



Investigational (Experimental) Services, New and Emerging Medical Technologies and Procedures, and Other Non-Covered Services

Published: 01/01/2025

Next Review: 11/2025

Last Review: 01/2025

Medicare Link(s) Revised: 01/01/2025

IMPORTANT REMINDER

The Medicare Advantage Medical Policy manual is not intended to override the member Evidence of Coverage (EOC), which defines the insured's benefits, nor is it intended to dictate how providers are to practice medicine. Physicians and other health care providers are expected to exercise their medical judgment in providing the most appropriate care for the individual member.

The Medicare Advantage Medical Policies are designed to provide guidance regarding the decision-making process for the coverage or non-coverage of services or procedures in accordance with the member EOC and the Centers of Medicare and Medicaid Services (CMS) policies, when available. In the event of a conflict, applicable CMS policy or EOC language will take precedence over the Medicare Advantage Medical Policy. In the absence of CMS guidance for a requested service or procedure, the health plan may apply their Medical Policy Manual or MCG™ criteria, both of which are developed with an objective, evidence-based process using scientific evidence, current generally accepted standards of medical practice, and authoritative clinical practice guidelines.

Medicare and EOCs exclude from coverage, among other things, services or procedures considered to be investigational, cosmetic, or not medically necessary, and in some cases, providers may bill members for these non-covered services or procedures. Providers are encouraged to inform members in advance when they may be financially responsible for the cost of non-covered or excluded services.

DESCRIPTION

INVESTIGATIONAL (EXPERIMENTAL) SERVICES

Title XVIII of the Social Security Act, §1862(a)(1)(A) prohibits Medicare coverage for items and services which are not “reasonable and necessary” for the diagnosis and treatment of an injury or illness or to improve the functioning of a malformed body member. According to the *Medicare Claims Processing Manual, Chapter 23, §30.A*, if a procedure or device lacks scientific evidence regarding safety and efficacy because it is investigational or experimental, the service is noncovered because it is not reasonable and necessary to treat illness or injury.^[1]

In the absence of a national coverage determination (NCD), local coverage determination (LCD), or other Medicare coverage guidance, Medicare regulations allow a Medicare Advantage Organization (MAO) to make its own coverage determination, applying an objective, evidence-based process, based on authoritative evidence.^[2]

It is important to note the presence of a payment amount in the Medicare Physicians' Fee Schedule (MPFS) does not imply that Medicare has determined the service to be a "reasonable and necessary" covered service.^[1] In addition, according to the Medicare Benefit Policy Manual, Chapter 14, while U.S. Food and Drug Administration (FDA) approval does not automatically guarantee coverage under Medicare, in order to even be *considered* for coverage under Medicare, devices must be either FDA- or Institutional Review Board (IRB)-approved. Therefore, any device that has not received FDA-approval would not be considered medically reasonable or necessary.^[3] The FDA reviews data from well-designed studies and clinical trials in order to determine safety and effectiveness prior to approval for sale, but does not establish medical necessity of that device or drug. While Medicare may adopt FDA determinations regarding safety and effectiveness, CMS or Medicare contractors evaluate whether or not the drug or device is reasonable and necessary for the Medicare population under §1862(a)(1)(A). (*Note, not all services or procedures are subject to FDA review and approval.*)

Requests for health care services, treatments, procedures, or devices that are not addressed in an NCD, LCD, or other Medicare reference, or not specified as "covered" in Medicare benefit manuals or other transmittals may be reviewed to ensure sufficient evidence regarding safety and efficacy is available, ensuring the services are medically reasonable and necessary for members. (*See the "Policy Guidelines" below for important notes regarding Medicare and investigational services.*)

MEDICARE ADVANTAGE POLICY CRITERIA

Note: For services provided in the context of a clinical trial, or medical devices related to Category A or B Investigational Device Exemption (IDE) studies, please see Cross References

Procedures and items that are subject to Coverage with Evidence Development (CED) criteria may be addressed in separate Medicare Advantage medical policies when those services are reviewed by the health plan.^[4] National coverage determinations (NCDs) that require CED can be found on the CMS web page for [Coverage with Evidence Development](#). (See Cross References)

The following are new and emerging medical technologies reported with Category III CPT codes. These codes are generally created to track new, unproven therapies, devices, and tests. There are a number of reasons a service may be non-covered, including but not limited to, national coverage determination (NCD) guidance, lack of FDA approval, or the

service is not considered “medically reasonable or necessary” under Title XVIII of the Social Security Act, §1862(a)(1)(A).

IMPORTANT NOTE: This list is not intended to be an all-inclusive list. Some procedures may be addressed in specific Medicare Advantage medical policies and therefore, would not be included in this Medicare medical policy, but the same rationale in this policy could apply. Other services not included in this list may also be non-covered. The absence or removal of a code from this medical policy does not imply coverage.

| Codes | Number | Description & Manufacturer Information (when applicable) | Non-Coverage Rationale |
|--------------|---------------|---|---|
| CPT | 0219T | Placement of a posterior intrafacet implant(s), unilateral or bilateral, including imaging and placement of bone graft(s) or synthetic device(s), single level; cervical (e.g., NuFix [NUTECH SPINE, Inc.] or TruFUSE®) | Noridian local coverage article <i>Billing and Coding: Facet Joint Interventions for Pain Management</i> (A58405) |
| | 0220T | ; thoracic | |
| | 0221T | ; lumbar | |
| | 0222T | ; each additional vertebral segment (List separately in addition to code for primary procedure) | |
| | 0443T | Real-time spectral analysis of prostate tissue by fluorescence spectroscopy, including imaging guidance (List separately in addition to code for primary procedure) (e.g., Precision Biopsy ClariCore Optical Biopsy System®) | As of most recent review, this has not received FDA-approval |
| | 0444T | Initial placement of a drug-eluting ocular insert under one or more eyelids, including fitting, training, and insertion, unilateral or bilateral | As of most recent review, this has not received FDA-approval |
| | 0445T | Subsequent placement of a drug-eluting ocular insert under one or more eyelids, including re-training, and removal of existing insert, unilateral or bilateral | |
| | 0469T | Retinal polarization scan, ocular screening with on-site automated results, bilateral | Medicare Status “N” code; Therefore, non-covered for Medicare and Medicare Advantage |
| | 0481T | Injection(s), autologous white blood cell concentrate (autologous protein solution), any site, including image guidance, harvesting and preparation, when performed | As of most recent review, this has not received FDA-approval |

