United Healthcare Medicare Advantage

UnitedHealthcare Medicare Advantage
Policy Guideline Update Bulletin: November 2021

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Policy Guideline Updates

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Policy Title	**Approval Date**	**Summary of Changes**
Ambulatory EEG Monitoring (NCD 160.22)	Oct. 13, 2021	**Applicable Codes** • Added ICD-10 diagnosis code G40.42 • Added notation to indicate ICD-10 diagnosis code G92 was "deleted Sep. 30, 2021"
Aprepitant for Chemotherapy-Induced Emesis (NCD 110.18)	Oct. 13, 2021	**Related Policies** • Added reference link to the Medicare Advantage Policy Guideline titled *KX Modifier* **Supporting Information** • Updated *References* section to reflect the most current information

Biomarkers in Cardiovascular Risk Assessment	Oct. 13, 2021	**Related Policies**
		• Added reference link to the Medicare Advantage Reimbursement Policy titled *Molecular Pathology Policy, Professional and Facility*
		• Removed reference link to the Medicare Advantage Policy Guideline titled *Category III CPT Codes*
		Applicable Codes
		• Updated language pertaining to CPT code 0111T:
		  ○ Added notation to indicate code was "deleted Dec. 31, 2020"
		  ○ Removed reference link to the Medicare Advantage Policy Guideline titled *Category III CPT Codes*
		Supporting Information
		• Updated *References* section to reflect the most current information

Chimeric Antigen Receptor (CAR) T-cell Therapy (NCD 110.24)	Oct. 13, 2021	**Applicable Codes** • Added HCPCS codes C9076, C9081, and Q2054 **Definitions** • Updated definition of "Risk Evaluation and Mitigation Strategy (REMS)" **Supporting Information** • Updated *References* section to reflect the most current information
Clinical Diagnostic Laboratory Services	Oct. 13, 2021	**Applicable Codes** • Added CPT codes 0018M, 0255U, 0256U, 0257U, 0258U, 0259U, 0260U, 0261U, 0262U, 0263U, 0264U, 0265U, 0266U, 0267U, 0268U, 0269U, 0270U, 0271U, 0272U, 0273U, 0274U, 0275U, 0276U, 0277U, 0278U, 0279U, 0280U, 0281U, 0282U, 0283U, 0284U, 0285U, 0286U, 0287U, 0288U, 0289U, 0290U, 0291U, 0292U, 0293U, 0294U, 0295U, 0296U, 0297U, 0298U, 0299U, 0300U, 0301U, 0302U, 0303U, 0304U, 0305U, 80220, 80503, 80504, 80505, 80506, 81349, 81523, 81560, 82653, 83521, 83529, 86015, 86036, 86037, 86051, 86052, 86053, 86231, 86258, 86362, 86363, 86364, 86381, 86596, and 87154

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Clinical Diagnostic Laboratory Services (continued)	Oct. 13, 2021	• Updated language pertaining to CPT code 0139U; removed notation indicating code is not covered when submitted with screening diagnosis • Revised description for CPT codes 0051U and 0139U **Supporting Information** • Updated *References* section to reflect the most current information
Long Term EEG Monitoring	Oct. 13, 2021	**Applicable Codes** • Added ICD-10 diagnosis codes G40.42, G40.833, and G40.834
Molecular Diagnostic Infectious Disease Testing	Oct. 13, 2021	**Applicable Codes** • Updated list of applicable ICD-10 diagnosis codes: *For CPT codes 87631, 87636, 87637, 0240U, and 0241U (Facility Only)* ○ Added R05.1, R05.2, R05.3, R05.8, T80.82XS, Z92.850, Z92.858, and Z92.86 ○ Added notation to indicate R05 was "deleted Sep. 30, 2021" *For CPT Codes 87505 and 87506 (Facility Only)* ○ Added M31.19 *For CPT Codes 0097U and 87507 (Facility Only)* ○ Added D89.44, T80.82XS, Z92.850, Z92.858, and Z92.86 **Supporting Information** • Updated *References* section to reflect the most current information
Podiatry	Oct. 13, 2021	**Policy Summary** *Overview* • Updated list of conditions for/in which routine foot care is not excluded from Medicare coverage; replaced "[presence of] metabolic, neurologic or *vascular conditions* that may require scrupulous foot care by a professional" with "[presence of] metabolic, neurologic or *peripheral disease* that may require scrupulous foot care by a professional" • Updated language pertaining to coverage of routine foot care services to indicate: ○ Covered exceptions to routine foot care services are considered medically necessary once (1) in 60 days ○ Routine foot care services performed more often than every 60 days will be denied unless documentation is submitted with the claim to substantiate the increased frequency *Guidelines* • Updated language pertaining to submission of claims using a Q7, Q8, or Q9 modifier to indicate the provider must document in the medical record the appropriate signs and symptoms as outlined in Class Findings A, B, and/or C along with the complicating condition(s)

