Medicare Medical Policy

New and Emerging Technologies and Other Non-Covered Services

MEDICARE MEDICAL POLICY NUMBER: 220

Effective Date: 1/1/2024

Last Review Date: 11/2023

Next Annual Review: 8/2024

INSTRUCTIONS FOR USE: Company Medicare Medical Policies serve as guidance for the administration of plan benefits and do not constitute medical advice nor a guarantee of coverage. Company Medicare Medical Policies are reviewed annually to guide the coverage or non-coverage decision-making process for services or procedures in accordance with member benefit contracts (otherwise known as Evidence of Coverage or EOCs) and Centers of Medicare and Medicaid Services (CMS) policies, manuals, and other CMS rules and regulations. In the absence of a CMS coverage determination or specific regulation for a requested service, item or procedure, Company policy criteria or applicable utilization management vendor criteria may be applied. These are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. 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.

The Company reserves the right to determine the application of Medicare Medical Policies and make revisions to these policies at any time. Any conflict or variance between the EOC and Company Medical Policy will be resolved in favor of the EOC.

SCOPE: Providence Health Plan, Providence Health Assurance, and Providence Plan Partners as applicable (referred to individually as “Company” and collectively as “Companies”).

☒ Medicare Only

MEDICARE COVERAGE CRITERIA

IMPORTANT NOTE: More than one Centers for Medicare and Medicaid Services (CMS) reference may apply to the same health care service, such as when more than one coverage policy is available (e.g., both an NCD and LCD exist). All references listed should be considered for coverage decision-making. The Company uses the most current version of a Medicare reference available at the time of publication; however, these websites are not maintained by the Company, so Medicare references and their corresponding hyperlinks may change at any time. If there is a conflict between the Company Medicare Medical Policy and CMS guidance, the CMS guidance will govern.

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.

Service	Medicare Guidelines
NOTE: All services in this medical policy are considered **not medically necessary** for Medicare Plan members.	
Services or devices **with** specific Medicare guidance or regulation	I. 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): A. Medicare statutory exclusion; 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. 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)

Services or devices **without** specific Medicare guidance	II.	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 New and Emerging Technologies and Other Non-Covered Services, **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. Services which use Company non-coverage outcomes have had a peer-reviewed evidence analysis performed.*

IMPORTANT NOTICE: While some services or items may appear medically indicated for an individual, they may also be a direct exclusion of Medicare or the member's benefit plan. Such excluded services or items by Medicare and member EOCs include, but are not limited to, services or procedures considered to be cosmetic, not medical in nature, or those considered not medically reasonable or necessary under *Title XVIII of the Social Security Act, §1862(a)(1)(A).* If there is uncertainty regarding coverage of a service or item, please review the member EOC or submit a pre-service organization determination request. Note that the Medicare Advance Beneficiary Notice of Noncoverage (ABN) form **cannot** be used for Medicare Advantage members. *(Medicare Advance Written Notices of Non-coverage. MLN006266 May 2021)*

POLICY CROSS REFERENCES

None

The full Company portfolio of Medicare Medical Policies is available online and can be accessed here.

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.

REGULATORY STATUS

U.S. FOOD & DRUG ADMINISTRATION (FDA)

While clearance by the Food and Drug Administration (FDA) is a prerequisite for Medicare coverage, the 510(k) premarket clearance process does not in itself establish medical necessity. Medicare payment policy is determined by the interaction of numerous requirements, including but not limited to, the availability of a Medicare benefit category and other statutory requirements, coding and pricing guidelines, as well as national and local coverage determinations and clinical evidence.

BILLING GUIDELINES AND CODING

GENERAL

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

CODES*		
CPT		See Tables below
HCPCS		See Tables below

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.

Table 1: CPT/HCPCS codes that are not medically necessary based on *Medicare policy, guideline, or regulation*.

Table 1: CPT/HCPCS codes that are not medically necessary based on *Medicare policy, guideline, or regulation*.		
Code	Description	Medicare Rationale, Product, and Manufacturer (when available or applicable, may not be an all-inclusive list or may be examples only)
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	TBS iNsight™ Medicare determines preventive benefit coverage and this testing would be considered non-covered as a screening test per Medicare statute.[2]
77091	Trabecular bone score (TBS), structural condition of the bone microarchitecture; technical calculation only	TBS iNsight™ Medicare determines preventive benefit coverage and this testing would be considered non-covered as a screening test per Medicare statute.[2]
77092	Trabecular bone score (TBS), structural condition of the bone microarchitecture; interpretation and report on fracture-risk only by other qualified health care professional	TBS iNsight™ Medicare determines preventive benefit coverage and this testing would be considered non-covered as a screening test per Medicare statute.[2]
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	LCA: MolDX: PreDx (A55599)
97026	Application of a modality to 1 or more areas; infrared	• Medicare Status "R" code • NCD for Infrared Therapy Devices (270.6) • 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).

Table 1: CPT/HCPCS codes that are not medically necessary based on *Medicare policy, guideline, or regulation*.		
97546	Work hardening/conditioning; each additional hour (List separately in addition to code for primary procedure)	• 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).
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	• LCD Facet Joint Interventions for Pain Management (L38803) • 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	• LCD Facet Joint Interventions for Pain Management (L38803) • LCA: Billing and Coding: Facet Joint Interventions for Pain Management (A58405)
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	• LCD Facet Joint Interventions for Pain Management (L38803) • LCA: Billing and Coding: Facet Joint Interventions for Pain Management (A58405)
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)	• LCD Facet Joint Interventions for Pain Management (L38803) • LCA: Billing and Coding: Facet Joint Interventions for Pain Management (A58405)
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.