| | | |
|-------|---|--|
| 0515T | Insertion of wireless cardiac stimulator for left ventricular pacing, including device interrogation and programming, and imaging supervision and interpretation, when performed; complete system (includes electrode and generator [transmitter and battery]) (e.g., WiSE™ CRT System [EBR Systems, Inc]) | As of most recent review, this has not received FDA-approval |
| 0516T | ; electrode only | |
| 0517T | Insertion of wireless cardiac stimulator for left ventricular pacing, including device interrogation and programming, and imaging supervision and interpretation, when performed; both component(s) of pulse generator (battery and transmitter) only | |
| 0518T | Removal of pulse generator for wireless cardiac stimulator for left ventricular pacing;battery component only | |
| 0519T | Removal and replacement of pulse generator for wireless cardiac stimulator for left ventricular pacing, including device interrogation and programming; both components (battery and transmitter) | |
| 0520T | Removal and replacement of pulse generator for wireless cardiac stimulator for left ventricular pacing, including device interrogation and programming; battery component only | |
| 0521T | Interrogation device evaluation (in person) with analysis, review and report, includes connection, recording, and disconnection per patient encounter, wireless cardiac stimulator for left ventricular pacing (e.g., WiSE™ CRT System [EBR Systems, Inc]) | |
| 0522T | Programming device evaluation (in person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis, including review and report, wireless cardiac stimulator for left ventricular pacing (e.g., WiSE™ CRT System [EBR Systems, Inc]) | |

| | | |
|-------|---|--|
| 0547T | Bone-material quality testing by microindentation(s) of the tibia(s), with results reported as a score (e.g., OsteoProbe® [Active Life Scientific, Inc.] | As of most recent review, this has not received FDA-approval |
| 0553T | Percutaneous transcatheter placement of iliac arteriovenous anastomosis implant, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention (Deleted 01/01/2025) | As of most recent review, this has not received FDA-approval |
| 0559T | Anatomic model 3D-printed from image data set(s); first individually prepared and processed component of an anatomic structure | Not medically reasonable or necessary under Medicare and §1862(a)(1)(A). This is to plan a surgery, it does not “treat or diagnosis” an illness or injury. |
| 0560T | ; each additional individually prepared and processed component of an anatomic structure (List separately in addition to code for primary procedure) | |
| 0561T | Anatomic guide 3D-printed and designed from image data set(s); first anatomic guide | <i>Codes 0559T-0562T are for services which provide a printed physical multi-dimensional model of a patient’s anatomy to aid in the planning of surgical procedures.</i> |
| 0562T | ; each additional anatomic guide (List separately in addition to code for primary procedure) | |
| 0567T | Permanent fallopian tube occlusion with degradable biopolymer implant, transcervical approach, including transvaginal ultrasound (e.g., FemBloc® [Femasys, Inc.]) (Deleted 01/01/2025) | As of most recent review, this has not received FDA-approval. |
| 0568T | Introduction of mixture of saline and air for sonosalpingography to confirm occlusion of fallopian tubes, transcervical approach, including transvaginal ultrasound and pelvic ultrasound (e.g., FemBloc® [Femasys, Inc.]) (Deleted 01/01/2025) | As of most recent review, this has not received FDA-approval. |
| 0571T | Insertion or replacement of implantable cardioverter-defibrillator system with substernal electrode(s), including all imaging guidance and electrophysiological evaluation (includes defibrillation threshold evaluation, induction of arrhythmia, evaluation of | As of most recent review, this has not received FDA-approval. |

| | |
|-------|---|
| | sensing for arrhythmia termination, and programming or reprogramming of sensing or therapeutic parameters), when performed |
| 0572T | Insertion of substernal implantable defibrillator electrode |
| 0574T | Repositioning of previously implanted substernal implantable defibrillator-pacing electrode |
| 0575T | Programming device evaluation (in person) of implantable cardioverter-defibrillator system with substernal electrode, with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis, review and report by a physician or other qualified health care professional |
| 0576T | Interrogation device evaluation (in person) of implantable cardioverter-defibrillator system with substernal electrode, with analysis, review and report by a physician or other qualified health care professional, includes connection, recording and disconnection per patient encounter |
| 0577T | Electrophysiologic evaluation of implantable cardioverter defibrillator system with substernal electrode (includes defibrillation threshold evaluation, induction of arrhythmia, evaluation of sensing for arrhythmia termination, and programming or reprogramming of sensing or therapeutic parameters) |
| 0578T | Interrogation device evaluation(s) (remote), up to 90 days, substernal lead implantable cardioverter-defibrillator system with interim analysis, review(s) and report(s) by a physician or other qualified health care professional |
| 0579T | Interrogation device evaluation(s) (remote), up to 90 days, substernal lead implantable cardioverter-defibrillator system, remote data acquisition(s), receipt of transmissions and technician review, technical support and distribution of results |

| | | |
|-------|--|---|
| 0582T | Transurethral ablation of malignant prostate tissue by high-energy water vapor thermotherapy, including intraoperative imaging and needle guidance | As of most recent review, this has not received FDA-approval. |
| 0602T | Glomerular filtration rate (GFR) measurement(s), transdermal, including sensor placement and administration of a single dose of fluorescent pyrazine agent (e.g., Transdermal GFR System [MediBeacon]) | As of most recent review, this has not received FDA-approval. |
| 0603T | Glomerular filtration rate (GFR) monitoring, transdermal, including sensor placement and administration of more than one dose of fluorescent pyrazine agent, each 24 hours | |
| 0604T | Optical coherence tomography (OCT) of retina, remote, patient-initiated image capture and transmission to a remote surveillance center unilateral or bilateral; initial device provision, set-up and patient education on use of equipment (e.g., Home OCT [Notal Vision]) | As of most recent review, this has not received FDA-approval. |
| 0605T | Optical coherence tomography (OCT) of retina, remote, patient-initiated image capture and transmission to a remote surveillance center unilateral or bilateral; remote surveillance center technical support, data analyses and reports, with a minimum of 8 daily recordings, each 30 days | |
| 0606T | Optical coherence tomography (OCT) of retina, remote, patient-initiated image capture and transmission to a remote surveillance center unilateral or bilateral; review, interpretation and report by the prescribing physician or other qualified health care professional of remote surveillance center data analyses, each 30 days | |
| 0613T | Percutaneous transcatheter implantation of interatrial septal shunt device, including right and left heart catheterization, intracardiac echocardiography, and imaging guidance by the proceduralist, when performed (e.g., V-Wave Shunt [V-Wave Medical]) | As of most recent review, this has not received FDA-approval. |

