Medicare Medical Policy

New and Emerging Technologies and Other Non-Covered Services

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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”).

PRODUCT AND BENEFIT APPLICATION

☒ 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 **subject to** an available Medicare coverage policy, 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** a Medicare coverage policy	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

"MA organizations may create publicly accessible internal coverage criteria that are based on current evidence in widely used treatment guidelines or clinical literature when coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs. Current, widely-used treatment guidelines are those developed by organizations representing clinical medical specialties, and refers to guidelines for the treatment of specific diseases or conditions. Acceptable clinical literature includes large, randomized controlled trials or prospective cohort studies with clear results, published in a peer-reviewed journal, and specifically designed to answer the relevant clinical question, or large systematic reviews or meta-analyses summarizing the literature of the specific clinical question."[2] *(CFR § 422.101(b)(6))*

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 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, removal, or omission from this list does **not** necessarily imply a service or technology is covered.

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

NOTES: *Specific devices and products listed in the following tables may not be an all-inclusive list, but rather may only represent examples of the relevant technology. The "Effective Date" listed is the date the code was effective, which may or may not be the same date Medicare or the Medicare contractor (MAC) non-coverage position was effective.*

Table 1.1

Table 1: CPT/HCPCS codes that are not medically necessary based on a specific *Medicare policy or article*.		
Code	Description	Medicare Rationale, Product, and Manufacturer (when available or applicable, may not be an all-inclusive list or may be examples only)
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)
0219T **0220T** **0221T** **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; cervical 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 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 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	LCA: Billing and Coding: Facet Joint Interventions for Pain Management (A58405)

Table 1: CPT/HCPCS codes that are not medically necessary based on a specific *Medicare policy or article*.		
	additional vertebral segment (List separately in addition to code for primary procedure)	
0469T	Retinal polarization scan, ocular screening with on-site automated results, bilateral	Medicare Status "N" code. As a non-covered Traditional Medicare service, this would be covered for Medicare Advantage plans only if there is a Supplemental Benefit available that calls this service out directly.
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 is headquartered in NY, but laboratory testing services are performed in Lake Forest, CA. Therefore, the Noridian J-E LCD L39262 and LCA A59032 is applied.
0312U	Autoimmune diseases (eg, systemic lupus erythematosus [SLE]), analysis of 8 IgG 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 *(Effective 4/1/2022)*	Avise® Lupus, Exagen Inc. (Vista, California) This test is considered not medically reasonable or necessary. The LCA A59641 requires proteomic testing to undergo a technical assessment (TA) to determine Medicare coverage. This test has **not** yet undergone the required TA review by the MolDX Contractor and therefore does **not** meet the LCA requirements for coverage.
~~**0369U**~~	**TERMED 6/30/2025** ~~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**~~	**TERMED 6/30/2025** ~~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	Qlear UTI (Lifescan Labs of Illinois and Thermo Fisher Scientific, California)

Table 1: CPT/HCPCS codes that are not medically necessary based on a specific *Medicare policy or article*.		
	16 bacterial organisms and 1 fungal organism, multiplex amplified probe technique via quantitative polymerase chain reaction (qPCR), urine	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).
~~**0373U**~~	**TERMED 6/30/2025** ~~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**~~	**TERMED 6/30/2025** ~~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 L37750 requires TA review. This test does not have the required TA review.
0452U	Oncology (bladder), methylated PENK DNA detection by linear target enrichment-quantitative methylation-specific real-time PCR (LTE-qMSP), urine, reported as likelihood of bladder cancer	EarlyTect® Bladder Cancer Detection (EarlyTect® BCD) (Promis Diagnostics, Inc.; California) LCD for Lab: Bladder/Urothelial Tumor Markers (L36678)
0506U	Gastroenterology (Barrett's esophagus), esophageal cells, DNA methylation analysis by next-generation sequencing of at least 89	EndoSign® Barrett's Esophagus Test (Cyted Health Inc.)

Table 1: CPT/HCPCS codes that are not medically necessary based on a specific *Medicare policy or article*.		
	differentially methylated genomic regions, algorithm reported as likelihood for Barrett's esophagus	According to this laboratory's website, this test is **not** performed in the U.S. (it is performed in the UK). According to Medicare Benefit Policy Manual, Chapter 16, 10 - General Exclusions from Coverage, services which are "not provided within United States" are general exclusion from Medicare coverage, and therefore, testing services that are not performed in the U.S. would also be ineligible for Medicare coverage. When or if these testing services become available in the U.S., coverage can be reevaluated.
0531U	Infectious disease (acid-fast bacteria and invasive fungi), DNA (673 organisms), next-generation sequencing, plasma	NeXGen™ Fungal/AFB NGS Assay (Eurofins Viracor, LLC & Exagen Inc.; Kansas or Missouri) The states of Kansas and Missouri are served by the Medicare Contractor (MAC) Wisconsin Physician Services. Molecular diagnostic tests in the WPS service area are subject to LCD L36807, which states a technical assessment (TA) is required to determine Medicare coverage. This test has **not** yet undergone the required TA review by the MolDX Contractor and therefore does **not** meet requirements for coverage.
0573U	Oncology (pancreas), 3 biomarkers (glucose, carcinoembryonic antigen, and gastricsin), pancreatic cyst lesion fluid, algorithm reported as categorical mucinous or non-mucinous	Amplified Sciences PanCystPro™ (Amplified Sciences, Inc.; California) The states of California is served by the Medicare Contractor (MAC) Noridian, under Jurisdiction E (J-E). Molecular diagnostic tests in the Noridian service area are subject to LCD L35160, which states a technical assessment (TA) is required to determine Medicare coverage. This test has **not** yet undergone the required TA review by the MolDX Contractor and therefore does **not** meet requirements for coverage.
0599U	Oncology (pancreatic cancer), multiplex immunoassay of ICAM1, TIMP1, CTSD, THBS1, and CA 19-9, serum, diagnostic algorithm reported as positive or negative	PancreaSure is a blood test intended to detect pancreatic cancer at stage 1 and 2. It's intended for individuals at elevated risk for pancreatic cancer due to family

Table 1: CPT/HCPCS codes that are <u>not medically necessary</u> based on a specific *Medicare policy or article*.		
		history or genetic mutations. This test is non-covered as a screening test under Medicare.
0600U	Infectious disease (wound infection), identification of 65 organisms and 30 antibiotic resistance genes, wound swab, real-time PCR, reported as positive or negative for each organism	FidaLab Molecular Wound Infection Test (FidaLab LLC; Washington) The State of Washington is served by the Medicare Contractor (MAC) Noridian, Jurisdiction F (JF). Molecular diagnostic tests in the JF service area are subject to LCD L39001, which states a technical assessment (TA) is required to determine Medicare coverage. This test has **not** yet undergone the required TA review by the MolDX Contractor and therefore does **not** meet requirements for coverage. This test is also listed as **not** covered in the DEX Registry. Molecular/genetic testing is not standard of care (SOC). SOC is a culture-based gram stain.
0601U	Infectious disease (periprosthetic joint infection), analysis of 11 biomarkers (alpha defensins 1–3, C-reactive protein, microbial antigens for Staphylococcus [SPA, SPB], Enterococcus, Candida, and C. acnes, total nucleated cell count, percent neutrophils, RBC count, and absorbance at 280 nm) using immunoassays, hematology, clinical chemistry, synovial fluid, and diagnostic algorithm reported as a probability score	Synovasure® Comprehensive PJI Test Panel with SynTuition™ (CD Laboratories, Inc.; Indiana) The State of Indiana is served by the Medicare Contractor (MAC) Wisconsin Physician Services, Jurisdiction 8 (J08), and molecular syndromic panel tests for infectious disease in this service area are subject to LCD L39044, which states tests which do not have FDA approval or clearance must undergo a technical assessment (TA) review by the MolDX Contractor to assess Medicare coverage. This test has **not** yet undergone this required review and therefore does **not** meet LCD requirements for coverage. Authoritative bodies such as the Musculoskeletal Infection Society (MSIS), International Consensus Meeting (ICM), and European Bone and Joint Infection Society (EBJIS) currently recommend using synovial fluid biomarkers—including white blood cell (WBC) counts, polymorphonuclear neutrophils (PMN) percentage, synovial C-reactive protein

Table 1: CPT/HCPCS codes that are not medically necessary based on a specific *Medicare policy or article*.		
		(CRP), alpha-defensin, and culture—as part of their diagnostic criteria for PJI.
A6000	Non-contact wound warming wound cover for use with the non-contact wound warming device and warming card	• Medicare Status "N" code • NCD for Noncontact Normothermic Wound Therapy (270.2)
E0469 **A7021**	Lung expansion airway clearance, continuous high frequency oscillation, and nebulization device Supplies and accessories for lung expansion airway clearance, continuous high frequency oscillation, and nebulization device (e.g., handset, nebulizer kit, biofilter)	Volara™ System (Baxter) NCD: Intrapulmonary Percussive Ventilator (IPV) (240.5) **Note:** This non-coverage position is specific to the use of oscillation and lung expansion (OLE) therapy in a **home** setting. It would not apply to OLE therapy rendered in a facility setting. OLE therapy in a facility should not be reported with this code.
E0231	Non-contact wound warming device (temperature control unit, ac adapter and power cord) for use with warming card and wound cover.	• NCD: 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	
G0255	Current perception threshold/sensory nerve conduction test, (sNCT) per limb, any nerve *(CMS-assigned Status "N" code)*	NCD for Sensory Nerve Conduction Threshold Tests (sNCTs) (160.23)
M0076	Prolotherapy	All of the following Medicare references apply to Prolotherapy (note that some may only be relevant to specific indications). • NCD: Prolotherapy, Joint Sclerotherapy, and Ligamentous Injections with Sclerosing Agents (150.7) • Local Coverage Determination (LCD): Facet Joint Interventions for Pain Management (~~L38803~~) ***(As of 4/16/2026, see LCD L38801)*** • LCD: Trigger Point Injections (L36859) • Local Coverage Article (LCA): Billing and Coding: Platelet Rich Plasma Injections for Non-Wound Injections (A58790)
M0300	IV chelation therapy (chemical endarterectomy)	• NCD: Chelation Therapy for Treatment of Atherosclerosis (20.21)

Table 1: CPT/HCPCS codes that are not medically necessary based on a specific *Medicare policy or article*.		
		• NCD: Ethylenediamine-Tera-acetic (EDTA) Chelation Therapy for Treatment of Atherosclerosis (20.22)
A4575	Topical hyperbaric oxygen chamber, disposable	LCD: Oxygen and Oxygen Equipment (L33797)
E0446	Topical oxygen delivery system, not otherwise specified, includes all supplies and accessories	

Table 1.2

Bone Strength and Fracture Risk Assessments, Including Structural Condition of the Bone		
Device/Product, and Manufacturer Information (when applicable)		TBS iNsight™ VirtuOst Fracture Risk Assessment
Code(s)	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
	77090	Trabecular bone score (TBS), structural condition of the bone microarchitecture; technical preparation and transmission of data for analysis to be performed elsewhere
	77091	Trabecular bone score (TBS), structural condition of the bone microarchitecture; technical calculation only
	77092	Trabecular bone score (TBS), structural condition of the bone microarchitecture; interpretation and report on fracture-risk only by other qualified health care professional
	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
	0555T	Bone strength and fracture risk using finite element analysis of functional data, and bone-mineral density, utilizing data from a computed tomography scan; retrieval and transmission of the scan data
	0556T	Bone strength and fracture risk using finite element analysis of functional data, and bone-mineral density, utilizing data from a computed tomography scan; assessment of bone strength and fracture risk and bone mineral density
	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 and Coverage Notes		**Applicable Medicare Coverage Policy, Regulation, or Guideline** • Medicare Program Integrity Manual, Chapter 3 - Verifying Potential Errors and Taking Corrective Actions, §3.6.2.1 - Coverage Determinations

	• Medicare Benefit Policy Manual, Chapter 16 - General Exclusions From Coverage, §10 - General Exclusions from Coverage • Medicare Benefit Policy Manual, Chapter 16 - General Exclusions From Coverage, §90 - Routine Services and Appliances **Medicare-Based Non-Coverage Rationale** The Medicare Program Integrity Manual, Chapter 3, §3.6.2.1 states that an item or service may be denied coverage if the "The item or service is statutorily excluded on grounds other than §1862(a) (1) (A) of the Act." According to Medicare Benefit Policy Manual, Chapter 16 - General Exclusions From Coverage, 10 - General Exclusions from Coverage, **"routine services and appliances" are a general exclusion from Medicare coverage** (with the exception of preventive services noted in section 42 CFR 411.15(a)(1)). The above services are used as routine screening tools. While bone mass measurements (BMM) and bone mineral density screening are covered Medicare preventive benefits, BMM and bone density screenings outside the scope of NCD 150.3 would be considered non-covered under Medicare statute.[3] These services are not included as part of the Medicare Preventive Services chart, found on the CMS website. Therefore, if these services are performed for a Medicare Advantage member, they will be considered **not medically necessary** under Section 1862(a)(1) of the Social Security Act.

Table 1.3

3-D Printed Anatomic Models and Pre-planning of Procedures		
Device/Product, and Manufacturer Information (when applicable)		
Code(s)	0559T	Anatomic model 3D-printed from image data set(s); first individually prepared and processed component of an anatomic structure
	0560T	Anatomic model 3D-printed from image data set(s); each additional individually prepared and processed component of an anatomic structure (List separately in addition to code for primary procedure)
	0561T	Anatomic guide 3D-printed and designed from image data set(s); first anatomic guide
	0562T	Anatomic guide 3D-printed and designed from image data set(s); each additional anatomic guide (List separately in addition to code for primary procedure)
	1030T	Creation of digital 3D model from surface mesh files of patient-specific anatomy (eg, final anatomic representation [FAR]), cumulative time for up to 30 days; initial 30 minutes
	1031T	Creation of digital 3D model from surface mesh files of patient-specific anatomy (eg, final anatomic representation [FAR]), cumulative time for up to

		30 days; each additional 30 minutes (List separately in addition to code for primary procedure)
	1032T	Creation of digital 3D model from surface mesh files of patient-specific anatomy (eg, final anatomic representation [FAR]) and digital simulation, cumulative time for up to 30 days; initial 60 minutes
	1033T	Creation of digital 3D model from surface mesh files of patient-specific anatomy (eg, final anatomic representation [FAR]) and digital simulation, cumulative time for up to 30 days; each additional 30 minutes (List separately in addition to code for primary procedure)
	1034T	Creation of digital 3D model from surface mesh files of patient-specific anatomy (eg, final anatomic representation [FAR]), digital simulation, and computational analyses (eg, computational fluid dynamics, finite element analysis), cumulative time for up to 30 days; initial 90 minutes
	1035T	Creation of digital 3D model from surface mesh files of patient-specific anatomy (eg, final anatomic representation [FAR]), digital simulation, and computational analyses (eg, computational fluid dynamics, finite element analysis), cumulative time for up to 30 days; each additional 30 minutes (List separately in addition to code for primary procedure)
	C8001	3D anatomical segmentation imaging for preoperative planning, data preparation and transmission, obtained from previous diagnostic computed tomographic or magnetic resonance examination of the same anatomy
	C9793	3D predictive model generation for pre-planning of a cardiac procedure, using data from cardiac computed tomographic angiography and/or magnetic resonance imaging with report
Medicare and Coverage Notes		**Applicable Medicare Coverage Policy, Regulation, or Guideline** • Medicare Managed Care Manual, Chapter 4 - Benefits and Beneficiary Protections, §10.2 – Basic Rule • §1862(a)(1)(A) of the Act • Medicare Benefit Policy Manual, Chapter 16 - General Exclusions From Coverage, §10 - General Exclusions from Coverage • CMS National Correct Coding Initiative (NCCI), Chapter 1 – General Correct Coding Policies, B. Coding Based on Standards of Medical/Surgical Practice • CMS NCCI), Chapter 1 – General Correct Coding Policies, C. Medical/Surgical Package **Medicare-Based Non-Coverage Rationale** Medicare Managed Care Manual, Chapter 4 - Benefits and Beneficiary Protections, §10.2 – Basic Rule "The scope of the benefits under Part A and Part B is defined in the Act. Part A and Part B benefits are discussed in sections 1812 and 1832 of the Act, respectively, while section 1861 of the Act lays out the definition of medical and other health services. Specific health care services must fit into one of these benefit categories, and not

	be otherwise excluded from coverage under the Medicare program (see §1862 for exclusions)… "In general, Medicare coverage and payment is contingent upon a determination that: • A service is in a covered benefit category; • A service is not specifically excluded from Medicare coverage by the Act; and • The item or service is "reasonable and necessary" for the diagnosis or treatment of an illness or injury, to improve functioning of a malformed body member, or is a covered preventive service." According to Medicare Benefit Policy Manual, Chapter 16 - General Exclusions From Coverage, 10 - General Exclusions from Coverage, **services which are "not reasonable and necessary" are a general exclusion from Medicare coverage.** The services listed in this table are **not medically reasonable or necessary** under Medicare and *§1862(a)(1)(A)* because the intended purpose of the service or item is **not** to diagnose or treat an illness or injury or improve the function of a malformed body member, nor does it fall under a covered preventive service category. Therefore, the nature of the service represented by the code does not meet Medicare coverage requirements. In addition, pre-procedural services which integral to a surgical procedure are considered a component of the surgical procedure and are **not** eligible for separate payment because "[s]ervices integral to HCPCS/CPT code defined procedures are included in those procedures based upon the standards of medical/surgical practice."

Table 1.4

Vertebral Body Tethering		
Device/Product, and Manufacturer Information (when applicable)		Tether Vertebral Body Tethering System (Zimmer Biomet)
Code(s)	0656T	Anterior lumbar or thoracolumbar vertebral body tethering, anterior; up to 7 vertebral segments
	0657T	Anterior lumbar or thoracolumbar vertebral body tethering, anterior; 8 or more vertebral segments
	0790T	Revision (eg, augmentation, division of tether), replacement, or removal of thoracolumbar or lumbar vertebral body tethering, including thoracoscopy, when performed
	22836	Anterior thoracic vertebral body tethering, including thoracoscopy, when performed; up to 7 vertebral segments
	22837	Anterior thoracic vertebral body tethering, including thoracoscopy, when performed; 8 or more vertebral segments

	22838	Revision (eg, augmentation, division of tether), replacement, or removal of thoracic vertebral body tethering, including thoracoscopy, when performed
Medicare and Coverage Notes		**Applicable Medicare Coverage Policy, Regulation, or Guideline** • CMS Final Rule CMS-3421-FN. Medicare Program; Transitional Coverage for Emerging Technologies • Medicare Managed Care Manual, Chapter 4 - Benefits and Beneficiary Protections, §10.2 – Basic Rule • §1862(a)(1)(A) of the Act • Medicare Benefit Policy Manual, Chapter 16 - General Exclusions From Coverage, §10 - General Exclusions from Coverage **Medicare-Based Non-Coverage Rationale** Medicare Managed Care Manual, Chapter 4 - Benefits and Beneficiary Protections, §10.2 – Basic Rule "The scope of the benefits under Part A and Part B is defined in the Act. Part A and Part B benefits are discussed in sections 1812 and 1832 of the Act, respectively, while section 1861 of the Act lays out the definition of medical and other health services. Specific health care services must fit into one of these benefit categories, and not be otherwise excluded from coverage under the Medicare program (see §1862 for exclusions)… "In general, Medicare coverage and payment is contingent upon a determination that: • A service is in a covered benefit category; • A service is not specifically excluded from Medicare coverage by the Act; and • The item or service is "reasonable and necessary" for the diagnosis or treatment of an illness or injury, to improve functioning of a malformed body member, or is a covered preventive service." According to Medicare Benefit Policy Manual, Chapter 16 - General Exclusions From Coverage, 10 - General Exclusions from Coverage, **services which are "not reasonable and necessary" are a general exclusion from Medicare coverage.** "[I]ndividuals representative of the Medicare population are often excluded from the studies used to generate the evidence reviewed by FDA… Where there is limited evidence on the health outcomes for individuals in the Medicare population, there may be insufficient evidence to support a full coverage national coverage determination under section 1862(a)(1)(A) of the Act…" When studies exclusion criteria results in exclusion of older patients with comorbidities, then "a device's potential benefits and harms for older patients with more comorbidities may not be well understood at the time of FDA market authorization" and "when there is a lack of evidence

	specific to the Medicare population, it makes it difficult for CMS to ensure that devices are not posing additional risks in the Medicare population." The services listed in this table are **not medically reasonable or necessary** under Medicare and *§1862(a)(1)(A)* because this system received FDA humanitarian device exemption (HDE) approval in August, 2019 as a treatment of ***skeletally immature*** patients. Given that the age of Medicare entitlement is 65 years of age (with some exception), the majority of the Medicare population would **not** be considered "skeletally immature," making the use of this system on these individuals outside of the HUD intended use and thus outside the scope of study regarding safety, efficacy, and impact on health outcomes.

Table 1.5

Digital Therapy Treatment of Amblyopia		
Device/Product, and Manufacturer Information (when applicable)		CureSight™ Luminopia (Luminopia Inc.)
Code(s)	0687T	Treatment of amblyopia using an online digital program; device supply, educational set-up, and initial session
	0688T	Treatment of amblyopia using an online digital program; assessment of patient performance and program data by physician or other qualified health care professional, with report, per calendar month
	0704T	Remote treatment of amblyopia using an eye tracking device; device supply with initial set-up and patient education on use of equipment
	0705T	Remote treatment of amblyopia using an eye tracking device; surveillance center technical support including data transmission with analysis, with a minimum of 18 training hours, each 30 days
	0706T	Remote treatment of amblyopia using an eye tracking device; interpretation and report by physician or other qualified health care professional, per calendar month
	A9292	Prescription digital visual therapy, software-only, FDA cleared, per course of treatment
Medicare and Coverage Notes		**Applicable Medicare Coverage Policy, Regulation, or Guideline** • CMS Final Rule CMS-3421-FN. Medicare Program; Transitional Coverage for Emerging Technologies • Medicare Managed Care Manual, Chapter 4 - Benefits and Beneficiary Protections, §10.2 – Basic Rule • §1862(a)(1)(A) of the Act • Medicare Benefit Policy Manual, Chapter 16 - General Exclusions From Coverage, §10 - General Exclusions from Coverage • Medicare Benefit Policy Manual, Chapter 14 – Medical Devices, §10 - Coverage of Medical Devices **Medicare-Based Non-Coverage Rationale**

Medicare Managed Care Manual, Chapter 4 - Benefits and Beneficiary Protections, §10.2 – Basic Rule

> "The scope of the benefits under Part A and Part B is defined in the Act. Part A and Part B benefits are discussed in sections 1812 and 1832 of the Act, respectively, while section 1861 of the Act lays out the definition of medical and other health services. Specific health care services must fit into one of these benefit categories, and not be otherwise excluded from coverage under the Medicare program (see §1862 for exclusions)…
>
> "In general, Medicare coverage and payment is contingent upon a determination that:
>
> • A service is in a covered benefit category;
> • A service is not specifically excluded from Medicare coverage by the Act; and
> • The item or service is "reasonable and necessary" for the diagnosis or treatment of an illness or injury, to improve functioning of a malformed body member, or is a covered preventive service."

According to Medicare Benefit Policy Manual, Chapter 16 - General Exclusions From Coverage, 10 - General Exclusions from Coverage, **services which are "not reasonable and necessary" are a general exclusion from Medicare coverage.**

"[I]ndividuals representative of the Medicare population are often excluded from the studies used to generate the evidence reviewed by FDA… Where there is limited evidence on the health outcomes for individuals in the Medicare population, there may be insufficient evidence to support a full coverage national coverage determination under section 1862(a)(1)(A) of the Act…" When studies exclusion criteria results in exclusion of older patients with comorbidities, then "a device's potential benefits and harms for older patients with more comorbidities may not be well understood at the time of FDA market authorization" and "when there is a lack of evidence specific to the Medicare population, it makes it difficult for CMS to ensure that devices are not posing additional risks in the Medicare population."

As of the most recent review, the CureSight™ system has been studied for use in the pediatric population, there is no study regarding the application to Medicare population. Luminopia is indicated for use in patients aged 4-7 years old.

The services listed in this table are **not medically reasonable or necessary** under Medicare and *§1862(a)(1)(A)* because it is not expected there will be clinical utility studies applicable to the Medicare population as these products are not meant to be used in older individuals.