Table 1: CPT/HCPCS codes that are <u>not medically necessary</u> based on *Medicare policy, guideline, or regulation*.		
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	As of the most recent review, devices designed specifically for ablation of the renal sympathetic nerves have 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	As of the most recent review, the technology represented by this code has not received FDA approval.
0469T	Retinal polarization scan, ocular screening with on-site automated results, bilateral	Medicare Status "N" code
~~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 product 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	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.
0544T	Transcatheter mitral valve annulus reconstruction, with implantation of	Cardioband™ Mitral Valve Reconstruction System (Edwards Lifesciences)

Table 1: CPT/HCPCS codes that are <u>not medically necessary</u> based on *Medicare policy, guideline, or regulation*.		
	adjustable annulus reconstruction device, percutaneous approach including transseptal puncture	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. 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, which has received the European CE mark approval. However, this device has not yet

Table 1: CPT/HCPCS codes that are <u>not medically necessary</u> based on *Medicare policy, guideline, or regulation*.		
		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).
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	Medicare determines preventive benefit coverage and this testing would be considered non-covered as a screening test per Medicare statute.[2]
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	Medicare determines preventive benefit coverage and this testing would be considered non-covered as a screening test per Medicare statute.[2]
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	Medicare determines preventive benefit coverage and this testing would be considered non-covered as a screening test per Medicare statute.[2]
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)	(See 0559T above)
0561T	Anatomic guide 3D-printed and designed from image data set(s); first anatomic guide	(See 0559T above)
0562T	Anatomic guide 3D-printed and designed from image data set(s); each additional	(See 0559T above)

Table 1: CPT/HCPCS codes that are not medically necessary based on *Medicare policy, guideline, or regulation*.		
	anatomic guide (List separately in addition to code for primary procedure)	
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)	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 reasonable and necessary for unrelated reasons (e.g., pain, infection, etc.).

Table 1: CPT/HCPCS codes that are <u>not medically necessary</u> based on *Medicare policy, guideline, or regulation*.		
0571T	Insertion or replacement of implantable cardioverter-defibrillator system with substernal electrode(s), including all imaging guidance and electrophysiological evaluation (includes defibrillation threshold evaluation, induction of arrhythmia, evaluation of sensing for arrhythmia termination, and programming or reprogramming of sensing or therapeutic parameters), when performed	(See 0570T above)
0572T	Insertion of substernal implantable defibrillator electrode	(See 0570T above)
0573T	Removal of substernal implantable defibrillator electrode	(See 0570T above)
0574T	Repositioning of previously implanted substernal implantable defibrillator-pacing electrode	(See 0570T above)
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	(See 0570T above)
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	(See 0570T above)
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)	(See 0570T above)
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	(See 0570T above)

Table 1: CPT/HCPCS codes that are not medically necessary based on *Medicare policy, guideline, or regulation*.		
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	(See 0570T above)
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	As of the most recent review, the technology/device/procedure represented by this code has not received FDA approval.
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	As of the most recent review, the technology/device/procedure represented by this code has not received FDA approval.
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	As of the most recent review, the technology/device/procedure represented by this code has not received FDA approval.
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.

Table 1: CPT/HCPCS codes that are <u>not medically necessary</u> based on *Medicare policy, guideline, or regulation*.		
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	As of the most recent review, the technology/device/procedure represented by this code has not received FDA approval.
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	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.
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	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.
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	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.
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	As of the most recent review, the technology/device/procedure represented by this code has not received FDA approval.

Table 1: CPT/HCPCS codes that are <u>not medically necessary</u> based on *Medicare policy, guideline, or regulation*.		
	catheterization, pulmonary artery angiography, and all imaging guidance	
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 (eg, for measurement of deoxyhemoglobin, oxyhemoglobin, and ratio of tissue oxygenation) , other than for screening for peripheral arterial disease, image acquisition, interpretation, and report; first anatomic site	Not medically reasonable or necessary under Medicare and §1862(a)(1)(A). This is used to determine oxygenation levels in superficial tissues for patients with potential circulatory compromise, but it does not "treat or diagnosis" an illness or injury.
~~**0641T**~~	**TERMED 12/31/2023** ~~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~~	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.
~~**0642T**~~	**TERMED 12/31/2023** ~~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~~	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.
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.
22836	Anterior thoracic vertebral body tethering, including thoracoscopy, when performed; up to 7 vertebral segments	See 0656T below
22837	Anterior thoracic vertebral body tethering, including thoracoscopy, when performed; 8 or more vertebral segments	See 0656T below
22838	Revision (eg, augmentation, division of tether), replacement, or removal of thoracic vertebral body tethering, including thoracoscopy, when performed	
0656T	Anterior lumbar or thoracolumbar vertebral body tethering, anterior; up to 7 vertebral segments	Tether Vertebral Body Tethering System (Zimmer Biomet)

Table 1: CPT/HCPCS codes that are <u>not medically necessary</u> based on *Medicare policy, guideline, or regulation*.		
		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	Anterior lumbar or thoracolumbar vertebral body tethering, anterior; 8 or more 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.
0790T	Revision (eg, augmentation, division of tether), replacement, or removal of thoracolumbar or lumbar vertebral body tethering, including thoracoscopy, when performed	See 0656T above
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	iDose (Glaukos) As of the most recent review, the technology/device/procedure represented by this code has not received FDA approval.
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	CureSight™:

Table 1: CPT/HCPCS codes that are <u>not medically necessary</u> based on *Medicare policy, guideline, or regulation*.		
	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.
A9292	Prescription digital visual therapy, software-only, FDA cleared, per course of treatment	Luminopia (Luminopia Inc.) This product is indicated for use in patients aged 4-7 years old. It is not expected there will be clinical utility studies applicable to the Medicare population as this product is not meant to be used in older individuals.
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)	Not medically reasonable or necessary under Medicare and §1862(a)(1)(A). This does not "treat or diagnosis" an illness or injury.
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.
0697T	Quantitative magnetic resonance for analysis of tissue composition (eg, fat, iron, water content), including multiparametric	This is not a magnetic resonance procedure covered under the Medicare NCD 220.2. Not medically reasonable or necessary under

Table 1: CPT/HCPCS codes that are <u>not medically necessary</u> based on *Medicare policy, guideline, or regulation*.		
	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	Medicare and §1862(a)(1)(A). This analyzes body composition to determine if more invasive procedures (i.e., biopsies) are needed, it does not "treat or diagnosis" an illness or injury.
0698T	Quantitative magnetic resonance for analysis of tissue composition (eg, fat, iron, water content), including multiparametric data acquisition, data preparation and transmission, interpretation and report, obtained with diagnostic MRI examination of the same anatomy (eg, organ, gland, tissue, target structure); multiple organs (List separately in addition to code for primary procedure)	This is not a magnetic resonance procedure covered under the Medicare NCD 220.2. Not medically reasonable or necessary under Medicare and §1862(a)(1)(A). This analyzes body composition to determine if more invasive procedures (i.e., biopsies) are needed, it does not "treat or diagnosis" an illness or injury.
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)	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.
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	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.

