MEDICAL POLICY	Investigational and Non-Covered Medical Technologies (Medicare Only)
Effective Date: 1/1/2022  1/1/2022 Medical Officer Date	Medical Policy Number: 220 Medical Policy Committee Approved Date:7/17; 12/17; 3/18; 6/18; 8/18; 12/18; 1/19; 3/19; 5/19; 9/19; 11/19; 12/19; 4/2020; 6/2020; 07/2020; 8/2020; 9/2020; 10/2020; 12/2020; 2/2021; 3/2021; 5/2021; 6/2021; 8/2021; 9/2021; 11/2021

See Policy CPT/HCPCS CODE section below for any prior authorization requirements

SCOPE:

Providence Health Plan, Providence Health Assurance, Providence Plan Partners, and Ayin Health Solutions as applicable (referred to individually as "Company" and collectively as "Companies").

APPLIES TO:

Medicare Only

POLICY CRITERIA

I. Rationale for non-coverage is provided for many services within this policy. Medicare-based reasons for non-coverage may include, but are not limited to, any of the following (A-E):
   A. Medicare statutory exclusions;
   B. Lack of U.S. Food and Drug Administration (FDA) approval (when applicable);
      i. To be considered for coverage under Medicare, devices must be either FDA- or Institutional Review Board (IRB)-approved. Any device that has not received the appropriate and necessary regulatory approval would not be considered medically reasonable or necessary.[1]
   C. A Medicare policy (i.e., coverage manual, national coverage determination [NCD], local coverage determination [LCD], or article [LCA], etc.) indicates non-coverage; or
   D. I service or technology does not meet Medicare's medical and reasonable threshold requirements under *Title XVIII of the Social Security Act, Section 1862(a)(1)(A)* (i.e., the service or technology does not "treat or diagnose an illness or injury"); or
   E. The service is not anticipated to be a service intended for use by the Medicare population (e.g., services intended for use in the pediatric population).

II. For all other services, non-coverage is due to a lack of sufficient evidence to support the clinical utility, diagnostic efficacy, and/or safety of these technologies following a

review of relevant clinical practice guidelines, as well as the ECRI, Hayes, Cochrane, and PubMed databases. Additional high-quality studies are needed to establish the long-term efficacy, durability, and safety of these technologies for any condition. The Company position of non-coverage for these services can be found in the Commercial medical policy, *Investigational and Non-Covered Medical Technologies (All Lines of Business Except Medicare)*.

a. In the absence of a Medicare coverage policy or guidance, Medicare guidelines allow a Medicare Advantage Organization (MAO) to make coverage determinations, applying an objective, evidence-based process, based on authoritative evidence. *(Medicare Managed Care Manual, Chapter. 4, §90.5)*

BILLING GUIDELINES

Claims for these services will always be reviewed when they are billed with an unlisted procedure code.

CPT/HCPCS CODES

Medicare Only

The following CPT/HCPCS codes are not covered based on Medicare-based policies or guidelines. See below for details. Note, this list is **not** an all-inclusive list of Medicare non-covered services. Exclusion from this list does not imply a service or technology is covered.

CODE	DESCRIPTION	MEDICARE RATIONALE, PRODUCT, AND MANUFACTURER (when available)
77089	Trabecular bone score (TBS), structural condition of the bone microarchitecture; using dual X-ray absorptiometry (DXA) or other imaging data on gray-scale variogram, calculation, with interpretation and report on fracture-risk	TBS iNsight™ Medicare determines preventive benefit coverage and this testing would be considered non-covered as a screening test per Medicare statute.[2]
77090	Trabecular bone score (TBS), structural condition of the bone microarchitecture; technical preparation and transmission of data for analysis to be performed elsewhere	
77091	Trabecular bone score (TBS), structural condition of the bone	

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	microarchitecture; technical calculation only	
77092	Trabecular bone score (TBS), structural condition of the bone microarchitecture; interpretation and report on fracture-risk only by other qualified health care professional	
81506	Endocrinology (type 2 diabetes), biochemical assays of seven analytes (glucose, HbA1c, insulin, hs-CRP, adiponectin, ferritin, interleukin 2-receptor alpha), utilizing serum or plasma, algorithm reporting a risk score	Local Coverage Article (LCA): MolDX: PreDx (A55599)
97026	Application of a modality to 1 or more areas; infrared	• Medicare Status "R" code • National Coverage Determination (NCD) for Infrared Therapy Devices (270.6) • Local Coverage Article (LCA): Billing and Coding: Wound Care (A55909)
97545	Work hardening/conditioning; initial 2 hours	• Medicare Status "R" code • Not medically reasonable or necessary under *Title XVIII of the Social Security Act, Section 1862(a)(1)(A)* (performed for the purpose of conditioning for a return to work and not to diagnose or treat a medical condition).
97546	Work hardening/conditioning; each additional hour (List separately in addition to code for primary procedure)	
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	Local Coverage Determination (LCD) Facet Joint Interventions for Pain Management (L38803) and companion Local Coverage Article (LCA): Billing and Coding: Facet Joint Interventions for Pain Management (A58405)
0220T	Placement of a posterior intrafacet implant(s), unilateral or bilateral, including imaging and placement of bone graft(s) or synthetic device(s), single level; thoracic	
0221T	Placement of a posterior intrafacet implant(s), unilateral or bilateral, including imaging and placement of	

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	bone graft(s) or synthetic device(s), single level; lumbar	
0222T	Placement of a posterior intrafacet implant(s), unilateral or bilateral, including imaging and placement of bone graft(s) or synthetic device(s), single level; each additional vertebral segment (List separately in addition to code for primary procedure)	
0333T	Visual evoked potential, screening of visual acuity, automated, with report	For *asymptomatic* individuals, this testing would be considered non-covered as a screening test per Medicare statute.[2] Coverage may be allowed on appeal if this test is used for *diagnostic* purposes for **symptomatic** individuals when the ordering physician will use these test results to make a diagnosis or make treatment decisions for a relevant illness or condition.
0335T	Insertion of sinus tarsi implant	If used for flat foot, not covered per *Medicare Benefit Policy Manual, Chapter 15 – Covered Medical and Other Health Services, §–90 - Foot Care, B. Exclusions from Coverage, 1. Treatment of Flat Foot*. If used for any other indication, non-coverage is based on the Company policy position.
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	As of the most recent review, devices designed specifically for ablation of the renal sympathetic nerves have not received FDA-approval.
0339T	; bilateral	

