MEDICAL POLICY	New and Emerging Technologies and Other Non-Covered Services (Medicare Only)
Effective Date: 1/1/2023	Medical Policy Number: 220
 1/1/2023	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; 12/2021; 2/2022; 3/2022; 4/2022; 6/2022; 8/2022; 10/2022; 11/2022
Medical Officer Date	

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

MEDICARE POLICY CRITERIA

NOTE: This policy is not an all-inclusive list of services or items not covered or not paid separately by Medicare or by the Company for Medicare Advantage members.

I. All services in this medical policy are considered **not medically necessary** for Medicare Plan members.

A. Rationale for non-coverage of the services listed in Table 1 is Medicare-based policy or regulation. Sources for non-coverage may include, but are not limited to, any of the following (A-E):

i. Medicare statutory exclusion;
ii. Lack of U.S. Food and Drug Administration (FDA) approval (when applicable);
1. 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]
iii. A Medicare policy (i.e., coverage manual, national coverage determination [NCD], local coverage determination [LCD], or article [LCA], etc.) indicates non-coverage; or

iv. 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
v. 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).

B. For services listed in Table 2, in the absence of specific Medicare policy, 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 medical policy for Investigational and Non-Covered Medical Technologies (All Lines of Business Except Medicare), **unless a different policy is otherwise noted**. *"Investigational" services are considered not medically necessary for Medicare Plan members. See Policy Guidelines below for more information.*

POLICY GUIDELINES

Medicare and Medical Necessity

The Company policy for *PHA Medicare Medical Policy Development and Application* (MP50) provides details regarding Medicare's definition of medical necessity and the hierarchy of Medicare references and resources during the development of medical policies, as well as the Plan's use of evidence-based processes for policy development. In the absence of Medicare coverage policies (e.g., manual, national coverage determination [NCD], local coverage determination [LCD], article [LCA], etc.), Medicare regulatory guidelines do allow Medicare Advantage Organizations (MAOs) to make their own coverage determinations, as long as the MAO applies an objective, evidence-based process, based on authoritative evidence. *(Medicare Managed Care Manual, Ch. 4, §90.5)*

Following an evidence-based assessment of current peer-reviewed medical literature, the Company may consider certain medical services or technologies to be "investigational." The term "investigational" is not limited to devices or technologies which have not received the appropriate governmental regulatory approval (e.g., U.S. Food and Drug Administration [FDA]), but rather may also mean the procedure, device, or technology does not meet all of the Company's technology assessment criteria, as detailed within the Company policy for *Definition: Experimental/Investigational* (MP5).

Only medically reasonable and necessary services or items which treat illness or injury are eligible for Medicare coverage, as outlined in *Title XVIII of the Social Security Act, §1862(a)(1)(A)*. Thus, services which lack scientific evidence regarding safety and efficacy because they are investigational are "not medically reasonable or necessary" for Medicare Plan members. *(Medicare Claims Processing Manual, Ch. 23, §30 A)*

Investigational Device Exemption (IDE) Studies

Some services may be listed as not medically necessary in this policy, but if rendered in the context of a **Medicare-approved** IDE study, the Company non-coverage position can be reconsidered. Documentation must support participation in the IDE study, as well as identify the study in question, including the national clinical trial (NCT) number. To view Medicare-approved IDE studies, see the CMS website for IDEs.

BILLING GUIDELINES

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

CPT/HCPCS CODES

NOTE: This is not an all-inclusive list of services or items not covered or not paid separately by Medicare or by the Company for Medicare Advantage members. Exclusion or omission from this list does **not** necessarily imply a service or technology is covered.

Medicare Only

Table 1. The following CPT/HCPCS codes are **not medically necessary** based on Medicare policy, guideline, or regulation. See below for details. Note, this list is **not** an all-inclusive list of Medicare non-covered services.

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	

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	preparation and transmission of data for analysis to be performed elsewhere	
77091	Trabecular bone score (TBS), structural condition of the bone 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	

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0221T	Placement of a posterior intrafacet implant(s), unilateral or bilateral, including imaging and placement of 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	As of the most recent review, devices designed specifically for ablation of the renal sympathetic nerves have not received FDA-approval.