| | | |
|-------|---|---|
| 0614T | Removal and replacement of substernal implantable defibrillator pulse generator | As of most recent review, this has not received FDA-approval. |
| 0620T | Endovascular venous arterialization, tibial or peroneal vein, with transcatheter placement of intravascular stent graft(s) and closure by any method, including percutaneous or open vascular access, ultrasound guidance for vascular access when performed, all catheterization(s) and intraprocedural roadmapping and imaging guidance necessary to complete the intervention, all associated radiological supervision and interpretation, when performed (e.g., LimFlow Stent Graft System) | As of most recent review, this has not received FDA-approval. |
| 0627T | Percutaneous injection of allogeneic cellular and/or tissue-based product, intervertebral disc, unilateral or bilateral injection, with fluoroscopic guidance, lumbar; first level (e.g., Viable Allograft Supplemental Disc Regeneration [VAST] [Via Disc] [Vivex Biologics]) | As of most recent review, this has not received FDA-approval. |
| 0628T | ; each additional level (List separately in addition to code for primary procedure) | |
| 0629T | Percutaneous injection of allogeneic cellular and/or tissue-based product, intervertebral disc, unilateral or bilateral injection, with CT guidance, lumbar; first level | |
| 0630T | ; each additional level (List separately in addition to code for primary procedure) | |
| 0631T | Transcutaneous visible light hyperspectral imaging measurement of oxyhemoglobin, deoxyhemoglobin, and tissue oxygenation, with interpretation and report, per extremity (e.g., HyperView™ [HyperMed Imaging, Inc.] | Not medically reasonable or necessary under Medicare and §1862(a)(1)(A). This is used to determine oxygenation levels in superficial tissues for patients with potential circulatory compromise, but it does not “treat or diagnosis” an illness or injury. |

| | | |
|-------|--|--|
| 0632T | Percutaneous transcatheter ultrasound ablation of nerves innervating the pulmonary arteries, including right heart catheterization, pulmonary artery angiography, and all imaging guidance (e.g., Therapeutic IntraVascular UltraSound [TIVUS™; SoniVie Ltd.] | As of most recent review, this has not received FDA-approval. |
| 0639T | Wireless skin sensor thermal anisotropy measurement(s) and assessment of flow in cerebrospinal fluid shunt, including ultrasound guidance, when performed (e.g., Flowsense™ [Rhaeos]) | As of most recent review, this has not received FDA-approval. |
| 0640T | Noncontact near-infrared spectroscopy (eg, for measurement of deoxyhemoglobin, oxyhemoglobin, and ratio of tissue oxygenation), other than for screening for peripheral arterial disease, image acquisition, interpretation, and report; first anatomic site | Not medically reasonable or necessary under Medicare and §1862(a)(1)(A). This is used to determine oxygenation levels in superficial tissues for patients with potential circulatory compromise, but it does not “treat or diagnosis” an illness or injury. |
| 0645T | Transcatheter implantation of coronary sinus reduction device including vascular access and closure, right heart catheterization, venous angiography, coronary sinus angiography, imaging guidance, and supervision and interpretation, when performed (e.g., Neovasc Reducer™ System) | In October 2020, FDA panel summary indicating no clear evidence of effectiveness or benefit/harm ratio. (FDA web page) Procedures which lack scientific evidence regarding safety and efficacy are noncovered by Medicare as they are considered not reasonable or necessary (<i>Medicare Claims Processing Manual, Ch. 23, §30 A</i>) under the Social Security Act Sec.1862 (a)(1)(A). |
| 0660T | Implantation of anterior segment intraocular nonbiodegradable drug-eluting system, internal approach | As of most recent review, this has not received FDA-approval. |

| | | |
|-------|---|---|
| 0661T | Removal and reimplantation of anterior segment intraocular nonbiodegradable drug-eluting implant | |
| 0672T | Endovaginal cryogen-cooled, monopolar radiofrequency remodeling of the tissues surrounding the female bladder neck and proximal urethra for urinary incontinence | As of most recent review, this has not received FDA-approval. |
| 0674T | Laparoscopic insertion of new or replacement of permanent implantable synchronized diaphragmatic stimulation system for augmentation of cardiac function, including an implantable pulse generator and diaphragmatic lead(s) | |
| 0675T | Laparoscopic insertion of new or replacement of diaphragmatic lead(s), permanent implantable synchronized diaphragmatic stimulation system for augmentation of cardiac function, including connection to an existing pulse generator; first lead | |
| 0676T | Laparoscopic insertion of new or replacement of diaphragmatic lead(s), permanent implantable synchronized diaphragmatic stimulation system for augmentation of cardiac function, including connection to an existing pulse generator; each additional lead | |
| 0677T | Laparoscopic repositioning of diaphragmatic lead(s), permanent implantable synchronized diaphragmatic stimulation system for augmentation of cardiac function, including connection to an existing pulse generator; first repositioned lead | |
| 0678T | Laparoscopic repositioning of diaphragmatic lead(s), permanent implantable synchronized diaphragmatic stimulation system for augmentation of cardiac function, including connection to an existing pulse generator; each additional repositioned lead (List separately in addition to code for primary procedure) | |
| 0679T | Laparoscopic removal of diaphragmatic lead(s), permanent implantable synchronized diaphragmatic stimulation system for augmentation of cardiac function | |
| 0680T | Insertion or replacement of pulse generator only, permanent implantable synchronized diaphragmatic stimulation system for augmentation of cardiac function, with connection to existing lead(s) | |
| 0681T | Relocation of pulse generator only, permanent implantable synchronized diaphragmatic stimulation system for | |