Table 1: CPT/HCPCS codes that are <u>not medically necessary</u> based on *Medicare policy, guideline, or regulation*.		
0706T	Remote treatment of amblyopia using an eye tracking device; interpretation and report by physician or other qualified health care professional, per calendar month	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.
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.).

Table 1: CPT/HCPCS codes that are not medically necessary based on *Medicare policy, guideline, or regulation*.		
0727T	Removal and replacement of implanted vestibular device, unilateral	(See 0725T above)
0728T	Diagnostic analysis of vestibular implant, unilateral; with initial programming	(See 0725T above)
0729T	Diagnostic analysis of vestibular implant, unilateral; with subsequent programming	(See 0725T above)
0731T	Augmentative AI-based facial phenotype analysis with report	Not medically reasonable or necessary under Medicare and §1862(a)(1)(A). Code 0731T is for facial recognition based on artificial intelligence (AI) to detect underlying facial patterns thought to be beneficial for diagnosis or screening.
0795T	Transcatheter insertion of permanent dual-chamber leadless pacemaker, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography) and device evaluation (eg, interrogation or programming), when performed; complete system (ie, right atrial and right ventricular pacemaker components)	Aveir™ DR Dual-Chamber Pacemaker (Abbott) See the Medicare NCD for Leadless Pacemakers (20.8.4). According to NCD 20.8.4, leadless pacemakers are eligible for coverage under the Medicare coverage with evidence development (CED) provision. Unless provided within the context of a Medicare-approved study, a leadless pacemaker is **not medically necessary** for Medicare under §1862(a)(1)(A). *(To confirm participation in a Medicare-approved study, the NCT number must be provided and be verified as a Medicare-approved study on the CMS CED website for leadless pacemakers.)* 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 (0798T-0800T) may be considered medically reasonable and necessary for unrelated reasons (e.g., pain, infection, etc.).
0796T	Transcatheter insertion of permanent dual-chamber leadless pacemaker, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography) and device evaluation (eg, interrogation or programming), when performed; right atrial pacemaker component (when an existing	(See 0795T above)

Table 1: CPT/HCPCS codes that are <u>not medically necessary</u> based on *Medicare policy, guideline, or regulation*.		
	right ventricular single leadless pacemaker exists to create a dual-chamber leadless pacemaker system)	
0797T	Transcatheter insertion of permanent dual-chamber leadless pacemaker, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography) and device evaluation (eg, interrogation or programming), when performed; right ventricular pacemaker component (when part of a dual-chamber leadless pacemaker system)	(See 0795T above)
0801T	Transcatheter removal and replacement of permanent dual-chamber leadless pacemaker, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography) and device evaluation (eg, interrogation or programming), when performed; dual-chamber system (ie, right atrial and right ventricular pacemaker components)	(See 0795T above)
0802T	Transcatheter removal and replacement of permanent dual-chamber leadless pacemaker, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography) and device evaluation (eg, interrogation or programming), when performed; right atrial pacemaker component	(See 0795T above)
0803T	Transcatheter removal and replacement of permanent dual-chamber leadless pacemaker, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography) and device evaluation (eg, interrogation or programming), when performed; right ventricular pacemaker component (when part of a dual-chamber leadless pacemaker system)	(See 0795T above)
0804T	Programming device evaluation (in person) with iterative adjustment of implantable device to test the function of device and to select optimal permanent programmed values, with analysis, review, and report, by a physician or other qualified health care	(See 0795T above)

Table 1: CPT/HCPCS codes that are <u>not medically necessary</u> based on *Medicare policy, guideline, or regulation*.		
	professional, leadless pacemaker system in dual cardiac chambers	
0823T	Transcatheter insertion of permanent single-chamber leadless pacemaker, right atrial, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography and/or right ventriculography, femoral venography, cavography) and device evaluation (eg, interrogation or programming), when performed	(See 0795T above)
0824T	Transcatheter removal of permanent single-chamber leadless pacemaker, right atrial, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography and/or right ventriculography, femoral venography, cavography), when performed	(See 0795T above)
0825T	Transcatheter removal and replacement of permanent single-chamber leadless pacemaker, right atrial, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography and/or right ventriculography, femoral venography, cavography) and device evaluation (eg, interrogation or programming), when performed	(See 0795T above)
0826T	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, leadless pacemaker system in single-cardiac chamber	(See 0795T above)
0805T	Transcatheter superior and inferior vena cava prosthetic valve implantation (ie, caval valve implantation [CAVI]); percutaneous femoral vein approach	preCARDIA The Superior Vena Caval Occlusion in Subjects With Acute Decompensated Heart Failure or VENUS-HF study (NCT03836079; G180213), which is evaluating the preCARDIA device, is a Medicare-approved Category B IDE study as of 3/2020. Unless provided within the context of a Medicare-approved IDE study, the preCARDIA system is not medically necessary for Medicare under §1862(a)(1)(A). (To confirm participation in a Medicare-approved IDE study, the NCT

Table 1: CPT/HCPCS codes that are not medically necessary based on *Medicare policy, guideline, or regulation*.		
		number must be provided and be verified as a Medicare-approved study on the CMS website for IDEs.)
0806T	Transcatheter superior and inferior vena cava prosthetic valve implantation (ie, caval valve implantation [CAVI]); open femoral vein approach	(See 0805T above)
0860T	Noncontact near-infrared spectroscopy (eg, for measurement of deoxyhemoglobin, oxyhemoglobin, and ratio of tissue oxygenation), for screening for peripheral arterial disease, including provocative maneuvers, image acquisition, interpretation, and report, one or both lower extremities	
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 KidneyIntelX™ 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.
0114U	Gastroenterology (Barrett's esophagus), VIM and CCNA1 methylation analysis, esophageal cells, algorithm reported as likelihood for Barrett's esophagus	EsoGuard™ (Lucid Diagnostics) Lucid Diagnostics has locations in NY, CA, and MA. The Noridian J-E LCD L39262 and LCA A59032 is applied for testing performed in any of these locations.
0117U	Pain management, analysis of 11 endogenous analytes (methylmalonic acid,	Foundation PISM, Ethos Laboratories