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0443T	Real-time spectral analysis of prostate tissue by fluorescence spectroscopy, including imaging guidance (List separately in addition to code for primary procedure) (Precision Biopsy ClariCore Optical Biopsy System®)	As of the most recent review, the technology represented by this code 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 the most recent review, the technology represented by this code 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
0481T	Injection(s), autologous white blood cell concentrate (autologous protein solution), any site, including image guidance, harvesting and preparation, when performed	As of the most recent review, the product represented by this code has not received FDA approval.
0493T	Contact near-infrared spectroscopy studies of lower extremity wounds (eg, for oxyhemoglobin measurement)	As of the most recent review, the technology represented by this code has not received FDA approval.
0510T	Removal of sinus tarsi implant	If used for flat foot, not covered per *Medicare Benefit Policy Manual, Chapter 15 – Covered Medical and Other Health Services, §–90 - Foot Care, B. Exclusions from Coverage, 1. Treatment of Flat Foot*. If used for any other indication, non-coverage is based on the Company policy position.
0511T	Removal and reinsertion of sinus tarsi implant	
0512T	Extracorporeal shock wave for integumentary wound healing, including topical application and dressing care; initial wound	As of the most recent review, the technology represented by this code has not received FDA approval.
0513T	Extracorporeal shock wave for integumentary wound healing,	

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	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])	WiSE™ CRT System (EBR Systems, Inc.) As of the most recent review, the technology represented by this code has not received FDA approval. Note: While placement of the system or device will be non-covered, –removal **without** replacement (0518T) in some situations may be considered medically reasonable and necessary for unrelated reasons (e.g., pain, infection, etc.). See the *Medicare Benefit Policy Manual, Chapter 16, §–80 - Services Related to and Required as a Result of Services Which Are Not Covered Under Medicare* for more information.
0516T	Insertion of wireless cardiac stimulator for left ventricular pacing, including device interrogation and programming, and imaging supervision and interpretation, when performed; electrode only	
0517T	Insertion of wireless cardiac stimulator for left ventricular pacing, including device interrogation and programming, and imaging supervision and interpretation, when performed; pulse generator component(s) (battery and/or transmitter) only	
0519T	Removal and replacement of wireless cardiac stimulator for left ventricular pacing; pulse generator component(s) (battery and/or transmitter)	
0520T	Removal and replacement of wireless cardiac stimulator for left ventricular pacing; 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	

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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	
0533T	Continuous recording of movement disorder symptoms, including bradykinesia, dyskinesia, and tremor for 6 days up to 10 days; includes set-up, patient training, configuration of monitor, data upload, analysis and initial report configuration, download review, interpretation and report	Kinesia™ (Cleveland Medical Devices, Inc.} and Tremoromete7lexibleAble Systems, Inc.) This service is not medically reasonable or necessary under *Title XVIII of the Social Security Act, Section 1862(a)(1)(A)*. It does not "treat or diagnosis" an illness or injury.
0534T	Continuous recording of movement disorder symptoms, including bradykinesia, dyskinesia, and tremor for 6 days up to 10 days; set-up, patient training, configuration of monitor	
0535T	Continuous recording of movement disorder symptoms, including bradykinesia, dyskinesia, and tremor for 6 days up to 10 days; data upload, analysis and initial report configuration	
0536T	Continuous recording of movement disorder symptoms, including bradykinesia, dyskinesia, and tremor for 6 days up to 10 days; download review, interpretation and report	
0544T	Transcatheter mitral valve annulus reconstruction, with implantation of adjustable annulus reconstruction device, percutaneous approach including transseptal puncture	Cardioband™ Mitral Valve Reconstruction System (Edwards Lifesciences) According to the *Medicare Benefit Policy Manual, Chapter 14*, while FDA approval does not automatically guarantee coverage under Medicare, in order to be considered for coverage under Medicare, devices must be either FDA- or Institutional

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		Review Board (IRB)-approved. Any device that has not received FDA-approval would not be considered medically reasonable or necessary because it would lack the scientific evidence regarding safety and efficacy and would be considered investigational or experimental. An exception to this would be devices used in the context of a Medicare-approved investigational device exemption (IDE) study. Therefore, unless provided within the context of a Medicare-approved IDE study, TMVAR is not considered medically reasonable or necessary for Medicare under §1862(a)(1)(A).
0545T	Transcatheter tricuspid valve annulus reconstruction with implantation of adjustable annulus reconstruction device, percutaneous approach	Cardioband™ Tricuspid Valve Reconstruction System (Edwards Lifesciences) According to the *Medicare Benefit Policy Manual, Chapter 14*, while FDA approval does not automatically guarantee coverage under Medicare, in order to be considered for coverage under Medicare, devices must be either FDA- or Institutional Review Board (IRB)-approved. Any device that has not received FDA-approval would not be considered medically reasonable or necessary because it would lack the scientific evidence regarding safety and efficacy and would be considered investigational or experimental. An exception to this would be devices used in the context of a Medicare-approved investigational device exemption (IDE) study. At present, the only transcatheter tricuspid valve annuloplasty reconstruction device approved for patient use anywhere in world is the Edwards Cardioband Tricuspid Valve Reconstruction System,

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		which has received the European CE mark approval. However, this device has not yet received U.S. FDA approval, nor does it have Medicare-approval under an investigational device exception (IDE) study. Therefore, TTVAR is not considered medically reasonable or necessary for Medicare under §1862(a)(1)(A).
0547T	Bone-material quality testing by microindentation(s) of the tibia(s), with results reported as a score	OsteoProbe® (Active Life Scientific, Inc.). As of the most recent review, the technology represented by this code 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 the most recent review, the technology represented by this code has not received FDA approval.
0554T	Bone strength and fracture risk using finite element analysis of functional data, and bone-mineral density, utilizing data from a computed tomography scan; retrieval and transmission of the scan data, assessment of bone strength and fracture risk and bone mineral density, interpretation and report	Medicare determines preventive benefit coverage and this testing would be considered non-covered as a screening test per Medicare statute.[2]
0555T	Bone strength and fracture risk using finite element analysis of functional data, and bone-mineral density, utilizing data from a computed tomography scan; retrieval and transmission of the scan data	
0556T	Bone strength and fracture risk using finite element analysis of functional data, and bone-mineral density, utilizing data from a computed tomography scan; assessment of bone strength and fracture risk and bone mineral density	

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0557T	Bone strength and fracture risk using finite element analysis of functional data, and bone-mineral density, utilizing data from a computed tomography scan; interpretation and report	
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 multidimensional model of a patient's anatomy to aid in the planning of surgical procedures.
0560T	Anatomic model 3D-printed from image data set(s); 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	Anatomic guide 3D-printed and designed from image data set(s); each additional anatomic guide (List separately in addition to code for primary procedure)	
0564T	Oncology, chemotherapeutic drug cytotoxicity assay of cancer stem cells (CSCs), from cultured CSCs and primary tumor cells, categorical drug response reported based on percent of cytotoxicity observed, a minimum of 14 drugs or drug combinations	ChemoID® NCD for Human Tumor Stem Cell Drug Sensitivity Assays (190.7)
0567T	Permanent fallopian tube occlusion with degradable biopolymer implant, transcervical approach, including transvaginal ultrasound	FemBloc® (Femasys, Inc.) As of the most recent review, the technology represented by this code 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	FemBloc® (Femasys, Inc.) As of the most recent review, the technology represented by this code has not received FDA approval.