| | | |
|-------|--|--|
| 0682T | <p>augmentation of cardiac function, with connection to existing dual leads</p> <p>Removal of pulse generator only, permanent implantable synchronized diaphragmatic stimulation system for augmentation of cardiac function</p> | |
| 0683T | <p>Programming device evaluation (in-person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis, review and report by a physician or other qualified health care professional, permanent implantable synchronized diaphragmatic stimulation system for augmentation of cardiac function</p> | |
| 0684T | <p>Peri-procedural device evaluation (in-person) and programming of device system parameters before or after a surgery, procedure, or test with analysis, review, and report by a physician or other qualified health care professional, permanent implantable synchronized diaphragmatic stimulation system for augmentation of cardiac function</p> | |
| 0685T | <p>Interrogation device evaluation (in-person) with analysis, review and report by a physician or other qualified health care professional, including connection, recording and disconnection per patient encounter, permanent implantable synchronized diaphragmatic stimulation system for augmentation of cardiac function</p> | |
| 0686T | <p>Histotripsy (ie, non-thermal ablation via acoustic energy delivery) of malignant hepatocellular tissue, including image guidance</p> | |
| 0697T | <p>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</p> | <p>This is not a magnetic resonance procedure covered under the Medicare NCD 220.2. Not medically reasonable or necessary under Medicare and §1862(a)(1)(A). This analyzes body composition to determine if more invasive procedures (i.e., biopsies) are needed, it does not “treat or diagnosis” an illness or injury.</p> |

| | | |
|-------|---|---|
| 0698T | Quantitative magnetic resonance for analysis of tissue composition (eg, fat, iron, water content), including multiparametric data acquisition, data preparation and transmission, interpretation and report, obtained with diagnostic MRI examination of the same anatomy (eg, organ, gland, tissue, target structure); multiple organs (List separately in addition to code for primary procedure) | This is not a magnetic resonance procedure covered under the Medicare NCD 220.2. Not medically reasonable or necessary under Medicare and §1862(a)(1)(A). This analyzes body composition to determine if more invasive procedures (i.e., biopsies) are needed, it does not “treat or diagnosis” an illness or injury. |
| 0719T | Posterior vertebral joint replacement, including bilateral facetectomy, laminectomy, and radical discectomy, including imaging guidance, lumbar spine, single segment | As of most recent review, has not received FDA-approval. |
| 0725T | Vestibular device implantation, unilateral | Does not fall under audiological diagnostic testings as defined by Medicare Benefit Policy Manual, Chap. 15, Section 80.3. As of most recent review, has not received FDA-approval. |
| 0726T | Removal of implanted vestibular device, 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 | |
| 0732T | Immunotherapy administration with electroporation, intramuscular | As of most recent review, has not received FDA-approval. |
| 0738T | Treatment planning for magnetic field induction ablation of malignant prostate tissue, using data from previously performed magnetic resonance imaging (MRI) examination | As of most recent review, has not received FDA-approval. |
| 0739T | Ablation of malignant prostate tissue by magnetic field induction, including all | |

| | | |
|-------|--|--|
| | intraoperative, transperineal needle/catheter placement for nanoparticle installation and intraoperative temperature monitoring, thermal dosimetry, bladder irrigation, and magnetic field nanoparticle activation | |
| 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 | As of most recent review, has not received FDA-approval. |
| 0745T | Cardiac focal ablation utilizing radiation therapy for arrhythmia; noninvasive arrhythmia localization and mapping of arrhythmia site (nidus), derived from anatomical image data (eg, CT, MRI, or myocardial perfusion scan) and electrical data (eg, 12-lead ECG data), and identification of areas of avoidance | As of most recent review, has not received FDA-approval. |
| 0746T | Cardiac focal ablation utilizing radiation therapy for arrhythmia; conversion of arrhythmia localization and mapping of arrhythmia site (nidus) into a multidimensional radiation treatment plan | |
| 0747T | Cardiac focal ablation utilizing radiation therapy for arrhythmia; delivery of radiation therapy, arrhythmia | |
| 0748T | Injections of stem cell product into perianal perifistular soft tissue, including fistula preparation (eg, removal of setons, fistula curettage, closure of internal openings) | As of most recent review, has not received FDA-approval. |
| 0764T | Assistive algorithmic electrocardiogram risk-based assessment for cardiac dysfunction (eg, low-ejection fraction, pulmonary hypertension, hypertrophic cardiomyopathy); related to concurrently performed electrocardiogram (List separately in addition to code for primary procedure) | |
| 0765T | Assistive algorithmic electrocardiogram risk-based assessment for cardiac | |

| | | |
|-------|---|--|
| | dysfunction (eg, low-ejection fraction, pulmonary hypertension, hypertrophic cardiomyopathy); related to previously performed electrocardiogram | |
| 0770T | Virtual reality technology to assist therapy (List separately in addition to code for primary procedure) | As of most recent review, has not received FDA-approval. |
| 0776T | Therapeutic induction of intra-brain hypothermia, including placement of a mechanical temperature-controlled cooling device to the neck over carotids and head, including monitoring (eg, vital signs and sport concussion assessment tool 5 [SCAT5]), 30 minutes of treatment | As of most recent review, has not received full FDA-approval. |
| 0781T | Bronchoscopy, rigid or flexible, with insertion of esophageal protection device and circumferential radiofrequency destruction of the pulmonary nerves, including fluoroscopic guidance when performed; bilateral mainstem bronchi | As of most recent review, has not received FDA-approval. |
| 0782T | Bronchoscopy, rigid or flexible, with insertion of esophageal protection device and circumferential radiofrequency destruction of the pulmonary nerves, including fluoroscopic guidance when performed; unilateral mainstem bronchus | |
| 0793T | Percutaneous transcatheter thermal ablation of nerves innervating the pulmonary arteries, including right heart catheterization, pulmonary artery angiography, and all imaging guidance | As of most recent review, this has not received FDA-approval. |
| 0794T | Patient-specific, assistive, rules-based algorithm for ranking pharmaco-oncologic treatment options based on the patient's tumor-specific cancer marker information obtained from prior molecular pathology, immunohistochemical, or other pathology results which have been previously interpreted and reported separately | Noridian local coverage article Algorithm definition as a component of a laboratory test (A58674). Medical necessity has not been demonstrated for this algorithm. |
| 0811T | Remote multi-day complex uroflowmetry (eg, calibrated electronic equipment); setup and patient education on use of equipment | Not medically reasonable or necessary under Medicare and |
| 0812T | Remote multi-day complex uroflowmetry (eg, calibrated electronic equipment); device supply with automated report generation, up to 10 days | §1862(a)(1)(A). This is used to monitor urine flow remotely, but it does not |