Table 1: CPT/HCPCS codes that are not medically necessary based on *Medicare policy, guideline, or regulation*.		
	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).
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 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	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

Table 1: CPT/HCPCS codes that are not medically necessary based on *Medicare policy, guideline, or regulation*.		
	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	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.
0369U	Infectious agent detection by nucleic acid (DNA and RNA), gastrointestinal pathogens, 31 bacterial, viral, and parasitic organisms and identification of 21 associated antibiotic-resistance genes, multiplex amplified probe technique	GI assay (Gastrointestinal Pathogen with ABR) (Lab Genomics LLC, Thermo Fisher Scientific; California) LCD L39001 requires TA review in the absence of FDA approval. This test does not have the required TA review nor is it included as a covered test in the companion LCA (A58720).
0370U	Infectious agent detection by nucleic acid (DNA and RNA), surgical wound pathogens, 34 microorganisms and identification of 21 associated antibiotic-resistance genes, multiplex amplified probe technique, wound swab	Lesion Infection (Wound) (Lab Genomics LLC, Thermo Fisher Scientific; California) LCD L39001 requires TA review in the absence of FDA approval. This test does not have the required TA review nor is it included as a covered test in the companion LCA (A58720).
0371U	Infectious agent detection by nucleic acid (DNA or RNA), genitourinary pathogen, semiquantitative identification, DNA from 16 bacterial organisms and 1 fungal organism, multiplex amplified probe technique via quantitative polymerase chain reaction (qPCR), urine	Qlear UTI (Lifescan Labs of Illinois and Thermo Fisher Scientific, California) LCD L39001 requires TA review in the absence of FDA approval. This test does not have the required TA review nor is it included as a covered test in the companion LCA (A58720).
0372U	Infectious disease (genitourinary pathogens), antibiotic-resistance gene detection, multiplex amplified probe technique, urine, reported as an antimicrobial stewardship risk score	Qlear UTI – Reflex ABR (Lifescan Labs of Illinois and Thermo Fisher Scientific, California) LCD L39001 requires TA review in the absence of FDA approval. This test does not have the required TA review nor is it included as a covered test in the companion LCA (A58720).

Table 1: CPT/HCPCS codes that are not medically necessary based on *Medicare policy, guideline, or regulation*.		
0373U	Infectious agent detection by nucleic acid (DNA and RNA), respiratory tract infection, 17 bacteria, 8 fungus, 13 virus, and 16 antibiotic-resistance genes, multiplex amplified probe technique, upper or lower respiratory specimen	Respiratory Pathogen with ABR (RPX) (Lab Genomics LLC and Thermo Fisher Scientific, California) LCD L39001 requires TA review in the absence of FDA approval. This test does not have the required TA review nor is it included as a covered test in the companion LCA (A58720).
0374U	Infectious agent detection by nucleic acid (DNA or RNA), genitourinary pathogens, identification of 21 bacterial and fungal organisms and identification of 21 associated antibiotic-resistance genes, multiplex amplified probe technique, urine	Urogenital Pathogen with Rx Panel (UPX) (Lab Genomics LLC and Thermo Fisher Scientific, California) LCD L39001 requires TA review in the absence of FDA approval. This test does not have the required TA review nor is it included as a covered test in the companion LCA (A58720).
0387U	Oncology (melanoma), autophagy and beclin 1 regulator 1 (AMBRA1) and loricrin (AMLo) by immunohistochemistry, formalinfixed paraffin-embedded (FFPE) tissue, report for risk of progression	AMBLor® Melanoma Prognostic test, Avero® Diagnostics (UK based company, with locations in Washington and Texas) LCD L37748 requires TA review. This test does not have the required TA review.
0394U	Perfluoroalkyl substances (PFAS) (eg, perfluorooctanoic acid, perfluorooctane sulfonic acid), 16 PFAS compounds by liquid chromatography with tandem mass spectrometry (LC-MS/MS), plasma or serum, quantitative	PFAS Testing & PFASure™, National Medical Services, NMS Labs, Inc. (Pennsylvania) This test looks for exposure-based substances in the workplace. This would not be medically reasonable or necessary, but rather, would be the responsibility of an employer.
0399U	Neurology (cerebral folate deficiency), serum, detection of anti-human folate receptor IgGbinding antibody and blocking autoantibodies by enzyme-linked immunoassay (ELISA), qualitative, and blocking autoantibodies, using a functional blocking assay for IgG or IgM, quantitative, reported as positive or not detected	FRAT® (Folate Receptor Antibody Test), Religen Inc. (Pennsylvania) This test is only likely to be used for conditions generally associated with pediatrics (children). It is not expected it will have clinical utility for a Medicare Advantage plan member.
0429U	Human papillomavirus (HPV), oropharyngeal swab, 14 high-risk types (ie, 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and 68)	Omnipathology Oropharyngeal HPV PCR Test, OmniPathology Solutions, Medical Corporation This test is used as a screening test. HPV screening used outside of NCD 210.2.1 is not covered under Medicare.

Table 1: CPT/HCPCS codes that are not medically necessary based on *Medicare policy, guideline, or regulation*.		
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)
A9268	Programmer for transient, orally ingested capsule	VIBRANT® System (Vibrant Gastro System) While CMS developed a HCPCS code for this product, CMS also stated this product has no Benefit Category under Medicare.
A9269	Programable, transient, orally ingested capsule, for use with external programmer, per month	See A9268 above
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.
C9790	Histotripsy (ie, non-thermal ablation via acoustic energy delivery) of malignant renal tissue, including image guidance	As of the date of this policy update, there are no FDA-approved devices to deliver histotripsy.
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] • 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	• Noridian "Noncovered Items" list[3] • NCD for Noncontact Normothermic Wound Therapy (270.2)