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	angiography when performed; unilateral	
0339T	; bilateral	
0443T	Real-time spectral analysis of prostate tissue by fluorescence spectroscopy, including imaging guidance (List separately in addition to code for primary procedure) (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~~	**TERMED 12/31/2022** ~~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,	

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	including topical application and dressing care; initial wound	
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)	As of the most recent review, the technology represented by this code has not received FDA approval.
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	

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	report, includes connection, recording, and disconnection per patient encounter, wireless cardiac stimulator for left ventricular pacing	
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 Tremoromete8lexibleAble 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

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		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. 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

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		tricuspid valve annuloplasty reconstruction device approved for patient use anywhere in world is the Edwards Cardioband Tricuspid Valve Reconstruction System, 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	

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	data, and bone-mineral density, utilizing data from a computed tomography scan; assessment of bone strength and fracture risk and bone mineral density	
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	
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)	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.
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)	
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.
0569T	Transcatheter tricuspid valve repair, percutaneous approach; initial prosthesis	TriClip™ Transcatheter Tricuspid Valve Repair System (Abbott)

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0570T	Transcatheter tricuspid valve repair, percutaneous approach; each additional prosthesis during same session (List separately in addition to code for primary procedure)	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.)*
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	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 Services Which Are Not Covered Under Medicare*, removal **without** replacement (0580T) may be considered medically

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	therapeutic parameters), when performed	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)	
0578T	Interrogation device evaluation(s) (remote), up to 90 days, substernal lead implantable cardioverter-defibrillator system with interim analysis, review(s)	

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	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 technical support, data analyses and reports, with a minimum of 8 daily recordings, each 30 days	

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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 angiography; data preparation and transmission	

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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, interpretation and report, each flap or wound	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.

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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.
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	
0687T	Treatment of amblyopia using an online digital program; device supply, educational set-up, and initial session	CureSight™:

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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	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.
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 injury. This system has been studied for use in relation to sports medicine.

Table 1. The following CPT/HCPCS codes are **not medically necessary** based on Medicare policy, guideline, or regulation. See below for details. Note, this list is **not** an all-inclusive list of Medicare non-covered services.

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	
0706T	Remote treatment of amblyopia using an eye tracking device; interpretation and report by physician or other	

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	qualified health care professional, per calendar month	
0716T	Cardiac acoustic waveform recording with automated analysis and generation of coronary artery disease risk score	This test determines risk of coronary artery disease (CAD). Under Medicare, testing to determine risk of a condition or illness is considered screening. Therefore, this procedure is **not medically necessary** as a screening procedure per Medicare statute.[2]
0725T	Vestibular device implantation, unilateral	Examples include, but may not be limited to, the following: • Cochlear Vestibular Implant (CVI) • Labyrinth Devices MVI™ Multichannel Vestibular Implant The Multichannel Vestibular Implant Early Feasibility Study (NCT02725463; G150198), which is evaluating the Labyrinth device, is a Medicare-approved Category B IDE study as of 8/2021. The VertiGO! trial (NCT04918745) is not a Medicare approved IDE study. Therefore, unless provided within the context of a Medicare-approved IDE study, a vestibular implant is **not medically 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.)* Note: According to the *Medicare Benefit Policy Manual, Chapter 16, §–80 - Services Related to and Required as a Result of Services Which Are Not Covered Under Medicare*, removal **without** replacement (0726T) may be considered medically reasonable and necessary for unrelated reasons (e.g., pain, infection, etc.).
0727T	Removal and replacement of implanted vestibular device, unilateral	
0728T	Diagnostic analysis of vestibular implant, unilateral; with initial programming	
0729T	Diagnostic analysis of vestibular implant, unilateral; with subsequent programming	
0731T	Augmentative AI-based facial phenotype analysis with report	Not medically reasonable or necessary under Medicare and §1862(a)(1)(A).