| | | |
|-------|---|---|
| | | “treat or diagnosis” an illness or injury. |
| 0814T | Percutaneous injection of calcium-based biodegradable osteoconductive material, proximal femur, including imaging guidance, unilateral | As of most recent review, this has not received FDA-approval. |
| 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) | Not medically reasonable or necessary under Medicare and §1862(a)(1)(A). This is used to determine oxygenation levels in superficial tissues for patients with potential circulatory compromise, but it does not “treat or diagnosis” an illness or injury. |
| 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 | |
| 0861T | Removal of pulse generator for wireless cardiac stimulator for left ventricular pacing; both components (battery and transmitter) | As of most recent review, this has not received FDA-approval. |
| 0862T | Relocation of pulse generator for wireless cardiac stimulator for left ventricular pacing, including device interrogation and programming; battery component only | |
| 0863T | Relocation of pulse generator for wireless cardiac stimulator for left ventricular pacing, including device interrogation and programming; transmitter component only | |
| 0865T | Quantitative magnetic resonance image (MRI) analysis of the brain with comparison to prior magnetic resonance (MR) study(ies), including lesion identification, characterization, and quantification, with brain volume(s) quantification and/or severity score, when performed, data preparation and transmission, interpretation and report, obtained without diagnostic MRI examination of the brain during the same session | Not medically reasonable or necessary under Medicare and §1862(a)(1)(A). This quantifies procedure and characterizes brain lesions. It does not “treat or diagnosis” an illness or injury. |
| 0866T | Quantitative magnetic resonance image (MRI) analysis of the brain with comparison to prior magnetic resonance (MR) study(ies), including lesion detection, characterization, and quantification, with brain volume(s) quantification and/or severity score, when performed, data preparation and transmission, interpretation and report, obtained with diagnostic MRI examination of | Not medically reasonable or necessary under Medicare and §1862(a)(1)(A). This quantifies procedure and characterizes brain lesions. It does not “treat or diagnosis” an illness or injury. |

| | | |
|-------|---|---|
| | the brain (List separately in addition to code for primary procedure) | |
| 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 | As of most recent review, this has not received FDA-approval. |
| 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 | |
| 0876T | Duplex scan of hemodialysis fistula, computer-aided, limited (volume flow, diameter, and depth, including only body of fistula) | As of most recent review, this has not received FDA-approval. |
| 0881T | Cryotherapy of the oral cavity using temperature regulated fluid cooling system, including placement of an oral device, monitoring of patient tolerance to treatment, and removal of the oral device | As of most recent review, this has not received FDA-approval. |
| 0884T | Esophagoscopy, flexible, transoral, with initial transendoscopic mechanical dilation (eg, nondrug-coated balloon) followed by therapeutic drug delivery by drug-coated balloon catheter for esophageal stricture, including fluoroscopic guidance, when performed | As of most recent review, this has not received FDA-approval. |
| 0885T | Colonoscopy, flexible, with initial transendoscopic mechanical dilation (eg, nondrug-coated balloon) followed by therapeutic drug delivery by drug-coated balloon catheter for colonic stricture, including fluoroscopic guidance, when performed | |
| 0886T | Sigmoidoscopy, flexible, with initial transendoscopic mechanical dilation (eg, nondrug-coated balloon) followed by | |

| | | |
|-------|--|---|
| | therapeutic drug delivery by drug-coated balloon catheter for colonic stricture, including fluoroscopic guidance, when performed | |
| 0888T | Histotripsy (ie, non-thermal ablation via acoustic energy delivery) of malignant renal tissue, including imaging guidance | As of most recent review, this has not received FDA-approval. |
| 0893T | Noninvasive assessment of blood oxygenation, gas exchange efficiency, and cardiorespiratory status, with physician or other qualified health care professional interpretation and report | Not medically reasonable or necessary under Medicare and §1862(a)(1)(A). This is used to determine oxygenation levels in superficial tissues for patients with potential circulatory compromise, but it does not “treat or diagnosis” an illness or injury. |
| 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 | Not medically reasonable or necessary under Medicare and §1862(a)(1)(A). does not “treat or diagnosis” an illness or injury. |
| 0901T | Placement of bone marrow sampling port, including imaging guidance when performed | As of most recent review, this has not received FDA-approval. |
| 0915T | Insertion of permanent cardiac contractility modulation-defibrillation system component(s), including fluoroscopic guidance, and evaluation and programming of sensing and therapeutic parameters; pulse generator and dual transvenous electrodes/leads (pacing and defibrillation) | As of most recent review, this has not received FDA-approval. |
| 0916T | Insertion of permanent cardiac contractility modulation-defibrillation system component(s), including fluoroscopic guidance, and evaluation and programming of sensing and therapeutic parameters; pulse generator only | |
| 0917T | Insertion of permanent cardiac contractility modulation-defibrillation system component(s), including fluoroscopic guidance, and evaluation and programming of sensing and therapeutic parameters; single transvenous lead (pacing or defibrillation) only | |
| 0918T | Insertion of permanent cardiac contractility modulation-defibrillation system component(s), including fluoroscopic guidance, and evaluation and programming of sensing and therapeutic parameters; dual | |

| | |
|-------|--|
| | transvenous leads (pacing and defibrillation) only |
| 0919T | Removal of a permanent cardiac contractility modulation-defibrillation system component(s); pulse generator only |
| 0920T | Removal of a permanent cardiac contractility modulation-defibrillation system component(s); single transvenous pacing lead only |
| 0921T | Removal of a permanent cardiac contractility modulation-defibrillation system component(s); single transvenous defibrillation lead only |
| 0922T | Removal of a permanent cardiac contractility modulation-defibrillation system component(s); dual (pacing and defibrillation) transvenous leads only |
| 0923T | Removal and replacement of permanent cardiac contractility modulation-defibrillation pulse generator only |
| 0924T | Repositioning of previously implanted cardiac contractility modulation-defibrillation transvenous electrode(s)/lead(s), including fluoroscopic guidance and programming of sensing and therapeutic parameters |
| 0925T | Relocation of skin pocket for implanted cardiac contractility modulation-defibrillation pulse generator |
| 0926T | Programming device evaluation (in person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis, including review and report, implantable cardiac contractility modulation-defibrillation system |
| 0927T | Interrogation device evaluation (in person) with analysis, review, and report, including connection, recording, and disconnection, per patient encounter, implantable cardiac contractility modulation-defibrillation system |
| 0928T | Interrogation device evaluation (remote), up to 90 days, cardiac contractility modulation-defibrillation system with interim analysis and report(s) by a physician or other qualified health care professional |
| 0929T | Interrogation device evaluation (remote), up to 90 days, cardiac contractility modulation-defibrillation system, remote data acquisition(s), receipt of transmissions, technician review, technical support, and distribution of results |
| 0930T | Electrophysiologic evaluation of cardiac contractility modulation-defibrillator leads, including defibrillation-threshold evaluation |