Table 1: CPT/HCPCS codes that are not medically necessary based on *Medicare policy, guideline, or regulation*.		
E0711	Upper extremity medical tubing/lines enclosure or covering device, restricts elbow range of motion	Exersides™ Refraint™ System While CMS developed a HCPCS code for this product, CMS also stated this product has no Benefit Category under Medicare.
K1004	Low frequency ultrasonic diathermy treatment device for home use	The PainShield MD NCD 280.1 indicates diathermy machines are not appropriate for home use. In addition, while CMS developed a HCPCS code for this product, CMS also stated this product has no Benefit Category under Medicare.
K1035	Molecular diagnostic test reader, nonprescription self-administered and self-collected use, FDA approved, authorized or cleared	Cue Reader While CMS developed a HCPCS code for this product, CMS also stated this product has no Benefit Category under Medicare.
K1036	Supplies and accessories (e.g., transducer) for low frequency ultrasonic diathermy treatment device, per month	(See K1004 above for the PainShield MD)
M0300	IV chelation therapy (chemical endarterectomy)	• NCD: Chelation Therapy for Treatment of Atherosclerosis (20.21) • NCD: Ethylenediamine-Tera-acetic (EDTA) Chelation Therapy for Treatment of Atherosclerosis (20.22)

Table 2: CPT/HCPCS codes which are considered not medically necessary based on *Criterion II in the "Medicare Coverage Criteria" table above*.

Table 2: CPT/HCPCS codes which are considered not medically necessary based on *Criterion II in the "Medicare Coverage Criteria" table above*.		
Code	Description	Medicare Rationale, Product, and Manufacturer (when available or applicable; may not be an all-inclusive list or may be examples only)
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)	
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	SENSIMED Triggerfish® by Sensimed AG

Table 2: CPT/HCPCS codes which are considered not medically necessary based on *Criterion II in the "Medicare Coverage Criteria" table above*.		
	blocking and/or wedge, and/or compensator(s)	
92972	Percutaneous transluminal coronary lithotripsy (List separately in addition to code for primary procedure)	
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 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*.)*
93591	Percutaneous transcatheter closure of paravalvular leak; initial occlusion device, aortic valve	(See 93590 above)
93592	Percutaneous transcatheter closure of paravalvular leak; each additional occlusion device (List separately in addition to code for primary procedure)	(See 93590 above)
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	
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 storage with patient initiated data transmitted to a remote surveillance center for up to 30 days; technical support and	

Table 2: CPT/HCPCS codes which are considered not medically necessary based on *Criterion II in the "Medicare Coverage Criteria" table above*.		
	patient instructions, surveillance, analysis, and transmission of daily and emergent data reports as prescribed by a physician or other qualified health care professional	
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 The Assessment of Implantable CCM in the Heart Failure Group With Higher Ejection Fraction, or AIM HIGHer study (NCT05064709; G200042), which is evaluating the use of Cardiac Contractility Modulation Therapy via OPTIMIZER™ Smart Mini System, is a Medicare-approved Category B IDE study as of 1/2022. 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*.)* 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, §180 - Services Related to and Required as a Result of Services Which Are Not Covered Under Medicare* for more information.
0409T	; pulse generator only	(See 0408T above)
0410T	; atrial electrode only	(See 0408T above)
0411T	; ventricular electrode only	(See 0408T above)
0414T	Removal and replacement of permanent cardiac contractility modulation system pulse generator only	(See 0408T above)
0415T	Repositioning of previously implanted cardiac contractility modulation transvenous electrode (atrial or ventricular lead)	(See 0408T above)
0416T	Relocation of skin pocket for implanted cardiac contractility modulation pulse generator	(See 0408T above)

Table 2: CPT/HCPCS codes which are considered not medically necessary based on *Criterion II in the "Medicare Coverage Criteria" table above*.		
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	(See 0408T above)
0418T	Interrogation device evaluation (in person) with analysis, review and report, includes connection, recording and disconnection per patient encounter, implantable cardiac contractility modulation system	(See 0408T above)
C1824	Generator, cardiac contractility modulation (implantable)	(See 0408T above)
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.
~~**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)~~	
~~**0487T**~~	**TERMED 12/31/2022** ~~Biomechanical mapping, transvaginal, with report~~	
~~**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~~	
~~**0492T**~~	**TERMED 12/31/2022** ~~; each additional 20 sq cm, or part thereof (List separately in addition to code for primary procedure)~~	
0507T	Near-infrared dual imaging (ie, simultaneous reflective and trans- illuminated light) of	

Table 2: CPT/HCPCS codes which are considered <u>not medically necessary</u> based on *Criterion II in the "Medicare Coverage Criteria" table above*.		
	meibomian glands, unilateral or bilateral, with interpretation and report	
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	(See 0525T above)
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	(See 0525T above)
0528T	Programming device evaluation (in person) of intracardiac ischemia monitoring system with iterative adjustment of programmed values, with analysis, review, and report	(See 0525T above)
0529T	Interrogation device evaluation (in person) of intracardiac ischemia monitoring system with analysis, review, and report	(See 0525T above)
0530T	Removal of intracardiac ischemia monitoring system, including all imaging supervision and interpretation; complete system (electrode and implantable monitor)	(See 0525T above)
0531T	; electrode only	(See 0525T above)
0532T	; implantable monitor only	(See 0525T above)
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	

Table 2: CPT/HCPCS codes which are considered not medically necessary based on *Criterion II in the "Medicare Coverage Criteria" table above*.		
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	
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.

Table 2: CPT/HCPCS codes which are considered not medically necessary based on *Criterion II in the "Medicare Coverage Criteria" table above*.		
0610T	Magnetic resonance spectroscopy, determination and localization of discogenic pain (cervical, thoracic, or lumbar); transmission of biomarker data for software analysis	Previously used NCD 220.2.1; however, with the retirement of the NCD, the Company policy now applies.
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	Previously used NCD 220.2.1; however, with the retirement of the NCD, the Company policy now applies.
0612T	Magnetic resonance spectroscopy, determination and localization of discogenic pain (cervical, thoracic, or lumbar); interpretation and report	Previously used NCD 220.2.1; however, with the retirement of the NCD, the Company policy now applies.
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
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	CustomFlex Artificial Iris, Human Optics
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	CustomFlex Artificial Iris, Human Optics
0643T	Transcatheter left ventricular restoration device implantation including right and left heart catheterization and left ventriculography when performed, arterial approach	Revivent TC System – BioVentrix The Clinical Study of the BioVentrix Revivent TC™ System for Treatment of Left Ventricular Aneurysms ALIVE-EA (American Less Invasive Ventricular Enhancement-Expanded Access study (NCT05710042; G160013), which is evaluating the use of the ReviventTC™ system, is a Medicare-approved Category B IDE study as of 5/2023. In addition, the Clinical Study of the BioVentrix Revivent TC™ System for Treatment of Left Ventricular Aneurysms study (NCT02931240; G160013), also evaluating this system, is a Medicare-approved Category B IDE study as of 3/2017.