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		Code 0731T is for facial recognition based on artificial intelligence (AI) to detect underlying facial patterns thought to be beneficial for diagnosis or screening.
0736T	Colonic lavage, 35 or more liters of water, gravity-fed, with induced defecation, including insertion of rectal catheter	National Coverage Determination (NCD) for Colonic Irrigation (100.7)
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 acid, xanthurenic acid, homocysteine, pyroglutamic acid, vanilmandelate, 5-	Foundation PISM, Ethos Laboratories While this test may provide information during workup, the test results do not

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	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	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).
0152U	Infectious disease (bacteria, fungi, parasites, and DNA viruses), DNA, PCR and next-generation sequencing, plasma, detection of >1,000 potential microbial organisms for significant positive pathogens	Karius® (Karius; California) This test is considered not medically reasonable or necessary. The LCD L35160 requires molecular diagnostic testing to undergo a technical assessment (TA) to determine Medicare coverage. The LCD L39001 includes this same requirement for tests which do not have FDA-approval or clearance. This test is not FDA-approved. It has been reviewed by the MolDX Contractor and determined to be "not covered."
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

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		Medicare's requirements to be considered medically reasonable or necessary. *(LCD L35000; Published by National Government Services)*
0352U	Infectious disease (bacterial vaginosis and vaginitis), multiplex amplified probe technique, for detection of bacterial vaginosis–associated bacteria (BVAB-2, Atopobium vaginae, and Megasphera type 1), algorithm reported as detected or not detected and separate detection of Candida species (C. albicans, C. tropicalis, C. parapsilosis, C. dubliniensis), Candida glabrata/Candida krusei, and trichomonas vaginalis, vaginal-fluid specimen, each result reported as detected or not detected	Xpert® Xpress MPV (Cepheid®) This test is non-covered as a screening test under Medicare. Coverage exceptions may be made on appeal if not used as a screening tool when coverage criteria from LCD L39003 are met **and** if the test is included as a covered test in the companion LCA (A58726).
0353U	Infectious agent detection by nucleic acid (DNA), Chlamydia trachomatis and Neisseria gonorrhoeae, multiplex amplified probe technique, urine, vaginal, pharyngeal, or rectal, each pathogen reported as detected or not detected	Xpert® CT/NG (Cepheid®) This test is a non-covered screening test under Medicare. Coverage exceptions may be made on appeal and when coverage criteria from LCD L39003 are met **and** if the test is included as a covered test in the companion LCA (A58726).
0354U	Human papilloma virus (HPV), high-risk types (ie, 16, 18, 31, 33, 45, 52 and 58) qualitative mRNA expression of E6/E7 by quantitative polymerase chain reaction (qPCR)	PreTect HPV-Proofer' 7 (GenePace Laboratories, LLC & PreTech) This test is used as a screening test. HPV screening used outside of NCD 210.2.1 is not 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.
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] • NCD for Noncontact Normothermic Wound Therapy (270.2)

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C9780	Insertion of central venous catheter through central venous occlusion via inferior and superior approaches (e.g., inside-out technique), including imaging guidance *(Surfacer® Inside-Out® Access Catheter System)*	The Surfacer® Inside-Out® Access Catheter system is currently undergoing trials and 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

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CODE	DESCRIPTION	TECHNOLOGY AND/OR MANUFACTURER AND ADDITIONAL NOTES (when available)
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)	
64628	Thermal destruction of intraosseous basivertebral nerve, including all imaging guidance; first 2 vertebral bodies, lumbar or sacral	Intracept Intraosseous Nerve Ablation System See the Company medical policy for Back: Ablative Procedures to Treat Back and Neck Pain (All Lines of Business Except Medicare)
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 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
93590	Percutaneous transcatheter closure of paravalvular leak; initial occlusion device, mitral valve	While transcatheter repair of paravalvular leaks has been performed, there are currently no FDA-approved

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93591	Percutaneous transcatheter closure of paravalvular leak; initial occlusion device, aortic valve	devices for this indication. Devices such as the Amplatzer Vascular Plug are commonly used off-label for this purpose. The PARADIGM trial (NCT0448982; G200097) is a Medicare-approved Category B IDE study as of 1/15/2021. Coverage may be approved for members enrolled in the Medicare-approved study. Otherwise, coverage is not 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.)*
93592	Percutaneous transcatheter closure of paravalvular leak; each additional occlusion device (List separately in addition to code for primary procedure)	
95919	Quantitative pupillometry with physician or other qualified health care professional interpretation and report, unilateral or bilateral	
0329T	Monitoring of intraocular pressure for 24 hours or longer, unilateral or bilateral, with interpretation and report	
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	