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0569T	Transcatheter tricuspid valve repair, percutaneous approach; initial prosthesis	TriClip™ Transcatheter Tricuspid Valve Repair System (Abbott) According to the *Medicare Benefit Policy Manual, Chapter 14*, while FDA approval does not automatically guarantee coverage under Medicare, in order to be considered for coverage under Medicare, devices must be either FDA- or Institutional Review Board (IRB)-approved. Any device that has not received FDA-approval would not be considered medically reasonable or necessary because it would lack the scientific evidence regarding safety and efficacy and would be considered investigational or experimental. An exception to this would be devices used in the context of a Medicare-approved investigational device exemption (IDE) study. No device for transcatheter tricuspid valve repair (TTVr) with a percutaneous approach, including Abbott's TriClip™ Transcatheter Tricuspid Valve Repair System, has been approved by the FDA. Therefore, unless provided within the context of a Medicare-approved IDE study, TTVR is not considered medically reasonable or necessary for Medicare under §1862(a)(1)(A). *(To confirm participation in a Medicare-approved IDE study, the NCT number must be provided and be verified as a Medicare-approved study on the CMS website for IDEs.)*
0570T	Transcatheter tricuspid valve repair, percutaneous approach; each additional prosthesis during same session (List separately in addition to code for primary procedure)	
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,	As of the most recent review, the device/procedure represented by this code has not received FDA approval. Note: According to the *Medicare Benefit Policy Manual, Chapter 16, §–80 - Services Related to and Required as a Result of*

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	evaluation of sensing for arrhythmia termination, and programming or reprogramming of sensing or therapeutic parameters), when performed	*Services Which Are Not Covered Under Medicare*, removal **without** replacement (0580T) may be considered medically reasonable and necessary for unrelated reasons (e.g., pain, infection, etc.).
0572T	Insertion of substernal implantable defibrillator electrode	
0573T	Removal 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	Electrophysiological 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)	

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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 the most recent review, the technology/device/procedure represented by this code 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	As of the most recent review, the technology/device/procedure represented by this code 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	As of the most recent review, the technology/device/procedure represented by this code 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	

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	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	As of the most recent review, the technology/device/procedure represented by this code has not received FDA approval.
0614T	Removal and replacement of substernal implantable defibrillator pulse generator	As of the most recent review, the technology/device/procedure represented by this code has not received FDA approval.
0621T	Trabeculostomy ab interno by laser	As of the most recent review, the technology/device/procedure represented by this code 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	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	Automated quantification and characterization of coronary atherosclerotic plaque to assess severity of coronary disease, using data from coronary computed tomographic	

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	angiography; data preparation and transmission	
0625T	Automated quantification and characterization of coronary atherosclerotic plaque to assess severity of coronary disease, using data from coronary computed tomographic angiography; computerized analysis of data from coronary computed tomographic angiography	
0626T	Automated quantification and characterization of coronary atherosclerotic plaque to assess severity of coronary disease, using data from coronary computed tomographic angiography; review of computerized analysis output to reconcile discordant data, interpretation and report	
0631T	Transcutaneous visible light hyperspectral imaging measurement of oxyhemoglobin, deoxyhemoglobin, and tissue oxygenation, with interpretation and report, per extremity	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	As of the most recent review, the technology/device/procedure represented by this code 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	As of the most recent review, the technology/device/procedure represented by this code has not received FDA approval.
0640T	Noncontact near-infrared spectroscopy studies of flap or wound (eg, for measurement of deoxyhemoglobin, oxyhemoglobin, and ratio of tissue oxygenation [StO2]); image acquisition,	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

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	interpretation and report, each flap or wound	does not "treat or diagnosis" an illness or injury.
0641T	Noncontact near-infrared spectroscopy studies of flap or wound (eg, for measurement of deoxyhemoglobin, oxyhemoglobin, and ratio of tissue oxygenation [StO2]); image acquisition only, each flap or wound	
0642T	Noncontact near-infrared spectroscopy studies of flap or wound (eg, for measurement of deoxyhemoglobin, oxyhemoglobin, and ratio of tissue oxygenation [StO2]); interpretation and report only, each flap or wound	
0646T	Transcatheter tricuspid valve implantation/replacement (TTVI) with prosthetic valve, percutaneous approach, including right heart catheterization, temporary pacemaker insertion, and selective right ventricular or right atrial angiography, when performed	Intrepid Transcatheter Mitral Valve Replacement System (Medtronic) See notes related to 0570T above.
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	EchoMRI Body Composition Analysis 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,	

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	target structure); single organ (List separately in addition to code for primary procedure)	
0656T	Vertebral body tethering, anterior; up to 7 vertebral segments	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 population would not be "skeletally immature," making the use of this system on these individuals outside of the HUD intended use.
0657T	Vertebral body tethering, anterior; 8 or more vertebral segments	
0660T	Implantation of anterior segment intraocular nonbiodegradable drug-eluting system, internal approach	iDose (Glaukos) As of the most recent review, the technology/device/procedure represented by this code has not received FDA approval.
0661T	Removal and reimplantation of anterior segment intraocular nonbiodegradable drug-eluting implant	
0686T	Histotripsy (ie, non-thermal ablation via acoustic energy delivery) of malignant hepatocellular tissue, including image guidance	HistoSonics As of the most recent review, the technology/device/procedure represented by this code has not received FDA approval. This device not appear to be available in the US and is considered to be investigational. However, the trial #HOPE4LIVER (NCT04573881; G200253) is a Medicare-approved Category A IDE study as¾ 3/4/2021. Coverage may be approved for members enrolled in the Medicare-approved study. If not, no coverage is available for this procedure/service. *(To confirm participation in a Medicare-approved IDE study, the NCT number must be provided and be verified as a Medicare-approved study on the CMS website for IDEs.)*

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0687T	Treatment of amblyopia using an online digital program; device supply, educational set-up, and initial session	CureSight™: As of the most recent review, the technology/device/procedure represented by this code has not received FDA approval. While this system has been studied for use in the pediatric population, there is no study regarding the application to Medicare population.
0688T	Treatment of amblyopia using an online digital program; assessment of patient performance and program data by physician or other qualified health care professional, with report, per calendar month	
0689T	Quantitative ultrasound tissue characterization (non-elastographic), including interpretation and report, obtained without diagnostic ultrasound examination of the same anatomy (eg, organ, gland, tissue, target structure)	Not medically reasonable or necessary under Medicare and §1862(a)(1)(A). This does not "treat or diagnosis" an illness or injury.
0690T	Quantitative ultrasound tissue characterization (non-elastographic), including interpretation and report, obtained with diagnostic ultrasound examination of the same anatomy (eg, organ, gland, tissue, target structure) (List separately in addition to code for primary procedure)	
0691T	Automated analysis of an existing computed tomography study for vertebral fracture(s), including assessment of bone density when performed, data preparation, interpretation, and report	Not medically reasonable or necessary under Medicare and §1862(a)(1)(A). This is artificial intelligence for the detection of vertebral fractures, reading what has already been read by the treating physician or radiologist. This does not "treat or diagnosis" an illness or injury and thus does not meet Medi'are's medical necessity threshold.
0693T	Comprehensive full body computer-based markerless 3D kinematic and kinetic motion analysis and report	OpenPose-based markerless motion capture Not medically reasonable or necessary under Medicare and §1862(a)(1)(A). This does not "treat or diagnosis" an illness or

