Subject: CATEGORY III CPT CODES		Original Effective Date: 07/10/2018
Policy Number: MCP-321	**Revision Date(s):**	
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DISCLAIMER

This Molina clinical policy (MCP) is intended to facilitate the Utilization Management process. 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 (i.e., 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 Molina clinical policy document and provide the directive for all Medicare members. [1]

DESCRIPTION OF PROCEDURE/SERVICE/PHARMACEUTICAL [2-3]

The American Medical Association (AMA) develops Current Procedural Terminology (CPT) Category III codes defined as a set of temporary codes for emerging technology, services, procedures, and service paradigms. Category III codes allow data collection for these services/procedures. If a Category III code is available, this code must be reported instead of a Category I unlisted code. The use of theses 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, with regard to clinical efficacy, safety, applicability to clinical practice, or payer coverage. Theses 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 by the use of alphanumeric characters, (ie, four digits followed by the letter T).

Section 1862(a)(1)(A) of the Social Security Act (SSA) [1] 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; and
- 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. [1]

POSITION STATEMENT [1-2-3]

Molina Healthcare considers all services and procedures listed in the current and future Category III CPT code list as investigational, experimental and unproven* **except when** there is a specific Centers for Medicare and Medicaid Services (CMS) National or Local Coverage Determinations (NCD or LCD) [1] OR Molina Clinical Policy (MCP) or Molina Clinical Review (MCR)** that addresses medically necessary indications for the specific category III CPT code.

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

****Please reference the Corporate Molina Clinical Policy SharePoint site for a list of current medical and pharmacy MCP's and MCR's available at this link:** https://molinahealthcare.sharepoint.com/sites/CPS-MCPMCR/default.aspx

REFERENCES

1. Centers for Medicare & Medicaid Services (CMS). Medicare Coverage Database. National coverage determination (NCD) Search. Local Coverage Determination (LCD): Category III CPT® Codes (L34370, L33392, L34995). Accessed at: https://www.cms.gov/medicare-coverage-database/new-search/search.aspx
2. American Medical Association (AMA). Category III Codes. Accessed at: https://www.ama-assn.org/practice-management/category-iii-codes
3. 2021 Optum360, LLC. [Website]. EncoderPro Current Procedural Terminology (CPT®), Professional Edition, American Medical Association AMA CPT® Section Guidelines on Category III Codes.

REVIEW/REVISION HISTORY

7/10/18: New Policy
9/18/19, 4/23/20, 4/5/21: Policy reviewed, no changes.