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0379T	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; 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	

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	connection, recording and disconnection per patient encounter, implantable cardiac contractility modulation system	
C1824	Generator, cardiac contractility modulation (implantable)	
K1030	External recharging system for battery (internal) for use with implanted cardiac contractility modulation generator, replacement only	
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*
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	

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0435T	Programming device evaluation of implanted neurostimulator pulse generator system for central sleep apnea; single session	*Services Which Are Not Covered Under Medicare* for more information.
0436T	Programming device evaluation of implanted neurostimulator pulse generator system for central sleep apnea; during sleep study	
~~0470T~~	**TERMED 12/31/2022** ~~Optical coherence tomography (OCT) for microstructural and morphological imaging of skin, image acquisition, interpretation, and report; first lesion~~	
~~0471T~~	**TERMED 12/31/2022** ~~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~~	**TERMED 12/31/2022** ~~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~~	**TERMED 12/31/2022** ~~Ablative laser treatment, non-contact, full field and fractional ablation, open wound, per day, total treatment surface area; first 20 sq cm or less~~	

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~~0492T~~	**TERMED 12/31/2022** ~~; 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	
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	

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	interpretation; complete system (electrode and implantable monitor)	
0531T	; electrode only	
0532T	; implantable monitor only	
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	

Table 2. The following CPT/HCPCS codes do not have specific Medicare policy or guidance. Therefore, the following codes are considered **not medically necessary** based on Criterion I.B 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 lens or intraocular lens, without insertion of intraocular lens	CustomFlex Artificial Iris, Human Optics

Table 2. The following CPT/HCPCS codes do not have specific Medicare policy or guidance. Therefore, the following codes are considered **not medically necessary** based on Criterion I.B in the "Policy Criteria" table above.		
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
0659T	Transcatheter intracoronary infusion of supersaturated oxygen in conjunction with percutaneous coronary revascularization	TherOx Downstream® System, TherOx Inc.

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	during acute myocardial infarction, including catheter placement, imaging guidance (eg, fluoroscopy), angiography, and radiologic supervision and interpretation	
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)	
0681T	Relocation of pulse generator only, permanent implantable synchronized diaphragmatic stimulation system for augmentation of cardiac function, with connection to existing dual leads	

Table 2. The following CPT/HCPCS codes do not have specific Medicare policy or guidance. Therefore, the following codes are considered **not medically necessary** based on Criterion I.B in the "Policy Criteria" table above.		
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	
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	

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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	
0715T	Percutaneous transluminal coronary lithotripsy (List separately in addition to code for primary procedure)	
0720T	Percutaneous electrical nerve field stimulation, cranial nerves, without implantation	IB-stim, (formally Neuro-Stim)
0730T	Trabeculotomy by laser, including optical coherence tomography (OCT) guidance	Excimer (ExTra ELT)
0732T	Immunotherapy administration with electroporation, intramuscular	
0733T	Remote real-time, motion capture-based neurorehabilitative therapy ordered by a physician or other qualified health care professional; supply and technical support, per 30 days	Examples may include, but are not limited to, the following therapies offered by Hinge and SWORD Health
0734T	Remote real-time, motion capture-based neurorehabilitative therapy ordered by a physician or other qualified health care professional; treatment management services by a physician or other qualified health care professional, per calendar month	
0735T	Preparation of tumor cavity, with placement of a radiation therapy applicator for intraoperative radiation therapy (IORT) concurrent with primary craniotomy (List separately in addition to code for primary procedure)	
0737T	Xenograft implantation into the articular surface	
0738T	Treatment planning for magnetic field induction ablation of malignant prostate tissue, using data from previously performed magnetic resonance imaging (MRI) examination	Visualase Laser Ablation, Medtronic (see also code 0655T)