The following CPT/HCPCS codes are not covered based on Medicare-based policies or guidelines. See below for details. Note, this list is **not** an all-inclusive list of Medicare non-covered services. Exclusion from this list does not imply a service or technology is covered.

		injury. This system has been studied for use in relation to sports medicine.
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)	
0700T	Molecular fluorescent imaging of suspicious nevus; first lesion	Orlucent™ handheld fluorescent molecular imaging system As of the most recent review, the technology/device/procedure represented by this code has not received FDA approval.
0701T	Molecular fluorescent imaging of suspicious nevus; each additional lesion (List separately in addition to code for primary procedure)	
0704T	Remote treatment of amblyopia using an eye tracking device; device supply with initial set-up and patient education on use of equipment	CureSight™: As of the most recent review, the technology/device/procedure represented by this code has not received FDA approval. While this system has been studied for use in the pediatric population, there is no study regarding the application to Medicare population.
0705T	Remote treatment of amblyopia using an eye tracking device; surveillance center technical support including data transmission with analysis, with a minimum of 18 training hours, each 30 days	

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0706T	Remote treatment of amblyopia using an eye tracking device; interpretation and report by physician or other qualified health care professional, per calendar month	
0083U	Oncology, response to chemotherapy drugs using motility contrast tomography, fresh or frozen tissue, reported as likelihood of sensitivity or resistance to drugs or drug combinations	Onco4D™ LCD L37630/LCA A56073
0096U	Human papillomavirus (HPV), high-risk types (ie, 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, 68), male urine	HPV, High-Risk, Male Urine 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/symptoms, and ordering physician will use test results for diagnosis or treatment decisions.
0105U	Nephrology (chronic kidney disease), multiplex electrochemiluminescent immunoassay (ECLIA) of tumor necrosis factor receptor 1A, receptor superfamily 2 (TNFR1, TNFR2), and kidney injury molecule-1 (KIM-1) combined with longitudinal clinical data, including APOL1 genotype if available, and plasma (isolated fresh or frozen), algorithm reported as probability score for rapid kidney function decline (RKFD)	KidneyIntelX™ The KidneyIntelXTM test is used to identify individuals most likely to experience fast-progressing kidney disease. The results are not used to diagnose or make direct treatment decisions for an illness or injury, as required for Medicare under the Social Security Act, §1862(a)(1)(A). Therefore, this test is considered not medically necessary.
0117U	Pain management, analysis of 11 endogenous analytes (methylmalonic	Foundation PISM, Ethos Laboratories

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	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 workup, 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).
0156U	Copy number (eg, intellectual disability, dysmorphology), sequence analysis	SMASH™ (Marvel Genomics™ (New York) This test is not considered medically reasonable or necessary. For Medicare members, tests for diseases or conditions that manifest signs or symptoms in childhood are considered not medically reasonable or necessary as they are not usually relevant to the Medicare population. Under Medicare, testing is only considered reasonable and necessary when the test results directly impact treatment or management of the beneficiary. Confirming a known diagnosis is also not considered reasonable or necessary under Medicare, and also many pharmacogenomic applications of molecular pathology testing do not meet Medicare's requirements to be considered medically reasonable or necessary. *(LCD L35000; Published by National Government Services)*
A6000	Non-contact wound warming wound cover for use with the non-contact wound warming device and warming card	• Medicare Status "N" code • Noridian "Noncovered Items" list[3] • National Coverage Determination (NCD) for Noncontact Normothermic Wound Therapy (270.2)
C9780	Insertion of central venous catheter through central venous occlusion via	The Surfacer® Inside-Out® Access Catheter system is currently undergoing trials and

The following CPT/HCPCS codes are not covered based on Medicare-based policies or guidelines. See below for details. Note, this list is **not** an all-inclusive list of Medicare non-covered services. Exclusion from this list does not imply a service or technology is covered.		
	inferior and superior approaches (e.g., inside-out technique), including imaging guidance *(Surfacer® Inside-Out® Access Catheter System)*	evaluation and there is an associated Medicare-approved investigational device exemption (IDE) study for this product (*Evaluation of the Surfacer System Approach to Central Venous Access;* NCT03209050); however, it is classified as a ***Category A*** device. According to the *Medicare Managed Care Manual, Chapter 4 – Benefits and Beneficiary Protections, §10.7.2 – Payment for Investigational Device Exemption (IDE) Studies*, "MAOs are responsible for payment of claims related to enrollees' participation in both Category A and B IDE studies that are covered by the MAC with jurisdiction over the MA plan's service area. The MAO is responsible for payment of routine care items and services in CMS-approved Category A… studies… **CMS will not approve Category A devices because they are statutorily excluded from coverage."** Therefore, while routine care and services are eligible for coverage, including unrelated care, Category A devices are not.
E0231	Non-contact wound warming device (temperature control unit, ac adapter and power cord) for use with warming card and wound cover.	• Noridian "Noncovered Items" list[3] • National Coverage Determination (NCD) for Noncontact Normothermic Wound Therapy (270.2)
E0232	Warming card for use with the non contact wound warming device and non contact wound warming wound cover	
K1004	Low frequency ultrasonic diathermy treatment device for home use, includes all components and accessories	The PainShield MD NCD 280.1 indicates diathermy machines are not appropriate for home use

The following CPT/HCPCS codes do not have specific Medicare policy or guidance. Therefore, the following codes are subject to Criterion II in the "Policy Criteria" table above.		
CODE	**DESCRIPTION**	**TECHNOLOGY AND/OR MANUFACTURER AND**

The following CPT/HCPCS codes do not have specific Medicare policy or guidance. Therefore, the following codes are subject to Criterion II in the "Policy Criteria" table above.

		ADDITIONAL NOTES (when available)
30468	Repair of nasal valve collapse with subcutaneous/submucosal lateral wall implant(s)	LATERA® absorbable nasal implant (Stryker)
57465	Computer-aided mapping of cervix uteri during colposcopy, including optical dynamic spectral imaging and algorithmic quantification of the acetowhitening effect (List separately in addition to code for primary procedure)	
61736	Laser interstitial thermal therapy (LITT) of lesion, intracranial, including burr hole(s), with magnetic resonance imaging guidance, when performed; single trajectory for 1 simple lesion	
61737	Laser interstitial thermal therapy (LITT) of lesion, intracranial, including burr hole(s), with magnetic resonance imaging guidance, when performed; multiple trajectories for multiple or complex lesion(s)	
64628	Thermal destruction of intraosseous basivertebral nerve, including all imaging guidance; first 2 vertebral bodies, lumbar or sacral	
64629	Thermal destruction of intraosseous basivertebral nerve, including all imaging guidance; each additional vertebral body, lumbar or sacral (List separately in addition to code for primary procedure)	
~~C9752~~	TERMED 12/31/2021 ~~Destruction of intraosseous basivertebral nerve, first two vertebral bodies, including imaging guidance (e. g., fluoroscopy), lumbar/sacrum~~	
~~C9753~~	TERMED 12/31/2021 ~~Destruction of intraosseous basivertebral nerve, each additional vertebral body, including imaging guidance (e. g., fluoroscopy), lumbar/sacrum (list~~	

