

DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. Policies are not a supplementation or recommendation for treatment; Providers are solely responsible for the diagnosis, treatment and clinical recommendations for the Member. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (e.g., will be paid for by Molina) for a particular Member. The Member's benefit plan determines coverage – each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their Providers will need to consult the Member's benefit plan to determine if there are any exclusion(s) or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a Member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid Members. CMS's Coverage Database can be found on the CMS website. The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this MCP and provide the directive for all Medicare members. References included were accurate at the time of policy approval and publication.

OVERVIEW

Current Procedural Terminology (CPT) Category III codes are developed by the American Medical Association (AMA) and are defined as a set of temporary codes for emerging technology, services, procedures, and service paradigms. Category III codes enable the collection of data for these services or procedures. If a Category III code is available, this code must be reported rather than a Category I unlisted code. The use of these codes allows physicians and other qualified health care professionals, insurers, health services researchers, and health policy experts to identify emerging technology, services, procedures, and service paradigms for clinical efficacy, utilization, and outcomes.

The inclusion of a service or procedure as a Category III code does not constitute a finding of support, or lack thereof, regarding clinical efficacy, safety, applicability to clinical practice, or payer coverage. These codes may not conform to the usual requirements for CPT Category I codes established by the AMA. For Category I codes, the AMA requires that the service/procedure be performed by many health care professionals in clinical practice in multiple locations and that FDA approval, as appropriate, has already been received. The nature of emerging technology, services, procedures, and service paradigms is such that these requirements may not be met. For these reasons, temporary codes for emerging technology, services, procedures, and service paradigms have been placed in a separate section of the CPT code set, and the codes are differentiated from Category I CPT codes using alphanumeric characters (e.g., four digits followed by the letter T).

Section 1862(a)(1)(A) of the Social Security Act (SSA) (AMA, n.d.) is the statutory basis for denying payment for types of care, items, services, and procedures, not excluded by any other statutory clause while meeting all technical requirements for coverage, that are determined to be any of the following:

- Not generally accepted by the medical community as safe and effective in the setting and for the condition for which it is used;
- Not proven safe and effective based on peer review or scientific literature;
- Experimental;
- Not medically necessary for a particular patient;
- Furnished at a level, duration, or frequency that is not medically appropriate;
- Not furnished in accordance with accepted standards of medical practice; or
- Not furnished in a setting appropriate to the patient's medical needs and condition.

Items and services must be established as safe and effective to be considered medically necessary. That is, the items and services must be:

- Consistent with the symptoms of diagnosis of the illness or injury under treatment.
- Necessary for, and consistent with, generally accepted professional medical standards of care (e.g., not experimental).
- Not furnished primarily for the convenience of the patient or of the provider or supplier.
- Furnished at the most appropriate level of care that can be provided safely and effectively to the patient.

Medical devices that are not approved for marketing by the Food and Drug Administration (FDA) are considered investigational by Medicare and are not considered reasonable and necessary for the diagnosis or treatment of illness or injury, or to improve the functioning of a malformed body member. Program payment, therefore, may not be made for medical procedures and services performed using devices that have not been approved for marketing by the FDA or for those not included in an FDA-approved investigational device exemption (IDE) trial.

COVERAGE POLICY

Molina Healthcare considers all services and procedures listed in the current and future Category III CPT code list as **experimental, investigational, and unproven*** except when there is a specific Centers for Medicare and Medicaid Services (CMS) National or Local Coverage Determination (NCD or LCD), state guidance, Molina Clinical Policy, or an MCG Guideline that addresses medically necessary indications for the specific category III CPT code.

**Reference MCP-184 Experimental and Investigational Services for definition of experimental, investigational, and unproven services.*

DOCUMENTATION REQUIREMENTS. Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

SUMMARY OF MEDICAL EVIDENCE

There are no published guidelines or recommendations by national/professional societies and organizations.

SUPPLEMENTAL INFORMATION

None.