	In addition, as of the most recent review, CureSight™ has not received FDA approval. 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. Devices which have 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**. According to Medicare Benefit Policy Manual, Chapter 16 - General Exclusions From Coverage, 10 - General Exclusions from Coverage, services and items which are "investigational" are a general exclusion from Medicare coverage. Services and items 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)*

Table 1.6

Products with No Medicare Benefit Category		
Device/Product, and Manufacturer Information (when applicable)		VIBRANT® System (Vibrant Gastro System) Natural Cycles Exersides™ Refraint™ System The PainShield MD Cue Reader
Code(s)	A9268	Programmer for transient, orally ingested capsule
	A9269	Programable, transient, orally ingested capsule, for use with external programmer, per month
	A9293	Fertility cycle (contraception & conception) tracking software application, FDA cleared, per month, includes accessories (e.g., thermometer)
	E0711	Upper extremity medical tubing/lines enclosure or covering device, restricts elbow range of motion
	K1004	Low frequency ultrasonic diathermy treatment device for home use
	K1035	Molecular diagnostic test reader, nonprescription self-administered and self-collected use, FDA approved, authorized or cleared
	K1036	Supplies and accessories (e.g., transducer) for low frequency ultrasonic diathermy treatment device, per month
Medicare and Coverage Notes		**Applicable Medicare Coverage Policy, Regulation, or Guideline** • Medicare Program Integrity Manual, Chapter 3 - Verifying Potential Errors and Taking Corrective Actions, §3.6.2.1 - Coverage Determinations • Medicare Benefit Policy Manual, Chapter 15 – Covered Medical and Other Health Services, §110.8 – DMEPOS Benefit Category Determinations *(Search for keywords of the code description to find the product in the 110.8 table)*

Medicare-Based Non-Coverage Rationale

The Medicare Program Integrity Manual, Chapter 3, §3.6.2.1 states that an item or service **may be denied coverage if the "item or service does not fall into a Medicare benefit category."**

While CMS developed a HCPCS code for each of the above products, CMS also concluded that none of the products represented by the above HCPCS codes fall under a benefit category under Medicare. CMS may also determine that devices may be classified as DME, but may still not fall into an established *DMEPOS* benefit category.

Therefore, because these items do not fall into a Medicare benefit category, they are **not medically necessary**.

The CMS decision specific to each product can be found in the following citations:

- VIBRANT® System: https://www.cms.gov/files/document/2023-hcpcs-application-summary-biannual-1-2023-non-drug-and-non-biological-items-and-services.pdf
- *Natural Cycles: https://www.cms.gov/files/document/2023-hcpcs-application-summary-biannual-2-2023-non-drug-and-non-biological-items-and-services.pdf
- Exersides™ Refraint™ System: https://www.cms.gov/files/document/2022-hcpcs-application-summary-biannual-2-2022-non-drug-and-non-biological-items-and-services.pdf
- PainShield®: https://www.cms.gov/files/document/2022-hcpcs-application-summary-biannual-1-2022-non-drug-and-non-biological-items-and-services.pdf
- Cue Reader: https://www.cms.gov/files/document/2022-hcpcs-application-summary-biannual-2-2022-non-drug-and-non-biological-items-and-services.pdf

**Evidence-Based Review of Natural Cycles*

A review of the ECRI, Hayes, Cochrane, and PubMed databases was conducted regarding the use of Natural Cycles and following an evidence based review, it was determined:

> "Evidence is currently insufficient to support the use of this service. The evidence base lacks comparison to other birth control methods. Despite data on more than 60,000 people, all studies provide very-low-quality evidence. Available studies are at high risk of bias because of lack of control groups. Studies included convenience samples of individuals subscribing to the service and willing to be included in the studies and may not be representative of the general

	population who may use the app. Studies also had high attrition. For people who provide data through 12-month follow-up, Natural Cycles' effectiveness is reported at ≥92%; 70% is considered typical for the conventional fertility awareness method. Randomized controlled trials comparing Natural Cycles with other birth control methods are needed to assess comparative effectiveness, but none are ongoing."

Table 1.7

Proprietary Human Papillomavirus (HPV) Testing		
Device/Product, and Manufacturer Information (when applicable)		HPV, High-Risk, Male Urine (Molecular Testing Labs; Washington) ~~PreTect HPV-Proofer' 7 (GenePace Laboratories, LLC & PreTech) (GenePace Laboratories, LLC; Indiana)~~ Omnipathology Oropharyngeal HPV PCR Test (OmniPathology Solutions, California) Proofer 7 HPV mRNA E6 and E7 Biomarker (Global Diagnostics Labs, LLC, PreTect AS, a Mel-Mont Medical, Inc.; Georgia) QuantiVirus™ HPV E6/E7 mRNA Test for Cervical Cancer (DiaCarta Inc.; California)
Code(s)	0096U	Human papillomavirus (HPV), high-risk types (ie, 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, 68), male urine
	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)
	0463U	Oncology (cervix), mRNA gene expression profiling of 14 biomarkers (E6 and E7 of the highest-risk human papillomavirus [HPV] types 16, 18, 31, 33, 45, 52, 58), by real-time nucleic acid sequence-based amplification (NASBA), exo- or endocervical epithelial cells, algorithm reported as positive or negative for increased risk of cervical dysplasia or cancer for each biomarker
	0502U	Human papillomavirus (HPV), E6/E7 markers for high-risk types (16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and 68), cervical cells, branched-chain capture hybridization, reported as negative or positive for high risk for HPV
Medicare and Coverage Notes		**Applicable Medicare Coverage Policy, Regulation, or Guideline** • Medicare Program Integrity Manual, Chapter 3 - Verifying Potential Errors and Taking Corrective Actions, §3.6.2.1 - Coverage Determinations • Medicare Benefit Policy Manual, Chapter 16 - General Exclusions From Coverage, §10 - General Exclusions from Coverage • Medicare Benefit Policy Manual, Chapter 16 - General Exclusions From Coverage, §90 - Routine Services and Appliances **Medicare-Based Non-Coverage Rationale**

	The Medicare Program Integrity Manual, Chapter 3, §3.6.2.1 states that an item or service **may be denied coverage if the "The item or service is statutorily excluded on grounds other than §1862(a) (1) (A) of the Act."** According to Medicare Benefit Policy Manual, Chapter 16 - General Exclusions From Coverage, 10 - General Exclusions from Coverage, **"routine services and appliances" are a general exclusion from Medicare coverage** (with the exception of preventive services noted in section 42 CFR 411.15(a)(1)). All of the above listed tests are used for HPV screening, and HPV screening outside of those covered under NCD 210.2.1 are considered **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, which means at-home or tests available without a physician order would also be non-covered under Medicare.

Table 1.8

Products and Services Which Do Not Meet Medicare's Statutory Requirements for Coverage		
Device/Product, and Manufacturer Information (when applicable)		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 Medicare's medical necessity threshold.
Code(s)	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)
	0690T	Quantitative ultrasound tissue characterization (non-elastographic), including interpretation and report, obtained with diagnostic ultrasound examination of the same anatomy (eg, organ, gland, tissue, target structure) (List separately in addition to code for primary procedure)
	0691T	Automated analysis of an existing computed tomography study for vertebral fracture(s), including assessment of bone density when performed, data preparation, interpretation, and report *(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 Medicare's medical necessity threshold.)*
	0693T	Comprehensive full body computer-based markerless 3D kinematic and kinetic motion analysis and report *(OpenPose-based markerless motion capture - This system has been studied for use in relation to sports medicine.)*
	0697T	Quantitative magnetic resonance for analysis of tissue composition (eg, fat, iron, water content), including multiparametric data acquisition, data preparation and transmission, interpretation and report, obtained without diagnostic MRI examination of the same anatomy (eg, organ, gland, tissue, target structure) during the same session; multiple organs *(This is not a magnetic resonance procedure covered under the Medicare NCD 220.2. 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. 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.)*
	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])*
	0731T	Augmentative AI-based facial phenotype analysis with report *(Facial recognition based on artificial intelligence (AI) to detect underlying facial patterns thought to be beneficial for diagnosis or screening)*
	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 *(By its definition, this code is specific to when performed for **screening** purposes.)*
	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 member.)*
	0457U	Perfluoroalkyl substances (PFAS) (eg, perfluorooctanoic acid, perfluorooctane sulfonic acid), 9 PFAS compounds by LC-MS/MS, plasma or serum, quantitative *(PFAS (Forever Chemicals) 9 Panel, Quest Diagnostics® - 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.)*
	0535U	Perfluoroalkyl substances (PFAS) (eg, perfluorooctanoic acid, perfluorooctane sulfonic acid), by liquid chromatography with tandem mass spectrometry (LCMS/MS), plasma or serum, quantitative *(PFAS Testing & PFASure®FT by National Medical Services [NMS Labs]. This test is used for "Monitoring for exposure to Per- and Polyfluorinated alkyl substances. This*

		would not meet Medicare's medically reasonable or necessary criteria to diagnosis or treat an illness or condition.)
	0589U	Perfluoroalkyl substances (PFAS) (eg, perfluorooctanoic acid, perfluorooctane sulfonic acid), 24 PFAS compounds by high-performance liquid chromatography with tandem mass spectrometry (LCMS/MS), plasma or serum, quantitative *(Used to report the PFAS [Forever Chemicals] Panel 2 – 24 PFAS, Quest Diagnostics®)*
Medicare and Coverage Notes		**Applicable Medicare Coverage Policy, Regulation, or Guideline** • Medicare Managed Care Manual, Chapter 4 - Benefits and Beneficiary Protections, §10.2 – Basic Rule • §1862(a)(1)(A) of the Act • Medicare Benefit Policy Manual, Chapter 16 - General Exclusions From Coverage, §10 - General Exclusions from Coverage **Medicare-Based Non-Coverage Rationale** Medicare Managed Care Manual, Chapter 4 - Benefits and Beneficiary Protections, §10.2 – Basic Rule "The scope of the benefits under Part A and Part B is defined in the Act. Part A and Part B benefits are discussed in sections 1812 and 1832 of the Act, respectively, while section 1861 of the Act lays out the definition of medical and other health services. Specific health care services must fit into one of these benefit categories, and not be otherwise excluded from coverage under the Medicare program (see §1862 for exclusions)… "In general, Medicare coverage and payment is contingent upon a determination that: • A service is in a covered benefit category; • A service is not specifically excluded from Medicare coverage by the Act; and • The item or service is "reasonable and necessary" for the diagnosis or treatment of an illness or injury, to improve functioning of a malformed body member, or is a covered preventive service." According to Medicare Benefit Policy Manual, Chapter 16 - General Exclusions From Coverage, 10 - General Exclusions from Coverage, **services which are "not reasonable and necessary" are a general exclusion from Medicare coverage.** The services listed in this table are **not medically reasonable or necessary** under Medicare and *§1862(a)(1)(A)* because the intended clinical purpose of the service or item is **not** to diagnose or treat an illness or injury or improve the function of a malformed body member, nor does it fall under a covered preventive service category. Therefore, the nature of the service represented by the code does not meet Medicare coverage requirements.

Table 1.9

Transcatheter Mitral Valve Annulus Reconstruction		
Device/Product, and Manufacturer Information (when applicable)		Cardioband™ Mitral Valve Reconstruction System (Edwards Lifesciences)
Code(s)	0544T	Transcatheter mitral valve annulus reconstruction, with implantation of adjustable annulus reconstruction device, percutaneous approach including transseptal puncture
Medicare and Coverage Notes		**Applicable Medicare Coverage Policy, Regulation, or Guideline** • Medicare Benefit Policy Manual, Chapter 14 – Medical Devices, §10 - Coverage of Medical Devices • Medicare Benefit Policy Manual, Chapter 16 - General Exclusions From Coverage, §10 - General Exclusions from Coverage **Medicare-Based Non-Coverage Rationale** 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**. According to Medicare Benefit Policy Manual, Chapter 16 - General Exclusions From Coverage, 10 - General Exclusions from Coverage, **services which are "investigational" are an exclusion from Medicare coverage.** Services and items 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)* As of the most recent review, the technology/device/procedure represented by this code has not received FDA approval. Therefore, the above code is considered **not medically necessary**. However, this device **is** the focus of a Medicare-approved IDE study (*Cardioband Mitral System*; NCT03016975). Therefore, coverage may be approved for members enrolled in a Medicare-approved study. *(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.)*

Table 1.10

Transcatheter Tricuspid Valve Annulus Reconstruction

Device/Product, and Manufacturer Information (when applicable)		Cardioband™ Tricuspid Valve Reconstruction System (Edwards Lifesciences)
Code(s)	0545T	Transcatheter tricuspid valve annulus reconstruction with implantation of adjustable annulus reconstruction device, percutaneous approach
Medicare and Coverage Notes		**Applicable Medicare Coverage Policy, Regulation, or Guideline** • Medicare Benefit Policy Manual, Chapter 14 – Medical Devices, §10 - Coverage of Medical Devices • Medicare Benefit Policy Manual, Chapter 16 - General Exclusions From Coverage, §10 - General Exclusions from Coverage **Medicare-Based Non-Coverage Rationale** 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**. According to Medicare Benefit Policy Manual, Chapter 16 - General Exclusions From Coverage, 10 - General Exclusions from Coverage, **services which are "investigational" are an exclusion from Medicare coverage**. Services and items 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)* 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. As of the most recent review, the technology represented by this code has not received FDA approval. Therefore, the above code is considered **not medically necessary**. However, this device is the focus of a Medicare-approved investigational device exception (IDE) study (*Edwards Cardioband Tricuspid Valve Reconstruction System Early Feasibility Study*; NCT03382457). Therefore, coverage may be approved for members enrolled in a Medicare-approved study. *(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 that in the above IDE study, the device has been 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.

Table 1.11

Transurethral Water Vapor Ablation of Malignant Prostate Tissue		
Device/Product, and Manufacturer Information (when applicable)		Vanquish Water Vapor Ablation System (Francis Medical, Inc.)
Code(s)	0582T	Transurethral ablation of malignant prostate tissue by high-energy water vapor thermotherapy, including intraoperative imaging and needle guidance
Medicare and Coverage Notes		**Applicable Medicare Coverage Policy, Regulation, or Guideline** • Medicare Benefit Policy Manual, Chapter 14 – Medical Devices, §10 - Coverage of Medical Devices • Medicare Benefit Policy Manual, Chapter 16 - General Exclusions From Coverage, §10 - General Exclusions from Coverage **Medicare-Based Non-Coverage Rationale** 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**. According to Medicare Benefit Policy Manual, Chapter 16 - General Exclusions From Coverage, 10 - General Exclusions from Coverage, **services which are "investigational" are an exclusion from Medicare coverage**. Services and items 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)* As of the most recent review, the technology/device/procedure represented by this code has not received full FDA approval. Therefore, the above code is considered **not medically necessary**. However, this device has been granted a Breakthrough Device Designation as of Summer 2023 and it is also the focus of a Medicare-approved Category B IDE study (*Water Vapor Ablation for Localized Intermediate Risk Prostate Cancer (VAPOR 2)*; NCT05683691).

	Therefore, coverage may be approved for members enrolled in a Medicare-approved study. *(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*.)*

Table 1.12

Interatrial Septal Shunt Device		
Device/Product, and Manufacturer Information (when applicable)		InterAtrial Shunt Device (IASD) (Corvia Medical)
Code(s)	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
Medicare and Coverage Notes		**Applicable Medicare Coverage Policy, Regulation, or Guideline** • Medicare Benefit Policy Manual, Chapter 14 – Medical Devices, §10 - Coverage of Medical Devices • Medicare Benefit Policy Manual, Chapter 16 - General Exclusions From Coverage, §10 - General Exclusions from Coverage **Medicare-Based Non-Coverage Rationale** 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**. According to Medicare Benefit Policy Manual, Chapter 16 - General Exclusions From Coverage, 10 - General Exclusions from Coverage, **services which are "investigational" are an exclusion from Medicare coverage.** Services and items 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)* As of the most recent review, the technology/device/procedure represented by the above codes have not received FDA approval. Therefore, the above code is considered **not medically necessary**. However, this device has been granted a Breakthrough Device Designation in 2019 and it is also the focus of a Medicare-approved Category B IDE study (*Corvia Medical Interatrial Shunt Device (IASD) System II*; NCT03088033). Therefore, coverage may be approved for members enrolled in a Medicare-approved study. *(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.)

Table 1.13

Subcutaneous Peritoneal Ascites Pump System		
Device/Product, and Manufacturer Information (when applicable)		alfapump® System
Code(s)	0870T	Implantation of subcutaneous peritoneal ascites pump system, percutaneous, including pump-pocket creation, insertion of tunneled indwelling bladder and peritoneal catheters with pump connections, including all imaging and initial programming, when performed
	0871T	Replacement of a subcutaneous peritoneal ascites pump, including reconnection between pump and indwelling bladder and peritoneal catheters, including initial programming and imaging, when performed
	0872T	Replacement of indwelling bladder and peritoneal catheters, including tunneling of catheter(s) and connection with previously implanted peritoneal ascites pump, including imaging and programming, when performed
	0873T	Revision of a subcutaneously implanted peritoneal ascites pump system, any component (ascites pump, associated peritoneal catheter, associated bladder catheter), including imaging and programming, when performed
	0875T	Programming of subcutaneously implanted peritoneal ascites pump system by physician or other qualified health care professional
Medicare Coverage Policy or Regulatory Source		**Applicable Medicare Coverage Policy, Regulation, or Guideline** • Medicare Benefit Policy Manual, Chapter 14 – Medical Devices, §10 - Coverage of Medical Devices • Medicare Benefit Policy Manual, Chapter 16 - General Exclusions From Coverage, §10 - General Exclusions from Coverage **Medicare-Based Non-Coverage Rationale** 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**. According to Medicare Benefit Policy Manual, Chapter 16 - General Exclusions From Coverage, 10 - General Exclusions from Coverage, **services which are "investigational" are an exclusion from Medicare coverage**.

	Services and items 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)* As of the most recent review, the technology/device/procedure represented by the above codes have not received FDA approval. Therefore, the above codes are considered **not medically necessary**. However, this system is currently under clinical investigation (POSEIDON Study) and is being studied in adult patients with refractory or recurrent ascites due to cirrhosis. The POSEIDON Study (NCT03973866; G140126) is a Medicare-approved Category B IDE study as of 10/2019. Therefore, coverage may be approved for members enrolled in a Medicare-approved study. *(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*.)* **Removal of Non-Covered Devices** 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 (0874T) may be considered medically reasonable and necessary for unrelated reasons (e.g., pain, infection, etc.).

Table 1.14

Miscellaneous Services or Items Which have Not Received Appropriate Regulatory Approval		
Device/Product, and Manufacturer Information (when applicable)		Orlucent™ Handheld Fluorescent Molecular Imaging System ExTra ELT by ELT Sight
Code(s)	0621T	Trabeculostomy ab interno by laser
	0622T	; with use of ophthalmic endoscope
	0632T	Percutaneous transcatheter ultrasound ablation of nerves innervating the pulmonary arteries, including right heart 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
	0700T	Molecular fluorescent imaging of suspicious nevus; first lesion
	0701T	Molecular fluorescent imaging of suspicious nevus; each additional lesion (List separately in addition to code for primary procedure)
	0730T	Trabeculotomy by laser, including optical coherence tomography (OCT) guidance
Medicare and Coverage Notes		**Applicable Medicare Coverage Policy, Regulation, or Guideline** • Medicare Benefit Policy Manual, Chapter 14 – Medical Devices, §10 - Coverage of Medical Devices

	• Medicare Benefit Policy Manual, Chapter 16 – General Exclusions from Coverage, §10 – General Exclusions from Coverage **Medicare-Based Non-Coverage Rationale** 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**. According to Medicare Benefit Policy Manual, Chapter 16 - General Exclusions From Coverage, 10 - General Exclusions from Coverage, **services which are "investigational" are an exclusion from Medicare coverage**. Services and items 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)* As of the most recent review, the technology/device/procedure represented by the above codes have not received FDA approval. Therefore, the above codes are considered **not medically necessary**.

Table 1.15

Transdermal Glomerular filtration Rate (GFR) Measurements		
Device/Product, and Manufacturer Information (when applicable)		Transdermal GFR Measurement System and patented pharmaceutical Lumitrace (MediBeacon)
Code(s)	0602T	Glomerular filtration rate (GFR) measurement(s), transdermal, including sensor placement and administration of a single dose of fluorescent pyrazine agent
	0603T	Glomerular filtration rate (GFR) monitoring, transdermal, including sensor placement and administration of more than one dose of fluorescent pyrazine agent, each 24 hours
Medicare and Coverage Notes		**Applicable Medicare Coverage Policy, Regulation, or Guideline** • Medicare Benefit Policy Manual, Chapter 14 – Medical Devices, §10 - Coverage of Medical Devices • Medicare Benefit Policy Manual, Chapter 16 - General Exclusions From Coverage, §10 - General Exclusions from Coverage **Medicare-Based Non-Coverage Rationale**

	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**. According to Medicare Benefit Policy Manual, Chapter 16 - General Exclusions From Coverage, 10 - General Exclusions from Coverage, **services which are "investigational" are an exclusion from Medicare coverage**. Services and items 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)* As of the most recent review, the technology/device/procedure represented by the above codes have not received FDA approval. Therefore, the above codes are considered **not medically necessary**.

Table 1.16

Patient-Initiated Optical Coherence Tomography (OCT) of the Retina		
Device/Product, and Manufacturer Information (when applicable)		Home OCT (Notal Vision)
Code(s)	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
	0605T	Optical coherence tomography (OCT) of retina, remote, patient-initiated image capture and transmission to a remote surveillance center unilateral or bilateral; remote surveillance center technical support, data analyses and reports, with a minimum of 8 daily recordings, each 30 days
	0606T	Optical coherence tomography (OCT) of retina, remote, patient-initiated image capture and transmission to a remote surveillance center unilateral or bilateral; review, interpretation and report by the prescribing physician or other qualified health care professional of remote surveillance center data analyses, each 30 days
Medicare and Coverage Notes		**Applicable Medicare Coverage Policy, Regulation, or Guideline** • Medicare Benefit Policy Manual, Chapter 14 – Medical Devices, §10 - Coverage of Medical Devices • Medicare Benefit Policy Manual, Chapter 16 - General Exclusions From Coverage, §10 - General Exclusions from Coverage

	Medicare-Based Non-Coverage Rationale 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**. According to Medicare Benefit Policy Manual, Chapter 16 - General Exclusions From Coverage, 10 - General Exclusions from Coverage, **services which are "investigational" are an exclusion from Medicare coverage**. Services and items 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)* As of the most recent review, the technology/device/procedure represented by the above codes have not received FDA approval. Therefore, the above codes are considered **not medically necessary**.

Table 1.17

Implantable Vestibular Device		
Device/Product, and Manufacturer Information (when applicable)		Cochlear Vestibular Implant (CVI) Labyrinth Devices MVI™ Multichannel Vestibular Implant
Code(s)	0725T	Vestibular device implantation, unilateral
	0727T	Removal and replacement of implanted vestibular device, unilateral
	0728T	Diagnostic analysis of vestibular implant, unilateral; with initial programming
	0729T	Diagnostic analysis of vestibular implant, unilateral; with subsequent programming
Medicare and Coverage Notes		Not medically necessary under Section 1862(a)(1) of the Social Security Act. **Applicable Medicare Coverage Policy, Regulation, or Guideline** • Medicare Benefit Policy Manual, Chapter 14 – Medical Devices, §10 - Coverage of Medical Devices • Medicare Benefit Policy Manual, Chapter 16 - General Exclusions From Coverage, §10 - General Exclusions from Coverage **Medicare-Based Non-Coverage Rationale** 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**. According to Medicare Benefit Policy Manual, Chapter 16 - General Exclusions From Coverage, 10 - General Exclusions from Coverage, **services which are "investigational" are an exclusion from Medicare coverage**. Services and items 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)* As of the most recent review, the technology/device/procedure represented by the above codes have not received FDA approval. Therefore, the above codes are considered **not medically necessary**. However, this device is currently under clinical investigation (Multichannel Vestibular Implant Early Feasibility Study) and is being studied in adult patients with refractory or recurrent ascites due to cirrhosis. This study (NCT02725463; G150198) is a Medicare-approved Category B IDE study as of 8/2021. Therefore, coverage may be approved for members enrolled in a Medicare-approved study. *(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*.)* 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). **Evidence** The methodological limitations of vestibular implants include challenges in optimizing electrical stimulation profiles to effectively mimic natural vestibular inputs without causing adverse effects. Surgical implantation procedures need refinement to ensure precision and minimize trauma, preserving residual labyrinthine functions, including hearing. Many patients experienced hearing loss in the implanted ear, indicating the need for better techniques to prevent this outcome. Additionally, variability in individual anatomy and pathology complicates standardization. Establishing regulatory approval and creating a robust clinical care infrastructure, akin to cochlear implants, are also significant hurdles. These limitations highlight the need for further research to enhance device efficacy and patient outcomes. Therefore, vestibular implantation and related procedures are considered **not medically necessary** for the treatment of any indication.