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Policy Title	**Approval Date**	**Summary of Changes**
Podiatry	Oct. 13, 2021	**Applicable Codes** *HCPCS Codes* • Added notation to indicate G0245, G0246, and G0247 were "deleted Oct. 13, 2021" *Diagnosis Codes* • Updated list of applicable ICD-10 diagnosis codes: **For CPT Codes 11055, 11056, and 11057** ○ Added E75.244, I80.241, I80.242, I80.243, I80.249, I80.251, I80.252, I80.253, I80.259, I82.551, I82.552, I82.553, I82.559, I82.561, I82.562, I82.563, I82.569, L90.9, L91.9, L98.7, Q81.0, Q81.1, Q81.2, and Q81.8 ○ Removed E08.321, E08.329, E08.331, E08.339, E08.341, E08.349, E08.351, E08.359, E09.321, E09.329, E09.331, E09.339, E09.341, E09.349, E09.351, E09.359, E10.321, E10.329, E10.331, E10.339, E10.341, E10.349, E10.351, E10.359, E11.321, E11.329, E11.331, E11.339, E11.341, E11.349, E11.351, E11.359, E13.321, E13.329, E13.331, E13.339, E13.341, E13.349, E13.351, E13.359, and E85.8 ○ Revised description for I82.811 and I82.812 **For CPT Codes 11719, 11720, 11721, and HCPCS Code G0127** ○ Added E75.244, I80.241, I80.242, I80.243, I80.249, I80.251, I80.252, I80.253, I80.259, I82.551, I82.552, I82.553, I82.559, I82.561, I82.562, I82.563, I82.569, L11.0, L84, L85.0, L85.1, L85.2, L86, L87.0, L87.2, L90.9, L91.9, L98.7, Q81.0, Q81.1, Q81.2, Q81.8, Q81.9, and Q82.8 ○ Removed E08.321, E08.329, E08.331, E08.339, E08.341, E08.349, E08.351, E08.359, E09.321, E09.329, E09.331, E09.339, E09.341, E09.349, E09.351, E09.359, E10.321, E10.329, E10.331, E10.339, E10.341, E10.349, E10.351, E10.359, E11.321, E11.329, E11.331, E11.339, E11.341, E11.349, E11.351, E11.359, E13.321, E13.329, E13.331, E13.339, E13.341, E13.349, E13.351, E13.359, and E85.8 ○ Revised description for I82.811 and I82.812 **Definitions** • Removed definition of "Policy Outreach and Education (POE)" **Supporting Information** • Updated *References* section to reflect the most current information
Screening Pap Smears and Pelvic Examinations for Early Detection of Cervical or Vaginal Cancer (NCD 210.2)	Oct. 13, 2021	**Related Policies** • Removed reference link to the Medicare Advantage Policy Guideline titled *Clinical Diagnostic Laboratory Services* **Supporting Information** • Updated *References* section to reflect the most current information