The following CPT/HCPCS codes do not have specific Medicare policy or guidance. Therefore, the following codes are subject to Criterion II in the "Policy Criteria" table above.		
	~~separately in addition to code for primary procedure)~~	
64910	Nerve repair; with synthetic conduit or vein allograft (eg, nerve tube), each nerve	
77423	High energy neutron radiation treatment delivery; 1 or more isocenter(s) with coplanar or non-coplanar geometry with blocking and/or wedge, and/or compensator(s)	SENSIMED Triggerfish® by Sensimed AG
0278T	Transcutaneous electrical modulation pain reprocessing (eg, scrambler therapy), each treatment session (includes placement of electrodes)	
0329T	Monitoring of intraocular pressure for 24 hours or longer, unilateral or bilateral, with interpretation and report	
0342T	Therapeutic apheresis with selective HDL delipidation and plasma reinfusion	Neither the NCD for *Apheresis (Therapeutic Pheresis)* (110.14) nor the LCA for *Therapeutic Apheresis for Familial Hypercholesterolemia* (A54543) indicate this is a covered apheresis procedure. Therefore, the Company position for this service will be applied.
0351T	Optical coherence tomography of breast or axillary lymph node, excised tissue, each specimen; real-time intraoperative	RS-3000 Advance by NIDEK©
0352T	; interpretation and report, real-time or referred	
0353T	Optical coherence tomography of breast, surgical cavity; real-time intraoperative	
0354T	; interpretation and report, real-time or referred	
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	
0379T	Visual field assessment, with concurrent real time data analysis and accessible data	

The following CPT/HCPCS codes do not have specific Medicare policy or guidance. Therefore, the following codes are subject to Criterion II in the "Policy Criteria" table above.		
	storage with patient initiated data transmitted to a remote surveillance center for up to 30 days; 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	
0397T	Endoscopic retrograde cholangiopancreatography (ERCP), with optical endomicroscopy (List separately in addition to code for primary procedure)	
0408T	Insertion or replacement of permanent cardiac contractility modulation system, including contractility evaluation when performed, and programming of sensing and therapeutic parameters; pulse generator with transvenous electrodes	Cardiac Contractility Modulation (CCM) System – Optimizer Dynamic Note: While placement of the system or device will be non-covered, removal **without** replacement (0412T and 0413T) in some situations may be considered medically reasonable and necessary for unrelated reasons (e.g., pain, infection, etc.). See the *Medicare Benefit Policy Manual, Chapter 16, §–80 - Services Related to and Required as a Result of Services Which Are Not Covered Under Medicare* for more information.
0409T	; pulse generator only	
0410T	; atrial electrode only	
0411T	; ventricular electrode only	
0414T	Removal and replacement of permanent cardiac contractility modulation system pulse generator only	
0415T	Repositioning of previously implanted cardiac contractility modulation transvenous electrode (atrial or ventricular lead)	
0416T	Relocation of skin pocket for implanted cardiac contractility modulation pulse generator	
0417T	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, implantable cardiac contractility modulation system	
0418T	Interrogation device evaluation (in person) with analysis, review and report, includes connection, recording and disconnection	

The following CPT/HCPCS codes do not have specific Medicare policy or guidance. Therefore, the following codes are subject to Criterion II in the "Policy Criteria" table above.		
	per patient encounter, implantable cardiac contractility modulation system	
C1824	Generator, cardiac contractility modulation (implantable)	
0422T	Tactile breast imaging by computer-aided tactile sensors, unilateral or bilateral	Breastview Visual Mapping System by Medical Tactile, Inc. and iBreast Exam™ (iBE) by UE LifeSciences Inc.
0424T	Insertion or replacement of neurostimulator system for treatment of central sleep apnea; complete system (transvenous placement of right or left stimulation lead, sensing lead, implantable pulse generator)	remedē® System (Respicardia, Inc.) While the NCD for Phrenic Nerve Stimulator (160.19) addresses the use of phrenic nerve stimulation as an alternative for patients with respiratory insufficiency who are dependent upon the use of a mechanical ventilator as well as maintenance of a permanent tracheotomy stoma, it does not address the use of a phrenic nerve stimulator as a treatment of CSA. Therefore, the Company position for this service will be applied. Note: While placement of the system or device will be non-covered, removal **without** replacement (0428T-0430T) in some situations may be considered medically reasonable and necessary for unrelated reasons (e.g., pain, infection, etc.). See the *Medicare Benefit Policy Manual, Chapter 16, §–80 - Services Related to and Required as a Result of Services Which Are Not Covered Under Medicare* for more information.
0425T	Insertion or replacement of neurostimulator system for treatment of central sleep apnea; sensing lead only	
0426T	Insertion or replacement of neurostimulator system for treatment of central sleep apnea; stimulation lead only	
0427T	Insertion or replacement of neurostimulator system for treatment of central sleep apnea; pulse generator only	
0431T	Removal and replacement of neurostimulator system for treatment of central sleep apnea, pulse generator only	
0432T	Repositioning of neurostimulator system for treatment of central sleep apnea; stimulation lead only	
0433T	Repositioning of neurostimulator system for treatment of central sleep apnea; sensing lead only	
0434T	Interrogation device evaluation implanted neurostimulator pulse generator system for central sleep apnea	
0435T	Programming device evaluation of implanted neurostimulator pulse generator system for central sleep apnea; single session	
0436T	Programming device evaluation of implanted neurostimulator pulse generator	

The following CPT/HCPCS codes do not have specific Medicare policy or guidance. Therefore, the following codes are subject to Criterion II in the "Policy Criteria" table above.		
	system for central sleep apnea; during sleep study	
0470T	Optical coherence tomography (OCT) for microstructural and morphological imaging of skin, image acquisition, interpretation, and report; first lesion	
0471T	Optical coherence tomography (OCT) for microstructural and morphological imaging of skin, image acquisition, interpretation, and report; each additional lesion (List separately in addition to code for primary procedure)	
0485T	Optical coherence tomography (OCT) of middle ear, with interpretation and report; unilateral	
0486T	Optical coherence tomography (OCT) of middle ear, with interpretation and report; bilateral	
0487T	Biomechanical mapping, transvaginal, with report	
0489T	Autologous adipose-derived regenerative cell therapy for scleroderma in the hands; adipose tissue harvesting, isolation and preparation of harvested cells including incubation with cell dissociation enzymes, removal of non-viable cells and debris, determination of concentration and dilution of regenerative cells	
0490T	; multiple injections in one or both hands	
0491T	Ablative laser treatment, non-contact, full field and fractional ablation, open wound, per day, total treatment surface area; first 20 sq cm or less	
0492T	; each additional 20 sq cm, or part thereof (List separately in addition to code for primary procedure)	
0506T	Macular pigment optical density measurement by heterochromatic flicker photometry, unilateral or bilateral, with interpretation and report	