	Evidence Sources/Citations • A review of the ECRI, Hayes, Cochrane, and PubMed databases was conducted regarding the use of this technology. • Chow et al. Posture, Gait, Quality of Life, and Hearing with a Vestibular Implant. N Engl J Med 2021;384:521-532. DOI: 10.1056/NEJMoa2020457. PMID: 33567192. • Stultiens et al. The Next Challenges of Vestibular Implantation in Humans. J Assoc Res Otolaryngol. 2023 Aug;24(4):401-412. DOI: 10.1007/s10162-023-00906-1. PMID: 37516679. • Fornos et al. The vestibular implant: A probe in orbit around the human balance system. J Vestib Res. 2017;27(1):51-61. DOI: 10.3233/VES-170604. PMID: 28387690. **Removal of Non-Covered Devices** 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 1.18

COMS® One Therapy System for Wound Care		
Device/Product, and Manufacturer Information (when applicable)		COMS® One Therapy System
Code(s)	0906T	Concurrent optical and magnetic stimulation (COMS) therapy, wound assessment and dressing care; first application, total wound(s) surface area less than or equal to 50 sq cm
	0907T	Concurrent optical and magnetic stimulation (COMS) therapy, wound assessment and dressing care; each additional application, total wound(s) surface area less than or equal to 50 sq cm (List separately in addition to code for primary procedure)
Medicare and Coverage Notes		Not medically necessary under Section 1862(a)(1) of the Social Security Act. **Applicable Medicare Coverage Policy, Regulation, or Guideline** • Medicare Benefit Policy Manual, Chapter 14 – Medical Devices, §10 - Coverage of Medical Devices • Medicare Benefit Policy Manual, Chapter 16 - General Exclusions From Coverage, §10 - General Exclusions from Coverage **Medicare-Based Non-Coverage Rationale** 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**. According to Medicare Benefit Policy Manual, Chapter 16 - General Exclusions From Coverage, 10 - General Exclusions from Coverage, **services which are "investigational" are an exclusion from Medicare coverage**. Services and items 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)* As of the most recent review, the technology/device/procedure represented by the above codes have not received FDA approval. Therefore, the above codes are considered **not medically necessary** under *§1862(a)(1)(A).* However, the COMS One therapy system is currently under clinical investigation and is being studied (MAVERICKS clinical trial) in the treatment of refractory diabetic foot ulcers (DFUs). This study (NCT05758545; G220277) is a Medicare-approved Category B IDE study as of 6/2023. Coverage may be approved for members enrolled in this Medicare-approved IDE study. As of the most recent policy review, the NAZARÉ trial (NCT06528873), which is intended to study the COMS One device for chronic ulcers, is **not** a Medicare approved IDE study. *(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*.)* **Evidence** Evidence is insufficient to support the use of the COMS One Therapy System. No relevant studies or clinical practice guidelines addressing the service were identified. Additionally, the COMS One therapy system has not yet received regulatory approval in the U.S. Therefore, use of the COMS One Therapy System is considered **not medically necessary** for the treatment of any indication, **unless** provided within the context of a Medicare-***approved*** Category B investigational device exemption (IDE) study. Evidence Sources/Citations • A review of the ECRI, Hayes, Cochrane, and PubMed databases was conducted regarding the use of this service. • No published studies were identified. No clinical practice guidelines were identified.

Table 1.19

Non-Covered Blood Based Cancer Screening Tests		
Device/Product, and Manufacturer Information (when applicable)		IGoCheck™ (Blood-Based Colorectal Cancer Test), Milagen, Inc. MammoCheck™ (Blood-Based Breast Cancer Test), Milagen, Inc.
Code(s)	0558U	Oncology (colorectal), quantitative enzyme-linked immunosorbent assay (ELISA) for secreted colorectal cancer protein marker (BF7 antigen), using serum, result reported as indicative of response/no response to therapy or disease progression/regression
	0559U	Oncology (breast), quantitative enzyme-linked immunosorbent assay (ELISA) for secreted breast cancer protein marker (BF9 antigen), serum, result reported as indicative of response/no response to therapy or disease progression/regression
Medicare and Coverage Notes		**Applicable Medicare Coverage Policy, Regulation, or Guideline** • Medicare Program Integrity Manual, Chapter 3 - Verifying Potential Errors and Taking Corrective Actions, §3.6.2.1 - Coverage Determinations • Medicare Benefit Policy Manual, Chapter 16 - General Exclusions From Coverage, §10 - General Exclusions from Coverage • Medicare Benefit Policy Manual, Chapter 16 - General Exclusions From Coverage, §90 - Routine Services and Appliances **Medicare-Based Non-Coverage Rationale** The Medicare Program Integrity Manual, Chapter 3, §3.6.2.1 states that an item or service may be denied coverage if the "The item or service is statutorily excluded on grounds other than §1862(a) (1) (A) of the Act." According to Medicare Benefit Policy Manual, Chapter 16 - General Exclusions From Coverage, 10 - General Exclusions from Coverage, **"routine services and appliances" are a general exclusion from Medicare coverage** (with the exception of preventive services noted in section 42 CFR 411.15(a)(1)). The above services are used as routine screening tools. While colorectal and breast cancer screenings are covered Medicare preventive benefits, screening services outside the scope of associated NCDs 210.3 and 220.4 respectively, would be considered non-covered under Medicare statute.[3] Currently, no blood-based test is covered for breast cancer screening under Medicare, and these services are **not** included as part of the Medicare Preventive Services chart, found on the CMS website. Therefore, if these services are performed for a Medicare Advantage member, they will be considered **not medically necessary** under Section 1862(a)(1) of the Social Security Act.

Table 1.20

Carbonhand®	
Device/Product, and Manufacturer	Carbonhand® and the Carbonhand® replacement glove (Bioservo)

Information (when applicable)		
Code(s)	A8005	Powered, cable driven grip assist glove, hand, finger, includes microprocessor, pressure sensors, all components and accessories, custom fitted
	A8006	Powered, cable driven grip assist glove, hand, finger, includes pressure sensors, glove replacement only
Medicare and Coverage Notes		**Applicable Medicare Coverage Policy, Regulation, or Guideline** • Second Biannual (B2) Centers for Medicare & Medicaid Services' (CMS') Healthcare Common Procedure Coding System (HCPCS) Level II Final Coding, Benefit Category and Payment Determinations agenda **Medicare-Based Non-Coverage Rationale** According to the Second Biannual (B2) Centers for Medicare & Medicaid Services' (CMS') Healthcare Common Procedure Coding System (HCPCS) Level II Final Coding, Benefit Category and Payment Determinations agenda document, the Final Medicare Benefit Category Determination made by CMS was "no Medicare DMEPOS benefit category" because the device doesn't meet CMS requirements to be considered a brace. The CMS Final determination was: Because the Carbonhand® glove device lacks the inherent rigidity, mechanical joints, and static pressure vectors found in the cited L-code devices, it does not satisfy the criteria for a brace. …For a device to be classified as a brace, the rigid or semi-rigid elements must be the primary means of providing orthopedic stabilization or limitation of movement. In this case, the sensors do not provide the structural "stiffness" (88 FR 77837) required to support the hand or fingers in a therapeutic position when the motor is inactive. We appreciate that the Carbonhand® may be effective and useful in assisting with hand grip. However, after reviewing the application, public meeting presentation, and written comments, we are finalizing our preliminary benefit category determination that the Carbonhand® does not meet the Medicare definitions in regulations of a brace at 42 CFR 410.2 or durable medical equipment at 42 CFR 414.202. ***and*** The Carbonhand® Replacement Glove does not meet the requirements for classification as a DME item, nor does it meet the criteria as a brace, as explained in application HCP250627GH4P4.

Table 1.21

Permanent Filter for Stroke Prevention in Atrial Fibrillation	
Device/Product, and Manufacturer	Vine™ (Javelin Medical)

Information (when applicable)		
Code(s)	C8010	Percutaneous placement of permanent common carotid embolic protection device, including all system components and imaging guidance; bilateral
Medicare and Coverage Notes		**Applicable Medicare Coverage Policy, Regulation, or Guideline** • Medicare Benefit Policy Manual, Chapter 14 – Medical Devices, §10 - Coverage of Medical Devices • Medicare Benefit Policy Manual, Chapter 16 - General Exclusions From Coverage, §10 - General Exclusions from Coverage **Medicare-Based Non-Coverage Rationale** 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**. According to Medicare Benefit Policy Manual, Chapter 16 - General Exclusions From Coverage, 10 - General Exclusions from Coverage, **services which are "investigational" are an exclusion from Medicare coverage**. Services and items 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)* As of the most recent policy review, the technology represented by this code has not received FDA approval. Therefore, the above code is considered **not medically necessary**. However, this device is the focus of a Medicare-approved investigational device exception (IDE) study (*Carotid Implants for PreveNtion of STrokE ReCurrEnce From Large Vessel Occlusion in Atrial Fibrillation Patients Treated With Oral Anticoagulation or INTERCEPT*; NCT05723926, G220272). Therefore, coverage may be approved for members enrolled in a Medicare-approved study. *(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.)*

Table 1.XX

Device/Product, and Manufacturer Information (when applicable)		**Blank table left intentionally - Placeholder for future services/technologies added to the Table 1 set of codes**
Code(s)		

Medicare and Coverage Notes	**Applicable Medicare Coverage Policy, Regulation, or Guideline** • XXX • XXX **Medicare-Based Non-Coverage Rationale** XXX

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

NOTES: *Specific devices and products listed in the following tables may not be an all-inclusive list, but rather may only represent examples of the relevant technology. The "Effective Date" listed is the date the code was effective, which may or may not be the same date the Company's non-coverage position was effective.*

Table 2.1

Non-Human Leukocyte Antibody (non-HLA) Testing		
Device/Product, and Manufacturer Information (when applicable)		Autoantibody to NonHuman Leukocyte Antigen (non-HLA) (Mayo Clinic Jacksonville)
Code(s)	0581U	Transplantation medicine, antibody to non-human leukocyte antigens (nonHLA), blood specimen, flow cytometry, single- antigen bead technology, 39 targets, individual positive antibodies reported *(Effective 10/1/2025)*
Medicare Coverage Notes and Evidence Summary		This service is not medically necessary under Section 1862(a)(1) of the Social Security Act. While there are local coverage articles for Human Leukocyte Antigen (HLA) testing, there are no coverage policies for non-human leukocyte antigen (non-HLA) testing. Therefore, Medicare coverage criteria are considered "not fully established," so internal coverage criteria will be applied, based on an evidence review of the references and guidelines cited below. Although non-HLA autoantibodies have been increasingly recognized for their potential role in graft injury and antibody-mediated rejection, routine clinical testing for these antibodies is not currently supported due to several limitations. First, there is no standardized or widely validated assay for detecting non-HLA antibodies, resulting in inconsistent and non-comparable results across laboratories. Second, while associations between these antibodies and poor transplant outcomes have been observed, their prognostic value remains uncertain and lacks robust validation in large-scale, prospective clinical studies. Third, there are no proven therapeutic interventions specifically targeting non-HLA antibody-mediated injury that have demonstrated improved outcomes in randomized trials. As a result, major clinical guidelines do not recommend routine testing, and the presence of these antibodies does not yet inform actionable changes in patient management. Consequently, non-HLA autoantibody testing remains investigational and is primarily used in research settings or specialized transplant centers, such as Mayo Clinic Jacksonville, where ongoing studies aim to clarify their clinical relevance. Therefore, non-HLA autoantibody testing is considered **not medically necessary** for the treatment of any indication.
Sources/Citations		• A review of the ECRI, Hayes, Cochrane, and PubMed databases was conducted regarding the use of these services.

	• Non-HLA Antibodies in Kidney Transplantation: Pathogenesis, Clinical Impact, and Management (Transplantology, 2025) • Frontiers in Transplantation: Challenges in Non-HLA Antibody Testing (2025) • Editorial: A Hill of Needs - Non-HLA Antibodies and Transplantation (Frontiers in Immunology, 2022)

Table 2.2

Nerve Repair with Synthetic Conduit or Vein Allograft		
Device/Product, and Manufacturer Information (when applicable)		N/A
Code(s)	64910	Nerve repair; with synthetic conduit or vein allograft (eg, nerve tube), each nerve *(Effective 1/1/2007)*
	C9352	Microporous collagen implantable tube (neuragen nerve guide), per centimeter length *(Effective 1/1/2008)*
	C9353	Microporous collagen implantable slit tube (neurawrap nerve protector), per centimeter length *(Effective 1/1/2008)*
	C9355	Collagen nerve cuff (neuromatrix), per 0. 5 centimeter length *(Effective 1/1/2008)*
	C9361	Collagen matrix nerve wrap (neuromend collagen nerve wrap), per 0.5 centimeter length *(Effective 7/1/2009)*
Medicare Coverage Notes and Evidence Summary		These services are not medically necessary under Section 1862(a)(1) of the Social Security Act. Medicare coverage criteria are considered "not fully established," so internal coverage criteria will be applied, based on an evidence review of the references and guidelines cited below. There is insufficient scientific evidence to support the efficacy of conduits and nerve allografts for bridging the defects resulting from peripheral nerve injuries. The evidence base consists only of very small case series and case reports. Limitations of the case series include non-standardized assessment of outcomes, lack of comparator groups, lack of statistical analysis of findings, and heterogeneity in patient populations. In addition, the type and severity of the nerve injury varied substantially between studies. While one clinical practice guideline endorsed the use of processed nerve allografts in digital nerves, this conclusion was made on the basis of low -quality evidence with design limitations that undermine results' validity and generalizability (e.g., small sample sizes, lack of long-term follow-up, non-randomized groups, retrospective case series.) Additional studies are needed to determine whether or not the use of synthetic conduits or nerve allografts provide an improvement in health outcomes when used to repair peripheral nerve injuries. Therefore, the use of conduits and nerve allografts is considered **not medically necessary** as a treatment any indication, including peripheral nerve injuries and neuromas.
Sources/Citations		• Boston Medical Center. Health Net Plan. Medical Policy. Nerve Repairs for Peripheral Nerve Injuries Using Allografts, Autografts, and Conduits.

	Policy Number: OCA 3.701 Version Number: 11 Version Effective Date: 05/01/16. • Hayes, Inc. Processed Nerve Allografts with the Avance Nerve Graft (Axogen Corporation) for Peripheral Nerve Discontinuities. Updated May 11, 2023. Accessed Feb 12, 2024. https://evidence.hayesinc.com/report/htb.avance4778 • Salomon D, Miloro M, Kolokythas A. Outcomes of Immediate Allograft Reconstruction of Long-Span Defects of the Inferior Alveolar Nerve. J Oral Maxillofac Surg. 2016 Jun 14. • Papatheodorou LK, Williams BG, Sotereanos DG. Preliminary results of recurrent cubital tunnel syndrome treated with neurolysis and porcine extracellular matrix nerve wrap. J Hand Surg Am. 2015 May;40(5):987-92. • Rbia N, Bulstra LF, Saffari TM, Hovius SER, Shin AY. Collagen Nerve Conduits and Processed Nerve Allografts for the Reconstruction of Digital Nerve Gaps: A Single-Institution Case Series and Review of the Literature. World Neurosurg. 2019 Jul;127:e1176-e1184. Doi: 10.1016/j.wneu.2019.04.087. Epub 2019 Apr 16. PMID: 31003028. • Isaacs J, Safa B. A Preliminary Assessment of the Utility of Large-Caliber Processed Nerve Allografts for the Repair of Upper Extremity Nerve Injuries. Hand (N Y). 2017 Jan;12(1):55-59. PMID: 28082844 • Yampolsky A, Ziccardi V, Chuang SK. Efficacy of Acellular Nerve Allografts in Trigeminal Nerve Reconstruction. J Oral Maxillofac Surg. 2017 Oct;75(10):2230-2234. PMID: 28336306. • National Institute for Health and Care Excellence. Processed nerve allografts to repair peripheral nerve discontinuities. Published Nov 22, 2017. https://www.nice.org.uk/guidance/ipg597/chapter/1-Recommendations.

Table 2.3

Percutaneous Transluminal Coronary Lithotripsy		
Device/Product, and Manufacturer Information (when applicable)		Shockwave Coronary Rx Lithoplasty System and Shockwave Medical Peripheral IVL System, both by Shockwave Medical Inc.
Code(s)	92972	Percutaneous transluminal coronary lithotripsy (List separately in addition to code for primary procedure) *(Effective 1/1/2024)*
	C1761	Catheter, transluminal intravascular lithotripsy, coronary *(Effective 7/1/2021)*
	C9764	Revascularization, endovascular, open or percutaneous, lower extremity artery(ies), except tibial/peroneal; with intravascular lithotripsy, includes angioplasty within the same vessel(s), when performed *(Effective 7/1/2020)*
	C9765	Revascularization, endovascular, open or percutaneous, lower extremity artery(ies), except tibial/peroneal; with intravascular lithotripsy, and transluminal stent placement(s), includes angioplasty within the same vessel(s), when performed *(Effective 7/1/2020)*
	C9766	Revascularization, endovascular, open or percutaneous, lower extremity artery(ies), except tibial/peroneal; with intravascular lithotripsy and

		atherectomy, includes angioplasty within the same vessel(s), when performed *(Effective 7/1/2020)*
	C9767	Revascularization, endovascular, open or percutaneous, lower extremity artery(ies), except tibeal/peroneal; with intravascular lithotripsy and transluminal stent placement(s), and atherectomy, includes angioplasty within the same vessel(s), when performed *(Effective 7/1/2020)*
	C9772	Revascularization, endovascular, open or percutaneous, tibial/peroneal artery(ies), with intravascular lithotripsy, includes angioplasty within the same vessel (s), when performed *(Effective 1/1/2021)*
	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 *(Effective 1/1/2021)*
	C9774	Revascularization, endovascular, open or percutaneous, tibial/peroneal artery(ies); with intravascular lithotripsy and atherectomy, includes angioplasty within the same vessel (s), when performed *(Effective 1/1/2021)*
	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 *(Effective 1/1/2021)*
Medicare Coverage Notes and Evidence Summary		These services are not medically necessary under Section 1862(a)(1) of the Social Security Act, **UNLESS** the services are rendered in the context of a Medicare-approved IDE study. As of the most recent review of this policy, Medicare-approved Category B IDE studies for this Shockwave include the following: • As of 12/13/2018: The Disrupt CAD III With the Shockwave Coronary IVL System study (NCT03595176; G180146), is evaluating the use of the Shockwave Coronary Rx Lithoplasty System with the Shockwave C2 Coronary IVL Catheter in Calcified Coronary Arteries. • As of 6/15/2023: Shockwave Intravascular Lithotripsy System with the Shockwave Mini S Peripheral IVL Catheter study (NCT05858905; G220300), is evaluating the use of the Shockwave Mini S Peripheral IVL Catheter. • As of 11/9/2023: The Disrupt CAD Duo study (NCT05966662; G230172), is evaluating the use of the Shockwave C2+ 2Hz Coronary IVL Catheter in Calcified Coronary Arteries. 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*.)* When **not** rendered in the context of an IDE study, Medicare coverage criteria are considered "not fully established," so internal coverage criteria will be applied, based on an evidence review of the references and guidelines cited below.

	There is insufficient evidence to support the use of the Shockwave Intravascular Lithotripsy for treating any indication, including coronary artery disease and peripheral artery disease. Current evidence is of poor quality and does not compare the addition of IVL to standard of care alone. Furthermore, no clinical guidelines were identified that support the use of IVL. Therefore, the Shockwave Intravascular Lithotripsy System (Shockwave Medical, Inc.) is considered **not medically necessary** for the treatment of any indication, including but not limited to coronary artery disease and peripheral artery disease.
Sources/Citations	• ECRI, Hayes, Cochrane, and PubMed databases • Shockwave Coronary Intravascular Lithotripsy System (Shockwave Medical, Inc.) for Treating Coronary Artery Disease. ECRI (2021). • Sattar et al. Coronary intravascular lithotripsy for coronary artery calcifications- systematic review of cases. PMID: 33889320. • Sheikh et al. Intravascular lithotripsy for severe coronary calcification: a systematic review. PMID: 34713678. • Shockwave Peripheral Intravascular Lithotripsy System for Treating Peripheral Artery Disease. ECRI (2023). • National Institutes for Health and Care Excellence (NICE). Intravascular lithotripsy for calcified coronary arteries during percutaneous coronary intervention. June 2020.

Table 2.4

Percutaneous Transcatheter Closure of Paravalvular Leak		
Device/Product, and Manufacturer Information (when applicable)		
Code(s)	93590	Percutaneous transcatheter closure of paravalvular leak; initial occlusion device, mitral valve *(Effective 1/1/2017)*
	93591	Percutaneous transcatheter closure of paravalvular leak; initial occlusion device, aortic valve *(Effective 1/1/2017)*
	93592	Percutaneous transcatheter closure of paravalvular leak; each additional occlusion device (List separately in addition to code for primary procedure) *(Effective 1/1/2017)*
Medicare Coverage Notes and Evidence Summary		These services are not medically necessary under Section 1862(a)(1) of the Social Security Act, **UNLESS** the services are rendered in the context of a Medicare-approved IDE study. 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*.)* When

	not rendered in the context of an IDE study, Medicare coverage criteria are considered "not fully established," so internal coverage criteria will be applied, based on an evidence review of the references and guidelines cited below. There are currently no FDA approved devices that are indicated for percutaneous transcatheter closure of paravalvular leak. Using devices such as the Amplatzer Vascular Plug is considered an off-label use. Therefore, percutaneous transcatheter closure of paravalvular leak is considered **not medically necessary**.
Sources/Citations	• ECRI, Hayes, Cochrane, and PubMed databases • National Institutes for Health and Care Excellence (NICE)

Table 2.5

Near-Infrared Dual Imaging of Meibomian Glands		
Device/Product, and Manufacturer Information (when applicable)		LipiScan Dynamic Meibomian Imager
Code(s)	0507T	Near-infrared dual imaging (ie, simultaneous reflective and trans- illuminated light) of meibomian glands, unilateral or bilateral, with interpretation and report *(Effective 7/1/2018)*
Medicare Coverage Notes and Evidence Summary		These services are not medically necessary under Section 1862(a)(1) of the Social Security Act. Medicare coverage criteria are considered "not fully established," so internal coverage criteria will be applied, based on an evidence review of the references and guidelines cited below. For individuals who have dry eye symptoms who receive near infrared dual imaging (e.g., LipiScan Dynamic Meibomian Imager) there are no randomized controlled trials (RCTs) to support the use of this technology on health outcomes. Additional RCTs with large sample sizes are needed to determine the effects of this technology on health outcomes. Furthermore, no clinical guidelines were identified recommending LipiScan. Therefore, use of the LipiScan device is considered **not medically necessary** for all indications.
Sources/Citations		• Tear Science Website • Nichols JJ, Berntsen DA, Mitchell GL, Nichols KK. An assessment of grading scales for meibography images. Cornea. 2005 May;24(4):382-8. Doi: 10.1097/01.ico.0000148291.38076.59. PMID: 15829792. • UpToDate. Blepharitis. Last updated No 6, 2023. Accessed Feb 12, 2024. https://www.uptodate.com/contents/blepharitis

Table 2.6

Iris Prosthesis Insertion	
Device/Product, and Manufacturer Information (when applicable)	CustomFlex Artificial Iris, Human Optics

Code(s)	66683	Implantation of iris prosthesis, including suture fixation and repair or removal of iris, when performed *(Effective 1/1/2025)*
	C1839	Iris prosthesis
Medicare Coverage Notes and Evidence Summary		These services are not medically necessary under Section 1862(a)(1) of the Social Security Act. Medicare coverage criteria are considered "not fully established," so internal coverage criteria will be applied, based on an evidence review of the references and guidelines cited below. There is insufficient evidence to support the use of the CustomFlex Artificial Iris for treating any indication, including congenital or traumatic aniridia. In general, sample populations are small, follow-up periods are short, studies are retrospective, study populations are heterogeneous, and surgical techniques vary precluding generalization of overall safety and efficacy. Large, prospective, multicenter studies are required In order to confirm findings and validate CustomFlex for individuals with congenital and acquired aniridia. Furthermore, no clinical guidelines were identified that support the use of this device. Therefore, the use of implanted artificial iris devices is considered **not medically necessary** for the treatment of any indication.
Sources/Citations		• ECRI, Hayes, Cochrane, and PubMed databases • Hayes. CustomFlex ArtificialIris (HumanOptics AG, Clinical Research Consultants Inc.) for Aniridia. • CustomFlex Artificial Iris Prosthesis (HumanOptics AG) for Repairing Iris Defects. ECRI (2021). • Romano et al. Artificial iris implantation in congenital aniridia: A systematic review. PMID: 3637930. • Ayers et al. Results of the United States Food and Drug Administration Clinical Trial of the CustomFlex Artificial Iris. PMID: 35131359. • National Institutes for Health and Care Excellence (NICE). Intravascular lithotripsy for calcified coronary arteries during percutaneous coronary intervention. June 2020.