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Self-Administered Drug(s) (SAD)
Self-Administered Drug(s) (SAD) (continued)
	Oct. 13, 2021	**Applicable Codes**
		• Added HCPCS codes J1628 and J3357
		• Added self-administered drug (SAD) end date for HCPCS codes C9399, J3490, J3590, and J9999 [Abatacept SQ (Orencia®)]: "Apr. 5, 2021"
		• Updated list of applicable drug names for:
		  ○ HCPCS codes C9399, J3490, J3590, J9999: Added Pasireotide (Signifor®)
		  ○ HCPCS codes J3490, J3590, J9999: Removed Tocilizumab Actemra
		Supporting Information
		• Updated *References* section to reflect the most current information

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Blood-Derived Products for Chronic Non-Healing Wounds (NCD 270.3)	Oct. 13, 2021	**Policy Summary**
		• Updated list of examples of platelet derived growth factor (PDGF) products; removed Procuren
		• Replaced language indicating "platelet-rich plasma (PRP) is different from previous products in that it contains whole cells including white cells, red cells, plasma, platelets, *fibrinogen*, stem cells, *macrophages*, and *fibroblasts*" with "PRP is different from previous products in that it contains whole cells including white cells, red cells, plasma, platelets, *fibrin*, stem cells, and *fibrocyte precursors*"
		Nationally Covered Indications
		• Revised language to indicate, effective for services performed on or after Apr. 13, 2021, the Centers for Medicare & Medicaid Services (CMS) will cover autologous PRP for the treatment of chronic non-healing diabetic wounds under *Section 1862(a)(1)(A) of the Social Security Act (the Act)* for a duration of 20 weeks, when prepared by devices whose Food and Drug Administration-cleared indications include the management of exuding cutaneous wounds, such as diabetic ulcers
		Nationally Noncovered Indications
		• Revised language to indicate the following services are not covered:
		  ○ Autologous PDGF for the treatment of chronic, non-healing cutaneous wounds; and
		  ○ Becaplermin, a non-autologous growth factor for chronic, non-healing subcutaneous wounds; and
		  ○ Autologous PRP for the treatment of acute surgical wounds when the autologous PRP is applied directly to the closed incision, or for dehiscent wounds
		Other
		• Revised language to indicate, effective for services performed on or after Apr. 13, 2021:

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Blood-Derived Products for Chronic Non-Healing Wounds (NCD 270.3) (continued)	Oct. 13, 2021	○ Coverage of autologous PRP for the treatment of chronic non-healing diabetic wounds beyond 20 weeks will be determined by local Contractors ○ Coverage of autologous PRP for the treatment of all other chronic non-healing wounds will be determined by the local Contractors under *Section 1862(a)(1)(A) of the Act* **Applicable Codes** • Removed Modifier code Q0 • Removed Condition code 30 **Supporting Information** • Updated *References* section to reflect the most current information
Colorectal Cancer Screening Tests (NCD 210.3)	Oct. 13, 2021	**Related Policies** • Added reference link to the Medicare Advantage Reimbursement Policy titled: ○ *Clinical Laboratory Improvement Amendments (CLIA) ID Requirement Policy, Professional* ○ *Laboratory Services Policy, Professional* ○ *Molecular Pathology Policy, Professional and Facility* **Policy Summary** ***Nationally Covered Indications*** **Blood-based Biomarker Tests (effective Jan. 19, 2021)** ***(new to policy)*** • Added language to indicate: ○ Blood-based DNA testing detects molecular markers of altered DNA that are contained in the cells shed into the blood by colorectal cancer and pre-malignant colorectal epithelial neoplasia ○ Effective for dates of service on or after Jan. 19, 2021, a blood-based biomarker test is covered as an appropriate colorectal cancer screening test once every 3 years for Medicare beneficiaries when performed in a Clinical Laboratory Improvement Act (CLIA)-certified laboratory, when ordered by a treating physician and when all of the following requirements are met: ▪ The patient is age 50-85 years; and ▪ Asymptomatic (no signs or symptoms of colorectal disease including but not limited to lower gastrointestinal pain, blood in stool, positive guaiac fecal occult blood test or fecal immunochemical test); and ▪ At average risk of developing colorectal cancer (no personal history of adenomatous polyps, colorectal cancer, or inflammatory bowel disease, including Crohn's Disease and ulcerative colitis; no family history of colorectal cancers or adenomatous polyps, familial adenomatous polyposis, or hereditary nonpolyposis colorectal cancer) ○ The blood-based biomarker screening test must have all of the following:

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Colorectal Cancer Screening Tests (NCD 210.3) (continued)	Oct. 13, 2021	▪ Food and Drug Administration (FDA) market authorization with an indication for colorectal cancer screening; and ▪ Proven test performance characteristics for a blood-based screening test with both sensitivity greater than or equal to 74% and specificity greater than or equal to 90% in the detection of colorectal cancer compared to the recognized standard (accepted as colonoscopy at this time), as minimal threshold levels, based on the pivotal studies included in the FDA labeling **Supporting Information** • Updated *References* section to reflect the most current information
Coverage of Drugs and Biologicals for Label and Off-Label Uses	Oct. 13, 2021	**Policy Summary** ***Guidelines*** • Removed language addressing payment exclusions for medications determined not to be reasonable and necessary (refer to the *Coverage Limitations* section) **Coverage Indications** • Revised language pertaining to compendia ratings to indicate: ○ A use is identified by a compendium as medically accepted if the: ▪ Indication is a Category 1 or 2A in NCCN, or Class I, Class IIa, or Class IIb in DrugDex; or ▪ Narrative text in AHFS-DI or Clinical Pharmacology is supportive, or ▪ Indication is listed in Lexi-Drugs as "Use: Off-Label" and rated as "Evidence Level A" ○ A use is not medically accepted by a compendium if the: ▪ Indication is a Category 3 in NCCN or a Class III in DrugDex; or ▪ Narrative text in AHFS or Clinical Pharmacology is "not supportive," or ▪ Indication is listed in Lexi-Drugs as "Use: Unsupported" ○ The complete absence of narrative text on a use is considered neither supportive nor non-supportive **Coverage Limitations** • Revised language pertaining to payment exclusions to indicate: ○ If a medication is determined not to be reasonable and necessary for diagnosis or treatment of an illness or injury according to these guidelines, the entire charge will be excluded (i.e., for both the drug and its administration) ○ Also excluded from payment is any charge for other services (such as office visits) which are primarily for the purpose of administering a non–covered injection (i.e., an injection that is not reasonable and necessary for the diagnosis or treatment of an illness or injury) **Supporting Information** • Updated *References* section to reflect the most current information

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L-Dopa (NCD 160.17)	Oct. 13, 2021	Policy Summary *Guidelines* • Added language pertaining to L-Dopa Enteral Suspension to indicate: ○ Establishment of the transabdominal port with a percutaneous endoscopic gastrostomy-jejunal tube (PEG-J) is performed under endoscopic guidance by a gastroenterologist or other healthcare provider experienced in this procedure ○ The PEG-J is considered a supply provided incident to a physician's service, and claims for this item are processed by the A/B MAC contractor ○ Claims to the DME MAC for the PEG-J will be rejected as wrong jurisdiction
Transcatheter Mitral Valve Repair (TMVR)/Transcatheter Edge-to-Edge Repair (TEER) for Mitral Valve Regurgitation (NCD 20.33)	Oct. 13, 2021	Title Change • Previously titled *Transcatheter Mitral Valve Repair (NCD 20.33)* Policy Summary • Replaced references to “transcatheter mitral valve repair (TMVR)” with “transcatheter edge-to-edge repair (TEER) of the mitral valve” *Overview* • Revised language to indicate: ○ TEER of the mitral valve is used in the treatment of mitral regurgitation ○ TEER approximates the anterior and posterior mitral valve leaflets by grasping them with a clipping device in an approach similar to a treatment developed in cardiac surgery called the Alfieri stitch Guidelines *Nationally Covered Indications* • Revised language to indicate: ○ The Centers for Medicare & Medicaid Services (CMS) covers *TEER of the mitral valve* under Coverage with Evidence Development (CED) with the following conditions: ▪ For the treatment of symptomatic moderate-to-severe or severe functional mitral regurgitation (MR) when the patient remains symptomatic despite stable doses of maximally tolerated guideline-directed medical therapy (GDMT) plus cardiac resynchronization therapy, if appropriate, or for the treatment of significant symptomatic degenerative MR when furnished according to an FDA-approved indication and when all of the following conditions are met: – The procedure is furnished with a system that has received FDA premarket approval (PMA) ▪ The patient (pre-operatively and post-operatively) is under the care of a heart team (a cohesive, multi-disciplinary, team of medical professionals); the heart team concept embodies collaboration and dedication