The following CPT/HCPCS codes do not have specific Medicare policy or guidance. Therefore, the following codes are subject to Criterion II in the "Policy Criteria" table above.		
0507T	Near-infrared dual imaging (ie, simultaneous reflective and trans-illuminated light) of meibomian glands, unilateral or bilateral, with interpretation and report	
0508T	Pulse-echo ultrasound bone density measurement resulting in indicator of axial bone mineral density, tibia	
0525T	Insertion or replacement of intracardiac ischemia monitoring system, including testing of the lead and monitor, initial system programming, and imaging supervision and interpretation; complete system (electrode and implantable monitor)	AngelMed® Guardian System by Angel Medical Systems Note: While placement of the system or device will be non-covered, removal **without** replacement (0530T-0532T) in some situations may be considered medically reasonable and necessary for unrelated reasons (e.g., pain, infection, etc.). See the *Medicare Benefit Policy Manual, Chapter 16, §–80 - Services Related to and Required as a Result of Services Which Are Not Covered Under Medicare* for more information.
0526T	Insertion or replacement of intracardiac ischemia monitoring system, including testing of the lead and monitor, initial system programming, and imaging supervision and interpretation; electrode only	
0527T	Insertion or replacement of intracardiac ischemia monitoring system, including testing of the lead and monitor, initial system programming, and imaging supervision and interpretation; implantable monitor only	
0528T	Programming device evaluation (in person) of intracardiac ischemia monitoring system with iterative adjustment of programmed values, with analysis, review, and report	
0529T	Interrogation device evaluation (in person) of intracardiac ischemia monitoring system with analysis, review, and report	
0530T	Removal of intracardiac ischemia monitoring system, including all imaging supervision and interpretation; complete system (electrode and implantable monitor)	
0531T	; electrode only	
0532T	; implantable monitor only	

The following CPT/HCPCS codes do not have specific Medicare policy or guidance. Therefore, the following codes are subject to Criterion II in the "Policy Criteria" table above.		
C1833	Monitor, cardiac, including intracardiac lead and all system components (implantable)	
0546T	Radiofrequency spectroscopy, real time, intraoperative margin assessment, at the time of partial mastectomy, with report	MarginProbe
0581T	Ablation, malignant breast tumor(s), percutaneous, cryotherapy, including imaging guidance when performed, unilateral	
0583T	Tympanostomy (requiring insertion of ventilating tube), using an automated tube delivery system, iontophoresis local anesthesia	
0594T	Osteotomy, humerus, with insertion of an externally controlled intramedullary lengthening device, including intraoperative imaging, initial and subsequent alignment assessments, computations of adjustment schedules, and management of the intramedullary lengthening device	FITBONE® System PRECICE UNYTE® Nail
0598T	Noncontact real-time fluorescence wound imaging, for bacterial presence, location, and load, per session; first anatomic site (eg, lower extremity)	
0599T	Noncontact real-time fluorescence wound imaging, for bacterial presence, location, and load, per session; each additional anatomic site (eg, upper extremity) (List separately in addition to code for primary procedure)	
0607T	Remote monitoring of an external continuous pulmonary fluid monitoring system, including measurement of radiofrequency-derived pulmonary fluid levels, heart rate, respiration rate, activity, posture, and cardiovascular rhythm (eg, ECG data), transmitted to a remote 24-hour attended surveillance center; set-up and patient education on use of equipment	

The following CPT/HCPCS codes do not have specific Medicare policy or guidance. Therefore, the following codes are subject to Criterion II in the "Policy Criteria" table above.		
0608T	Remote monitoring of an external continuous pulmonary fluid monitoring system, including measurement of radiofrequency-derived pulmonary fluid levels, heart rate, respiration rate, activity, posture, and cardiovascular rhythm (eg, ECG data), transmitted to a remote 24-hour attended surveillance center; analysis of data received and transmission of reports to the physician or other qualified health care professional	
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	Previously used NCD 220.2.1; however, with the retirement of the NCD, the Company policy now applies.
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	
0615T	Eye-movement analysis without spatial calibration, with interpretation and report	
0616T	Insertion of iris prosthesis, including suture fixation and repair or removal of iris, when performed; without removal of crystalline	CustomFlex Artificial Iris, Human Optics

The following CPT/HCPCS codes do not have specific Medicare policy or guidance. Therefore, the following codes are subject to Criterion II in the "Policy Criteria" table above.		
	lens or intraocular lens, without insertion of intraocular lens	
0617T	Insertion of iris prosthesis, including suture fixation and repair or removal of iris, when performed; with removal of crystalline lens and insertion of intraocular lens	
0618T	Insertion of iris prosthesis, including suture fixation and repair or removal of iris, when performed; with secondary intraocular lens placement or intraocular lens exchange	
0643T	Transcatheter left ventricular restoration device implantation including right and left heart catheterization and left ventriculography when performed, arterial approach	Revivent TC System – BioVentrix
0644T	Transcatheter removal or debulking of intracardiac mass (eg, vegetations, thrombus) via suction (eg, vacuum, aspiration) device, percutaneous approach, with intraoperative reinfusion of aspirated blood, including imaging guidance, when performed	AngioVac System
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	Neovasc Reducer
0647T	Insertion of gastrostomy tube, percutaneous, with magnetic gastropexy, under ultrasound guidance, image documentation and report	Puma-G System (Ultrasound Gastronomy)
0655T	Transperineal focal laser ablation of malignant prostate tissue, including transrectal imaging guidance, with MR-fused images or other enhanced ultrasound imaging	Visualase Laser Ablation, Medtronic
0658T	Electrical impedance spectroscopy of 1 or more skin lesions for automated melanoma risk score	Nevisense, SciBase

The following CPT/HCPCS codes do not have specific Medicare policy or guidance. Therefore, the following codes are subject to Criterion II in the "Policy Criteria" table above.		
0659T	Transcatheter intracoronary infusion of supersaturated oxygen in conjunction with percutaneous coronary revascularization during acute myocardial infarction, including catheter placement, imaging guidance (eg, fluoroscopy), angiography, and radiologic supervision and interpretation	TherOx Downstream® System, TherOx Inc.
0673T	Ablation, benign thyroid nodule(s), percutaneous, laser, including imaging guidance	EchoLaser X4 System
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)	VisONE® Synchronized Diaphragmatic StimulationTM therapy (SDS® therapy) Note: While placement of the system or device will be non-covered, removal **without** replacement (0679T & 0682T) in some situations may be considered medically reasonable and necessary for unrelated reasons (e.g., pain, infection, etc.). See the *Medicare Benefit Policy Manual, Chapter 16, §–80 - Services Related to and Required as a Result of Services Which Are Not Covered Under Medicare* for more information.
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	; each additional lead (List separately in addition to code for primary procedure)	
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	; each additional repositioned lead (List separately in addition to code for primary procedure)	
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)	

The following CPT/HCPCS codes do not have specific Medicare policy or guidance. Therefore, the following codes are subject to Criterion II in the "Policy Criteria" table above.		
0681T	Relocation of pulse generator only, permanent implantable synchronized diaphragmatic stimulation system for augmentation of cardiac function, with connection to existing dual leads	
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	
0695T	Body surface-activation mapping of pacemaker or pacing cardioverter-defibrillator lead(s) to optimize electrical synchrony, cardiac resynchronization therapy device, including connection, recording, disconnection, review, and report; at time of implant or replacement	