Table 2.7

Transcatheter Left Ventricular Restoration Device		
Device/Product, and Manufacturer Information (when applicable)		AccuCinch Ventricular Restoration System and Revivent TC System – BioVentrix
Code(s)	0643T	Transcatheter left ventricular restoration device implantation including right and left heart catheterization and left ventriculography when performed, arterial approach *(Effective 7/1/2021)*
Medicare Coverage Notes and Evidence Summary		The AccuCinch Ventricular Restoration System has been granted Breakthrough Device Designation by the FDA. However, these services are not medically necessary under Section 1862(a)(1) of the Social Security Act, **UNLESS** the services are rendered in the context of a Medicare-approved IDE study. As of the most recent review of this policy, Medicare-approved Category B IDE studies include the following: • 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. • 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. Coverage may be considered 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*.)* When **not** rendered in the context of an IDE study, Medicare coverage criteria are considered "not fully established," so internal coverage criteria will be applied, based on an evidence review of the references and guidelines cited below. There is insufficient evidence to support ventricular restorative devices (e.g., AccuCinch and BioVentrix Revivent TC™ System) for any indication, including heart failure. Additionally, while the FDA has granted the AccuCinch device the "Breakthrough Device Designation", it has yet to receive FDA approval. Coverage may be considered for members enrolled in one of these Medicare-approved studies. Otherwise, ventricular restorative devices such as AccuCinch and the BioVentrix Revivent TC™ System are considered **not medically necessary** for the treatment of any indication.
Sources/Citations	• ECRI, Hayes, Cochrane, and PubMed databases • Clinical evidence assessment on the AccuCinch Restoration System. ECRI (2022).

Table 2.8

Subchondral Calcium Phosphate (SCP) Injection (Subchondroplasty)		
Device/Product, and Manufacturer Information (when applicable)		N/A
Code(s)	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 *(Effective 1/1/2022)*
	0869T	Injection(s), bone-substitute material for bone and/or soft tissue hardware fixation augmentation, including intraoperative imaging guidance, when performed *(Effective 7/1/2024)*
Medicare Coverage Notes and Evidence Summary		These services are not medically necessary under Section 1862(a)(1) of the Social Security Act. Medicare coverage criteria are considered "not fully established," so internal coverage criteria will be applied, based on an evidence review of the references and guidelines cited below.

	There is not enough evidence to support the use of subchondral calcium phosphate injections for knee bone marrow lesions. The current evidence is very poor. Long term, randomized studies are needed to determine efficacy and safety of the injections. Furthermore, no guidelines were identified recommending subchondroplasty for bone osteoarthritis or any other indication. Therefore, subchondral calcium phosphate injections (subchondroplasty) are considered **not medically necessary** for all indications, including the treatment of bone osteoarthritis
Sources/Citations	• ECRI, Hayes, Cochrane, and PubMed databases • Hayes. Subchondral Calcium Phosphate Injections for Knee Bone Marrow Lesions. (2023). Hayes reviewed studies by the following: ○ Farr and Cohen (2013) ○ Cohen and Sharkey (2016) ○ Levy and Cousins (2020) ○ Krebs et al. (2020) ○ Chua et al. (2021) ○ Pasqualotto et al. (2021) ○ Chatterjee et al. (2015) • No relevant clinical practice guidelines were identified

Table 2.9

MyoPro™ Myoelectric Upper Limb Orthotic		
Device/Product, and Manufacturer Information (when applicable)		MyoPro™ myoelectric upper limb **orthotics** *(NOTE: Myoelectric **prosthetics** are addressed in a separate medical policy.)*
Code(s)	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 *(Effective 1/1/2019)*
	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 *(Effective 1/1/2019)*
Medicare Coverage Notes and Evidence Summary		According to *Social Security Act §1861(s)(9),* while orthoses may be covered under the Medicare Braces Benefit, all durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) need to be **both** medically reasonable and medically necessary to meet the functional needs of the individual patient. Under Medicare, only medically reasonable and necessary services are covered *(Title XVIII of the Social Security Act, §1862(a)(1)(A)).* Coverage of DMEPOS includes determining if there is a "less costly alternative" which can provide the needed and appropriate therapeutic benefit for the individual. Items which provide features beyond what is necessary to support the body member would fall under the category of an ""upgrade"" Upgrades include "excess components" to an orthotic device (e.g., a feature, an accessory, or a service) that are in addition to, or more extensive and/or more expensive than what is reasonable and necessary under Medicare's coverage requirements.

	While there is coding instruction provided by the Medicare Pricing, Data Analysis and Coding (PDAC) contractor, no specific Medicare coverage policy or guidance (e.g., manual, national coverage determination [NCD], local coverage determination [LCD] article [LCA], etc.) was identified specific to the MyoPro device or technology. Since Medicare coverage criteria are considered "not fully established," internal coverage criteria will be applied, based on an evidence review of the references and guidelines cited below. Evidence is insufficient to recommend the use of the MyoPro orthosis for any indication. No other payors are covering this device at this time, just the myoelectric upper limb prostheses with stand body-powered prosthetic devices that meet criteria. Recent Hayes reviews and an ECRI review identified too few published articles to consider evidence sufficient to support this technology. Therefore, the MyoPro orthosis is considered **not medically necessary** for any indication.
Sources/Citations	• ECRI, Hayes, Cochrane, and PubMed databases • No relevant clinical practice guidelines were identified • Medicare Claims Processing Manual, Pub. #100-04, Chapter 20–- Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS), §10.1.3–- Prosthetics and Orthotics (Leg, Arm, Back, and Neck Braces, Trusses, and Artificial Legs, Arms, and Eyes)–- Coverage Definition • Medicare Claims Processing Manual, Pub. #100-04, Chapter 20–- Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS), §120–- DME MACs–- Billing Procedures Related To Advanced Beneficiary Notice (ABN) Upgrades • Medicare Benefit Policy Manual, Pub. #100-02, Chapter 15–- Covered Medical and Other Health Services, §110.1–- Definition of Durable Medical Equipment, C. Necessary and Reasonable, 2. Reasonableness of the Equipment • Palmetto PDAC website for MyoPro® coding; Available at: MyoPro® (Myomo, Inc.) Assist Device–- Correct Coding – Revised

Table 2.10

MicroGenDX qPCR & NGS		
Device/Product, and Manufacturer Information (when applicable)		MicroGenDX qPCR & NGS
Code(s)	0112U	Infectious agent detection and identification, targeted sequence analysis (16S and 18S rRNA genes) with drug-resistance gene *(Effective 10/1/2019)*
Medicare Coverage Notes and Evidence Summary		These services are not medically necessary under Section 1862(a)(1) of the Social Security Act. Medicare coverage criteria are considered "not fully established," so internal coverage criteria will be applied, based on an evidence review of the references and guidelines cited below. There is not enough evidence to show that the MicroGen DX Next-Gen DNA Sequencing test has established clinical utility. Furthermore, there is no evidence to show that it can be used to manage treatment decisions and/or

	improve health outcomes for any indication. In addition, no clinical practice guidelines recommend the use of this test. Therefore, the MicroGen DX Next-Gen DNA Sequencing test is considered **not medically necessary** for the diagnosis of infectious diseases. These tests are not current standard of care, and do not meet Medicare's medically "reasonable" and necessary requirements. Non-coverage of these tests does not limit access to care for patients as clinically acceptable alternative test options are available.
Sources/Citations	• ECRI, Hayes, Cochrane, and PubMed databases • Hayes molecular test assessment for Karius Test to diagnose Infections in immunocompromised or vulnerable hospitalized patients (2022, updated 2023) • McDonald M, Kameh D, Johnson ME, Johansen TEB, Albala D, Mouraviev V. A Head-to-Head Comparative Phase II Study of Standard Urine Culture and Sensitivity Versus DNA Next-generation Sequencing Testing for Urinary Tract Infections. Rev Urol. 2017;19(4):213-220. doi: 10.3909/riu0780. PMID: 29472825; PMCID: PMC5811878. • Tarabichi M, Shohat N, Goswami K, Parvizi J. Can next generation sequencing play a role in detecting pathogens in synovial fluid? Bone Joint J. 2018 Feb;100-B(2):127-133. doi: 10.1302/0301-620X.100B2.BJJ-2017-0531.R2. PMID: 29437053.

Table 2.11

Avise® Lupus		
Device/Product, and Manufacturer Information (when applicable)		aisle® DX Disease Activity Index (Progentec Diagnostics, Inc.; Oklahoma) and aisle® DX Flare Risk Index (Progentec Diagnostics, Inc.; Oklahoma)
Code(s)	0446U	Autoimmune diseases (systemic lupus erythematosus [SLE]), analysis of 10 cytokine soluble mediator biomarkers by immunoassay, plasma, individual components reported with an algorithmic risk score for current disease activity *(Effective 4/1/2024)*
	0447U	Autoimmune diseases (systemic lupus erythematosus [SLE]), analysis of 11 cytokine soluble mediator biomarkers by immunoassay, plasma, individual components reported with an algorithmic prognostic risk score for developing a clinical flare *(Effective 4/1/2024)*
Medicare Coverage Notes and Evidence Summary		These services are not medically necessary under Section 1862(a)(1) of the Social Security Act. The Part B Medicare Contractor (MAC) for this laboratory location of Oklahoma is Novitas Solutions. While this MAC provides an LCD for biomarkers in general (LCD L35062), they do not provide specific coverage policy criteria for proteomic testing. The LCD L35062 states coverage is predicated on an underlying performance of acceptable, high-quality analytical validity for such testing, as well as recognized decision impact by the clinical community. Since Medicare coverage criteria are considered "not fully established," internal coverage criteria based on an evidence review of the references and guidelines cited

	below will be used to determine if these tests meet the LCD coverage requirements. Evidence is currently insufficient to support the use of the Avise Lupus Test. No evidence-based clinical practice guidelines were identified that address this service. Prospective diagnostic cohort studies that assess the test's clinical validity are needed, and comparative studies of patients whose diagnosis is guided by Avise Lupus and standard laboratory testing are needed to assess the test's clinical utility. The diagnosis of SLE remains complex and no single test or combination of tests are completely accurate. Therefore, serum biomarker panel testing for lupus and other connective tissue diseases (e.g. Avise Lupus Test) is considered **not medically necessary** for the treatment of any indication, including diagnosing systemic lupus erythematosus.
Sources/Citations	• ECRI, Hayes, Cochrane, and PubMed databases • ECRI published genetic test assessment about the Avise Lupus Test. (2023). • Alexander et al. A multianalyte assay panel with cellbound complement activation products demonstrates clinical utility in systemic lupus erythematosus. PMID: 34253650. • O'Malley et al. Complement activation products vs standard ANA testing: Treatment outcomes, diagnosis, and economic impact (CAPSTONE) in systemic lupus erythematosus. PMID: 35775579. Wallce et al. Randomised prospective trial to assess the clinical utility of multianalyte assay panel with complement activation products for the diagnosis of SLE. PMID: 31592328. • American College of Rheumatology (ACR). 2019 European League Against Rheumatism/American College of Rheumatology Classification Criteria for Systemic Lupus Erythematosus. 2019.

Table 2.13

Predictive Kidney Disease Testing		
Device/Product, and Manufacturer Information (when applicable)		NaviDKD™ Predictive Diagnostic Screening for Kidney Health test kits (Journey Biosciences, Inc.) PromarkerD (Sonic Reference Laboratory; Texas) Promarker®D, Proteomics International USA
Code(s)	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 *(Effective 4/1/2023)*
	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 *(Effective 4/1/2023)*
	0579U	Nephrology (diabetic chronic kidney disease), enzyme-linked immunosorbent assay (ELISA) of apolipoprotein A4 (APOA4), CD5 antigen-like (CD5L) combined with estimated glomerular filtration rate (GFR), age, plasma, algorithm reported as a risk score for kidney function decline *(Effective 10/1/2025)*
Medicare Coverage Notes and Evidence Summary		These services are not medically necessary under Section 1862(a)(1) of the Social Security Act. Medicare coverage criteria are considered "not fully established," so internal coverage criteria will be applied, based on an evidence review of the references and guidelines cited below. Evidence is currently insufficient to support the use of the tests for the prediction of renal decline in people with diabetes. There is currently a lack of high-quality studies and clinical practice guidelines that assess the PromarkerD Test System and no studies were identified on NaviDKD. Large studies with long-term follow-up that demonstrate clinical utility are necessary to definitively determine medical necessity. NICE guidelines recommend against the use of PromarkerD. Patients with diabetes should be tested annually for diabetic kidney disease; testing for patients' risk profile for DKD among this population is not considered standard of care. Tests for the prediction of renal decline (E.g., NaviDKD, PromarkerD) are considered **not medically necessary** for the treatment of any indication, including but not limited to assessing the risk of diabetic kidney disease (DKD) in patients with diabetes.
Sources/Citations		• ECRI, Hayes, Cochrane, and PubMed databases • Peters, et al. Canagliflozin Attenuates PromarkerD Diabetic Kidney Disease Risk Prediction Scores. PMID: 37176686. • Peters, et. al. PromarkerD Predicts Renal Function Decline in Type 2 Diabetes in the Canagliflozin Cardiovascular Assessment Study (CANVAS). PMID: 33036174. • Fusfeld, et. al. Evaluation of the clinical utility of the PromarkerD in-vitro test in predicting diabetic kidney disease and rapid renal decline through a conjoint analysis. PMID: 35913946. • Bringans, et. al. The New and the Old: Platform Cross-Vlaidation of Immunoaffinity MASS Spectrometry versus ELISA for PromarkerD, a Predictive Testfor Diabetic Kidney Disease. PMID: 33126588. • Bringans, et. al. A robust multiplex immunoaffinity mass spectrometry assay (PromarkerD) for clinical prediction of diabetic kidney disease. PMID: 33093819. • Bringans, et. al. Immunoaffinity Mass Spectrometry Diagnostic Tests for Multi-Biomarker Assays. PMID: 36781787. • Drinkwater, et. al. Assessment of biomarkers associated with rapid renal decline in the detection of retinopathy and its progression in type 2 diabetes: The Fremantle Diabetes Study Phase II. PMID: 33495038. • Peters, et. al. Validation of a protein biomarker test for predicting renal decline in type 2 diabetes: The Fremantle Diabetes Study Phase II. PMID: 31669066.

	• National Institute for Health and Care Excellence. PromarkerD for predicting the risk of diabetic kidney disease in people with type 2 diabetes. Published December 2022. https://www.nice.org.uk/advice/mib312/chapter/summary. Accessed 3/26/2024.

Table 2.14

XV Lung Ventilation Analysis Software (XV LVAS)		
Device/Product, and Manufacturer Information (when applicable)		XV Lung Ventilation Analysis Software (XV LVAS)
Code(s)	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 *(Effective 7/1/2023)*
	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 *(Effective 7/1/2023)*
	0877T	Augmentative analysis of chest computed tomography (CT) imaging data to provide categorical diagnostic subtype classification of interstitial lung disease; obtained without concurrent CT examination of any structure contained in previously acquired diagnostic imaging *(Effective 7/1/2024)*
	0878T	Augmentative analysis of chest computed tomography (CT) imaging data to provide categorical diagnostic subtype classification of interstitial lung disease; obtained with concurrent CT examination of the same structure *(Effective 7/1/2024)*
	0879T	Augmentative analysis of chest computed tomography (CT) imaging data to provide categorical diagnostic subtype classification of interstitial lung disease; radiological data preparation and transmission *(Effective 7/1/2024)*
	0880T	Augmentative analysis of chest computed tomography (CT) imaging data to provide categorical diagnostic subtype classification of interstitial lung disease; physician or other qualified health care professional interpretation and report *(Effective 7/1/2024)*
Medicare Coverage Notes and Evidence Summary		These services are not medically necessary under Section 1862(a)(1) of the Social Security Act. Medicare coverage criteria are considered "not fully established," so internal coverage criteria will be applied, based on an evidence review of the references and guidelines cited below. Evidence is currently insufficient to support the use of this service. There is currently a lack of high-quality studies and clinical practice guidelines that assess the XV LVAS® System. Large studies with long-term follow-up that demonstrate clinical utility are necessary to definitively determine medical

	necessity. Therefore, the XV LVAS® System is considered **not medically necessary** for the treatment of any indication.
Sources/Citations	• ECRI, Hayes, Cochrane, and PubMed databases. • No relevant clinical guidelines were identified. • Yamashiro T, Moriya H, Tsubakimoto M, et al. Preoperative assessment of parietal pleural invasion/adhesion of subpleural lung cancer: Advantage of software-assisted analysis of 4-dimensional dynamic-ventilation computed tomography. Eur Radiol. 2019;29(10):5247-5252. • Nagatani Y, Hashimoto M, Oshio Y, et al. Preoperative assessment of localized pleural adhesion: Utility of software-assisted analysis on dynamic-ventilation computed tomography. Eur J Radiol. 2020;133:109347.

Table 2.15

Gastric Electrophysiology Mapping with Simultaneous (GEMS) patient symptom profiling		
Device/Product, and Manufacturer Information (when applicable)		Gastric Electrophysiology Mapping with Simultaneous (GEMS) patient symptom profiling
Code(s)	0868T	High-resolution gastric electrophysiology mapping with simultaneous patient-symptom profiling, with interpretation and report *(Effective 7/1/2024)*
Medicare Coverage Notes and Evidence Summary		These services are not medically necessary under Section 1862(a)(1) of the Social Security Act. Medicare coverage criteria are considered "not fully established," so internal coverage criteria will be applied, based on an evidence review of the references and guidelines cited below. Evidence is currently insufficient to support the use of this service. There is currently a lack of high-quality studies and clinical practice guidelines that address this service. No evidence-based clinical practice guidelines exist as well. Therefore, gastric electrophysiology mapping is considered **not medically necessary** for the treatment of any indication.
Sources/Citations		• ECRI, Hayes, Cochrane, and PubMed databases. No studies were identified. • No relevant clinical guidelines were identified.

Table 2.16

PrecivityAD® Blood Tests for Alzheimer's Disease Prediction		
Device/Product, and Manufacturer Information (when applicable)		PrecivityAD® blood test (C2N Diagnostics LLC; Missouri) Precivity-ApoE™ (C2N Diagnostics, LLC; Missouri)
Code(s)	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 *(Effective 10/1/2023)*
	0596U	Neurology (Alzheimer disease), plasma, 3 distinct isoform-specific peptides (APOE2, APOE3, and APOE4) by liquid chromatography with tandem mass spectrometry (LCMS/MS), reported as an APOE prototype *(Effective 10/1/2025)*
Medicare Coverage Notes and Evidence Summary		These services are not medically necessary under Section 1862(a)(1) of the Social Security Act. Medicare coverage criteria are considered "not fully established," so internal coverage criteria will be applied, based on an evidence review of the references and guidelines cited below. **For PrecivityAD® blood test (C2N Diagnostics LLC; Missouri)** There is insufficient evidence to support beta amyloid immunoprecipitation with quantitation by liquid chromatography with tandem mass spectrometry (LC-MS/MS) and qualitative ApoE isoform-specific proteotyping. There is also a lack of comparison to standard of care testing. Therefore, beta amyloid immunoprecipitation with quantitation by liquid chromatography with tandem mass spectrometry (LC-MS/MS) and qualitative ApoE isoform-specific proteotyping is considered **not medically necessary** for the treatment of any indication. **For Precivity-ApoE™ (C2N Diagnostics, LLC; Missouri):** There is not enough evidence to support the use of APOE genetic testing for guiding diagnosis or risk assessment in Alzheimer's disease. A clinical utility evaluation found no peer-reviewed studies demonstrating that APOE testing improves diagnostic accuracy, alters clinical management, or leads to better health outcomes in either symptomatic individuals or asymptomatic individuals with a family history of the disease. Ethical concerns were noted, including psychological distress and lack of actionable medical interventions. Major professional organizations do not recommend APOE testing for predictive purposes, and multiple health plans classify the test as investigational or do not have published policies. Although APOE genotype may enhance the performance of certain biomarker algorithms, clinical guidelines do not support its use for risk prediction in asymptomatic individuals. Therefore, APOE genetic testing is considered **not medically necessary** for the diagnosis or risk assessment of Alzheimer's disease.
Sources/Citations		• ECRI, Hayes, Cochrane, and PubMed databases. No studies were identified. • Iino et al. Quantification of Amyloid-β in Plasma by Simple and Highly Sensitive Immunoaffinity Enrichment and LC-MS/MS Assay. PMID: 33462584. 2021. • Hayes. APOE Genetic Testing for Alzheimer Disease. 2 May 2018. • National Institute on Aging. The National Institute on Aging/Alzheimer's Association recommendations on the application of apolipoprotein E genotyping to Alzheimer's disease. 16 Dec 1996. PMID: 8993494. • Alzheimer's Association

Table 2.17

In-Person Monitoring & Intervention During Psychedelic Medication Therapy		
Device/Product, and Manufacturer Information (when applicable)		
Code(s)	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 *(Effective 1/1/2024)*
	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) *(Effective 1/1/2024)*
	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) *(Effective 1/1/2024)*
Medicare Coverage Notes and Evidence Summary		These services are not medically necessary under Section 1862(a)(1) of the Social Security Act. Medicare coverage criteria are considered "not fully established," so internal coverage criteria will be applied, based on an evidence review of the references and guidelines cited below. Evidence is currently insufficient to support the use of this psychedelic medication (e.g. ketamine) for the treatment of any indication. There is currently a lack of high-quality studies and clinical practice guidelines that assess these services. Large studies with long-term follow-up that demonstrate clinical utility are necessary to definitively determine medical necessity. Therefore, In-Person Monitoring and Intervention During Psychedelic Medication Therapy (e.g. ketamine) is considered **not medically necessary** for the treatment of any indication, including but not limited to psychiatric disorders (e.g. depression), chronic pain or chronic daily headache.
Sources/Citations		• ECRI, Hayes, Cochrane, and PubMed databases • ECRI published genetic test assessment about the Avise Lupus Test. (2023). • Schoevers et al (2016). Oral ketamine for the treatment of pain and treatment-resistant depression. PMID: 26834167. • Lauritsen et al (2016). Intravenous ketamine for subacute treatment of refractory chronic migraine: a case series. PMID: 27878523. • Pomeroy et al (2018). Ketamine Infusions for Treatment Refractory Headache. PMID: 28025837. • American Society of Regional Anesthesia and Pain Medicine (ASRA), The American Academy of Pain (AAP) and The American Society of Anesthesiologists (ASA). Consensus Guidelines on the Use of Intravenous Ketamine Infusions for Acute Pain Management From the American

	Society of Regional Anesthesia and Pain Medicine, the American Academy of Pain Medicine, and the American Society of Anesthesiologists. PMID: 29870457. • American Psychiatric Association (APA). A Consensus Statement on the Use of Ketamine in the Treatment of Mood Disorders. PMID: 28249076.

Table 2.18

Breast Opto-Acoustic Imaging		
Device/Product, and Manufacturer Information (when applicable)		
Code(s)	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) *(Effective 1/1/2024)*
Medicare Coverage Notes and Evidence Summary		These services are not medically necessary under Section 1862(a)(1) of the Social Security Act. Medicare coverage criteria are considered "not fully established," so internal coverage criteria will be applied, based on an evidence review of the references and guidelines cited below. There is insufficient evidence to support opto-acoustic imaging of the breast. Evidence is minimal and does not show this technology results in an improvement in the net health outcomes. No evidence-based clinical practice guidelines exist as well. Therefore, optoacoustic imaging of the breast is considered **not medically necessary** for the treatment of any indication, including but not limited to breast cancer.
Sources/Citations		• ECRI, Hayes, Cochrane, and PubMed databases. • Dogan et al. Optoacoustic Imaging and Gray-Scale US Features of Breast Cancers: Correlation with Molecular Subtypes. Radiology. 2019;292(3):564-572. • Menezes et al. Optoacoustic imaging of the breast: correlation with histopathology and histopathologic biomarkers. Eur Radiol. 2019;29(12):6728-6740. • No relevant clinical guidelines were identified, and NCCN breast cancer guidelines do not mention this technology.