| | | |
|-------|--|---|
| | (induction of arrhythmia, evaluation of sensing and therapy for arrhythmia termination), at time of initial implantation or replacement with testing of cardiac contractility modulation-defibrillator pulse generator | |
| 0931T | Electrophysiologic evaluation of cardiac contractility modulation-defibrillator leads, including defibrillation-threshold evaluation (induction of arrhythmia, evaluation of sensing and therapy for arrhythmia termination), separate from initial implantation or replacement with testing of cardiac contractility modulation-defibrillator pulse generator | |
| 0933T | Transcatheter implantation of wireless left atrial pressure sensor for long-term left atrial pressure monitoring, including sensor calibration and deployment, right heart catheterization, transseptal puncture, imaging guidance, and radiological supervision and interpretation | As of most recent review, this has not received FDA-approval. |
| 0934T | Remote monitoring of a wireless left atrial pressure sensor for up to 30 days, including data from daily uploads of left atrial pressure recordings, interpretation(s) and trend analysis, with adjustments to the diuretics plan, treatment paradigm thresholds, medications or lifestyle modifications, when performed, and report(s) by a physician or other qualified health care professional | |
| 0936T | Photobiomodulation therapy of retina, single session | As of most recent review, this has not received FDA-approval. |
| 0937T | External electrocardiographic recording for greater than 15 days up to 30 days by continuous rhythm recording and storage; including recording, scanning analysis with report, review and interpretation by a physician or other qualified health care professional | As of most recent review, this has not received FDA-approval. |
| 0938T | External electrocardiographic recording for greater than 15 days up to 30 days by continuous rhythm recording and storage; recording (including connection and initial recording) | |
| 0939T | External electrocardiographic recording for greater than 15 days up to 30 days by continuous rhythm recording and storage; scanning analysis with report | |
| 0940T | External electrocardiographic recording for greater than 15 days up to 30 days by | |

| | | | |
|--------------|------------------|--|---|
| HCPCS | C9783 | continuous rhythm recording and storage; Review and interpretation by a physician or other qualified health care professional Blinded procedure for transcatheter implantation of coronary sinus reduction device or placebo control, including vascular access and closure, right heart catheterization, venous and coronary sinus angiography, imaging guidance and supervision and interpretation when performed in an approved investigational device exemption (ide) study | Comparable code to 0645T |
| | C9790 | Histotripsy (ie, non-thermal ablation via acoustic energy delivery) of malignant renal tissue, including image guidance (Deleted 07/01/2024) | |
| | E0715 | Intravaginal device intended to strengthen pelvic floor muscles during kegel exercises The Flyte wand is not intended to withstand repeated use by successive patients and does not meet the 3-year useful lifetime requirement of the DME benefit category. | Not medically reasonable or necessary per Medicare program guidance at section 280.1 of chapter 1, part 4 of the Medicare National Coverage Determinations Manual (Pub. 100-3) indicates that massage devices are personal comfort items excluded from Medicare coverage by section 1862(a)(6) of the Social Security Act. |
| | E0716 | Supplies and accessories for intravaginal device intended to strengthen pelvic floor muscles during kegel exercises | |

Proprietary Laboratory Analysis (PLA) and Multianalyte Assay Codes

The following laboratory tests are considered “not medically reasonable or necessary” under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). Jurisdiction of claims for laboratory services furnished by an independent laboratory normally lies with the carrier serving the area in which the laboratory test is performed.^[5] Specific Medicare guidance for each test is noted below:

IMPORTANT NOTE: This list is updated routinely with codes as they are released. **It is not intended to be an all-inclusive list.** The absence of a test code from this medical policy does not imply coverage, as some tests may be addressed in other Medicare Advantage medical policies.

| Codes | Number | Description and Non-coverage Rationale | Test Information |
|--------------|---------------|---|-------------------------|
|--------------|---------------|---|-------------------------|

| | | | |
|------------|-------|---|--|
| CPT | 0015M | <p>Adrenal cortical tumor, biochemical assay of 25 steroid markers, utilizing 24-hour urine specimen and clinical parameters, prognostic algorithm reported as a clinical risk and integrated clinical steroid risk for adrenal cortical carcinoma, adenoma, or other adrenal malignancy</p> <ul style="list-style-type: none"> ✓ Not medically reasonable or necessary under Medicare and §1862(a)(1)(A). This test provides a risk score, it does not “treat or diagnosis” an illness or injury. | <p><i>Adrenal Mass Panel, 24 Hour, Urine</i></p> <p>Mayo Clinic (MN)</p> |
| | 0052U | <p>Lipoprotein, blood, high resolution fractionation and quantitation of lipoproteins, including all five major lipoprotein classes and subclasses of HDL, LDL, and VLDL by vertical auto profile ultracentrifugation</p> <ul style="list-style-type: none"> ✓ MoIDX: Biomarkers in Cardiovascular Risk Assessment (L36129) (<i>Medicare has coverage for defined cholesterol tests. Non-coverage of lipoprotein subclasses from this LCD is applied to this test.</i>) | <p><i>VAP Cholesterol Test</i></p> <p>VAP Diagnostics Laboratory, Inc. (AL)</p> |
| | 0058U | <p>Oncology (Merkel cell carcinoma), detection of antibodies to the Merkel cell polyoma virus oncoprotein (small T antigen), serum, quantitative</p> <ul style="list-style-type: none"> • The MoIDX Program requires labs to submit a technology assessment (TA) to provide evidence of analytical and clinical validity (AV/CV), and clinical utility (CU). (<i>Noridian article A54554</i>) • The Noridian LCD L36256 states reimbursement is only allowed for “approved tests... for dates of service consistent with the effective date of the coverage determination” after MoIDX review. • If a test does not have a coverage determination, then coverage is not allowed because evidence of clinical validity or utility has not been established via the TA review process. • This test is not considered medically reasonable and necessary under SSA §1862(a)(1)(A) until a MoIDX review is complete and coverage is indicated by MoIDX or Noridian. | <p><i>Merkel SmT Oncoprotein Antibody Titer test</i></p> <p>University of Washington, Department of Laboratory Medicine (WA)</p> |
| | 0059U | <p>Oncology (Merkel cell carcinoma), detection of antibodies to the Merkel cell polyoma virus capsid protein (VP1), serum, reported as positive or negative</p> <ul style="list-style-type: none"> • The MoIDX Program requires labs to submit a technology assessment (TA) to provide evidence of analytical and clinical validity | <p><i>Merkel Virus VP1 Capsid Antibody test</i></p> <p>University of Washington, Department of Laboratory Medicine (WA)</p> |