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Transcatheter Mitral Valve Repair (TMVR)/Transcatheter Edge-to-Edge Repair (TEER) for Mitral Valve Regurgitation (NCD 20.33) (continued)	Oct. 13, 2021	across medical specialties to offer optimal patient-centered care and must include the following members with experience and training as specified: – Cardiac surgeon • With ≥ 20 mitral valve surgeries per year or ≥ 40 over two years, 50% of which are mitral valve repairs; and • Who is board eligible or certified in cardiothoracic surgery or similar foreign equivalent – Interventional cardiologist • With professional experience of ≥ 50 career structural heart disease procedures; or ≥ 30 left-sided structural procedures per year; and • With participation in ≥ 20 career trans-septal interventions including 10 as primary or co-primary operator; and • Who is board eligible or certified in interventional cardiology or similar foreign equivalent – Interventional echocardiographer (cardiologist or anesthesiologist) • With professional experience of ≥ 10 trans-septal guidance procedures and ≥ 30 structural heart procedures; and • Who is board eligible or certified in transesophageal echocardiography with advanced training as required for privileging by the hospital where the TEER is performed – Heart failure cardiologist experienced in treating patients with advanced heart failure (only required for functional MR patients); and – Providers from other physician groups as well as advanced patient practitioners, nurses, research personnel, and administrators ▪ Each patient's suitability for surgical mitral valve repair, TEER, or palliative therapy must be evaluated, documented, and made available to other heart team members; additionally, for patients with functional MR, the heart team heart failure cardiologist must document that the patient has persistent symptoms despite maximally tolerated GDMT and cardiac resynchronization therapy, if appropriate, as described below: – For patients with functional MR: the heart team interventional cardiologist and heart team heart failure cardiologist independently evaluate the patient using information in the medical record and a face-to-face examination; to decrease patient burden, the heart team heart failure cardiologist may meet this requirement through a review of the patient's records and images if the patient has an established relationship with a cardiologist experienced in treating patients with advanced heart failure – For patients with degenerative MR: the heart team interventional cardiologist and heart team cardiac surgeon must independently evaluate the patient using information in the medical record and a face-to-face examination