Table 2: CPT/HCPCS codes which are considered not medically necessary based on *Criterion II in the "Medicare Coverage Criteria" table above*.		
		Coverage may be approved for members enrolled in one of these Medicare-approved studies. 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.)*
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 The Efficacy of the COronary SInus Reducer in Patients With Refractory Angina II, or COSIRA-II study (NCT05102019; G160196), which is evaluating the use of the Neovasc Reducer system, is a Medicare-approved Category B IDE study as of 11/2021. 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.)*
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 during acute myocardial infarction, including	TherOx Downstream® System, TherOx Inc. The Incorporating Supersaturated Oxygen in Shock or ISO-SHOCK study (NCT04876040;

Table 2: CPT/HCPCS codes which are considered not medically necessary based on *Criterion II in the "Medicare Coverage Criteria" table above*.		
	catheter placement, imaging guidance (eg, fluoroscopy), angiography, and radiologic supervision and interpretation	G210023), which is evaluating the use of the SSO2 Downstream System, is a Medicare-approved Category B IDE study as of 10/2021. In addition, the Evaluation of Intracoronary Hyperoxemic Oxygen Therapy in Anterior Acute Myocardial Infarction Patients, or IC-HOT study (NCT02603835; G120029), also evaluating this system, is a Medicare-approved Category B IDE study as of 2/2016. Coverage may be approved for members enrolled in one of these Medicare-approved studies. 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*.)*
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 Stimulation™ 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	(See 0674T above)
0676T	; each additional lead (List separately in addition to code for primary procedure)	(See 0674T above)
0677T	Laparoscopic repositioning of diaphragmatic lead(s), permanent implantable	(See 0674T above)

Table 2: CPT/HCPCS codes which are considered <u>not medically necessary</u> based on *Criterion II in the "Medicare Coverage Criteria" table above*.		
	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)	(See 0674T above)
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)	(See 0674T above)
0681T	Relocation of pulse generator only, permanent implantable synchronized diaphragmatic stimulation system for augmentation of cardiac function, with connection to existing dual leads	(See 0674T 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	(See 0674T above)
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	(See 0674T above)
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	(See 0674T above)
0695T	Body surface-activation mapping of pacemaker or pacing cardioverter-defibrillator lead(s) to optimize electrical synchrony, cardiac resynchronization therapy device, including connection,	

Table 2: CPT/HCPCS codes which are considered not medically necessary based on *Criterion II in the "Medicare Coverage Criteria" table above*.		
	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	
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**~~	**TERMED 12/31/2023** ~~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	Examples may include, but are not limited to, the following therapies offered by Hinge and SWORD Health
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	

Table 2: CPT/HCPCS codes which are considered not medically necessary based on *Criterion II in the "Medicare Coverage Criteria" table above*.		
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)
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	Visualase Laser Ablation, Medtronic (see also code 0655T)
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); related to previously performed electrocardiogram	

Table 2: CPT/HCPCS codes which are considered <u>not medically necessary</u> based on *Criterion II in the "Medicare Coverage Criteria" table above*.		
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 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	

Table 2: CPT/HCPCS codes which are considered not medically necessary based on *Criterion II in the "Medicare Coverage Criteria" table above*.		
	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	(See 0781T above)
0791T	Motor-cognitive, semi-immersive virtual reality–facilitated gait training, each 15 minutes (List separately in addition to code for primary procedure)	
0793T	Percutaneous transcatheter thermal ablation of nerves innervating the pulmonary arteries, including right heart catheterization, pulmonary artery angiography, and all imaging guidance	
0794T	Patient-specific, assistive, rules-based algorithm for ranking pharmaco-oncologic treatment options based on the patient's	CureMatch, Inc. (California)

Table 2: CPT/HCPCS codes which are considered not medically necessary based on *Criterion II in the "Medicare Coverage Criteria" table above*.		
	tumor-specific cancer marker information obtained from prior molecular pathology, immunohistochemical, or other pathology results which have been previously interpreted and reported separately	
0807T	Pulmonary tissue ventilation analysis using software-based processing of data from separately captured cinefluorograph images; in combination with previously acquired computed tomography (CT) images, including data preparation and transmission, quantification of pulmonary tissue ventilation, data review, interpretation and report	XV Lung Ventilation Analysis Software (XV LVAS)
0808T	Pulmonary tissue ventilation analysis using software-based processing of data from separately captured cinefluorograph images; in combination with computed tomography (CT) images taken for the purpose of pulmonary tissue ventilation analysis, including data preparation and transmission, quantification of pulmonary tissue ventilation, data review, interpretation and report	(See 0807T above)
0820T	Continuous in-person monitoring and intervention (eg, psychotherapy, crisis intervention), as needed, during psychedelic medication therapy; first physician or other qualified health care professional, each hour	
0821T	Continuous in-person monitoring and intervention (eg, psychotherapy, crisis intervention), as needed, during psychedelic medication therapy; second physician or other qualified health care professional, concurrent with first physician or other qualified health care professional, each hour (List separately in addition to code for primary procedure)	
0822T	Continuous in-person monitoring and intervention (eg, psychotherapy, crisis intervention), as needed, during psychedelic medication therapy; clinical staff under the direction of a physician or other qualified health care professional, concurrent with first physician or other qualified health care professional, each hour (List separately in addition to code for primary procedure)	