Table 2. The following CPT/HCPCS codes do not have specific Medicare policy or guidance. Therefore, the following codes are considered **not medically necessary** based on Criterion I.B in the "Policy Criteria" table above.		
0739T	Ablation of malignant prostate tissue by magnetic field induction, including all intraprocedural, transperinealneedle/catheter placement for nanoparticle installation and intraprocedural temperature monitoring, thermal dosimetry, bladder irrigation, and magnetic field nanoparticle activation	
0743T	Bone strength and fracture risk using finite element analysis of functional data and bone mineral density (BMD), with concurrent vertebral fracture assessment, utilizing data from a computed tomography scan, retrieval and transmission of the scan data, measurement of bone strength and BMD and classification of any vertebral fractures, with overall fracture-risk assessment, interpretation and report	
0744T	Insertion of bioprosthetic valve, open, femoral vein, including duplex ultrasound imaging guidance, when performed, including autogenous or nonautogenous patch graft (eg, polyester, ePTFE, bovine pericardium), when performed	VenoValve procedure. Clinical trials are ongoing.
0748T	Injections of stem cell product into perianal perifistular soft tissue, including fistula preparation (eg, removal of setons, fistula curettage, closure of internal openings)	
0764T	Assistive algorithmic electrocardiogram risk-based assessment for cardiac dysfunction (eg, low-ejection fraction, pulmonary hypertension, hypertrophic cardiomyopathy); related to concurrently performed electrocardiogram (List separately in addition to code for primary procedure)	
0765T	Assistive algorithmic electrocardiogram risk-based assessment for cardiac dysfunction (eg, low-ejection fraction, pulmonary hypertension, hypertrophic cardiomyopathy);	

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	related to previously performed electrocardiogram	
0770T	Virtual reality technology to assist therapy (List separately in addition to code for primary procedure)	
0771T	Virtual reality (VR) procedural dissociation services provided by the same physician or other qualified health care professional performing the diagnostic or therapeutic service that the VR procedural dissociation supports, requiring the presence of an independent, trained observer to assist in the monitoring of the patient's level of dissociation or consciousness and physiological status; initial 15 minutes of intraservice time, patient age 5 years or older	
0772T	Virtual reality (VR) procedural dissociation services provided by the same physician or other qualified health care professional performing the diagnostic or therapeutic service that the VR procedural dissociation supports, requiring the presence of an independent, trained observer to assist in the monitoring of the patient's level of dissociation or consciousness and physiological status; each additional 15 minutes intraservice time (List separately in addition to code for primary service)	
0773T	Virtual reality (VR) procedural dissociation services provided by a physician or other qualified health care professional other than the physician or other qualified health care professional performing the diagnostic or therapeutic service that the VR procedural dissociation supports; initial 15 minutes of intraservice time, patient age 5 years or older	
0774T	Virtual reality (VR) procedural dissociation services provided by a physician or other qualified health care professional other than the physician or other qualified health care	

Table 2. The following CPT/HCPCS codes do not have specific Medicare policy or guidance. Therefore, the following codes are considered **not medically necessary** based on Criterion I.B in the "Policy Criteria" table above.

	professional performing the diagnostic or therapeutic service that the VR procedural dissociation supports; each additional 15 minutes intraservice time (List separately in addition to code for primary service)	
0776T	Therapeutic induction of intra-brain hypothermia, including placement of a mechanical temperature-controlled cooling device to the neck over carotids and head, including monitoring (eg, vital signs and sport concussion assessment tool 5 [SCAT5]), 30 minutes of treatment	
0777T	Real-time pressure-sensing epidural guidance system (List separately in addition to code for primary procedure)	Accuro (RIVANNA®)
0778T	Surface mechanomyography (sMMG) with concurrent application of inertial measurement unit (IMU) sensors for measurement of multi-joint range of motion, posture, gait, and muscle function	
0779T	Gastrointestinal myoelectrical activity study, stomach through colon, with interpretation and report	
0781T	Bronchoscopy, rigid or flexible, with insertion of esophageal protection device and circumferential radiofrequency destruction of the pulmonary nerves, including fluoroscopic guidance when performed; bilateral mainstem bronchi	dNerva® Lung Denervation or Nuvaira™ Lung Denervation Systems, used in a procedure called Targeted Lung Denervation The trial (NCT03639051; G180199) is a Medicare-approved Category B IDE study as of 4/2/2020. 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.)*
0782T	Bronchoscopy, rigid or flexible, with insertion of esophageal protection device and circumferential radiofrequency destruction of the pulmonary nerves, including fluoroscopic guidance when performed; unilateral mainstem bronchus	