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Transcatheter Mitral Valve Repair (TMVR)/Transcatheter Edge-to-Edge Repair (TEER) for Mitral Valve Regurgitation (NCD 20.33) (continued)	Oct. 13, 2021	▪ An interventional cardiologist or cardiac surgeon from the heart team must perform the mitral valve TEER and an interventional echocardiographer from the heart team must perform transesophageal echocardiography during the procedure – The interventional echocardiographer may not also furnish anesthesiology during the same procedure – The interventional cardiologist and cardiac surgeon may jointly participate in the intra-operative technical aspects of TEER as appropriate – All physicians who participate in the procedure must have device-specific training as required by the manufacturer ▪ Mitral valve TEERs must be furnished in a hospital with the appropriate infrastructure that includes but is not limited to: – On-site heart valve surgery and interventional cardiology programs – Hospital volume requirements below must be met and maintained: • ≥ 20 mitral valve surgical procedures for severe MR per year or ≥ 40 over two years, of which at least 10 (or 20 over two years) must be mitral valve repairs; and • ≥ 2 physicians with cardiac surgery privileges experienced in valvular surgery; and • ≥ 1 physician with interventional cardiology privileges; and • ≥ 300 percutaneous coronary interventions (PCIs) per year ▪ The heart team and hospital are participating in a prospective, national, audited registry that comprehensively enrolls TEER patients, accepts all manufactured devices, follows the patient for at least one year; and complies with relevant regulations relating to protecting human research subjects, including *45 Code of Federal Regulations (CFR) Part 46 and 21 CFR Parts 50 & 56* – The following outcomes must be tracked by the registry; and the registry must be designed to permit identification and analysis of patient-, practitioner-, and facility-level variables that predict each of these outcomes: • All-cause mortality • Stroke • Major vascular events • Renal complications • Functional capacity • Repeat TEER or other mitral procedures • Transient ischemic attacks (TIAs) and • Quality of life (QoL)

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Transcatheter Mitral Valve Repair (TMVR)/Transcatheter Edge-to-Edge Repair (TEER) for Mitral Valve Regurgitation (NCD 20.33) (continued)	Oct. 13, 2021	▪ The registry shall collect all data necessary and have a written executable analysis plan in place to address the following questions; specifically, for the CED bullet below, this must be addressed through a composite metric – For the below CED questions, the results must be reported publicly as described in CED criterion k: • When TEER procedures are performed outside a controlled clinical study, how do outcomes and adverse events compare to the pivotal clinical studies? • How do the demographics of registry patients compare to the pivotal studies? • How do outcomes and adverse events in subpopulations compare to patients in the pivotal clinical studies? • What is the long-term (5 year) durability of the device? • What are the long-term (year) outcomes and adverse events? ▪ Consistent with *Section 1142 of the Social Security Act (the Act)*, the Agency for Healthcare Research and Quality (AHRQ) supports clinical research studies that CMS determines meet the above-listed standards and address the above-listed research questions ○ Mitral valve TEERs are covered for uses that are not expressly listed as an FDA-approved indication when performed within a clinical study that fulfills all of the following: ▪ An interventional cardiologist or cardiac surgeon must perform the mitral valve TEER and an interventional echocardiographer must perform transesophageal echocardiography during the procedure – The interventional echocardiographer may not also furnish anesthesiology during the same procedure – The interventional cardiologist and cardiac surgeon may jointly participate in the intra-operative technical aspects of TEER as appropriate – All physicians who participate in the procedure must have device specific training as required by the manufacturer ▪ As a fully-described, written part of its protocol, the clinical research trial must critically evaluate the following questions at 12 months or longer follow-up: – What is the rate of all-cause mortality in the intervention group? – What is the rate of re-operations (open surgical or transcatheter) of the mitral valve in the intervention group? – What is the rate of moderate-to-severe or severe MR in the intervention groups? ▪ As a fully-described, written part of its protocol, the clinical research study must critically evaluate not only each patient's quality of life pre- and post-TEER (minimum 1 year), but must also address at least one of the following questions: – What is the incidence of stroke? – What is the incidence of renal complications?