| | | |
|-------|---|--|
| | <p>(AV/CV), and clinical utility (CU). (<i>Noridian article A54554</i>)</p> <ul style="list-style-type: none"> • The Noridian LCD L36256 states reimbursement is only allowed for “approved tests... for dates of service consistent with the effective date of the coverage determination” after MoIDX review. • If a test does not have a coverage determination, then coverage is not allowed because evidence of clinical validity or utility has not been established via the TA review process. • This test is not considered medically reasonable and necessary under SSA §1862(a)(1)(A) until a MoIDX review is complete and coverage is indicated by MoIDX or Noridian. | |
| 0061U | <p>Transcutaneous measurement of five biomarkers (tissue oxygenation [StO₂], oxyhemoglobin [ctHbO₂], deoxyhemoglobin [ctHbR], papillary and reticular dermal hemoglobin concentrations [ctHb1 and ctHb2]), using spatial frequency domain imaging (SFDI) and multi-spectral analysis</p> <ul style="list-style-type: none"> • The MoIDX Program requires labs to submit a technology assessment (TA) to provide evidence of analytical and clinical validity (AV/CV), and clinical utility (CU). (<i>Noridian article A54552</i>) • The Noridian LCD L35160 states reimbursement is only allowed for “approved tests... for dates of service consistent with the effective date of the coverage determination” after MoIDX review. • If a test does not have a coverage determination, then coverage is not allowed because evidence of clinical validity or utility has not been established via the TA review process. • This test is not considered medically reasonable and necessary under SSA §1862(a)(1)(A) until a MoIDX review is complete and coverage is indicated by MoIDX or Noridian. | <p><i>Transcutaneous multispectral measurement of tissue oxygenation and hemoglobin using Spatial Frequency Domain Imaging (SFDI) test</i></p> <p>Modulated Imaging, Inc. (CA)</p> |
| 0062U | <p>Autoimmune (systemic lupus erythematosus), IgG and IgM analysis of 80 biomarkers, utilizing serum, algorithm reported with a risk score</p> <ul style="list-style-type: none"> • With limited exceptions (such as single gene tests), the MoIDX Program requires labs to submit a technology assessment (TA) to provide evidence of analytical and clinical validity (AV/CV), and clinical utility (CU). This is especially applicable to new tests (e.g., tests with multiple genes with or without algorithmic analysis with diagnostic and/or prognostic purposes that have not received FDA companion diagnostic status or been universally | <p><i>SLE-key Rule Out</i></p> <p>Veracis (VA)</p> |

| | | |
|-------|--|--|
| | <p>recognized by recognized authorities such as NCCN, ASCO or other professional societies). (<i>Palmetto LCD L35025</i>)</p> <ul style="list-style-type: none"> • The Palmetto LCD L35025 states reimbursement is only allowed for “approved tests... for dates of service consistent with the effective date of the coverage determination” after MoIDX review. • If a test does not have a coverage determination, then coverage is not allowed because evidence of clinical validity or utility has not been established via the TA review process. • This test is not considered medically reasonable and necessary under SSA §1862(a)(1)(A) until a MoIDX review is complete and coverage is indicated by MoIDX. | |
| 0063U | <p>Neurology (autism), 32 amines by LC-MS/MS, using plasma, algorithm reported as metabolic signature associated with autism spectrum disorder</p> <p>Molecular Pathology Procedures (L35000) (<i>Specifically see the language in the LCD that reads, “Molecular pathology tests for diseases or conditions that manifest severe signs or symptoms in newborns and in early childhood or that result in early death... could be subject to automatic denials since these tests are not usually relevant to a Medicare beneficiary.”</i>)</p> | <p><i>NPDX ASD ADM Panel I</i></p> <p>Stemina Biomarker Discovery, Inc d/b/a NeuroPointDX (WI)</p> |
| 0096U | <p>Human Papillomavirus (HPV), high-risk types (ie, 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, 68), male urine</p> <p>Most men who get HPV do not develop symptoms and the infection usually resolves by itself. This test is a screening test, and HPV screening testing used outside of NCD 210.2.1 is non-covered under Medicare. In addition, diagnostic tests that are not ordered by a physician for diagnostic or clinical decision-making are also non-covered under Medicare. Therefore, this test is non-covered under Medicare. Coverage exceptions may be made on appeal if this test is used for <i>diagnostic</i> purposes if a patient has signs or symptoms of disease, and the ordering physician will use these test results to make a diagnosis or make treatment decisions for a relevant illness or condition.</p> | <p><i>HPV, High Risk Male Urine</i></p> <p>Molecular Testing Labs (WA)</p> |

| | | |
|-------|---|--|
| 0117U | <p>Pain management, analysis of 11 endogenous analytes (methylmalonic acid, xanthurenic acid, homocysteine, pyroglutamic acid, vanilmandelate, 5- hydroxyindoleacetic acid, hydroxymethylglutarate, ethylmalonate, 3-hydroxypropyl mercapturic acid (3-HPMA), quinolinic acid, kynurenic acid), LCMS/MS, urine, algorithm reported as a pain-index score with likelihood of atypical biochemical function associated with pain</p> <p>While this test may provide information during work-up, the test results do not provide data used to diagnose a condition or make treatment decisions. Decisions are not made based on this testing that would not otherwise have been made <i>without</i> this test. Therefore, this test is considered not medically reasonable or necessary under SSA §1862(a)(1)(A).</p> | <p><i>Foundation PISM</i> Ethos Laboratories</p> |
| 0119U | <p>Cardiology, ceramides by liquid chromatography–tandem mass spectrometry, plasma, quantitative report with risk score for major cardiovascular events</p> <p>Minnesota: According to the article for <i>Molecular Pathology Procedures- Related to Molecular Policy Procedures LCD (L35000) (A56199)</i> Screening services such as pre-symptomatic genetic tests and services used to detect an undiagnosed disease or disease predisposition are not a Medicare benefit and are not covered. Similarly, Medicare may not reimburse the costs of tests/examinations that assess the risk of a condition unless the risk assessment clearly and directly effects the management of the patient.”</p> <p>Florida: The LCD for <i>Molecular Pathology Procedures L34519</i> includes the same notes as those mentioned above.</p> | <p><i>MI-HEART</i> <i>Ceramides, Plasma</i> Mayo Clinic Laboratory (MN and FL)</p> |
| 0251U | <p>Hepcidin-25, enzyme-linked immunosorbent assay (ELISA), serum or plasma</p> <p>For asymptomatic individuals, this testing would be considered non-covered, as a screening test. For symptomatic individuals, the NCD for <i>Serum Iron Studies (190.18)</i> provides coverage for iron</p> | <p><i>Intrinsic Hepcidin IDx™ Test</i> IntrinsicDx, Intrinsic LifeSciences™ LLC. (CA and FL)</p> |

