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Medicare Advantage Policy Manual **Policy ID:** M-MED149

Investigational (Experimental) Services and New and Emerging Medical Technologies and Procedures

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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, Section 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.[2]

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.[3]

The Noridian *LCD for Non-Covered Services (L35008)* states, "**It is important to note that the fact that a new service or procedure has been issued a CPT code or is FDA approved for a specific indication does not, in itself, make the procedure medically reasonable and necessary.**" In addition, 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.[2] The U.S. Food and Drug Administration (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).

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: This Medicare Advantage medical policy does not address services provided in the context of a clinical trial, or medical devices related to Category A or B Investigational Device Exemption (IDE) studies. For Clinical Trial and IDE study claim assistance, see the Centers for Medicare and Medicaid Services (CMS) website. (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.[1] 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. According to the Noridian Local Coverage Determination (LCD) for Non-Covered Services (L35008), ***all new Category III Codes are considered non-covered unless specifically approved for payment by CMS or the Noridian Healthcare Solutions (Noridian) medical directors and documented as approved in a published LCD or article*** (LCA). In most cases, these codes have been created to track new, unproven therapies and tests.

IMPORTANT NOTE: This list is updated routinely to supply the **most recent** Category III codes, as they are released. **It is not intended to be an all-inclusive list. The absence or removal of a Category III code from this medical policy does not imply coverage.** Some procedures may be addressed in other Medicare Advantage medical policies, while others may be non-covered, even when not found in any medical policy. Please see available Medicare Advantage medical policies for specific procedures, as well as the Noridian LCD for *Non-Covered Services (L35008)* and the LCA for *Additional Information Required for Coverage and Pricing for Category III CPT® Codes (A55681),* for additional Category III codes.

Codes	Number	Description
	~~0346T~~	~~Ultrasound, elastography (List separately in addition to code for primary procedure)~~ *(Code deleted 01/01/2019)*
	0543T	Transapical mitral valve repair, including transthoracic echocardiography, when performed, with placement of artificial chordae tendineae
	0544T	Transcatheter mitral valve annulus reconstruction, with implantation of adjustable annulus reconstruction device, percutaneous approach including transseptal puncture
	0545T	Transcatheter tricuspid valve annulus reconstruction with implantation of adjustable annulus reconstruction device, percutaneous approach
	0546T	Radiofrequency spectroscopy, real time, intraoperative margin assessment, at the time of partial mastectomy, with report
	0547T	Bone-material quality testing by microindentation(s) of the tibia(s), with results reported as a score
	0548T	Transperineal periurethral balloon continence device; bilateral placement, including cystoscopy and fluoroscopy
	0549T	; unilateral placement, including cystoscopy and fluoroscopy
	0550T	; removal, each balloon
	0551T	; adjustment of balloon(s) fluid volume
	0552T	Low-level laser therapy, dynamic photonic and dynamic thermokinetic energies, provided by a physician or other qualified health care professional
	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
	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	; retrieval and transmission of the scan data

	0556T	; assessment of bone strength and fracture risk and bone mineral density
	0557T	; interpretation and report
	0558T	Computed tomography scan taken for the purpose of biomechanical computed tomography analysis
	0559T	Anatomic model 3D-printed from image data set(s); first individually prepared and processed component of an anatomic structure
	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
	0562T	; each additional anatomic guide (List separately in addition to code for primary procedure)

Proprietary Laboratory Analyses (PLA) 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 PLA codes as they are released. **It is not intended to be an all-inclusive list.** The absence of a PLA test code from this medical policy does not imply coverage, as some PLA tests may be addressed in other Medicare Advantage medical policies.