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Transcatheter Mitral Valve Repair (TMVR)/Transcatheter Edge-to-Edge Repair (TEER) for Mitral Valve Regurgitation (NCD 20.33) (continued)	Oct. 13, 2021	– What is the incidence of worsening MR? – What is the incidence of TIAs? – What is the incidence of major vascular events? – What is the change in quality of life after TEER? – What is the change in the patient's functional capacity after TEER? ○ The clinical study must adhere to the following standards of scientific integrity and relevance to the Medicare population: ▪ The item or service meaningfully improves health outcomes of affected beneficiaries who are represented by the enrolled subjects ▪ The rationale for the study is well supported by available scientific and medical evidence ▪ The study results are not anticipated to unjustifiably duplicate existing knowledge studies ▪ The study design is methodologically appropriate, and the anticipated number of enrolled subjects is sufficient to answer the research question(s) being asked in the National Coverage Determination (NCD) ▪ The study is sponsored by an organization or individual capable of executing the proposed study completing it successfully ▪ The research study is in compliance with all applicable Federal regulations concerning the protection of human subjects found in the Code of Federal Regulations (CFR) at 45 CFR Part 46 – If a study is regulated by the Food and Drug Administration (FDA), it is also must be in compliance with 21 CFR Parts 50 and 56 – In addition, to further enhance the protection of human subjects in studies conducted under CED, the study must provide and obtain meaningful informed consent from patients regarding the risks associated with the study items and /or services, and the use and eventual disposition of the collected data ▪ All aspects of the research study are conducted according to appropriate standards of scientific integrity ▪ The study has a written protocol that clearly demonstrates adherence to the standards listed here as Medicare coverage requirements ▪ The study is not designed to exclusively test toxicity or disease pathophysiology in healthy individuals; such studies may meet this requirement only if the disease or condition being studied is life threatening as defined in 21 CFR ˜312.81(a) and the patient has no other viable treatment options ▪ The clinical research studies and registries are registered on the ClinicalTrials.gov website by the principal sponsor/investigator prior to the enrollment of the first study subject; registries are also registered in the Agency for Healthcare Quality (AHRQ) Registry of Patient Registries (RoPR) ▪ The research study protocol specifies the method and timing of public release of all prespecified outcomes to be measured including release of outcomes if outcomes are negative or study is terminated early

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Transcatheter Mitral Valve Repair (TMVR)/Transcatheter Edge-to-Edge Repair (TEER) for Mitral Valve Regurgitation (NCD 20.33) (continued)	Oct. 13, 2021	– The results must be made public within 12 months of the study's primary completion date, which is the date the final subject had final data collection for the primary endpoint, even if the trial does not achieve its primary aim – The results must include number started/completed, summary results for primary and secondary outcome measures, statistical analyses, and adverse events – Final results must be reported in a publicly accessibly manner; either in a peer-reviewed scientific journal (in print or on-line), in an on-line publicly accessible registry dedicated to the dissemination of clinical trial information such as ClinicalTrials.gov, or in journals willing to publish in abbreviated format (e.g., for studies with negative or incomplete results) ▪ The study protocol must explicitly discuss beneficiary subpopulations affected by the item or service under investigation, particularly traditionally underrepresented groups in clinical studies, how the inclusion and exclusion criteria affect enrollment of these populations, and a plan for the retention and reporting of said populations on the trial – If the inclusion and exclusion criteria are expected to have a negative effect on the recruitment or retention of underrepresented populations, the protocol must discuss why these criteria are necessary ▪ The study protocol explicitly discusses how the results are or are not expected to be generalizable to affected beneficiary subpopulations; separate discussions in the protocol may be necessary for populations eligible for Medicare due to age, disability or Medicaid eligibility ▪ Consistent with section 1142 of the Act, the Agency for Healthcare Research and Quality (AHRQ) supports clinical research studies that CMS determines meet the above-listed standards and address the above-listed research questions ▪ The principal investigator must submit the complete study protocol, identify the relevant CMS research question(s) that will be addressed and cite the location of the detailed analysis plan for those questions in the protocol, plus provide a statement addressing how the study satisfies each of the standards of scientific integrity (listed above), as well as the investigator's contact information, to the address below; the information will be reviewed, and approved studies will be identified on the CMS Website – Director, Coverage and Analysis Group Re: TEER CED Centers for Medicare & Medicaid Services (CMS) 7500 Security Blvd., Mail Stop S3-02-01 Baltimore, MD 21244-1850 – Email address for protocol submissions: clinicalstudynotification@cms.hhs.gov Email subject line: "CED TEER [name of sponsor/primary investigator]"