Table 2: CPT/HCPCS codes which are considered not medically necessary based on *Criterion II in the "Medicare Coverage Criteria" table above*.		
0857T	Opto-acoustic imaging, breast, unilateral, including axilla when performed, real-time with image documentation, augmentative analysis and report (List separately in addition to code for primary procedure)	
0859T	Noncontact near-infrared spectroscopy (eg, for measurement of deoxyhemoglobin, oxyhemoglobin, and ratio of tissue oxygenation), other than for screening for peripheral arterial disease, image acquisition, interpretation, and report; each additional anatomic site (List separately in addition to code for primary procedure)	
0864T	Low-intensity extracorporeal shock wave therapy involving corpus cavernosum, low energy	This code is used when the service is performed as a screening service. This would be non-covered under Medicare statute.[2]
C1761	Catheter, transluminal intravascular lithotripsy, coronary	Shockwave Coronary Rx Lithoplasty System The Disrupt CAD III With the Shockwave Coronary IVL System study (NCT03595176; G180146), which is evaluating the use of the Shockwave Coronary Rx Lithoplasty System, is a Medicare-approved Category B IDE study as of 12/2018. 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*.)*
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	Bullfrog Microinfusion device by Mercator Medsystems

Table 2: CPT/HCPCS codes which are considered not medically necessary based on *Criterion II in the "Medicare Coverage Criteria" table above*.		
	vessel, including radiological supervision and interpretation, when performed	
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. The Shockwave Intravascular Lithotripsy System with the Shockwave Mini S Peripheral IVL Catheter study (NCT05858905; G220300), which is evaluating the use of the Shockwave Medical Peripheral IVL System, is a Medicare-approved Category B IDE study as of 6/2023. 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*.)*
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	(See C9764 above)
C9766	Revascularization, endovascular, open or percutaneous, any vessel(s); with intravascular lithotripsy and atherectomy, includes angioplasty within the same vessel(s), when performed	(See C9764 above)
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	(See C9764 above)
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
31242	Nasal/sinus endoscopy, surgical; with destruction by radiofrequency ablation, posterior nasal nerve	RhinAer™ Stylus (Aerin Medical, Austin, TX)

Table 2: CPT/HCPCS codes which are considered not medically necessary based on *Criterion II in the "Medicare Coverage Criteria" table above*.		
31243	Nasal/sinus endoscopy, surgical; with destruction by cryoablation, posterior nasal nerve	Clarifix by Styker Inc. (previously Arrinex Inc.)
C9771	Nasal/sinus endoscopy, cryoablation nasal tissue(s) and/or nerve(s), unilateral or bilateral	Clarifix by Styker Inc. (previously Arrinex Inc.)
C9772	Revascularization, endovascular, open or percutaneous, tibial/peroneal artery(ies), with intravascular lithotripsy, includes angioplasty within the same vessel (s), when performed	(See C9764 above)
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)
C9787	Gastric electrophysiology mapping with simultaneous patient symptom profiling	Gastric Electrophysiology Mapping with Simultaneous (GEMS) patient symptom profiling
E0677	Non-pneumatic sequential compression garment, trunk	Koya Dayspring® trunk garment (Koya Medical, Inc.) Medicare has coverage guidance for pneumatic compression devices, but there is no Medicare guidance for non-pneumatic compression devices as of the date of this policy update. Therefore, Company policy coverage guidance for medical necessity will be applied.

Table 2: CPT/HCPCS codes which are considered <u>not medically necessary</u> based on *Criterion II in the "Medicare Coverage Criteria" table above*.		
E1905	Virtual reality cognitive behavioral therapy device (CBT), including pre-programmed therapy software	RelieVRx **NOTE:** CMS classification of this device as DME and provision of a fee amounts does not establish medical necessity.
K1007	Bilateral hip, knee, ankle, foot device, powered, includes pelvic component, single or double upright(s), knee joints any type, with or without ankle joints any type, includes all components and accessories, motors, microprocessors, sensors	Rewalk™ by ReWalk Robotics, previously Argo Medical Technologies
E3000	Speech volume modulation system, any type, including all components and accessories	SpeechVive device
~~**K1009**~~	**TERMED 12/31/2023** ~~Speech volume modulation system, any type, including all components and accessories~~	SpeechVive device
E0678	Non-pneumatic sequential compression garment, full leg	Koya Dayspring® and Koya Dayspring® Lite Systems (Koya Medical, Inc.) Medicare has coverage guidance for pneumatic compression devices, but there is no Medicare guidance for non-pneumatic compression devices as of the date of this policy update. Therefore, Company policy coverage guidance for medical necessity will be applied.
E0679	Non-pneumatic sequential compression garment, half leg	See E0678 above
E0680	Non-pneumatic compression controller with sequential calibrated gradient pressure	See E0678 above
E0681	Non-pneumatic compression controller without calibrated gradient pressure	See E0678 above
E0682	Non-pneumatic sequential compression garment, full arm	See E0678 above
	TERMED 12/31/2023 ~~Non-pneumatic compression controller with sequential calibrated gradient pressure~~	Koya Dayspring® System (Koya Medical, Inc.) Medicare has coverage guidance for pneumatic compression devices, but there is no Medicare guidance for non-pneumatic compression devices as of the date of this policy update. Therefore, Company policy coverage guidance for medical necessity will be applied.
~~**K1025**~~	**TERMED 12/31/2023** ~~Non-pneumatic sequential compression garment, full arm~~	(See K1024 above)

Table 2: CPT/HCPCS codes which are considered <u>not medically necessary</u> based on *Criterion II in the "Medicare Coverage Criteria" table above*.		
~~**K1031**~~	**TERMED 12/31/2023** ~~Non-pneumatic compression controller without calibrated gradient pressure~~	Koya Dayspring® Lite (Koya Medical, Inc.) Medicare has coverage guidance for pneumatic compression devices, but there is no Medicare guidance for non-pneumatic compression devices as of the date of this policy update. Therefore, Company policy coverage guidance for medical necessity will be applied.
~~**K1032**~~	**TERMED 12/31/2023** ~~Non-pneumatic sequential compression garment, full leg~~	(See K1031 above)
~~**K1033**~~	**TERMED 12/31/2023** ~~Non-pneumatic sequential compression garment, half leg~~	(See K1031 above)
L8701	Powered upper extremity range of motion assist device, elbow, wrist, hand with single or double upright(s), includes microprocessor, sensors, all components and accessories, custom fabricated	MyoPro™ myoelectric upper limb orthotics
L8702	Powered upper extremity range of motion assist device, elbow, wrist, hand, finger, single or double upright(s), includes microprocessor, sensors, all components and accessories, custom fabricated	MyoPro™ myoelectric upper limb orthotics
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,	MYCODART Dual Amplification Real Time PCR Panel for 4 Aspergillus species, RealTime Laboratories