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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 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	

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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); with intravascular lithotripsy and transluminal stent placement(s), and atherectomy, includes angioplasty within the same vessel (s), when performed	
C9781	Arthroscopy, shoulder, surgical; with implantation of subacromial spacer (e.g., balloon), includes debridement (e.g., limited or extensive), subacromial decompression, acromioplasty, and biceps tenodesis when performed	InSpace Subacromial Spacer (Stryker)
K1009	Speech volume modulation system, any type, including all components and accessories	SpeechVive device

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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, quantitative report with steady-state range for the prescribed drug(s) when detected	Oral OncolyticAssuranceRX
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™

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~~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)	
0228U	Oncology (prostate), multianalyte molecular profile by photometric detection of macromolecules adsorbed on nanosponge array slides with machine learning, utilizing first morning voided urine, algorithm reported as likelihood of prostate cancer	PanGIA Prostate, by Genetics Institute of America; Florida
0251U	Hepcidin-25, enzyme-linked immunosorbent assay (ELISA), serum or plasma	Intrinsic Hepcidin IDx™
0312U	Autoimmune diseases (eg, systemic lupus erythematosus [SLE]), analysis of 8 IgG autoantibodies and 2 cell-bound complement	Avise® Lupus, Exagen Inc. (Vista, California)

Table 2. The following CPT/HCPCS codes do not have specific Medicare policy or guidance. Therefore, the following codes are considered **not medically necessary** based on Criterion I.B in the "Policy Criteria" table above.

	activation products using enzyme-linked immunosorbent immunoassay (ELISA), flow cytometry and indirect immunofluorescence, serum, or plasma and whole blood, individual components reported along with an algorithmic SLE-likelihood assessment *(Not medically necessary under Section 1862(a)(1) of the Social Security Act)*	
0316U	Borrelia burgdorferi (Lyme disease), OspA protein evaluation, urine	Lyme Borrelia Nanotrap® Urine Antigen Test (Galaxy Diagnostics Inc.)
0344U	Hepatology (nonalcoholic fatty liver disease [NAFLD]), semiquantitative evaluation of 28 lipid markers by liquid chromatography with tandem mass spectrometry (LC-MS/MS), serum reported as at-risk for nonalcoholic steatohepatitis (NASH) or not NASH	OWLiver® (CIMA Sciences, LLC)
0346U	Beta amyloid, Aβ40 and Aβ42 by liquid chromatography with tandem mass spectrometry (LC-MS/MS), ratio, plasma	QUEST AD-Detect™, Beta-Amyloid 42/40 Ratio, Plasma (Quest Diagnostics; New Jersey)
0351U	Infectious disease (bacterial or viral), biochemical assays, tumor necrosis factor-related apoptosis-inducing ligand (TRAIL), interferon gamma-induced protein-10 (IP10), and C-reactive protein, serum, algorithm reported as likelihood of bacterial infection	MeMed BV® (MeMed Diagnostics, Ltd.)
0357U	Oncology (melanoma), artificial intelligence (AI)-enabled quantitative mass spectrometry analysis of 142 unique pairs of glycopeptide and product fragments, plasma, prognostic, and predictive algorithm reported as likely, unlikely, or uncertain benefit from immunotherapy agents	DAWN™ IO Melanoma (InterVenn Biosciences; California)
0358U	Neurology (mild cognitive impairment), analysis of β-amyloid 1-42 and 1-40, chemiluminescence enzyme immunoassay, cerebral spinal fluid, reported as positive, likely positive, or negative	Lumipulse® G β-Amyloid Ratio (1-42/1-40) Test (Fujirebio Diagnostics, Inc.; Pennsylvania)
0361U	Neurofilament light chain, digital immunoassay, plasma, quantitative	Neurofilament Light Chain (NfL) (Mayo Clinic)

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 10/25/2022]
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 10/25/2022]
3. Noridian Jurisdiction D (J-D) web page for *Noncovered Items*; Last Updated 9/27/2022; Available at: https://med.noridianmedicare.com/web/jddme/topics/noncovered-items [Cited 10/25/2022]