Table 2.19

Near-Infrared Spectroscopy		
Device/Product, and Manufacturer Information (when applicable)		InfraReDx LipiScan NIR Catheter Imaging System
Code(s)	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) *(Effective 1/1/2024)*
Medicare Coverage Notes and Evidence Summary		These services are not medically necessary under Section 1862(a)(1) of the Social Security Act. Medicare coverage criteria are considered "not fully established," so internal coverage criteria will be applied, based on an evidence review of the references and guidelines cited below. There is insufficient evidence to support the efficacy of near-infrared spectroscopy to assess coronary artery plaque vulnerability, behavioral disorders, or for the prediction of wound healing. Additional studies of good methodological quality are required to support the clinical utility and medical necessity of this technology. Furthermore, no clinical practice guidelines assessed the use of near-infrared spectroscopy for any indication. Therefore near-infrared spectrometry is considered **not medically necessary** for assessing coronary artery plaque vulnerability.
Sources/Citations		• ECRI, Hayes, Cochrane, and PubMed databases. Hayes News Release: FDA Approves New Device to Measure the Fat Composition of Coronary Plaque. Published 2008. Accessed 1/1/2018. • Waxman S, Dixon SR, ''Allier P, et al. In vivo validation of a catheter-based near-infrared spectroscopy system for detection of lipid core coronary plaques: initial results of the SPECTACL study. JACC Cardiovascular imaging. 2009;2(7):858-868. • Kawashima C, Tanaka Y, Inoue A, et al. Hyperfunction of left lateral prefrontal cortex and automatic thoughts in social anxiety disorder: A near-infrared spectroscopy study. J Affect Disord. 2016;206:256-260. • U.S. Food and Drug Administration 510(k) Premarket Notification Letter: LipiScan Cornary Imaging System. https://www.accessdata.fda.gov/cdrh_docs/pdf7/K072932.pdf. Published 2008. Accessed 1/1/1018. • No relevant clinical guidelines were identified.

Table 2.20

Corpus Cavernosum Low-intensity Extracorporeal Shock Wave Therapy		
Device/Product, and Manufacturer Information (when applicable)		
Code(s)	0864T	Low-intensity extracorporeal shock wave therapy involving corpus cavernosum, low energy *(Effective 1/1/2024)*
Medicare Coverage Notes and Evidence Summary		These services are not medically necessary under Section 1862(a)(1) of the Social Security Act. Medicare coverage criteria are considered "not fully established," so internal coverage criteria will be applied, based on an evidence review of the references and guidelines cited below. Low-intensity extracorporeal shockwave therapy (Li-ESWT) is a novel treatment for erectile dysfunction (ED), thought to stimulate neovascularization and nerve regeneration, and as such, has gained interest in treatment of ED related to radical prostatectomy or radiation therapy.

	Evidence is currently insufficient to support the use of low-intensity extracorporeal shockwave therapy (Li-ESWT). The shockwave generator types and protocols (energy settings, dosing, frequency of use, probe locations, and duration of therapy) were inconsistent between studies and consequently difficult to compare. Two clinical practice guidelines that address Li-ESWT currently recommend **against** the procedure for the treatment of erectile dysfunction due to a lack of high-quality evidence. Large, randomized controlled trials with uniform treatment parameters are needed to determine clinical utility. Therefore, low-intensity extracorporeal shockwave therapy is considered **not medically necessary** for the treatment of erectile dysfunction.
Sources/Citations	• ECRI, Hayes, Cochrane, and PubMed databases. • Matthew et. al. The use of low-intensity extracorporeal shockwave therapy in management of erectile dysfunction following prostate cancer treatment: a review of the current literature. PMID: 37426598. 2023. • Campbell et. al. Meta-analysis of randomized controlled trials that assess the efficacy of low-intensity shockwave therapy for the treatment of erectile dysfunction. PMID: 30956690. 2019. Brunckhorst et. al. A systematic review of the long-term efficacy of low-intensity shockwave therapy for vasculogenic erectile dysfunction. PMID: 2019. • Bakr andEl-Sakka. Extracorporeal Shockwave Therapy in Peyronie's Disease: Systematic Review and Meta-Analysis. PMID. 34511369. 2021. • American Urology Association (AUA). • Sexual Medicine Society of North America (SMSNA)

Table 2.21

Analysis of Bone Strength and Fracture Risk		
Device/Product, and Manufacturer Information (when applicable)		
Code(s)	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 *(Effective 1/1/2023)*
Medicare Coverage Notes and Evidence Summary		These services are not medically necessary under Section 1862(a)(1) of the Social Security Act. When the code is used when the service is performed as a screening service, it would be non-covered under Medicare statute.[2] For other uses of this code/test, Medicare coverage criteria are considered "not fully established," so internal coverage criteria will be applied, based on an evidence review of the references and guidelines cited below.

	Evidence is currently insufficient to support the use of this service. There is currently a lack of high-quality studies and clinical practice guidelines that address this service. No evidence-based clinical practice guidelines exist as well. Therefore, bone strength and fracture risk using finite element analysis of functional data and bone mineral density is considered **not medically necessary** for the treatment of any indication. In addition, because this code is used when the service is performed as a screening service, it would be non-covered under Medicare statute until such time that it is added to the Medicare list of designated preventive services.[3]
Sources/Citations	• ECRI, Hayes, Cochrane, and PubMed databases • ECRI published genetic test assessment about the Avise Lupus Test. (2023). • Johannesdottir and associates (2018) reviewed the ability of CT-based methods. • Groenen and colleagues (2018). • Rajapakse and Chang (2018). • Allaire and co-workers (2019).

Table 2.22

Insertion of Bioprosthetic Valve		
Device/Product, and Manufacturer Information (when applicable)		VenoValve procedure
Code(s)	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 *(Effective 1/1/2023)*
Medicare Coverage Notes and Evidence Summary		These services are not medically necessary under Section 1862(a)(1) of the Social Security Act. The device/procedure is still in an experimental phase with active trials to determine its efficacy in patients with chronic venous insufficiency. Medicare coverage criteria are considered "not fully established," so internal coverage criteria will be applied, based on an evidence review of the references and guidelines cited below. There is not enough evidence to support the use of VenoValve for treating venous insufficiency or any other indication. Only feasibility studies exist with short term data and small sample sizes. Larger, randomized, comparative studies are needed. Furthermore, no clinical guidelines recommend VenoValve. Therefore, VenoValve is considered **not medically necessary** for any indication, including treating venous insufficiency.
Sources/Citations		• ECRI, Hayes, Cochrane, and PubMed databases. • Ulloa JH, Glickman M. One-Year First-in-Human Success for VenoValve in Treating Patients With Severe Deep Venous Insufficiency. Vascular and Endovascular Surgery. 2022;56(3):277-283. • No relevant clinical guidelines were identified.

Table 2.23

Anumana Artificial Intelligence (AI)-based Electrocardiography		
Device/Product, and Manufacturer Information (when applicable)		Anumana artificial intelligence (AI)-based electrocardiography (ECG) algorithm, Sensora Artificial Intelligence Software (Eko Health, Inc.), and HeartSciences (MyoVista)
Code(s)	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) *(Effective 1/1/2023)*
	0765T	Assistive algorithmic electrocardiogram risk-based assessment for cardiac dysfunction (eg, low-ejection fraction, pulmonary hypertension, hypertrophic cardiomyopathy); related to previously performed electrocardiogram *(Effective 1/1/2023)*
	0962T	Assistive algorithmic analysis of acoustic and electrocardiogram recording for detection of cardiac dysfunction (eg, reduced ejection fraction, cardiac murmurs, atrial fibrillation), with review and interpretation by a physician or other qualified health care professional *(Effective 7/1/2025)*
Medicare Coverage Notes and Evidence Summary		These services are not medically necessary under Section 1862(a)(1) of the Social Security Act. Medicare coverage criteria are considered "not fully established," so internal coverage criteria will be applied, based on an evidence review of the references and guidelines cited below. Evidence is currently insufficient to support the use of AI-based algorithms for use in detection of cardiac dysfunction. AI-based algorithms are not widely used or accepted in clinical guidelines, evidence is limited to low-level retrospective studies, and the technology in general is new to the medical world. Therefore, artificial intelligence (AI)- based electrocardiography is considered **not medically necessary** for any indication.
Sources/Citations		• ECRI, Hayes, Cochrane, and PubMed databases. • Chen HY, Lin CS, Fang WH, et al. Artificial intelligence-enabled electrocardiography predicts left ventricular dysfunction and future cardiovascular outcomes: a retrospective analysis. J Per Med. 2022 Mar; 12(3):455-480. PMID 35330455. • ECRI Clinical Evidence Assessment. 2025. • No relevant clinical guidelines were identified.

Table 2.24

Alzheimer's Disease Testing Not Otherwise Addressed	
Device/Product, and Manufacturer Information (when applicable)	Lumipulse® G β-Amyloid Ratio (1-42/1-40) Test (Fujirebio Diagnostics, Inc.; Pennsylvania) Elecsys® PhosphoTau (181P) CSF (pTau181) and βAmyloid (1-42) CSF II (Abeta 42) Ratio (Roche Diagnostics Operations, Inc.; Indiana)

		Elecsys® Total Tau CSF (tTau) and βAmyloid (1-42) CSF II (Abeta 42) Ratio (Roche Diagnostics Operations, Inc.; Indiana) ALZpath pTau217 (Neurocode USA, Inc., Quanterix/ALZpath) PrecivityAD2™ (C2N Diagnostics, LLC, C2N Diagnostics, LLC) Glial Fibrillary Acidic Protein Blood Test (Neurocode USA, Inc. & Fujirebio Diagnostics, Inc.) LucentAD p-Tau 217 and LucentAD™ Complete (Quanterix Corporation) MAP-AD® (ADmit Therapeutics S.L.)
Code(s)	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 *(Effective 1/1/2023)*
	0445U	β-amyloid (Abeta42) and 62hosphor tau (181P) (pTau181), electrochemiluminescent immunoassay (ECLIA), cerebral spinal fluid, ratio reported as positive or negative for amyloid pathology *(Effective 4/1/2024)*
	0459U	β-amyloid (Abeta42) and total tau (tTau), electrochemiluminescent immunoassay (ECLIA), cerebral spinal fluid, ratio reported as positive or negative for amyloid pathology
	0479U	Tau, phosphorylated, pTau217
	0503U	Neurology (Alzheimer disease), beta amyloid (Aβ40, Aβ42, Aβ42/40 ratio) and tau-protein (ptau217, np-tau217, ptau217/nptau217 ratio), blood, immunoprecipitation with quantitation by liquid chromatography with tandem mass spectrometry (LC-MS/MS), algorithm score reported as likelihood of positive or negative for amyloid plaques
	0548U	Glial fibrillary acidic protein (GFAP), chemiluminescent enzyme immunoassay, using plasma *(Effective 4/1/2025)*
	~~0551U~~	**TERMED 12/31/2025** ~~Tau, phosphorylated, pTau217, by single-molecule array (ultrasensitive digital protein detection), using plasma *(Effective 4/1/2025)*~~
	0568U	Neurology (dementia), beta amyloid (Aβ40, Aβ42, Aβ42/40 ratio), tau-protein phosphorylated at residue (eg, pTau217), neurofilament light chain (NfL), and glial fibrillary acidic protein (GFAP), by ultra-high sensitivity molecule array detection, plasma, algorithm reported as positive, intermediate, or negative for Alzheimer pathology *(Effective 7/1/2025)*
	0649U	Neurology (Alzheimer disease), DNA, targeted next-generation sequencing (NGS) of AD-1 and AD-2 target regions, whole blood, prognostic algorithmic analysis, reported as categorization of cognitive status
Medicare Coverage Notes and Evidence Summary		These services are not medically necessary under Section 1862(a)(1) of the Social Security Act. Medicare coverage criteria are considered “not fully established,” so internal coverage criteria will be applied, based on an evidence review of the references and guidelines cited below. Currently the diagnosis of Alzheimer's disease (AD) is a clinical diagnosis, focusing on the exclusion of other causes of dementia. In 1984 the National

	Institute of Neurological and Communicative Disorders and Stroke (NINCDS) and the Alzheimer's and Related Disorders Association (ADRDA) published clinical criteria for the diagnosis of AD. These organizations defined three categories: possible, probable, and definite AD. The only difference between probable and definite AD is that the definite category requires a brain biopsy confirming the presence of characteristic neurofibrillary tangles. Note the ALZpath pTau217 test is not available in the U.S. Evidence is currently insufficient to support the use of this service. There is currently a lack of high-quality studies that demonstrate that testing for Alzheimer disease (AD)-related biomarkers improves health outcomes for people who have AD, dementia, or mild cognitive impairment (MCI). For the MAP-AD® test, the current evidence base is limited by several factors, including reliance on observational study designs, lack of large independent validation cohorts, and limited transparency regarding test performance characteristics. Moreover, no clinical guidelines based on research recommend the use of AD biomarker, nor do they include or recommend mitochondrial DNA–based gene or epigenetic profiling tests such as MAP AD® for routine prognostic assessment. For MAP-AD®, there is no direct evidence demonstrating that use of the test improves patient outcomes, clinical decision making, or healthcare utilization compared with standard approaches. Accordingly, while the clinical utility of MAP AD® remains unproven pending further rigorous validation and integration into evidence based care frameworks. Therefore, beta amyloid and biomarker testing (e.g. Lumipulse, Elecsys Beta Amyloid, ALZpath pTau217, PrecivityAD2™, LucentAD, MAP-AD®) are considered **not medically necessary** for the diagnosis of Alzheimer's disease and other forms of cognitive impairment (e.g. dementia).
Sources/Citations	• ECRI, Hayes, Cochrane, and PubMed databases. • ECRI. Genetic Test Assessment cerebrospinal fluid-based assays for aiding diagnosis of Alzheimer's disease. 2022. • International Working Group. • Alzheimer's Association. • National Institute on Aging/Alzheimer's Association Diagnostic Guidelines for Alzheimer's Disease.

Table 2.25

Neurofilament Light Chain (NfL)		
Device/Product, and Manufacturer Information (when applicable)		Neurofilament Light Chain (NfL) (Mayo Clinic) and Neurofilament Light Chain (NfL) (Neuromuscular Clinical Laboratory at Washington University in St. Louis School of Medicine; Missouri) Neurofilament Light Blood Test (Neurocode USA, Inc. & Fujirebio Diagnostics, Inc.)
Code(s)	~~0361U~~	**TERMED 12/31/2025** ~~Neurofilament light chain, digital immunoassay, plasma, quantitative~~ ~~*(Effective 1/1/2023)*~~

	0443U	Neurofilament light chain (NfL), ultra-sensitive immunoassay, serum or cerebrospinal fluid *(Effective 4/1/2024)*
	0547U	Neurofilament light chain (NfL), chemiluminescent enzyme immunoassay, plasma, quantitative *(Effective 4/1/2025)*
Medicare Coverage Notes and Evidence Summary		These services are not medically necessary under Section 1862(a)(1) of the Social Security Act. Medicare coverage criteria are considered "not fully established," so internal coverage criteria will be applied, based on an evidence review of the references and guidelines cited below. There is insufficient evidence in the published literature to support the efficacy and clinical utility of blood-based biomarker tests to either expedite the diagnosis of MS or measure the risk for rapid progression of disability in individuals with RRMS, CIS, or any other condition. Therefore, Neurofilament Light Chain (NfL) testing is considered **not medically necessary** for the testing of any condition, including but not limited to Alzheimer's Disease, other forms of dementia, and multiple sclerosis.
Sources/Citations		• Seiberl and colleagues (2023) • Williams and colleagues (2022)

Table 2.26

IpsiHand™ Upper Extremity Rehabilitation System		
Device/Product, and Manufacturer Information (when applicable)		IpsiHand™ Upper Extremity Rehabilitation System (Neurolutions)
Code(s)	E0738	Upper extremity rehabilitation system providing active assistance to facilitate muscle re-education, include microprocessor, all components and accessories *(Effective 4/1/2024)*
Medicare Coverage Notes and Evidence Summary		These services are not medically necessary under Section 1862(a)(1) of the Social Security Act. Note that the development of a HCPCS code by CMS, in addition to a determination that an item meets the Medicare requirements to be considered "DME," do **not** establish the item to be both medically reasonable and necessary under Medicare. Since Medicare coverage criteria are considered "not fully established," internal coverage criteria will be applied, based on an evidence review of the references and guidelines cited below, to evaluate the product and how it improves health outcomes. There is not enough evidence to support the use of the IpsiHand System for treating chronic stroke patients. The technology is new and has only had preliminary research publications. Larger randomized trials are needed to determine efficacy. Furthermore, no clinical guidelines address the new technology. Therefore, IpsiHand is considered **not medically necessary** for treating patients with stroke.
Sources/Citations		• Rustamov N, Souders L, Sheehan L, Carter A, Leuthardt EC. IpsiHand Brain-Computer Interface Therapy Induces Broad Upper Extremity Motor Recovery in Chronic Stroke. medRxiv. 2023:2023.2008.2026.23294320.

	• No clinical practice guidelines identified.

Table 2.27

Motus Hand and Foot		
Device/Product, and Manufacturer Information (when applicable)		Motus Hand and Motus Foot
Code(s)	E0739	Rehabilitation system with interactive interface providing active assistance in rehabilitation therapy, includes all components and accessories, motors, microprocessors, sensors *(Effective 4/1/2024)*
Medicare Coverage Notes and Evidence Summary		These services are not medically necessary under Section 1862(a)(1) of the Social Security Act. Medicare coverage criteria are considered "not fully established," so internal coverage criteria will be applied, based on an evidence review of the references and guidelines cited below. There is not enough evidence to support the use of Motus Hand or Motus Foot for the rehabilitation of stroke patients. No studies were identifying comparing this robotic therapy to standard care and no studies were identified measuring patient-centered outcomes. Furthermore, no clinical guidelines were identified that mention these devices or support robotic rehabilitation over standard of care. Therefore, Motus Hand and Motus Foot are considered **not medically necessary** as a rehabilitation tool for any indication.
Sources/Citations		• Kabir R, Sunny MSH, Ahmed HU, Rahman MH. Hand Rehabilitation Devices: A Comprehensive Systematic Review. Micromachines. 2022;13(7):1033. • Greenfied R, Jeter, Russell, Housley, Stephen N., Igot, Belykh. Robotics-Assisted Stroke Rehabilitation with Machine Learning-Based Residual Severity Classification Georgia State University. https://math.gsu.edu/ibelykh/neuroengineering_and_rehabilitation_submitted.pdf. Published 2022. Accessed 3/27/2024. • No clinical practice guidelines identified.

Table 2.28

AI Based Arrhythmia Mapping System		
Device/Product, and Manufacturer Information (when applicable)		vMap (Vektor Medical)
Code(s)	0897T	Noninvasive augmentative arrhythmia analysis derived from quantitative computational cardiac arrhythmia simulations, based on selected intervals of interest from 12-lead electrocardiogram and uploaded clinical parameters, including uploading clinical parameters with interpretation and report *(Effective 7/1/2024)*
Medicare Coverage Notes and Evidence Summary		These services are not medically necessary under Section 1862(a)(1) of the Social Security Act. Medicare coverage criteria are considered "not fully

	established," so internal coverage criteria will be applied, based on an evidence review of the references and guidelines cited below. Evidence is currently insufficient to support the use of AI-based arrhythmia mapping systems (e.g. vMap). There is currently a lack of high-quality studies and clinical practice guidelines that address this service. Many of the studies evaluating AI-based Arrhythmia Mapping Systems are small-scale or retrospective in nature, limiting the generalizability of their findings. Larger, well-designed clinical trials with long-term follow-up data are needed to validate the effectiveness and safety of these systems across different patient populations. Standardization of data collection and validation methods is essential to ensure the reliability and accuracy of these systems in clinical practice. Therefore, the use of AI-based arrhythmia mapping systems, such as vMap, is considered **not medically necessary** for the treatment of any indication, including but not limited to, arrhythmias.
Sources/Citations	• A review of the ECRI, Hayes, Cochrane, and PubMed databases was conducted regarding the use of this service. Below is a list of literature identified for available evidence. • Krummen et al. Forward-Solution Noninvasive Computational Arrhythmia Mapping: The VMAP Study. Published: Sept. 2022. PMID: 36069189. • No clinical practice guidelines identified.

Table 2.29

AI Based Cancer Mapping System		
Device/Product, and Manufacturer Information (when applicable)		Unfold AI (Avenda Health)
Code(s)	0898T	Noninvasive prostate cancer estimation map, derived from augmentative analysis of image-guided fusion biopsy and pathology, including visualization of margin volume and location, with margin determination and physician interpretation and report *(Effective 7/1/2024)*
Medicare Coverage Notes and Evidence Summary		These services are not medically necessary under Section 1862(a)(1) of the Social Security Act. Medicare coverage criteria are considered "not fully established," so internal coverage criteria will be applied, based on an evidence review of the references and guidelines cited below. Evidence is currently insufficient to support the use of AI-based prostate cancer mapping (e.g. Unfold AI (Avenda Health)). There is currently a lack of peer-reviewed studies and clinical practice guidelines that address this service. Large, well-designed clinical trials with long-term follow-up data are needed to validate the effectiveness and safety of these systems across different patient populations. Standardization of data collection and validation methods is also essential to ensure the reliability and accuracy of these systems in clinical practice. Therefore, the use of AI-based cancer mapping systems, such as Unfold AI, is considered **not medically necessary**

	for the treatment of any indication, including but not limited to, prediction of extraprostatic disease extensions.
Sources/Citations	• A review of the ECRI, Hayes, Cochrane, and PubMed databases was conducted regarding the use of this service. • No published studies were identified. • No clinical practice guidelines were identified.

Table 2.30

M-inSight Assay for Mulitple Myeloma		
Device/Product, and Manufacturer Information (when applicable)		M-inSight® Patient Definition Assay and M-inSight® Patient Follow-Up Assessment (Corgenix Clinical Laboratory)
Code(s)	~~0450U~~	**TERMED 9/30/2025** ~~Oncology (multiple myeloma), liquid chromatography with tandem mass spectrometry (LCMS/MS), monoclonal paraprotein sequencing analysis, serum, results reported as baseline presence or absence of detectable clonotypic peptides *(Effective 7/1/2024)*~~
	~~0451U~~	**TERMED 9/30/2025** ~~Oncology (multiple myeloma), LCMS/MS, peptide ion quantification, serum, results compared with baseline to determine monoclonal paraprotein abundance *(Effective 7/1/2024)*~~
Medicare Coverage Notes and Evidence Summary		These services are not medically necessary under Section 1862(a)(1) of the Social Security Act. Medicare coverage criteria are considered "not fully established," so internal coverage criteria will be applied, based on an evidence review of the references and guidelines cited below. This test is not FDA approved, and currently bone marrow minimal residual testing is considered to be standard of care. According to the test manufacturer website, this test is not covered by Medicare or Medicaid, or by any private health insurance. In addition, there is not enough evidence to support the use of blood-based mass spectrometry MRD assay, M-InSight, to monitor patients with multiple myeloma. The current available published literature presents small sample sizes and focuses on test sensitivity and specificity, without long term results investigating clinical utility. Furthermore, no clinical guidelines were identified that recommend M-Insight, and blood-based mass spectrometry MRD testing is not yet FDA approved. Therefore, M-InSight is considered **not medically necessary** for multiple myeloma monitoring.
Sources/Citations		• A review of the ECRI, Hayes, Cochrane, and PubMed databases was conducted regarding the use of this service. • Corgenix. MinSight. Ultra sensitive personalized MRD testing on blood. 2024. https://www.minsight-mrd.com/discover-m-insight/. Accessed 6/26/2024. • Di Stefano L, Mouktadi Z, Vimard V, et al. Blood-Based Mass Spectrometry MRD Tracking (M-InSight) in Multiple Myeloma Patients

	from Clinical Trial NCT02513186. Blood. 2023;142(Supplement 1):3360-3360. https://doi.org/10.1182/blood-2023-179382 • International Myeloma Foundation. MRD and Mass Spectrometry Testing. 2024. https://www.myeloma.org/mrd-mass-spectrometry-testing. Accessed 6/26/2024. • No clinical practice guidelines were identified that recommend blood-based mass spectrometry MRD tracking.

