transcutaneous multispectral measurement of tissue oxygenation*

		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 LCA 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.	*and hemoglobin using Spatial Frequency Domain Imaging (SFDI) test* Modulated Imaging, Inc. (Irving, 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 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.	*SLE-key Rule Out* Veracis (Virginia)

	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 (Madison, 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 (Vancouver, WA)
	0117U	Pain management, analysis of 11 endogenous analytes (methylmalonic acid, xanthurenic acid, 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.	*Foundation PISM* Ethos Laboratories

		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).	
	0119U	Cardiology, ceramides by liquid chromatography–tandem mass spectrometry, plasma, quantitative report with risk score for major cardiovascular events **Minnesota**: According to the LCA 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 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).	*Intrinsic Hepcidin IDx™ Test* IntrinsicDx, Intrinsic LifeSciences™ LLC. (CA and FL)

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.*