Codes	Number	Description	Test Information
	0052U	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 ✓ MolDX: Biomarkers in Cardiovascular Risk Assessment (L36129) *(Medicare has coverage for defined cholesterol tests. Non-coverage of lipoprotein subclasses from this LCD is applied to this test.)*	*VAP Cholesterol Test* VAP Diagnostics Laboratory, Inc. (Birmingham, AL)
	0058U	Oncology (Merkel cell carcinoma), detection of antibodies to the Merkel cell polyoma virus oncoprotein (small T antigen), serum, quantitative • The MolDX Program requires labs to submit a technology assessment (TA) to provide	*Merkel SmT Oncoprotein Antibody Titer test* University of Washington,

		evidence of analytical and clinical validity (AV/CV), and clinical utility (CU). *(Noridian LCA A54554)* • 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 MolDX 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 MolDX review is complete and coverage is indicated by MolDX or Noridian.	Department of Laboratory Medicine (Seattle, WA)
	0059U	Oncology (Merkel cell carcinoma), detection of antibodies to the Merkel cell polyoma virus capsid protein (VP1), serum, reported as positive or negative • The MolDX Program requires labs to submit a technology assessment (TA) to provide evidence of analytical and clinical validity (AV/CV), and clinical utility (CU). *(Noridian LCA A54554)* • 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 MolDX 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 MolDX review is complete and coverage is indicated by MolDX or Noridian.	*Merkel Virus VP1 Capsid Antibody test* University of Washington, Department of Laboratory Medicine (Seattle, WA)
	0061U	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 • The MolDX Program requires labs to submit a technology assessment (TA) to provide evidence of analytical and clinical validity	*Transcutaneous multispectral measurement of tissue oxygenation and hemoglobin using Spatial Frequency Domain Imaging (SFDI) test*

		(AV/CV), and clinical utility (CU). *(Noridian LCA A54552)* • 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 MolDX 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 MolDX review is complete and coverage is indicated by MolDX or Noridian.	Modulated Imaging, Inc. (Irving, CA)
	0062U	Autoimmune (systemic lupus erythematosus), IgG and IgM analysis of 80 biomarkers, utilizing serum, algorithm reported with a risk score • With limited exceptions (such as single gene tests), the MolDX 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 recognized by recognized authorities such as NCCN, ASCO or other professional societies). *(Palmetto LCD L35025)* • 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 MolDX 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 MolDX review is complete and coverage is indicated by MolDX.	*SLE-key Rule Out* Veracis (Virginia)
	0063U	Neurology (autism), 32 amines by LC-MS/MS, using plasma, algorithm reported as metabolic signature associated with autism spectrum disorder	*NPDX ASD ADM Panel I* Stemina Biomarker Discovery, Inc d/b/a

		Molecular Pathology Procedures (L35000) *(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.")*	NeuroPointDX (Madison, WI)
	0096U	Human Papillomavirus (HPV), high-risk types (ie, 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, 68), male urine 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 *diagnostic* 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.	*HPV, High Risk Male Urine* Molecular Testing Labs (Vancouver, WA)
	0117U	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 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 *without* this test. Therefore, this is considered not medically necessary under SSA §1862(a)(1)(A).	*Foundation PISM* Ethos Laboratories

	0119U	Cardiology, ceramides by liquid chromatography–tandem mass spectrometry, plasma, quantitative report with risk score for major cardiovascular events **Minnesota**: According to the LCD for *Molecular Pathology Procedures* (L35000), testing for the *risk* of developing a condition is an example of a non-covered (screening) test. In addition, in the LCA 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." **Florida**: The LCD for *Molecular Pathology Procedures* (L34519) includes the same notes as those mentioned above.	*MI-HEART Ceramides, Plasma* Mayo Clinic Laboratory (MN and FL)

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 Managed Care Manual, Chapter 4 - Benefits and Beneficiary Protections, §10.7.3 – Payment for Clinical Studies Approved Under Coverage with Evidence Development (CED)
2. 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
3. Medicare Managed Care Manual, Chapter 4 - Benefits and Beneficiary Protections, §90.5 – Creating New Guidance
4. Noridian LCA for Additional Information Required for Coverage and Pricing for Category III CPT® Codes (A55681)
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.*