Table 2.31

Breast Health Risk Assessment using Tears		
Device/Product, and Manufacturer Information (when applicable)		Auria® (Namida Lab, Inc.; Arkansas)
Code(s)	0458U	Oncology (breast cancer), S100A8 and S100A9, by enzyme-linked immunosorbent assay (ELISA), tear fluid with age, algorithm reported as a risk score *(Effective 7/1/2024)*
Medicare Coverage Notes and Evidence Summary		These services are not medically necessary under Section 1862(a)(1) of the Social Security Act. While CPT code 0458U is found in several MolDX LCAs for proteomic testing, these LCAs are not Novitas LCAs. The state of Arkansas is under Novitas jurisdiction (jurisdiction H or J-H), and Novitas does not generally use MolDX coverage or non-coverage guidelines. Therefore, these LCAs and any associated LCDs are not applicable. Since Medicare coverage criteria are considered "not fully established," internal coverage criteria will be applied, based on an evidence review of the references and guidelines cited below. Auria uses biomarkers in tears to catch any breast abnormalities. There remains insufficient evidence and clinical practice guidelines to support the use of biomarker tests using tears as a prediction/risk assessment of patients for breast cancer (including those of suspected breast cancer and/or those with family history of breast cancer). Therefore, biomarker testing from tears for breast cancer risk assessments (including Auria) is considered **not medically necessary** for the treatment of any indication, including but not limited to patients with suspected breast cancer and/or familial breast cancer history.
Sources/Citations		• A review of the ECRI, Hayes, Cochrane, and PubMed databases was conducted regarding the use of this service. • Daily, A. et al. Using tears as a non-invasive source for early detection of breast cancer. 2022. PMID: 35471994. • No clinical practice guidelines were identified that recommend biomarker testing using tears for breast abnormalities.

Table 2.32

Gait Modulation System

Device/Product, and Manufacturer Information (when applicable)		InTandem (MedRhythms Inc.)
Code(s)	E3200	Gait modulation system, rhythmic auditory stimulation, including restricted therapy software, all components and accessories, prescription only *(Effective 10/1/2024)*
Medicare Coverage Notes and Evidence Summary		These services are not medically necessary under Section 1862(a)(1) of the Social Security Act. Note that the development of a HCPCS code by CMS, in addition to a determination that an item meets the Medicare requirements to be considered "DME," do not establish the item to be both medically reasonable and necessary under Medicare. Since Medicare coverage criteria are considered "not fully established," internal coverage criteria will be applied, based on an evidence review of the references and guidelines cited below. There is insufficient evidence to support the safety and efficacy of a gait modulating system. There is also insufficient evidence to support significant clinical improvement with device. There is minimal evidence evaluating this technology, and no clinical practice guideline support. Additional evidence with comparative to standard practice, larger sample sizes, studies without high risk of bias, and larger volume of evidence. Therefore, gait modulation systems are considered **not medically necessary** for the treatment of any indication, including but not limited to gait impairment.
Sources/Citations		• A review of the ECRI, Hayes, Cochrane, and PubMed databases was conducted regarding the use of this service. • Smayda, et. al. Validating the Safe and Effective Use of a Neurorehabilitation System (InTandem) to Improve Walking in the Chronic Stroke Population: Usability Study. 2023. PMID: 37983080. • No clinical practice guidelines were identified to support the use of a gait modulating system.

Table 2.33

Therapeutic Drug Monitoring Using Non-Urine Specimens		
Device/Product, and Manufacturer Information (when applicable)		PrecisView® CNS, SyncView® Pain, SyncView® PainPlus, *and* SyncView® Rx (all by Phenomics Health™ Inc.; Michigan) SafeDrugs (Astraeus Lab, LLC)
Code(s)	0517U	Therapeutic drug monitoring, 80 or more psychoactive drugs or substances, LC-MS/MS, plasma, qualitative and quantitative therapeutic minimally and maximally effective dose of prescribed and non-prescribed medications *(Effective 10/1/2024)*
	0518U	Therapeutic drug monitoring, 90 or more pain and mental health drugs or substances, LC-MS/MS, plasma, qualitative and quantitative therapeutic minimally effective range of prescribed and non-prescribed medications *(Effective 10/1/2024)*

	0519U	Therapeutic drug monitoring, medications specific to pain, depression, and anxiety, LCMS/MS, plasma, 110 or more drugs or substances, qualitative and quantitative therapeutic minimally effective range of prescribed, non-prescribed, and illicit medications in circulation *(Effective 10/1/2024)*
	0520U	Therapeutic drug monitoring, 200 or more drugs or substances, LCMS/MS, plasma, qualitative and quantitative therapeutic minimally effective range of prescribed and non-prescribed medications *(Effective 10/1/2024)*
	0587U	Therapeutic drug monitoring, 60-150 drugs and metabolites, urine, saliva, quantitative liquid chromatography with tandem mass spectrometry (LCMS/MS), specimen validity, and algorithmic analyses for presence or absence of drug or metabolite, risk score predicted for adverse drug effects *(Effective 10/1/2025) (This code may be used for either urine drug testing or saliva drug testing)*
Medicare Coverage Notes and Evidence Summary		These services are not medically necessary under Section 1862(a)(1) of the Social Security Act. There is no Medicare coverage manual or NCD for therapeutic drug monitoring, and available LCDs are specific to ***urine*** drug testing. Therefore, since Medicare coverage criteria are considered "not fully established," internal coverage criteria will be applied, based on an evidence review of the references and guidelines cited below to review the product and how it improves health outcomes. Definitive testing is only recommended by clinical guidelines as a confirmatory test when presumptive testing does not offer a full picture of substances. Guidelines recommend testing for ***specific*** substances. Therefore broad spectrum testing, or testing for more than 7 drug classes per test, is considered **not medically necessary**.
Sources/Citations		• A review of the ECRI, Hayes, Cochrane, and PubMed databases was conducted regarding the use of this service. • Health Evidence Review Commission. Health Evidence Review Commission (HERC) Coverage Guidance: Urine Drug Testing. Approved 8/9/2018. https://www.oregon.gov/oha/HPA/DSI-HERC/EvidenceBasedReports/CG%20Urine%20Drug%20Testing.pdf. Accessed 11/3/2022. • Jarvis M, Williams J, Hurford M, et al. Appropriate Use of Drug Testing in Clinical Addiction Medicine. Journal of addiction medicine. 2017;11(3):163-17

Table 2.34

Sexually Transmitted Infection (STI) Pathogen Identification and Antibiotic Susceptibility Testing		
Device/Product, and Manufacturer Information (when applicable)		Ciprofloxacin Susceptibility of Neisseria gonorrhoeae *and* Macrolide Resistance of Mycoplasma genitalium (both by MedArbor Diagnostics & SpeeDx, Inc.; Pennsylvania)
Code(s)	0483U	Infectious disease (Neisseria gonorrhoeae), sensitivity, ciprofloxacin resistance (gyrA S91F point mutation), oral, rectal, or vaginal swab, algorithm reported as probability of fluoroquinolone resistance *(Effective 10/1/2024)*

	0484U	Infectious disease (Mycoplasma genitalium), macrolide sensitivity (23S rRNA point mutation), oral, rectal, or vaginal swab, algorithm reported as probability of macrolide resistance *(Effective 10/1/2024)*
Medicare Coverage Notes and Evidence Summary		These services are not medically necessary under Section 1862(a)(1) of the Social Security Act. Medicare coverage criteria are considered "not fully established," so internal coverage criteria will be applied, based on an evidence review of the references and guidelines cited below. Evidence is currently insufficient to support the use of sexually transmitted infection (STI) pathogen identification and antibiotic susceptibility testing with PCR technology, for any indication, including gonorrhea or mycoplasma genitalium (Mgen). There is currently a lack of high-quality studies and clinical practice guidelines that address this service. No evidence-based clinical practice guidelines exist as well. Therefore, sexually transmitted infection (STI) pathogen identification and antibiotic susceptibility testing with PCR technology is considered **not medically necessary** for the treatment of any indication, including gonorrhea or mycoplasma genitalium.
Sources/Citations		• A review of the ECRI, Hayes, Cochrane, and PubMed databases was conducted regarding the use of this service. • No published studies were identified. • No clinical practice guidelines were identified.

Table 2.35

Urinary Tract Infection Testing		
Device/Product, and Manufacturer Information (when applicable)		Urinary Tract Infection Testing (NxGen MDx LLC.; Michigan) BIOTIA-IDTM Urine NGS Assay (Biotia Inc.; New York)
Code(s)	0504U	Infectious disease (urinary tract infection), identification of 17 pathologic organisms, urine, realtime PCR, reported as positive or negative for each organism *(Effective 10/1/2024)*
	0590U	Infectious disease (bacterial and fungal), DNA of 44 organisms (34 bacteria, 10 fungi), urine, next-generation sequencing, reported as positive or negative for each organism *(Effective 10/1/2025)*
Medicare Coverage Notes and Evidence Summary		These services are not medically necessary under Section 1862(a)(1) of the Social Security Act. Medicare coverage criteria are considered "not fully established," so internal coverage criteria will be applied, based on an evidence review of the references and guidelines cited below. Standard diagnosis for symptomatic urinary tract infections (UTIs) is urinalysis or urine culture, depending on whether symptoms resolve or the frequency or recurrence. Currently, polymerase chain reaction (PCR) is not an accepted standard diagnostic tool for UTIs and there is not enough evidence to show efficacy over standard testing. Therefore, this Urinary Tract Infection Test by NxGen MDx is considered **not medically necessary**.

	This test is not current standard of care, and do not meet Medicare's medically "reasonable" and necessary requirements. Non-coverage does not limit access to care for patients as clinically acceptable alternative test options are available.
Sources/Citations	• A review of the ECRI, Hayes, Cochrane, and PubMed databases was conducted regarding the use of this service. • Szlachta-McGinn, Alec, et al. "Molecular diagnostic methods versus conventional urine culture for diagnosis and treatment of urinary tract infection: a systematic review and meta-analysis." *European Urology Open Science* 44 (2022): 113-124. • Colgan R, Williams M. Diagnosis and treatment of acute uncomplicated cystitis. Am Fam Physician. 2011 Oct 1;84(7):771-6. PMID: 22010614.

Table 2.36

Transcatheter Superior and Inferior Vena Cava Prosthetic Valve Implantation		
Device/Product, and Manufacturer Information (when applicable)		preCARDIA (preCARDIA Inc.)
Code(s)	0805T	Transcatheter superior and inferior vena cava prosthetic valve implantation (ie, caval valve implantation [CAVI]); percutaneous femoral vein approach *(Effective 7/1/2023)*
	0806T	Transcatheter superior and inferior vena cava prosthetic valve implantation (ie, caval valve implantation [CAVI]); open femoral vein approach *(Effective 7/1/2023)*
Medicare Coverage Notes and Evidence Summary		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. As of May 2023, the preCARDIA Occulsion System was given 510 premarket approval; however, FDA approval does not demonstrate medical necessity as defined by Medicare, nor does it automatically indicate Medicare coverage. However, this device is also the focus of a Medicare-approved Category B IDE study (*Superior Vena Caval Occlusion in Subjects With Acute Decompensated Heart Failure or VENUS-HF*; NCT03836079; G180213), evaluating the preCARDIA device. This IDE study is a Medicare-approved Category B IDE study as of 3/2020. While evidence is currently insufficient to support the use of caval or bi-caval valve implantation (CAVI) for transcatheter tricuspid valve repair or replacement, coverage exceptions may be made if the services are provided within the context of the above Medicare-approved IDE study. *(If not participating in the above IDE, please see the CMS website for IDEs to search for other possible Medicare-approved IDE studies related to this system.)* When **not** rendered in the context of an IDE study, Medicare coverage

	criteria are considered "not fully established," so internal coverage criteria will be applied, based on an evidence review of the references and guidelines cited below. Evidence is currently insufficient to support the use of caval or bi-caval valve implantation (CAVI) for transcatheter tricuspid valve repair or replacement. There is currently a lack of high-quality studies and clinical practice guidelines that address this service. No evidence-based clinical practice guidelines exist as well. Therefore, CAVI is considered **not medically necessary** for all indications, including tricuspid regurgitation or insufficiency.
Sources/Citations	• A review of the ECRI, Hayes, Cochrane, and PubMed databases was conducted regarding the use of this service. • Mattig I, Knebel F, Hewing B, Stangl V, Stangl K, Laule M, Dreger H. Impact of inferior caval valve implantation on severity of tricuspid regurgitation and right heart function. Echocardiography. 2020 Jul;37(7):999-1007. doi: 10.1111/echo.14760. Epub 2020 Jun 14. PMID: 32536000. • No clinical practice guidelines were identified.

Table 2.37

COMS® One Therapy System for Wound Care		
Device/Product, and Manufacturer Information (when applicable)		COMS® One Therapy System
Code(s)	0906T	Concurrent optical and magnetic stimulation (COMS) therapy, wound assessment and dressing care; first application, total wound(s) surface area less than or equal to 50 sq cm *(Effective 1/1/2025)*
	0907T	Concurrent optical and magnetic stimulation (COMS) therapy, wound assessment and dressing care; each additional application, total wound(s) surface area less than or equal to 50 sq cm (List separately in addition to code for primary procedure) *(Effective 1/1/2025)*
Medicare Coverage Notes and Evidence Summary		These services are not medically necessary under Section 1862(a)(1) of the Social Security Act. Medicare coverage criteria are considered "not fully established," so internal coverage criteria will be applied, based on an evidence review of the references and guidelines cited below. Evidence is insufficient to support the use of the COMS One Therapy System. No relevant studies or clinical practice guidelines addressing the service were identified. Additionally, the COMS One therapy system has not yet received regulatory approval in the U.S. Therefore, use of the COMS One Therapy System is considered **not medically necessary** for the treatment of any indication.
Sources/Citations		• A review of the ECRI, Hayes, Cochrane, and PubMed databases was conducted regarding the use of this service. • No published studies were identified. • No clinical practice guidelines were identified.

Table 2.38

Extraarticular Implantable Shock Absorber Knee Implant		
Device/Product, and Manufacturer Information (when applicable)		MISHA Knee System
Code(s)	C8003	Implantation of medial knee extraarticular implantable shock absorber spanning the knee joint from distal femur to proximal tibia, open, includes measurements, positioning and adjustments, with imaging guidance (eg, fluoroscopy) *(Effective 1/1/2025)* *There is no specific CPT code for the surgical implantation procedure (surgeon claim). Therefore, this should be billed with an unlisted code (e.g., 27599). As a C-code, HCPCS code C8003 would be reported on the hospital facility claim.*
Medicare Coverage Notes and Evidence Summary		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. As of April 2023, the MISHA™ Knee System was granted FDA-approval; however, FDA approval does not demonstrate medical necessity as defined by Medicare, nor does it automatically indicate Medicare coverage. These services are not medically necessary under Section 1862(a)(1) of the Social Security Act. Medicare coverage criteria are considered "not fully established," so internal coverage criteria will be applied, based on an evidence review of the references and guidelines cited below. There is insufficient evidence to support a shock or load absorber such as the MISHA knee system. Evidence is limited on this device, with conflict of interest, small sample sizes, limited comparative treatments, and no clinical practice guideline recommendations.
Sources/Citations		• ECRI published a Clinical Evidence Assessment in 2023. The authors found that there was "too few comparative data" and had limited confidence in the evidence when outcomes were evaluated. • Diduch et al. Implantable Shock Absorber Provides Superior Pain Relief and Functional Improvement Compared With High Tibial Osteotomy in Patients with Mild-to-Moderate Medial Knee Osteoarthritis: A 2-Year Report. Cartilage. 2023 Jun;14(2):152-163. DOI: 10.1177/19476035231157335. PMID: 36823955. • National Institute for Health and Care Excellence (NICE). Implantation of a shock or load absorber for mild to moderate symptomatic medial knee osteoarthritis. Published: 23 January 2015.

Table 2.39

3D Contour Simulation of Target Liver Lesion(s) and Simulation Angiogram with Pressure-Generating Catheter		
Device/Product, and Manufacturer Information (when applicable)		
Code(s)	0944T	3D contour simulation of target liver lesion(s) and margin(s) for image-guided percutaneous microwave ablation
	C8004	Simulation angiogram with use of a pressure-generating catheter (e.g., one-way valve, intermittently occluding), inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the angiogram, for subsequent therapeutic radioembolization of tumors
Medicare Coverage Notes and Evidence Summary		These services are not medically necessary under Section 1862(a)(1) of the Social Security Act. Medicare coverage criteria are considered "not fully established," so internal coverage criteria will be applied, based on an evidence review of the references and guidelines cited below. No evidence was identified that assessed the clinical utility of 3D contour simulation of target liver lesion(s) and margin(s) ablation or simulation angiogram with use of pressure-generating catheter. Additional high-quality studies are required in order to establish the effectiveness and safety of these treatment modalities. Therefore, these services for the treatment of liver tumors are considered **not medically necessary**.
Sources/Citations		• A review of the ECRI, Hayes, Cochrane, and PubMed databases was conducted regarding the use of these services. • No published studies were identified. • No clinical practice guidelines were identified.

Table 2.40

Sub-Scalp Continuous Electroencephalogram (EEG) Monitoring Device		
Device/Product, and Manufacturer Information (when applicable)		Minder®, 24/7EEG™ SubQ, and Epios™
Code(s)	0956T	Partial craniectomy, channel creation, and tunneling of electrode for sub-scalp implantation of an electrode array, receiver, and telemetry unit for continuous bilateral electroencephalography monitoring system, including imaging guidance *(Effective 7/1/2025)*
	0957T	Revision of sub-scalp implanted electrode array, receiver, and telemetry unit for electrode, when required, including imaging guidance *(Effective 7/1/2025)*
	0959T	Removal or replacement of magnet from coil assembly that is connected to continuous bilateral electroencephalography monitoring system, including imaging guidance *(Effective 7/1/2025)*
	0960T	Replacement of sub-scalp implanted electrode array, receiver, and telemetry unit with tunneling of electrode for continuous bilateral

		electroencephalography monitoring system, including imaging guidance *(Effective 7/1/2025)*
	1004T	Electronic analysis of implanted sub-scalp continuous bilateral electroencephalography monitoring system (eg, contact group[s], gain, bandpass filters) by physician or other qualified health care professional; without programming *(Effective 1/1/2026)*
	1005T	Electronic analysis of implanted sub-scalp continuous bilateral electroencephalography monitoring system (eg, contact group[s], gain, bandpass filters) by physician or other qualified health care professional; with programming, first 15 minutes face-to-face time with physician or other qualified health care professional *(Effective 1/1/2026)*
	1006T	Electronic analysis of implanted sub-scalp continuous bilateral electroencephalography monitoring system (eg, contact group[s], gain, bandpass filters) by physician or other qualified health care professional; with programming, each additional 15 minutes face-to-face time with physician or other qualified health care professional (List separately in addition to code for primary procedure) *(Effective 1/1/2026)*
	1007T	Electroencephalogram from implanted sub-scalp continuous bilateral electroencephalography monitoring system, physician or other qualified health care professional review of recorded events, analysis of spike and seizure detection, interpretation, and report, up to 30 days of recording without video *(Effective 1/1/2026)*
	1008T	Remote monitoring of sub-scalp implanted continuous bilateral electroencephalography monitoring system, device fitting, initial set-up, and patient education in wearing of system and use of equipment *(Effective 1/1/2026)*
	1009T	Remote monitoring of a sub-scalp implanted continuous bilateral electroencephalography monitoring system, physician or other qualified health care professional review of recorded events, analysis of spike and seizure detection, interpretation, and report, up to 30 days of recording without video *(Effective 1/1/2026)*
Medicare Coverage Notes and Evidence Summary		**Implantation of Devices** These services are not medically necessary under Section 1862(a)(1) of the Social Security Act. Medicare coverage criteria are considered "not fully established," so internal coverage criteria will be applied, based on an evidence review of the references and guidelines cited below. Sub-scalp EEG implantation via partial craniectomy represents a promising advancement in long-term neurological monitoring, particularly for patients with epilepsy. By enabling continuous, bilateral EEG recording over extended periods, this approach may improve diagnostic accuracy, support seizure forecasting, and reduce reliance on inpatient video EEG monitoring. Early studies suggest that sub-scalp EEG systems can reliably detect seizure activity and other brain wave patterns with signal quality comparable to traditional scalp EEG. However, the clinical utility of this procedure remains to be fully established. There is currently a lack of large-scale, peer-reviewed evidence demonstrating improved patient outcomes, cost-effectiveness, or superiority over existing diagnostic methods. Therefore, sub-scalp EEG

	implantation is considered **not medically necessary** for the treatment of any indication. **Removal of Non-Covered Devices** 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 (0958T) may be considered medically reasonable and necessary for unrelated reasons (e.g., pain, infection, etc.).
Sources/Citations	• A review of the ECRI, Hayes, Cochrane, and PubMed databases was conducted regarding the use of these services. • ECRI Clinical Evidence Assessment. 2025. • American Clinical Neuurophysiology Society (CNS).

Table 2.41

Endoluminal Temporary Colorectal Anastomosis Protection Device		
Device/Product, and Manufacturer Information (when applicable)		Colovac®
Code(s)	0967T	Transanal insertion of endoluminal temporary colorectal anastomosis protection device, including vacuum anchoring component and flexible sheath connected to external vacuum source and monitoring system *(Effective 7/1/2025)*
Medicare Coverage Notes and Evidence Summary		These services are not medically necessary under Section 1862(a)(1) of the Social Security Act. Medicare coverage criteria are considered "not fully established," so internal coverage criteria will be applied, based on an evidence review of the references and guidelines cited below. Colovac® is not yet FDA approved. However, the U.S. Food and Drug Administration (FDA) has granted Breakthrough Device Designation to Colovac, which is intended to expedite the development and review process for devices that offer significant advantages over existing treatments for life-threatening or irreversibly debilitating conditions. Colovac® is currently undergoing clinical evaluation in the U.S. and Europe and is not yet commercially available. Its approval will depend on the outcomes of ongoing pivotal studies and subsequent FDA review. Colovac® offers a novel, minimally invasive approach to protecting colorectal anastomoses following low anterior resection, with the goal of reducing reliance on diverting ileostomies. Early clinical studies suggest that the device can be safely implanted and retrieved, and may effectively shield the anastomosis from fecal contamination during the critical early healing period. In feasibility trials, Colovac+ enabled the avoidance of protective ileostomy in the majority of patients without increasing the risk of anastomotic leakage.

	However, the current evidence base is limited to small, early-phase studies, and no data yet demonstrate improved long-term outcomes or cost-effectiveness compared to standard care. Furthermore, the device has not been incorporated into clinical guidelines and remains investigational in the U.S. As such, while Colovac shows promise as an alternative to temporary stoma creation, its clinical utility remains to be fully established pending results from larger, randomized trials. Colovac® is considered investigational and services which lack scientific evidence regarding safety and efficacy because they are investigational are considered **not medically necessary** for Medicare members. *(Medicare Claims Processing Manual, Ch. 23, §30 A)*
Sources/Citations	• A review of the ECRI, Hayes, Cochrane, and PubMed databases was conducted regarding the use of these services. • De House, N, et al. Evaluation of the SafeHeal Colovac+ anastomosis protection device after low anterior resection for rectal cancer: the safe anastomosis feasibility evaluation (SAFE) 2019 trial. Surg Endosc. 2023 Sep;37(9):7385-7392. doi: 10.1007/s00464-023-10272-x. PMID: 37464064. • No clinical practice guidelines were identified.

Table 2.42

Percutaneous Laser Ablation of Breast Tumors		
Device/Product, and Manufacturer Information (when applicable)		Novilase® Interstitial Laser Therapy System (Novian Health)
Code(s)	0970T	Ablation, benign breast tumor (eg, fibroadenoma), percutaneous, laser, including imaging guidance when performed, each tumor *(Effective 7/1/2025)*
	0971T	Ablation, malignant breast tumor(s), percutaneous, laser, including imaging guidance when performed, unilateral *(Effective 7/1/2025)*
Medicare Coverage Notes and Evidence Summary		These services are not medically necessary under Section 1862(a)(1) of the Social Security Act. Medicare coverage criteria are considered "not fully established," so internal coverage criteria will be applied, based on an evidence review of the references and guidelines cited below. Novilase® is FDA-cleared for benign breast tumors, which aligns with CPT 0970T. For malignant breast tumors, Novilase has received FDA Breakthrough Device Designation but is not yet FDA-approved for this indication. It is currently being evaluated in a pivotal clinical trial (BR-003) for early-stage breast cancer. CPT 0971T was created to describe the investigational use of Novilase (or similar systems) for malignant breast tumor ablation, and is used in clinical trials or under investigational protocols.