The following CPT/HCPCS codes do not have specific Medicare policy or guidance. Therefore, the following codes are subject to Criterion II in the "Policy Criteria" table above.		
0696T	Body surface-activation mapping of pacemaker or pacing cardioverter-defibrillator lead(s) to optimize electrical synchrony, cardiac resynchronization therapy device, including connection, recording, disconnection, review, and report; at time of follow-up interrogation or programming device evaluation	
0707T	Injection(s), bone-substitute material (eg, calcium phosphate) into subchondral bone defect (ie, bone marrow lesion, bone bruise, stress injury, microtrabecular fracture), including imaging guidance and arthroscopic assistance for joint visualization	
C1761	Catheter, transluminal intravascular lithotripsy, coronary	Shockwave Coronary Rx Lithoplasty System
C9352	Microporous collagen implantable tube (neuragen nerve guide), per centimeter length	
C9353	Microporous collagen implantable slit tube (neurawrap nerve protector), per centimeter length	
C9355	Collagen nerve cuff (neuromatrix), per 0. 5 centimeter length	
C9361	Collagen matrix nerve wrap (neuromend collagen nerve wrap), per 0. 5 centimeter length	
C9759	Transcatheter intraoperative blood vessel microinfusion(s) (e. g. , intraluminal, vascular wall and/or perivascular) therapy, any vessel, including radiological supervision and interpretation, when performed	Bullfrog Microinfusion device by Mercator Medsystems
C9764	Revascularization, endovascular, open or percutaneous, any vessel(s); with intravascular lithotripsy, includes angioplasty within the same vessel(s), when performed	Shockwave Medical Peripheral IVL System by Shockwave Medical Inc.
C9765	Revascularization, endovascular, open or percutaneous, any vessel(s); with	

The following CPT/HCPCS codes do not have specific Medicare policy or guidance. Therefore, the following codes are subject to Criterion II in the "Policy Criteria" table above.		
	intravascular lithotripsy, and transluminal stent placement(s), includes angioplasty within the same vessel(s), when performed	
C9766	Revascularization, endovascular, open or percutaneous, any vessel(s); with intravascular lithotripsy and atherectomy, includes angioplasty within the same vessel(s), when performed	
C9767	Revascularization, endovascular, open or percutaneous, any vessel(s); with intravascular lithotripsy and transluminal stent placement(s), and atherectomy, includes angioplasty within the same vessel(s), when performed	
C9768	Endoscopic ultrasound-guided direct measurement of hepatic portosystemic pressure gradient by any method (list separately in addition to code for primary procedure)	Echotip by Cook Medical
C9771	Nasal/sinus endoscopy, cryoablation nasal tissue(s) and/or nerve(s), unilateral or bilateral	Clarifix by Arrinex Inc.
C9772	Revascularization, endovascular, open or percutaneous, tibial/peroneal artery(ies), with intravascular lithotripsy, includes angioplasty within the same vessel (s), when performed	Shockwave Medical Peripheral IVL System by Shockwave Medical Inc.
C9773	Revascularization, endovascular, open or percutaneous, tibial/peroneal artery(ies); with intravascular lithotripsy, and transluminal stent placement(s), includes angioplasty within the same vessel(s), when performed	
C9774	Revascularization, endovascular, open or percutaneous, tibial/peroneal artery(ies); with intravascular lithotripsy and atherectomy, includes angioplasty within the same vessel (s), when performed	
C9775	Revascularization, endovascular, open or percutaneous, tibial/peroneal artery(ies);	

The following CPT/HCPCS codes do not have specific Medicare policy or guidance. Therefore, the following codes are subject to Criterion II in the "Policy Criteria" table above.		
	with intravascular lithotripsy and transluminal stent placement(s), and atherectomy, includes angioplasty within the same vessel (s), when performed	
K1002	Cranial electrotherapy stimulation (CES) system, includes all supplies and accessories, any type	Alpha-Stim AID
K1009	Speech volume modulation system, any type, including all components and accessories	SpeechVive device
CODE	**DESCRIPTION**	**PROPRIETARY TEST NAME, MANUFACTURER AND ADDITIONAL NOTES (when available)**
0002U	Oncology (colorectal), quantitative assessment of three urine metabolites (ascorbic acid, succinic acid and carnitine) by liquid chromatography with tandem mass spectrometry (LC-MS/MS) using multiple reaction monitoring acquisition, algorithm reported as likelihood of adenomatous polyps	
0054U	Prescription drug monitoring, 14 or more classes of drugs and substances, definitive tandem mass spectrometry with chromatography, capillary blood, quantitative report with therapeutic and toxic ranges, including steady-state range for the prescribed dose when detected, per date of service	
0109U	Infectious disease (Aspergillus species), real-time PCR for detection of DNA from 4 species (A. fumigatus, A. terreus, A. niger, and A. flavus), blood, lavage fluid, or tissue, qualitative reporting of presence or absence of each species	MYCODART Dual Amplification Real Time PCR Panel for 4 Aspergillus species, RealTime Laboratories
0110U	Prescription drug monitoring, one or more oral oncology drug(s) and substances, definitive tandem mass spectrometry with chromatography, serum or plasma from capillary blood or venous blood,	Oral OncolyticAssuranceRX

The following CPT/HCPCS codes do not have specific Medicare policy or guidance. Therefore, the following codes are subject to Criterion II in the "Policy Criteria" table above.		
	quantitative report with steady-state range for the prescribed drug(s) when detected	
0112U	Infectious agent detection and identification, targeted sequence analysis (16S and 18S rRNA genes) with drug-resistance gene	MicroGenDX qPCR & NGS
0114U	Gastroenterology (Barrett's esophagus), VIM and CCNA1 methylation analysis, esophageal cells, algorithm reported as likelihood for Barrett's esophagus	EsoGuard™
~~0139U~~	CODE TERMED 09/31/2021 ~~Neurology (autism spectrum disorder [ASD]), quantitative measurements of 6 central carbon metabolites (ie, α-ketoglutarate, alanine, lactate, phenylalanine, pyruvate, and succinate), LC-MS/MS, plasma, algorithmic analysis with result reported as negative or positive (with metabolic subtypes of ASD)~~	
0166U	Liver disease, 10 biochemical assays (α2-macroglobulin, haptoglobin, apolipoprotein A1, bilirubin, GGT, ALT, AST, triglycerides, cholesterol, fasting glucose) and biometric and demographic data, utilizing serum, algorithm reported as scores for fibrosis, necroinflammatory activity, and steatosis with a summary interpretation	LiverFASt™
0206U	Neurology (Alzheimer disease); cell aggregation using morphometric imaging and protein kinase C-epsilon (PKCe) concentration in response to amylospheroid treatment by ELISA, cultured skin fibroblasts, each reported as positive or negative for Alzheimer disease	DISCERN™
0207U	Disease quantitative imaging of phosphorylated ERK1 and ERK2 in response to bradykinin treatment by in situ immunofluorescence, using cultured skin fibroblasts, reported as a probability index for Alzheimer disease (List separately in addition to code for primary procedure)	