CODING & BILLING INFORMATION

Codes	Codes Description
0479T	Fractional ablative laser fenestration of burn and traumatic scars for functional improvement; first 100 cm ² or part thereof, or 1% of body surface area of infants and children
0480T	Fractional ablative laser fenestration of burn and traumatic scars for functional improvement; each additional 100 cm ² , or each additional 1% of body surface area of infants and children, or part thereof (List separately in addition to code for primary procedure)
0475T	Recording of fetal magnetic cardiac signal using at least 3 channels; patient recording and storage data scanning with signal extraction technical analysis and result as well as supervision, review, and interpretation of report by a physician or other qualified health care professional
0476T	Recording of fetal magnetic cardiac signal using at least 3 channels; patient recording data scanning with raw electronic signal transfer of data and storage
0489T	Autologous adipose-derived regenerative cell therapy for scleroderma in the hands; adipose tissue harvesting, isolation and preparation of harvested cells including incubation with cell dissociation enzymes, removal of non-viable cells and debris, determination of concentration and dilution of regenerative cells
0492T	Ablative laser treatment, non-contact, full field and fractional ablation, open wound, per day, total treatment surface area; each additional 20 sq cm, or part thereof (List separately in addition to code for primary procedure)
0500T	Infectious agent detection by nucleic acid (DNA or RNA), human papillomavirus (HPV) for five or more separately reported high-risk HPV types (e.g., 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 68) (i.e., genotyping)
0542T	Myocardial imaging by magnetocardiography (MCG) for detection of cardiac ischemia, by signal acquisition using minimum 36 channel grid, generation of magnetic-field time-series images, quantitative analysis of magnetic dipoles, machine learning-derived clinical scoring, and automated report generation, single study; interpretation and report
0547T	Bone-material quality testing by microindentation(s) of the tibia(s), with results reported as a score

Molina Clinical Policy

Category III CPT Codes: Policy No. 321

Last Approval: 12/14/2022

Next Review Due By: December 2023



0559T	Anatomic model 3D-printed from image data set(s); first individually prepared and processed component of an anatomic structure
0592T	Health and well-being coaching face-to-face; individual, follow-up session, at least 30 minutes
0598T	Noncontact real-time fluorescence wound imaging, for bacterial presence, location, and load, per session; first anatomic site (e.g., lower extremity)
0603T	Glomerular filtration rate (GFR) monitoring, transdermal, including sensor placement and administration of more than one dose of fluorescent pyrazine agent, each 24 hours
0631T	Transcutaneous visible light hyperspectral imaging measurement of oxyhemoglobin, deoxyhemoglobin, and tissue oxygenation, with interpretation and report, per extremity
0639T	Wireless skin sensor thermal anisotropy measurement(s) and assessment of flow in cerebrospinal fluid shunt, including ultrasound guidance, when performed
0663T	Scalp cooling, mechanical; placement of device, monitoring, and removal of device (List separately in addition to code for primary procedure)
0664T	Donor hysterectomy (including cold preservation); open, from cadaver donor
0687T	Treatment of amblyopia using an online digital program; device supply, educational set-up, and initial session
0688T	Treatment of amblyopia using an online digital program; assessment of patient performance and program data by physician or other qualified health care professional, with report, per calendar month
0691T	Automated analysis of an existing computed tomography study for vertebral fracture(s), including assessment of bone density when performed, data preparation, interpretation, and report
0693T	Comprehensive full body computer-based markerless 3D kinematic and kinetic motion analysis and report
0700T	Molecular fluorescent imaging of suspicious nevus; first lesion
0702T	Remote therapeutic monitoring of a standardized online digital cognitive behavioral therapy program ordered by a physician or other qualified health care professional; supply and technical support, per 30 days
0703T	Remote therapeutic monitoring of a standardized online digital cognitive behavioral therapy program ordered by a physician or other qualified health care professional; management services by physician or other qualified health care professional, per calendar month
0704T	Remote treatment of amblyopia using an eye tracking device; device supply with initial set-up and patient education on use of equipment

CODING DISCLAIMER. Codes listed in this policy are for reference purposes only and may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry standard coding practices for all submissions. When improper billing and coding is not followed, Molina has the right to reject/deny the claim and recover claim payment(s). Due to changing industry practices, Molina reserves the right to revise this policy as needed.

APPROVAL HISTORY

12/14/2022	Policy revised. Coverage Policy section: Removed 'Molina Clinical Review (MCR)' and added 'MCG Care Guidelines.' Removed table of CPT code ranges. Inserted T-code table, including codes and T-code description.
4/13/2022	Policy reviewed, no changes to coverage criteria, updated CPT codes.
4/5/2021, 4/23/2020, 9/18/2019	Policy reviewed, no changes.
7/10/2018	New policy.

REFERENCES

1. American Medical Association (AMA). Category III codes. Available from [AMA](#). Accessed October 2022.
2. Centers for Medicare and Medicaid Services (CMS). Medicare coverage database (search: category III CPT® codes, L35490). Available from [CMS](#). Accessed October 2022.
3. Centers for Medicare and Medicaid Services (CMS). Billing and coding: Category III codes (article A56902). Available from [CMS](#). Accessed December 10, 2022
4. Optum360. EncoderPro Current Procedural Terminology (CPT®), professional edition: American Medical Association AMA CPT® section guidelines on category III codes. Available from [Optum](#). Registration and login required.

APPENDIX

Reserved for State specific information. Information includes, but is not limited to, State contract language, Medicaid criteria and other mandated criteria.