	Laser ablation of benign breast tumors, such as fibroadenomas, offers a minimally invasive alternative to surgical excision, with the potential for reduced scarring, faster recovery, and high patient satisfaction. Early clinical data, including results from the ABLATE registry, suggest that laser ablation is safe and effective for small, well-characterized fibroadenomas, with favorable cosmetic outcomes and low complication rates. However, the clinical utility of this approach remains limited by the lack of randomized controlled trials and long-term comparative data. Additionally, laser ablation is not yet endorsed by major clinical guidelines and is considered investigational in the U.S., who note that focused ultrasound and laser ablation remain investigational in the U.S. and should be performed only within clinical trials or registries. Laser ablation of *benign* breast tumors (e.g. Novilase Interstitial Laser Therapy) is considered **not medically necessary**, while laser ablation of *malignant* breast tumors is considered investigational. Services which lack scientific evidence regarding safety and efficacy because they are investigational are also considered **not medically necessary** for Medicare members. *(Medicare Claims Processing Manual, Ch. 23, §30 A)*
Sources/Citations	• American Breast Laser Ablation Therapy Evaluation (ABLATE): Monitoring the Long Term Safety and Efficacy of Novilase™ Breast Interstitial Laser Therapy in Real World Application. • American Society of Breast Surgeons (ASBrS).

Table 2.43

Intravascular Imaging of Extracranial Cerebral Vessels with Optical Coherence Tomography (OCT)		
Device/Product, and Manufacturer Information (when applicable)		
Code(s)	0984T	Intravascular imaging of extracranial cerebral vessels using optical coherence tomography (OCT) during diagnostic evaluation and/or therapeutic intervention, including all associated radiological supervision, interpretation, and report; initial vessel (List separately in addition to code for primary procedure) *(Effective 7/1/2025)*
	0985T	Intravascular imaging of extracranial cerebral vessels using optical coherence tomography (OCT) during diagnostic evaluation and/or therapeutic intervention, including all associated radiological supervision, interpretation, and report; each additional vessel (List separately in addition to code for primary procedure) *(Effective 7/1/2025)*
	0986T	Intravascular imaging of intracranial cerebral vessels using optical coherence tomography (OCT) during diagnostic evaluation and/or therapeutic intervention, including all associated radiological supervision,

		interpretation, and report; initial vessel (List separately in addition to code for primary procedure) *(Effective 7/1/2025)*
	0987T	Intravascular imaging of intracranial cerebral vessels using optical coherence tomography (OCT) during diagnostic evaluation and/or therapeutic intervention, including all associated radiological supervision, interpretation, and report; each additional vessel (List separately in addition to code for primary procedure) *(Effective 7/1/2025)*
Medicare Coverage Notes and Evidence Summary		**NOTE:** The above Category III codes are add-on codes. As such, they are reported with other CPT codes. While some of these base procedure CPT codes may be covered, the above add-on codes are considered **not medically necessary**. These services are not medically necessary under Section 1862(a)(1) of the Social Security Act. Medicare coverage criteria are considered "not fully established," so internal coverage criteria will be applied, based on an evidence review of the references and guidelines cited below. There is not enough evidence to support the use of optical coherence tomography for evaluating coronary artery disease. Furthermore, no clinical guidelines recommend OCT over ultrasound imaging, which is standard of care. Therefore, optical coherence tomography is considered not medically necessary for any test or indication. Therefore, optical coherence tomography is considered **not medically necessary** for any test or indication.
Sources/Citations		• A review of the ECRI, Hayes, Cochrane, and PubMed databases was conducted regarding the use of these services. • ECRI. Intravascular Optical Coherence Tomography for Evaluating Coronary Artery Disease, Sept 11, 2019. https://members.ecri.org/evidenceanalysis/intravascular-optical-coherence-tomography-for-evaluating-coronary-artery-d. Accessed 7/3/2025. • Members WC, Levine GN, Bates ER, et al. 2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention. Circulation. 2011;124(23):e574-e651. https://www.ahajournals.org/doi/abs/10.1161/CIR.0b013e31823ba622 • Lawton JS, Tamis-Holland JE, Bangalore S, et al. 2021 ACC/AHA/SCAI Guideline for Coronary Artery Revascularization: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. Circulation. 2022;145(3):e18-e114. https://www.ahajournals.org/doi/abs/10.1161/CIR.0000000000001038 • NICE. Optical coherence tomography to guide percutaneous coronary intervention. Interventional procedures guidance. 23 February 2014. https://www.nice.org.uk/guidance/ipg481/chapter/1-Recommendations

Table 2.44

Traumatic Brain Injury (TBI) Point Of Care Testing

Device/Product, and Manufacturer Information (when applicable)		i-STAT TBI, Abbott Point of Care test kit
Code(s)	0570U	Neurology (traumatic brain injury), analysis of glial fibrillary acidic protein (GFAP) and ubiquitin carboxylterminal hydrolase L1 (UCHL1), immunoassay, whole blood or plasma, individual components reported with the overall result of elevated or non-elevated based on threshold comparison *(Effective 7/1/2025)*
Medicare Coverage Notes and Evidence Summary		These services are not medically necessary under Section 1862(a)(1) of the Social Security Act. Medicare coverage criteria are considered "not fully established," so internal coverage criteria will be applied, based on an evidence review of the references and guidelines cited below. The i-STAT TBI cartridge is the first point-of-care test that measures the level of biomarkers associated with brain injury in whole blood to help assess patients with suspected mTBI within 24 hours after injury. There is not enough evidence to support the use of the i-STAT TBI test for aiding in the diagnosis of traumatic brain injury. The available studies have a number of limitations, including lack of randomization and retrospective design. There were no studies identified on clinical utility. Furthermore, the test was shown to have poor specificity and high rate of false positives. Therefore, the i-STAT TBI test is considered **not medically necessary** for the diagnosis of traumatic brain injury.
Sources/Citations		• ECRI Clinical Evidence Assessment. 2023. • No clinical practice guidelines were identified.

Table 2.45

Multispectral Imaging with Algorithmic Classification for Burn Healing Assessment		
Device/Product, and Manufacturer Information (when applicable)		Spectral AI's DeepView® MIMOSA Diagnostics' MIMOSA Pro
Code(s)	0972T	Assistive algorithmic classification of burn healing (ie, healing or nonhealing) by noninvasive multispectral imaging, including system set-up and acquisition, selection, and transmission of images, with automated generation of report *(Effective 7/1/2025)*
Medicare Coverage Notes and Evidence Summary		These services are not medically necessary under Section 1862(a)(1) of the Social Security Act. Medicare coverage criteria are considered "not fully established," so internal coverage criteria will be applied, based on an evidence review of the references and guidelines cited below. Multispectral imaging combined with algorithmic classification offers a promising approach for assessing burn wound healing potential. This technique, exemplified by platforms like Spectral AI's DeepView® and

	MIMOSA Diagnostics' MIMOSA Pro, enables non-invasive visualization of tissue characteristics such as oxygenation and perfusion. These systems aim to support early, objective decision-making in wound care by identifying tissue viability and predicting healing trajectories. Despite their technological innovation and potential to improve diagnostic accuracy, the clinical utility of these tools remains unproven. DeepView has shown encouraging results in early studies and has received Breakthrough Device Designation, but it is still under FDA review via the De Novo pathway. MIMOSA Pro is FDA 510(k) cleared, yet lacks large-scale, peer-reviewed evidence demonstrating improved outcomes or cost-effectiveness. Neither system is currently included in major clinical practice guidelines. As such, multispectral imaging with algorithmic classification should be considered investigational or adjunctive. These tools may offer value in complex or uncertain clinical scenarios, but further validation is needed before they can be integrated into routine care. Therefore, artificial intelligence (AI)- based electrocardiography is considered **not medically necessary** for any indication.
Sources/Citations	• A review of the ECRI, Hayes, Cochrane, and PubMed databases was conducted regarding the use of these services. • No clinical practice guidelines were identified.

Table 2.46

inFoods® IBS Test		
Device/Product, and Manufacturer Information (when applicable)		inFoods® IBS (Ethos Laboratories)
Code(s)	0598U	Gastroenterology (irritable bowel syndrome), IgG antibodies to 18 food items by microarray-based immunoassay, whole blood or serum, report as elevated (positive) or normal (negative) antibody levels *(Effective 10/1/2025)*
Medicare Coverage Notes and Evidence Summary		These services are not medically necessary under Section 1862(a)(1) of the Social Security Act. Medicare coverage criteria are considered "not fully established," so internal coverage criteria will be applied, based on an evidence review of the references and guidelines cited below. There is currently no evidence to support the use of the inFoods IBS test for aiding in the treatment of irritable bowel syndrome (IBS). Therefore, the inFoods IBS test is considered **not medically necessary** for the treatment of IBS.
Sources/Citations		• A review of the ECRI, Hayes, Cochrane, and PubMed databases was conducted regarding the use of these services. • There are in-progress studies on this test but there are no published peer-reviewed articles. • No clinical practice guidelines were identified.

Table 2.47

Low-Energy Lithotripsy and Acoustically Actuated Microspheres		
Device/Product, and Manufacturer Information (when applicable)		AVVIO Enhanced Lithotripsy System (ELS) System (Avvio Medical)
Code(s)	0991T	Cystourethroscopy, with low-energy lithotripsy and acoustically actuated microspheres, including imaging *(Effective 1/1/2026)*
Medicare Coverage Notes and Evidence Summary		This is a novel kidney stone treatment system using microbubble enhanced acoustic cavitation lithotripsy. There are active clinical trials evaluating this technology and thus, safety and efficacy are not clearly established at this time. However, as of the most recent review of this policy, Medicare-approved Category B IDE studies include the following: • Evaluation of Enhanced Lithotripsy System (ELS) in the Treatment of Urinary Stones, A Pivotal Trial; NCT06942949. 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*.)* When **not** rendered in the context of an IDE study, Medicare coverage criteria are considered "not fully established," so internal coverage criteria will be applied, based on an evidence review of the references and guidelines cited below. A review of the ECRI, Hayes, Cochrane, and PubMed databases was conducted regarding the clinical utility of the AVVIO Enhanced Lithotripsy System. No evidence was identified as of December of 2025. In addition, no clinical practice guidelines recommend the use of the AVVIO Enhanced Lithotripsy System for the treatment of ureteral stones. There is insufficient evidence to evaluate the safety, efficacy, and clinical utility of the AVVIO Enhanced Lithotripsy System for the treatment of ureteral stones. Therefore, the AVVIO Enhanced Lithotripsy System is considered **not medically necessary** for all indications.
Sources/Citations		• A review of the ECRI, Hayes, Cochrane, and PubMed databases was conducted regarding the use of these services. • There are no published peer-reviewed articles. • No clinical practice guidelines for this medical technology were identified.

Table 2.48

AI-Powered Cardiac Risk Assessment From Augmentative Software Analysis of Perivascular Fat	
Device/Product, and Manufacturer	CaRi-Heart® analysis

Information (when applicable)		
Code(s)	0992T	Noninvasive assessment of cardiac risk derived from augmentative software analysis of perivascular fat **without** concurrent computed tomography (CT) scan of the heart, including patient-specific clinical factors, with interpretation and report by a physician or other qualified health care professional *(Effective 1/1/2026)*
	0993T	Noninvasive assessment of cardiac risk derived from augmentative software analysis of perivascular fat **with** concurrent computed tomography scan of the heart, including patient-specific clinical factors, with interpretation and report by a physician or other qualified health care professional (List separately in addition to code for primary procedure) *(Effective 1/1/2026)*
Medicare Coverage Notes and Evidence Summary		These services are not medically necessary under Section 1862(a)(1) of the Social Security Act. Medicare coverage criteria are considered "not fully established," so internal coverage criteria will be applied, based on an evidence review of the references and guidelines cited below. CaRi-Heart® analysis is AI-powered analysis of perivascular fat and cardiovascular risk. It is an artificial-intelligence (AI) software tool that measures inflammation in the coronary arteries using images already captured during a standard Coronary CT Angiography (CCTA) exam. There are active clinical trials evaluating this technology (e.g., CARE-CCTA; NCT07220304), and thus, safety and efficacy are not clearly established at this time. There is insufficient evidence to evaluate the safety, efficacy, and clinical utility of CaRi-Heart Technology (Caristo Diagnostics). A rapid systemic review found only one eligible study that suggested CaRi-Heart Risk may predict 8-year cardiac death; however, the evidence was rated as high risk of bias and poorly applicable to UK practice. No studies reported clinical outcomes or cost data, and conceptual cost-effectiveness modelling was based on limited exploratory searches rather than robust evidence. Overall, the evidence base is underdeveloped, and whether CaRi-Heart improves care compared to current standards remains uncertain. In addition, No clinical practice guidelines recommend the use of CaRi-Heart Technology (Caristo Diagnostics). Therefore, CaRi-Heart Technology is considered **not medically necessary** for any indication.
Sources/Citations		• A review of the ECRI, Hayes, Cochrane, and PubMed databases was conducted regarding the use of these services. • Westwood, M., et al. A cloud-based medical device for predicting cardiac risk in suspected coronary artery disease: a rapid review and conceptual economic model. Health Technol Assess. 2024 Jul;28(31):1-105. doi: 10.3310/WYGC4096. PMID: 39023142. • No clinical practice guidelines for this medical technology were identified.

Table 2.49

Air Displacement Plethysmography (ADP) for Whole Body Composition Assessment

Device/Product, and Manufacturer Information (when applicable)		BOD POD GS-X (COSMED)
Code(s)	1002T	Air displacement plethysmography, whole-body composition assessment, with interpretation and report *(Effective 1/1/2026)*
Medicare Coverage Notes and Evidence Summary		These services are not medically necessary under Section 1862(a)(1) of the Social Security Act. Medicare coverage criteria are considered "not fully established," so internal coverage criteria will be applied, based on an evidence review of the references and guidelines cited below. There is insufficient evidence to evaluate the safety, efficacy, and clinical utility of the BOD POD GS-X by COSMED. Therefore, the BOD POD GS-X by COSMED is considered **not medically necessary** for any indication.
Sources/Citations		• A review of the ECRI, Hayes, Cochrane, and PubMed databases was conducted regarding the use of these services. • There are no published peer-reviewed articles. • No clinical practice guidelines for this medical technology were identified.

Table 2.50

Retritrack Eye Movement Monitor		
Device/Product, and Manufacturer Information (when applicable)		Retitrack device
Code(s)	1010T	Computerized ophthalmic analysis of monocular eye movements using retinal-based eye-tracking without spatial calibration, including fixation, microsaccades, drift, and horizontal saccades, when performed, unilateral or bilateral, with interpretation and report *(Effective 1/1/2026)*
Medicare Coverage Notes and Evidence Summary		These services are not medically necessary under Section 1862(a)(1) of the Social Security Act. Medicare coverage criteria are considered "not fully established," so internal coverage criteria will be applied, based on an evidence review of the references and guidelines cited below. The only publications on the Retitrack device include an abstract and a descriptive study of the device. There is currently not enough evidence to support the use of the Retitrack device in patients with neurologic or ophthalmic disease. No studies or clinical guidelines were identified in support of the device. Therefore, the Retitrack device is considered **not medically necessary** for any indication.
Sources/Citations		• A review of the ECRI, Hayes, Cochrane, and PubMed databases was conducted regarding the use of these services. • Mackanos M, Karp J, Liddle S, Luck N, Gray D, Sheehy C. A NOVEL TRACKING SCANNING LASER OPTHALMOSCOPE (TSLO) SYSTEM FOR FIXATION AND SACCADE QUANTIFICATION. Investigative Ophthalmology & Visual Science. 2022;63(7):4455 – F0134-4455 – F0134.

	• Putnam NM, Ramakrishnan B, Wang J. Feasibility of fixational and saccadic eye movement measurements with retinal-based methods in amblyopes. Investigative Ophthalmology & Visual Science. 2025;66(8):2200-2200. • No clinical practice guidelines for this medical technology were identified.

Table 2.51

Ab Interno Sclerostomy or Trabeculectomy		
Device/Product, and Manufacturer Information (when applicable)		*Unable to place a specific device to the code, so this was reviewed as a procedure.*
Code(s)	1012T	Motorized ab interno trephination of sclera (sclerostomy), or trabecular meshwork (trabeculostomy), 1 or more, including injection of antifibrotic agents, when performed *(Effective 1/1/2026)*
Medicare Coverage Notes and Evidence Summary		These services are not medically necessary under Section 1862(a)(1) of the Social Security Act. Medicare coverage criteria are considered "not fully established," so internal coverage criteria will be applied, based on an evidence review of the references and guidelines cited below. Ab interno trabeculotomy (AIT) is a minimally invasive surgical procedure used to treat glaucoma. It aims to lower your eye pressure by increasing drainage of fluid out of your eye. There is currently not enough evidence to support the use of ab interno trabeculectomy or sclerostomy for treating glaucoma. The identified studies show no benefit of ab interno trabeculectomy over standard trabeculectomy treatment and no clinical guidelines support the procedure. Studies indicated additional glaucoma procedures were performed after ab interno trabeculectomy more frequently than afer trabeculectomy, and authors concluded that ab interno trabeculectomy has a lower success rate than trabeculectomy. Therefore, ab interno trabeculectomy or sclerostomy is considered **not medically necessary** for treating glaucoma.
Sources/Citations		• A review of the ECRI, Hayes, Cochrane, and PubMed databases was conducted regarding the use of these services. • Jea SY, Francis BA, Vakili G, Filippopoulos T, Rhee DJ. Ab interno trabeculectomy versus trabeculectomy for open-angle glaucoma. Ophthalmology. 2012;119(1):36-42. • Burr J, Azuara-Blanco A, Avenell A, Tuulonen A. Medical versus surgical interventions for open angle glaucoma. Cochrane Database Syst Rev. 2012;2012(9):Cd004399. • Boland MV, Ervin AM, Friedman DS, et al. Comparative effectiveness of treatments for open-angle glaucoma: a systematic review for the U.S. Preventive Services Task Force. Ann Intern Med. 2013;158(4):271-279. • No clinical practice guidelines for this medical technology were identified.

Table 2.52

Device/Product, and Manufacturer Information (when applicable)		Verisante Aura device
Code(s)	1020T	Raman spectroscopy of 1 or more skin lesions, with probability score for malignant risk derived by algorithmic analysis of data from each lesion *(Effective 1/1/2026)*
Medicare Coverage Notes and Evidence Summary		These services are not medically necessary under Section 1862(a)(1) of the Social Security Act. Medicare coverage criteria are considered "not fully established," so internal coverage criteria will be applied, based on an evidence review of the references and guidelines cited below. Raman spectroscopy is a promising technique for assessing the malignant risk of skin lesions. It is intended to provide a real-time, non-invasive molecular fingerprint of the tissue to differentiate between cancerous and benign growths. At this time, the clinical utility of Raman spectroscopy has yet to be determined and investigation in rigorous, well designed and conducted trials that permit reasonable conclusions concerning the effect of the device on health outcomes is needed. There is not enough evidence to support the use of Raman spectroscopy for the evaluation of skin lesions. No peer reviewed studies were identified on the clinical utility of the test and no clinical guidelines were identified that support its use. Therefore, Raman spectroscopy is considered **not medically necessary** for the evaluation of skin lesions.
Sources/Citations		• A review of the ECRI, Hayes, Cochrane, and PubMed databases was conducted regarding the use of these services. • Lui H, Zhao J, McLean D, Zeng H. Real-time Raman spectroscopy for in vivo skin cancer diagnosis. Cancer Res. 2012;72(10):2491-2500. • No clinical practice guidelines for this medical technology were identified.

Table 2.53

Device/Product, and Manufacturer Information (when applicable)		Kihealth Inc® Diabetes Risk Test (Kihealth Inc® Laboratory)
Code(s)	0602U	Endocrinology (diabetes), insulin (INS) gene methylation using digital droplet PCR, insulin, and C-peptide immunoassay, serum, Hemoglobin A1c immunoassay, whole blood, algorithm reported as diabetes-risk score *(Effective 1/1/2026)*
Medicare Coverage Notes and Evidence Summary		The Kihealth Inc's Diabetes Risk test is a direct-to-consumer, at-home blood test that claims to assess early diabetes risk by measuring a proprietary biomarker of beta-cell turnover (referred to as "BetaDx"), along with

	C-peptide, insulin, and hemoglobin A1C in samples processed by a CLIA-certified laboratory. The test is marketed as being developed in collaboration with Yale University and is presented as the first method capable of detecting early beta-cell demise before more traditional markers like A1C rise. Under Medicare, this would be considered "screening." There are currently no published clinical validation studies or peer-reviewed evidence supporting the performance of Kihealth's proprietary marker or the combined panel. The company's marketing emphasizes the beta-cell turnover biomarker's potential to detect diabetes earlier than A1C, but this claim lacks independent validation in clinical trials or comparison studies. No sensitivity, specificity, clinical outcomes, or utility data are available in the public domain. The only publicly available information comes from commercial product pages and promotional materials, and no diagnostic accuracy, analytic validation, or clinical utility studies are documented. Clinical practice guidelines do not mention measuring beta-cell turnover biomarkers in synovial fluid or blood as part of any established guideline. Rather, major diabetes-screening guidelines—from the American Diabetes Association (ADA), the U.S. Preventive Services Task Force (USPSTF), and other bodies—recommend screening based on fasting glucose, A1C, or oral glucose tolerance test in asymptomatic adults at elevated risk. UpToDate's review on diabetes screening similarly covers A1C, fasting glucose, and OGTT methods, without any reference to emerging molecular markers like those offered by Kihealth. Thus, Karen Heath's test is not included or endorsed in UpToDate or evidence-based screening protocols. In the absence of peer-reviewed data or guideline recognition, the test is not considered established or medically necessary. It remains a consumer health product with unproven clinical utility, and it is not recommended or included in current professional diabetes screening guidelines. Therefore, Kihealth Inc® Diabetes Risk Test is considered **not medically necessary** for the treatment of any indication. In addition, for Medicare members, it would not be a covered benefit as direct-to-consumer tests (aka, at-home tests or over-the-counter tests) are direct member benefit exclusions, even if recommended by a health care provider. Non-coverage of this test does not compromise or limit access to medically necessary care, since other testing options are available and standard.
Sources/Citations	• A review of the ECRI, Hayes, Cochrane, and PubMed databases was conducted regarding the use of these services. • There are no published peer-reviewed articles. • No clinical practice guidelines for this test were identified.

Table 2.54

Abdominal Aortic Aneurysm (AAA) Endovascular Stabilization Treatment

Device/Product, and Manufacturer Information (when applicable)		Nectero Endovascular Stabilization Treatment (Nectero EAST®) System, by Nectero Medical Inc.
Code(s)	0994T	Endovascular delivery of aortic wall stabilization drug therapy through a sheath positioned within an abdominal aortic aneurysm, with aortic roadmapping, balloon occlusion, imaging guidance, and radiological supervision and interpretation; percutaneous *(Effective 1/1/2026)*
	0995T	Endovascular delivery of aortic wall stabilization drug therapy through a sheath positioned within an abdominal aortic aneurysm, with aortic roadmapping, balloon occlusion, imaging guidance, and radiological supervision and interpretation; open *(Effective 1/1/2026)*
Medicare Coverage Notes and Evidence Summary		These services are not medically necessary under Section 1862(a)(1) of the Social Security Act. Medicare coverage criteria are considered "not fully established," so internal coverage criteria will be applied, based on an evidence review of the references and guidelines cited below. For small to mid-sized AAA, there is currently no proven treatment, while larger aneurysms (AAAs larger than 5.5cm for men or 5.0cm for women) may be treated with endovascular repair or surgery. For small to mid-size AAAs, current standard practice is to place the patient under surveillance, or "watch and wait" to track the size and growth of the aneurysm. Nectero Medical is conducting a clinical trial for the Nectero Endovascular Stabilization Treatment (Nectero EAST®) System in small to mid-sized abdominal aortic aneurysms (AAA). The Nectero EAST System is an investigational novel treatment that may slow AAA growth, potentially reduce the risk of rupture/bursting of smaller AAAs, and/or prevent or significantly delay the need for major endovascular repair (EVAR) or open surgical repair. There is insufficient evidence to evaluate the safety, efficacy, and clinical utility of the Nectero Endovascular Aneurysm Stabilization Treatment (Nectero EAST®) system. Only one study was identified, but it had several limitations, including no comparison group, no proof of clinical utility over other procedures, and small sample size. Therefore, the Nectero Endovascular Aneurysm Stabilization Treatment (Nectero EAST®) system is considered **not medically necessary** for any indication.
Sources/Citations		• A review of the ECRI, Hayes, Cochrane, and PubMed databases was conducted regarding the use of these services. • Cheng, S., et al. A pilot study to evaluate a novel localized treatment to stabilize small- to medium-sized infrarenal abdominal aortic aneurysms. J Vasc Surg . 2023 Oct;78(4):929-935.e1. doi: 10.1016/j.jvs.2023.05.056. Epub 2023 Jun 15. PMID: 37330148. • No clinical practice guidelines for this medical technology were identified.