deficiency tests, but does not include hepcidin as a covered test. Non-coverage of this test is not considered restrictive under Medicare because there are other test options available to test for iron deficiency. Therefore, this test is considered not medically reasonable or necessary under SSA §1862(a)(1)(A).

0342U Oncology (pancreatic cancer), multiplex immunoassay of C5, C4, cystatin C, factor B, osteoprotegerin (OPG), gelsolin, IGFBP3, CA125 and multiplex electrochemiluminescent immunoassay (ECLIA) for CA19-9, serum, diagnostic algorithm reported qualitatively as positive, negative, or borderline

IMMray® PanCan-d
Immunovia, Inc. (MA)

- According to the article for Molecular Pathology Procedures- Related to Molecular Policy Procedures LCD (L35000) ([A56199](#)), screening services such as pre-symptomatic genetic tests and services used to detect an undiagnosed disease or disease predisposition are not a Medicare benefit and are not covered. Similarly, Medicare may not reimburse the costs of tests/examinations that assess the risk of a condition unless the risk assessment clearly and directly effects the management of the patient.”

0344U Hepatology (nonalcoholic fatty liver disease [NAFLD]), semiquantitative evaluation of 28 lipid markers by liquid chromatography with tandem mass spectrometry (LC-MS/MS), serum, reported as at-risk for nonalcoholic steatohepatitis (NASH) or not NASH

OWLiver
Cima Sciences (TX)

According to Billing and Coding: Molecular Pathology and Genetic Testing ([A58917](#)), screening services such as pre-symptomatic genetic tests and services used to detect an undiagnosed disease or disease predisposition are not a Medicare benefit and are not covered. Similarly, Medicare may not reimburse the costs of tests/examinations that assess the risk of a condition unless the risk assessment clearly and directly effects the management of the patient.”

| | |
|-------|---|
| 0361U | Neurofilament light chain, digital immunoassay, plasma, quantitative |
| | Not medically reasonable or necessary under Medicare and §1862(a)(1)(A). This is a marker associated with disease severity, it is not used in the diagnosis or treatment of any disorder. |
| 0443U | Neurofilament light chain (NfL), ultra-sensitive immunoassay, serum or cerebrospinal fluid |
| | Not medically reasonable or necessary under Medicare and §1862(a)(1)(A). This is a marker associated with disease severity, it is not used in the diagnosis or treatment of any disorder. |

POLICY GUIDELINES

To determine whether a medical technology is a proven, medically necessary service, device, or procedure, the MAO conducts literature searches and evaluates the published scientific evidence related to each technology. The published evidence is reviewed against five (5) technology assessment criteria. In order for a technology to be considered medically necessary, all five (5) criteria must be met. If any one or more of the following criteria are not met, then the technology is considered investigational:

1. The technology must have final approval from the appropriate government regulatory bodies (i.e., Food and Drug Administration [FDA]). An approval granted as an interim step (i.e., Treatment IND) in the governmental body's regulatory process is not sufficient.
2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes, and consist of well-designed and well-conducted investigations published in peer-reviewed journals. The quality of the studies and the consistency of the results are considered when evaluating the evidence.
3. The technology must improve the net health outcome (the technology's beneficial effects on health outcomes should outweigh any harmful effects on health outcomes).
4. The technology must be as beneficial as any established alternatives. This means the technology should improve the net health outcome as much as or more than established alternatives.
5. The improvement must be attainable outside the investigational settings. When used under the usual conditions of medical practice, the technology should be reasonably expected to satisfy technology evaluation criteria #3 and #4.

In addition to the above criteria, the following additional criteria apply to new diagnostic technologies (e.g., imaging studies, laboratory procedures, home monitoring devices):

1. Technical feasibility is demonstrated, including reproducibility and precision. For comparison among studies, a common standardized protocol for the new diagnostic technology is established.
2. For accurate interpretation of study results, sensitivities, specificities, and positive and negative predictive values compared to standards are established.
3. The clinical utility of a diagnostic technique, i.e., how the results of the study can be used to benefit patient management, is established. The clinical utility of both positive and negative tests must be established.

CROSS REFERENCES

[Medicare Advantage Medical Policy Development and Review](#), Introduction, Policy No. M-01

[Clinical Trials and Investigational Device Exemption \(IDE\) Studies](#), Medicine, Policy No. M-150

[Coverage with Evidence Development \(CED\) Studies and Registries](#), Medicine, Policy No. M-156

Various Medicare Advantage medical policies for specific procedures, services, or devices

REFERENCES

1. Medicare Claims Processing Manual, Chapter 23 - Fee Schedule Administration and Coding Requirements, [§30 - Services Paid Under the Medicare Physician's Fee Schedule, A. Physician's Services](#)
2. Medicare Managed Care Manual, Chapter 4 - Benefits and Beneficiary Protections, [§90.5 – Creating New Guidance](#)
3. Medicare Benefit Policy Manual, Chapter 14 - Medical Devices, [§10 - Coverage of Medical Devices](#)
4. Medicare Managed Care Manual, Chapter 4 - Benefits and Beneficiary Protections, [§10.7.3 – Payment for Clinical Studies Approved Under Coverage with Evidence Development \(CED\)](#)
5. Medicare Claims Processing Manual, Chapter 1 - General Billing Requirements, [§10.1.5.4 - Independent Laboratories](#)

***IMPORTANT NOTE:** Medicare Advantage medical policies use the most current Medicare references available at the time the policy was developed. Links to Medicare references will take viewers to external websites outside of the health plan's web control as these sites are not maintained by the health plan.