Table 2: CPT/HCPCS codes which are considered <u>not medically necessary</u> based on *Criterion II in the "Medicare Coverage Criteria" table above*.		
	qualitative reporting of presence or absence of each species	
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
~~**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)	DISCERN™
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	Avise® Lupus, Exagen Inc. (Vista, California)

Table 2: CPT/HCPCS codes which are considered <u>not medically necessary</u> based on *Criterion II in the "Medicare Coverage Criteria" table above*.		
	autoantibodies and 2 cell-bound complement 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, or venous whole blood, algorithm reported as likelihood of bacterial infection	MeMed BV® (MeMed Diagnostics, Ltd.)
~~**0357U**~~	**TERMED 9/30/2023** ~~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)
0376U	Oncology (prostate cancer), image analysis of at least 128 histologic features and clinical factors, prognostic algorithm determining the risk of distant metastases, and prostate cancer-specific mortality,	ArteraAI Prostate Test (Artera Inc.; Florida)

Table 2: CPT/HCPCS codes which are considered <u>not medically necessary</u> based on *Criterion II in the "Medicare Coverage Criteria" table above*.		
	includes predictive algorithm to androgen deprivation therapy response, if appropriate	
0384U	Nephrology (chronic kidney disease), carboxymethyllysine, methylglyoxal hydroimidazolone, and carboxyethyl lysine by liquid chromatography with tandem mass spectrometry (LCMS/MS) and HbA1c and estimated glomerular filtration rate (GFR), with risk score reported for predictive progression to high-stage kidney disease	NaviDKD™ Predictive Diagnostic Screening for Kidney Health test kits (Journey Biosciences, Inc.)
0385U	Nephrology (chronic kidney disease), apolipoprotein A4 (ApoA4), CD5 antigen-like (CD5L), and insulin-like growth factor binding protein 3 (IGFBP3) by enzyme-linked immunoassay (ELISA), plasma, algorithm combining results with HDL, estimated glomerular filtration rate (GFR) and clinical data reported as a risk score for developing diabetic kidney disease	PromarkerD (Sonic Reference Laboratory; Texas)
~~**0386U**~~	**TERMED 9/30/2023** ~~Gastroenterology (Barrett's esophagus), P16, RUNX3, HPP1, and FBN1 methylation analysis, prognostic and predictive algorithm reported as a risk score for progression to high-grade dysplasia or esophageal cancer~~	~~Envisage (Capsulomics, Inc.; Maryland)~~
0393U	Neurology (eg, Parkinson disease, dementia with Lewy bodies), cerebrospinal fluid (CSF), detection of misfolded α-synuclein protein by seed amplification assay, qualitative	SYNTap® Biomarker Test, Amprion Clinical Laboratory, Amprion Clinical Laboratory San Diego, CA
0412U	Beta amyloid, Aβ42/40 ratio, immunoprecipitation with quantitation by liquid chromatography with tandem mass spectrometry (LC-MS/MS) and qualitative ApoE isoform-specific proteotyping, plasma combined with age, algorithm reported as presence or absence of brain amyloid pathology	PrecivityAD® blood test (C2N Diagnostics LLC; Missouri)
0414U	Oncology (lung), augmentative algorithmic analysis of digitized whole slide imaging for 8 genes (ALK, BRAF, EGFR, ERBB2, MET, NTRK1-3, RET, ROS1), and KRAS G12C and PD-L1, if performed, formalin-fixed paraffin-embedded (FFPE) tissue, reported as positive or negative for each biomarker	LungOI (Imagene; Pennsylvania)
0418U	Oncology (breast), augmentative algorithmic analysis of digitized whole slide imaging of 8 histologic and immunohistochemical features, reported as a recurrence score	PreciseDx Breast Biopsy Test (PreciseDx, Inc.; New York)

***Coding Notes:**

- The code list above is provided as a courtesy and may not be all-inclusive. Inclusion or omission of a code from this policy neither implies nor guarantees reimbursement or coverage. Some codes may not require routine review for medical necessity, but they are subject to provider contracts, as well as member benefits, eligibility and potential utilization audit. According to Medicare, "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 issuance of a CPT or HCPCS code or the provision of a payment or fee amount by Medicare does **not** make a procedure medically reasonable or necessary or a covered benefit by Medicare. *(Medicare Claims Processing Manual, Chapter 23 - Fee Schedule Administration and Coding Requirements, §30 - Services Paid Under the Medicare Physician's Fee Schedule, A. Physician's Services)*
- All unlisted codes are reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is submitted for non-covered services addressed in this policy then it will be **denied as not covered**. If an unlisted code is submitted for potentially covered services addressed in this policy, to avoid post-service denial, **prior authorization is recommended**.
- **See the non-covered and prior authorization lists on the Company Medical Policy, Reimbursement Policy, Pharmacy Policy and Provider Information website for additional information.**
- HCPCS/CPT code(s) may be subject to National Correct Coding Initiative (NCCI) procedure-to-procedure (PTP) bundling edits and daily maximum edits known as "medically unlikely edits" (MUEs) published by the Centers for Medicare and Medicaid Services (CMS). This policy does not take precedence over NCCI edits or MUEs. Please refer to the CMS website for coding guidelines and applicable code combinations.

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]

POLICY REVISION HISTORY

DATE	REVISION SUMMARY
2/2023	Interim update (moved codes for Intracept to another policy)
3/2023	Interim update (added M0300 to policy)
4/2023	Interim update (added L8701, L8702, K1024, K1025, K1031, K1032, K1033 to policy). Removed select codes from policy (note that removal from this policy does not automatically warrant or guarantee coverage). Q2 2023 code updates.
6/2023	Interim update (moved 0228U from this policy to a different policy and moved 0114U from Table 1 to Table 2)
7/2023	Q3 2023 code updates
10/2023	Annual review and Q4 2023 code updates; reformatted tables and updated devices/systems which may be considered medically necessary only if performed in the context of a Medicare-approved study
1/2024	Interim update (moved code for colonic lavage to another policy) and Q1 2024 code updates