Table 2.55

<table>
<tr><th colspan="3">High-Intensity Focused Ultrasound (HIFU) of the Liver and Pancrease</th></tr>
<tr><td colspan="2">Device/Product, and Manufacturer Information (when applicable)</td><td>Edison System® (Histosonics)</td></tr>
<tr><td>Code(s)</td><td>0686T</td><td>Histotripsy (ie, non-thermal ablation via acoustic energy delivery) of malignant hepatocellular tissue, including image guidance</td></tr>
<tr><td></td><td>0888T</td><td>Histotripsy (ie, non-thermal ablation via acoustic energy delivery) of malignant renal tissue, including imaging guidance</td></tr>
<tr><td></td><td>1037T</td><td>Histotripsy (ie, non-thermal ablation via acoustic energy delivery) of malignant pancreatic tissue, including imaging guidance</td></tr>
<tr><td colspan="2">Medicare Coverage Notes and Evidence Summary</td><td>Not medically necessary under Section 1862(a)(1) of the Social Security Act.

Applicable Medicare Coverage Policy, Regulation, or Guideline

• Medicare Benefit Policy Manual, Chapter 16 - General Exclusions From Coverage, §10 - General Exclusions from Coverage

Medicare-Based Non-Coverage Rationale

According to Medicare Benefit Policy Manual, Chapter 16 - General Exclusions From Coverage, 10 - General Exclusions from Coverage, services which are “investigational” are an exclusion from Medicare coverage. Services and items 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)

On October 6, 2023, the Edison System® by Histosonics received breakthrough device designation (BDD) from the FDA. HistoSonics submitted a de novo request to expand use of the Edison histotripsy system to include destruction of kidney tumors. However, currently the system is only approved for destruction of liver tumors.

While clearance by the FDA is a prerequisite for Medicare coverage, FDA approval does not in itself establish medical necessity. Medicare coverage is determined by a number of factors, including but not limited to, the availability of a Medicare benefit category and other statutory requirements, as well as national and local coverage determinations and clinical evidence.

In addition, receiving a BDD by the FDA does not mean a device is formally FDA approved. The BDD designation indicates the device has the potential to be more effective for a life-threatening condition, but it does not guarantee market authorization. The product must still undergo the standard FDA review process to be cleared, approved, or granted de novo classification. As with all FDA reviews and decisions, breakthrough device designation isn’t a guarantee of Medicare coverage.</td></tr>
</table>

	The Medicare Transitional Coverage for Emerging Technologies (TCET) pathway is a relatively new mechanism for potential coverage of BDD technologies. It aims to provide faster access for Medicare beneficiaries by offering coverage for *up to five* breakthrough designation devices per year while gathering necessary evidence for future coverage decisions. Examples of medical technologies which are part of this TCET pilot program include the OPTIMIZER Smart System (Impulse Dynamics), the Symplicity Spyral™ Renal Denervation (Medtronic) and Paradise Ultrasound Denervation (Recor Medical, Inc.) systems, the TriClip G4 System (Abbott) and the EVOQUE Tricuspid Valve Replacement System (EVOQUE system; Edwards Lifesciences). However, the Edison System® by Histosonics is not currently a technology covered under this TCET pilot program. At this time, histotripsy is still investigational and is undergoing trials. There is a lack of high-quality data, including randomized clinical studies, that establish benefit and long-term clinical outcomes. Specific Medicare coverage criteria does not exist (i.e., there is no NCD, LCD, etc.), and therefore, Medicare coverage is considered "not fully established" for histotripsy. There are Medicare-approved IDE studies currently in progress, as this is still considered experimental/investigational. Investigational or experimental procedures do **not** meet Medicare criteria as a medically reasonable and necessary procedure, unless the service is rendered in the context of a Medicare-approved study or clinical trial. Medicare-approved Category B IDE studies available as of 3/2021 and 6/2023 include the following studies and coverage may be approved for members enrolled in one of these studies. • #HOPE4**LIVER** (NCT04573881; G200253) is a Medicare-approved Category B IDE study (previously a Category A IDE study) as of 3/4/2021. • #HOPE4**KIDNEY** (NCT05820087; G230008) is a Medicare-approved Category B IDE study as of 6/15/2023. ***Note:*** *There is no Medicare-approved Category B IDE study for* ***pancreas*** *tumors as of the date of this policy update.* Coverage may be provided for members enrolled and services performed in the context of one of these Medicare-approved studies. If not, coverage is **not** available for this procedure/service and they are considered **not medically necessary** 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.*)*
Sources/Citations	• A review of the ECRI, Hayes, Cochrane, and PubMed databases was conducted regarding the use of these services. • Hayes Inc. High-Intensity Focused Ultrasound (HIFU) for Treatment of Hepatocellular Carcinoma. Updated 2012; Archived 2016. https://evidence.hayesinc.com/report/htb.hifu2628. Accessed 10/21/2024. • Wu F, Wang Z-B, Chen W-Z, et al. Extracorporeal high intensity focused ultrasound ablation in the treatment of patients with large

	hepatocellular carcinoma. Annals of surgical oncology. 2004;11(12):1061. • Yang R, Reilly CR, Rescorla FJ, et al. High-intensity focused ultrasound in the treatment of experimental liver cancer. Archives of surgery. 1991;126(8):1002-1010. • Illing R, Kennedy J, Wu F, et al. The safety and feasibility of extracorporeal high-intensity focused ultrasound (HIFU) for the treatment of liver and kidney tumours in a Western population. British journal of cancer. 2005;93(8):890. • Wu F, Chen W-Z, Bai J, et al. Pathological changes in human malignant carcinoma treated with high-intensity focused ultrasound. Ultrasound in medicine & biology. 2001;27(8):1099-1106. • Kennedy J, Wu F, Ter Haar G, et al. High-intensity focused ultrasound for the treatment of liver tumours. Ultrasonics. 2004;42(1):931-935. • Zhang L, Zhu H, Jin C, et al. High-intensity focused ultrasound (HIFU): effective and safe therapy for hepatocellular carcinoma adjacent to major hepatic veins. European radiology. 2009;19(2):437. • Mendiratta-Lala M, Wiggermann P, Pech M, et al. The# HOPE4LIVER single-arm pivotal trial for histotripsy of primary and metastatic liver tumors. Radiology. 2024;312(3):e233051. • U.S. Food and Drug Administration. Classification Order. 10/6/2023. Edison System. https://www.accessdata.fda.gov/cdrh_docs/pdf22/DEN220087.pdf. Accessed 1/21/2026. • U.S. Food and Drug Administration. Breakthrough Devices Program. https://www.fda.gov/medical-devices/how-study-and-market-your-device/breakthrough-devices-program. Accessed 1.21.2026. • Medicare Approved Investigational Device Exemption (IDE) Studies. https://www.cms.gov/medicare/coverage/investigational-device-exemption-ide-studies/approved. Searched 1.21.2026.

Table 2.56

Esprit BTK Everolimus-Eluting Scaffold for Chronic Limb-Threatening Ischemia		
Device/Product, and Manufacturer Information (when applicable)		Esprit BTK Everolimus Eluting Resorbable Scaffold System (Abbott Medical)
Code(s)	C1743	Scaffold, endovascular non-coronary, resorbable drug eluting, with delivery system (implantable)
Medicare Coverage Notes and Evidence Summary		These services are not medically necessary under Section 1862(a)(1) of the Social Security Act. The Esprit BTK is used to treat patients with chronic limb-threatening ischemia, which is associated with rest pain, wounds that do not heal, amputation, and increased mortality. This condition is caused by a buildup fatty substances, such as cholesterol, and calcification that form “plaque” along the lining of the arteries. The plaque formation can reduce, or totally

	block blood flow to the lower limb, and lead to persistent wounds in the feet. The U.S. FDA granted PMA approval to the Esprit BTK everolimus-eluting resorbable scaffold system in April 2024 (P230036). Since then, FDA has granted six supplements pertaining to postapproval study protocols, shelf life extension, and process changes. The most recent labeled indications read: "The Esprit BTK Everolimus Eluting Resorbable Scaffold System is indicated for improving luminal diameter in infrapopliteal lesions in patients with [CLTI] and total scaffolding length up to 170 mm with a reference vessel diameter of ≥2.5 mm and ≤4.00 mm." There is not enough evidence to support the use of Esprit BTK scaffold for treating chronic limb threatening ischemia (CLTI). Only one randomized trial was identified. While results appear promising, evidence reported in one well-designed and -conducted randomized clinical trial (RCT) does not permit conclusions on Esprit and percutaneous transluminal angioplastys (PTA) comparative safety and effectiveness for key patient-oriented outcomes (i.e., CD-TLRs, above-ankle amputations, major reinterventions, perioperative mortality). The study reports too few events per outcome to be conclusive about whether Esprit is more effective than PTA for improving these outcomes. More data with clinical outcomes reported are needed to determine efficacy and safety. The RCT reports outcomes up to one-year follow-up. Additional studies that compare Esprit with PTA and report on patient-oriented outcomes at long-term follow-up (>3 years) are needed to assess comparative safety and effectiveness. In addition, no clinical guidelines were identified that recommend this treatment. Therefore, Espirit BTK scaffold is considered **not medically necessary** for treating CLTI.
Sources/Citations	• U.S. FDA website. Esprit BTK Everolimus Eluting Resorbable Scaffold System – P230036. Current as of 12/04/2024. • Varcoe et al. Drug-Eluting Resorbable Scaffold versus Angioplasty for Infrapopliteal Artery Disease. 2024 Jan 4. PMID: 37888915.

Table 2.57

Noninvasive Hemodynamic Assessment		
Device/Product, and Manufacturer Information (when applicable)		Cardiac Performance System (CPS™) (Sensydia)
Code(s)	1036T	Noninvasive hemodynamic assessment with pulmonary pressures and ejection fraction when performed, including passive acquisition of acoustic and electrical signals, augmentative algorithmic analysis, and generation of a clinical report with review, interpretation, and clinical integration by a physician or other qualified health care professional
Medicare Coverage Notes and Evidence Summary		These services are not medically necessary under Section 1862(a)(1) of the Social Security Act.

	The Cardiac Performance System (CPS™) is undergoing a multi-center pivotal study to evaluate its accuracy of hemodynamic assessment as compared to the gold-standard invasive right heart catheterization. The study's outcomes will support Sensydia's FDA submission and commercialization of CPS. As of the date of this review, there is not enough evidence to support the use of Cardiac Performance System by Sensydia for collecting hemodynamic measurements. Studies were limited by small sample size, lacking clinical outcome measurements and randomized controlled trial designs. In addition, no guidelines were identified recommending the use of the Cardiac Performance System. Therefore, the Cardiac Performance System (CPS™) by Sensydia is considered **not medically necessary**.
Sources/Citations	• A review of the ECRI, Hayes, Cochrane, and PubMed databases was conducted regarding the use of these services. • Mace MI, Lala A, Fendler TJ, Sauer AJ. Emerging use of pulmonary artery and cardiac pressure sensing technology in the management of worsening heart failure events. Heart Failure Reviews. 2025;30(5):869-881. https://doi.org/10.1007/s10741-025-10513-2

Table 2.58

Autologous Muscle Derived Cells for Gastro-Intestinal Repair (AMDC-GIR) for The Treatment of Tongue Dysphagia (TD)		
Device/Product, and Manufacturer Information (when applicable)		
Code(s)	1038T	Autologous muscle cell therapy, injection(s) of muscle progenitor cells into the tongue, including esophagoscopy, when performed
Medicare Coverage Notes and Evidence Summary		These services are not medically necessary under Section 1862(a)(1) of the Social Security Act. The Autologous Muscle Derived Cells for Treatment of Tongue Dysphagia (REVIVE) trial is a double-blind, randomized, placebo-controlled, multicenter clinical trial intended to evaluate the safety and efficacy of Autologous Muscle Derived Cells for Gastro-Intestinal Repair (AMDC-GIR) for the treatment of tongue dysphagia (TD) in male and female patients who have undergone surgery and/or chemo- and/or radiotherapy for squamous cell cancer of the oropharynx. *(NCT054216689)* There is not enough evidence to support the use of autologous muscle cell therapy for swallowing impairment. Available studies are limited by small sample size, poor study design, lack of randomization, and high risk of bias. Furthermore, no clinical guidelines were identified that support the use of this treatment. Therefore, autologous muscle therapy is considered **not medically necessary** for treating swallowing impairment post-cancer treatment or for any other indication.
Sources/Citations		• A review of the ECRI, Hayes, Cochrane, and PubMed databases was conducted regarding the use of these services.

	• Nativ-Zeltzer N, Kuhn MA, Evangelista L, et al. Autologous Muscle-Derived Cell Therapy for Swallowing Impairment in Patients Following Treatment for Head and Neck Cancer. Laryngoscope. 2022;132(3):523-527.

Table 2.59

Augmentative Algorithmic Analysis of Encephalographic Waveforms		
Device/Product, and Manufacturer Information (when applicable)		
Code(s)	1041T	Augmentative algorithmic analysis of encephalographic waveforms to identify the source and propagation of epileptiform activity, including artifact reduction with analysis of 3D localization of spike sources throughout the examination, 3D animations over time of high-amplitude event locations, high-frequency activity locations, and temporal relationships among locations, with interpretation and report by physician or other qualified health care professional, related to a previously performed electroencephalogram (EEG)
Medicare Coverage Notes and Evidence Summary		These services are not medically necessary under Section 1862(a)(1) of the Social Security Act. Augmentative algorithmic EEG analysis, including automated spike detection, artifact reduction, and 3D source localization, represents an evolution of traditional EEG interpretation intended to improve efficiency and localization of epileptiform activity. Early studies and subsequent literature suggest these techniques can reduce review burden and provide clinically useful adjunctive information, particularly in presurgical epilepsy evaluation; however, the evidence remains heterogeneous, largely adjunctive, and methodologically variable, with limitations related to accuracy, standardization, and generalizability. No major clinical guidelines currently recommend routine use of these advanced analytic approaches. Therefore, augmentative algorithmic analysis of encephalographic waveforms is considered **not medically necessary** for any indication.
Sources/Citations		• A review of the ECRI, Hayes, Cochrane, and PubMed databases was conducted regarding the use of these services. • Senhadji L, Dillenseger JL, Wendling F, Rocha C, Kinie A. Wavelet analysis of EEG for three-dimensional mapping of epileptic events. Ann Biomed Eng. 1995 Sep-Oct;23(5):543-52. doi: 10.1007/BF02584454. Erratum in: Ann Biomed Eng 1995 Nov-Dec;23(6):842. PMID: 7503457; PMCID: PMC1924879.

Table 2.60

Quantitative Magnetic Resonance for Analysis of Liver Tissue (Without Imaging)	
Device/Product, and Manufacturer	

Information (when applicable)		
Code(s)	1043T	Quantitative magnetic resonance, without imaging, for analysis of liver tissue, including assessment of 1 or more parameters (eg, proton density fat fraction [PDFF], water diffusion, T1-water relaxation time), with automatically generated report
Medicare Coverage Notes and Evidence Summary		These services are not medically necessary under Section 1862(a)(1) of the Social Security Act. Quantitative MR–based liver biomarker analysis demonstrates strong analytic validity and growing clinical validity, with potential advantages over biopsy, including noninvasiveness, reproducibility, and whole liver assessment. However, key limitations include variability across platforms and biomarkers, incomplete standardization, and limited evidence demonstrating impact on clinical decision making or patient outcomes compared with established care. Although correlations with histology and treatment response are promising, most data are derived from observational studies or research cohorts rather than routine practice settings. Accordingly, while quantitative MR biomarker testing may represent a significant advancement in noninvasive liver disease assessment, current evidence is insufficient to establish it as a replacement for biopsy or as a standard standalone diagnostic tool. Clinical practice guidelines and professional guidance from entities such as the American Association for the Study of Liver Diseases (AASLD) and the RSNA Quantitative Imaging Biomarkers Alliance (QIBA) consider its use best considered adjunctive for many clinical indications pending further validation of clinical utility and integration into guideline directed care pathways. Therefore, quantitative magnetic resonance–derived biomarker analysis of liver tissue (e.g., PDFF, T1 Mapping, Diffusion) is considered **not medically necessary** for assessment of liver disease.
Sources/Citations		• A review of the ECRI, Hayes, Cochrane, and PubMed databases was conducted regarding the use of these services. • Caussy et al. Noninvasive, Quantitative Assessment of Liver Fat by MRI-PDFF as an Endpoint in NASH Trials. Hepatology. 2018 Aug;68(2):763-772. doi: 10.1002/hep.29797. PMID: 29356032; PMCID: PMC6054824. • Ndaa et al. Reliable Monitoring of Patients With Metabolic Dysfunction-Associated Steatotic Liver Disease Using Imaging: A Systematic Literature Review and Meta-Analysis on Measurement Repeatability. Endocr Pract. 2026 Feb;32(2):258-267. doi: 10.1016/j.eprac.2025.09.205. Epub 2025 Oct 1. PMID: 41043587. • Rinella et al. AASLD Practice Guidance on the clinical assessment and management of nonalcoholic fatty liver disease. Hepatology. 2023 May 1;77(5):1797-1835. doi: 10.1097/HEP.0000000000000323. Epub 2023 Mar 17. PMID: 36727674; PMCID: PMC10735173. • Boss et al. The QIBA Profile for Diffusion-Weighted MRI: Apparent Diffusion Coefficient as a Quantitative Imaging Biomarker. Radiology.

	2024 Oct;313(1):e233055. doi: 10.1148/radiol.233055. PMID: 39377680; PMCID: PMC11537247.

Table 2.61

Subcutaneous Heart Failure Decompensation Monitor		
Device/Product, and Manufacturer Information (when applicable)		
Code(s)	1050T	Insertion, subcutaneous heart failure decompensation monitor, containing sensors that measure, at a minimum, heart rate, impedance, respiration rate, physical activity, heart sounds
	1051T	Removal of subcutaneous heart failure decompensation monitor
	1052T	Interrogation device evaluation(s), (in person or remote) up to 30 days, insertable subcutaneous heart failure decompensation monitor, analysis of physiologic parameters, including, at a minimum, heart rate, impedance, respiration rate, physical activity, heart sounds, with generation of a report, review and interpretation by a physician or other qualified health care professional
	1053T	Programming device evaluation (in person or remote) of subcutaneous heart failure decompensation monitor, with analysis of physiologic parameters, including, at a minimum, heart rate, impedance, respiration rate, physical activity, heart sounds, with generation of a report and review and interpretation by a physician or other qualified health care professional
Medicare Coverage Notes and Evidence Summary		These services are not medically necessary under Section 1862(a)(1) of the Social Security Act. The available evidence for implantable multi sensor physiologic monitoring systems shows variable impact on clinical outcomes, with some studies demonstrating reductions in hospitalization and mortality when monitoring is coupled with structured clinical response, while others show no significant benefit compared with standard care. Key limitations include heterogeneity in device technology and algorithms, reliance on indirect evidence from CIED based systems rather than dedicated subcutaneous devices, and variability in care pathways following alerts. In addition, there is limited evidence from large randomized trials specifically evaluating standalone subcutaneous multi sensor systems. Consequently, current evidence is insufficient to establish consistent clinical utility across broad populations. Therefore, implantable multi-sensor physiologic monitoring for early detection of heart failure decompensation is considered **not medically necessary**.
Sources/Citations		• A review of the ECRI, Hayes, Cochrane, and PubMed databases was conducted regarding the use of these services. • Hajduczok et al. Remote monitoring for heart failure using implantable devices: a systematic review, meta-analysis, and meta-regression of randomized controlled trials. Heart Fail Rev. 2022 Jul;27(4):1281-1300. doi: 10.1007/s10741-021-10150-5. Epub 2021 Sep 24. PMID: 34559368; PMCID: PMC8460850.

	• Kenny et al. Algorithm-based remote monitoring of heart failure risk data in people with cardiac implantable electronic devices: a systematic review and cost-effectiveness analysis. Health Technol Assess. 2025 Oct;29(50):1-160. doi: 10.3310/PPOH2916. PMID: 41108091; PMCID: PMC12666606. • Cajita et al. Integrated Health Technologies in Heart Failure: A Scientific Statement From the Heart Failure Society of America and the American Association of Heart Failure Nurses. J Card Fail. 2026 Mar;32(3):619-632. doi: 10.1016/j.cardfail.2025.08.029. Epub 2026 Jan 27. PMID: 41605748. • Heidenreich, P, Bozkurt, B, Aguilar, D. et al. 2022 AHA/ACC/HFSA Guideline for the Management of Heart Failure: Executive Summary: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. JACC. 2022 May, 79 (17) 1757–1780. https://doi.org/10.1016/j.jacc.2021.12.011.

Table 2.XX

Device/Product, and Manufacturer Information (when applicable)	**Blank table left intentionally - Placeholder for future services/technologies added to the Table 2 set of codes**
Code(s)	
Medicare Coverage Notes and Evidence Summary	These services are not medically necessary under Section 1862(a)(1) of the Social Security Act.
Sources/Citations	•

***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. Updated 11/2014. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c14.pdf. Accessed 3/2/2026.
2. US Government Publishing Office. Electronic code of federal regulations: part 422 – 42 CFR § 422.101 - Requirements relating to basic benefits
3. Medicare Preventive Services. https://www.cms.gov/Medicare/Prevention/PrevntionGenInfo/medicare-preventive-services/MPS-QuickReferenceChart-1.html. Accessed 3/2/2026.

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). Remove 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

4/2024	Interim update; align with CMS Final Rule Requirements regarding published policy criteria & evidence sources when there is no Medicare coverage policy or guidance; Q2 2024 code updates
5/2024	Interim update; update non-coverage rationale for TriClip™, the Aurora EV-ICD™ System, and for the Avise® Lupus test
7/2024	Interim update and Q3 2024 code updates
8/2024	Interim update; remove KidneyIntelX™ (addressed in a separate policy)
10/2024	Q4 2024 code updates
1/2025	Annual review and Q1 2025 code updates. Update format, remove select codes from policy (note that removal from this policy does not necessarily guarantee coverage).
3/2025	Interim update. Correct tricuspid valve replacement criteria (EVOQUE TTVR system)
3/24/2025	Interim update. Add reference to Medicare Decision Memo for TTVR, effective 3/19/2025.
4/2025	New annual review and Q2 2025 code updates
5/2025	Add codes for topical hyperbaric oxygen and related LCD, transfer codes for transcatheter tricuspid valve replacement to a separate policy
5/6/2025	Add codes for liver histotripsy and 3D contour simulation
7/2025	Interim update and Q3 2025 code updates. Add prolotherapy and applicable NCD
7/3/2025	Interim update. Add reference to CMS Decision Memo for T-TEER, effective 7/2/2025.
8/2025	Add code for sensory nerve conduction threshold tests (sNCTs) and related NCD, transfer codes for T-TEER to a separate policy
10/2025	Q4 2025 code updates
10/29/2025	Interim update. Add reference to Medicare Decision Memos for CCM and renal denervation for hypertension, both effective 10/28/25.
11/2025	Interim update. Transfer codes for CCM and renal denervation to separate policies
1/2026	Interim update to remove codes reviewed by Carelon. Also Q1 2026 code updates. (1/27/2026: Replaced LCD L37748 with LCD L37750 due to Noridian JF consolidation with JE LCD policies) (2/13/2026: Replaced multiple MolDX LCDs and LCAs due to Noridian JF consolidation with JE LCD policies)
3/2026	Annual review. Update Table 2 Set format and language for services with no fully established Medicare coverage guidance, remove select codes from policy (note that removal from this policy does not automatically warrant or guarantee coverage). Transfer Edison System from Table 1 Set to Table 2 Set.
4/2026	Q2 2026 code updates and update to Medicare guidelines for the FidaLab Molecular Wound Infection Test and Synovasure® tests (4/27/2026: Replaced LCD L38803 with LCD L38801 due to Noridian JF consolidation with JE LCD policies)
7/2026	Q3 2026 code updates