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Transcatheter Mitral Valve Repair (TMVR)/Transcatheter Edge-to-Edge Repair (TEER) for Mitral Valve Regurgitation (NCD 20.33) (continued)	Oct. 13, 2021	*Nationally Non-Covered Indications*
		• Revised language to indicate TEER of the mitral valve is not covered under the following circumstances:
		  ○ For patients in whom existing co-morbidities would preclude the expected benefit from a mitral valve TEER procedure
		  ○ In patients with untreated severe aortic stenosis
		Other (new to policy)
		• Added language to indicate CMS will consider published, peer-reviewed evidence periodically, following the effective date of this NCD and reconsider the policy when appropriate
		  ○ The NCD will expire 10 years from the effective date if it is not reconsidered during that time
		  ○ Upon expiration, coverage will be at the discretion of the Medicare Administrative Contractors
		Supporting Information
		• Updated *References* section to reflect the most current information

Vitamin B12 Injections to Strengthen Tendons, Ligaments, etc., of the Foot (NCD 150.6)	Oct. 13, 2021	Policy Summary *Overview* • Revised language to indicate Vitamin B12 is a water-soluble vitamin that is naturally present in some foods, added to others, and available as a dietary supplement and a prescription medication; because vitamin B12 contains the mineral cobalt, compounds with vitamin B12 activity are collectively called “cobalamins” Supporting Information • Updated *References* section to reflect the most current information

Retired

The following Policy Guideline has been retired effective Oct. 13, 2021:

- Hyperthermia for Treatment of Cancer (NCD 110.1)

General Information

This bulletin provides a list of new, updated, revised, replaced and/or retired UnitedHealthcare Medicare Advantage Policy Guidelines to reflect the most current clinical coverage rules and guidelines developed by the Centers for Medicare & Medicaid Services (CMS). The inclusion of a health service (e.g., test, drug, device or procedure) in this bulletin indicates only that UnitedHealthcare has recently adopted a new policy and/or updated, revised, replaced or retired an existing policy; it does not imply that UnitedHealthcare provides coverage for the health service. In the event of an inconsistency or conflict between the information provided in this bulletin and the posted policy, the provisions of the posted policy will prevail. Note that most benefit plan documents exclude from benefit coverage health services identified as investigational or unproven/not medically necessary. Physicians and other health care professionals may not seek or collect payment from a member for services not covered by the applicable benefit plan unless first obtaining the member's written consent, acknowledging that the service is not covered by the benefit plan and that they will be billed directly for the service.

UnitedHealthcare respects the expertise of the physicians, health care professionals, and their staff who participate in our network. Our goal is to support you and your patients in making the most informed decisions regarding the choice of quality and cost-effective care, and to support practice staff with a simple and predictable administrative experience. The Policy Update Bulletin was developed to share important information regarding UnitedHealthcare Medicare Advantage Policy Guideline updates. When information in this bulletin conflicts with applicable state and/or federal law, UnitedHealthcare follows such applicable federal and/or state law.

Policy Update Classifications

New

New coverage guidelines have been adopted for a health service (e.g., test, drug, device or procedure)

Updated

An existing policy has been reviewed and changes have not been made to the coverage guidelines; however, items such as the definitions or references may have been updated

Revised

An existing policy has been reviewed and revisions have been made to the coverage guidelines

Replaced

An existing policy has been replaced with a new or different policy

Retired

An existing policy has been retired because national and local coverage determinations from the Centers for Medicare and Medicaid Services (CMS) are no longer available or the applicable coverage guidelines are documented in another policy

Note: The absence of a policy does not automatically indicate or imply coverage. As always, coverage for a health service must be determined in accordance with the member's benefit plan and any applicable CMS, federal, or state regulatory requirements. Additionally, UnitedHealthcare reserves the right to review the clinical evidence supporting the safety and effectiveness of a medical technology prior to rendering a coverage determination.

The complete library of UnitedHealthcare Medicare Advantage Policy Guidelines is available at UHCprovider.com > Policies and Protocols > Medicare Advantage Policies > Policy Guidelines.