The following CPT/HCPCS codes do not have specific Medicare policy or guidance. Therefore, the following codes are subject to Criterion II in the "Policy Criteria" table above.		
0243U	Obstetrics (preeclampsia), biochemical assay of placental-growth factor, time-resolved fluorescence immunoassay, maternal serum, predictive algorithm reported as a risk score for preeclampsia	PGIF Preeclampsia Screen
0247U	Obstetrics (preterm birth), insulin-like growth factor-binding protein 4 (IBP4), sex hormone-binding globulin (SHBG), quantitative measurement by LC-MS/MS, utilizing maternal serum, combined with clinical data, reported as predictive-risk stratification for spontaneous preterm birth	PreTRM®
0251U	Hepcidin-25, enzyme-linked immunosorbent assay (ELISA), serum or plasma	Intrinsic Hepcidin IDxTM

DESCRIPTION

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. Section 1862 (a) (1) of the Social Security Act is the basis for denying payment for types of care, or specific items, services, or procedures that are not excluded by any other statutory clause and meet all technical requirements for coverage but are determined to be any of the following:

- Not generally accepted in the medical community as safe and effective in the setting and for the condition for which it is used.
- Not proven to be safe and effective based on peer review or scientific literature.
- Experimental.
- Not medically necessary in the particular case.
- Furnished at a level, duration or frequency that is not medically appropriate.
- Not furnished in accordance with accepted standards of medical practice.

OR

- Not furnished in a setting (such as inpatient care at a hospital or SNF, outpatient care through a hospital or physician's office or home care) appropriate to the patients' medical needs and condition.

To be considered medically necessary, items and services must have been established as safe and effective. That is, the items and services must be:

- Consistent with the symptoms or diagnosis of the illness or injury under treatment.

- Necessary and consistent with generally accepted professional medical standards (e. g. , not experimental or investigational).
- Not furnished primarily for the convenience of the patient, the attending physician or other physician or supplier.
- Furnished at the most appropriate level that can be provided safely and effectively to the patient.

Medicare is a defined benefit program; contractors sometimes have to decide whether a service fits one of the defined benefits categories. Services that this contractor considers non-covered because the service does not fit into a benefit category are also included on this list.

A service or procedure on the national non-coverage list may be non-covered for a variety of reasons. It may be non-covered based on a specific exclusion contained in the Medicare law (for example, acupuncture) it may be viewed as not yet proven safe and effective and, therefore, not medically reasonable and necessary; or it may be a procedure that is always considered cosmetic in nature and is denied on that basis. The precise basis for a national decision to non-cover a procedure may be found in the references cited in this policy. These national non-covered services are listed in this LCD for informational purposes only.

A service or procedure on the local list is always denied on the basis that Noridian does not believe it is ever medically reasonable and necessary. The Noridian list of LCD exclusions contains procedures that, for example, are:

- Experimental.
- Not proven safe and effective.

OR

- Not approved by the FDA.

Medical devices that are not approved for marketing by the Food and Drug Administration (FDA) are considered investigational by Medicare and are not considered reasonable and necessary for the diagnosis or treatment of illness or injury, or to improve functioning of a malformed body member. Program payment, therefore, may not be made for medical procedures and services performed using devices that have not been approved for marketing by the FDA or for those not included in an FDA-approved investigational (IDE) trial.

If a test, treatment or procedure is neither specifically covered nor excluded in Medicare law or guidelines, carriers must make a coverage determination that is based upon the general acceptance of the test, treatment or procedure by the professional medical community as an effective and proven treatment for the condition for which it is being used. Medicare will make payment only when a service is accepted as effective and proven. Some tests or services are obsolete and have been replaced by more advanced procedures. The tests or procedures may be paid only if the physician who performs them satisfactorily justifies the medical need for the procedure(s).

> "When processing a claim, carriers continue to determine if a service is reasonable and necessary to treat illness or injury. If a service is not reasonable and necessary to treat illness or injury for any reason (including lack of safety and efficacy because it is an experimental procedure, etc.), carriers consider the service noncovered notwithstanding the presence of a payment amount for the service in the Medicare fee schedule. The presence of a payment amount in the MPFS and the Medicare physician fee schedule database (MPFSDB) does not imply that CMS has determined that the service may be covered by Medicare. The nature of the status indicator in the database does not control coverage except where the status is N for noncovered. " *[Medicare Claims Processing Manual (CMS Pub. 100-04, Chapter 23, Section 30 A)]*

It is important to note that the fact that a new service or procedure has been issued a CPT code or is FDA approved for a specific indication does not, in itself, make the procedure medically reasonable and necessary. Noridian evaluates new services, procedures, drugs or technology and considers national and local policies before these new services may be considered Medicare covered services.

This LCD contains listings of numerous non-covered services which have no specific CPT code. Adding difficulty to correct coding for such services is the fact that there are many where two or more specific unlisted codes could arguably be used to designate the service. Initial preparation of the LCD to cover every possible code use – and more importantly, maintenance of the LCD as code changes occur – is difficult if not impossible.

Therefore, providers must bear in mind that any service that is described in any Noridian LCD as "non-covered" will remain non-covered no matter which CPT code is selected for billing. Since many of the unlisted codes, however, are also correctly used for billing of covered services, it is likely that prepay denial edits cannot be implemented into the claims processing computer system. Because of this, clearly non-covered services can in some instances be paid. Providers are reminded that these paid services will be subject to recoupment by Noridian, as well as other review contractors, including the Recovery Audit Contractors (RACs).

This is not an all-inclusive list of services not covered or not paid separately by Medicare.

INSTRUCTIONS FOR USE

Company Medical Policies serve as guidance for the administration of plan benefits. Medical policies do not constitute medical advice nor a guarantee of coverage. Company Medical Policies are reviewed annually and are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. The Companies reserve the right to determine the application of Medical Policies and make revisions to Medical Policies at any time. Providers will be given at least 60-days notice of policy changes that are restrictive in nature.

The scope and availability of all plan benefits are determined in accordance with the applicable coverage agreement. Any conflict or variance between the terms of the coverage agreement and Company Medical Policy will be resolved in favor of the coverage agreement.

REGULATORY STATUS

Mental Health Parity Statement

Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

REFERENCES

1. Medicare Benefit Policy Manual, Chapter 14 – Medical Devices, 10 - Coverage of Medical Devices; Last Updated 11/2014; Available at: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c14.pdf [Cited 11/08/2021]
2. Medicare Preventive Services web page; Last Updated 09/2021; Available at: https://www.cms.gov/Medicare/Prevention/PrevntionGenInfo/medicare-preventive-services/MPS-QuickReferenceChart-1.html [Cited 10/18/2021]
3. Noridian Jurisdiction D (J-D) web page for *Noncovered Items*; Last Updated 12/19/2019; Available at: https://med.noridianmedicare.com/web/jddme/topics/noncovered-items [Cited 10/08/2021]