Molina Clinical Policy
Category III CPT Codes: Policy No. 321

Last Approval: 4/5/2021
Next Review Due By: April 2022

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.[1] References included were accurate at the time of policy approval and publication.

OVERVIEW [2-3]

The American Medical Association (AMA) develops Current Procedural Terminology (CPT) Category III codes which are 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, (e.g., 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]

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)[1] **OR** Molina Clinical Policy (MCP) **OR** a Molina Clinical Review (MCR)** that addresses medically necessary indications for the specific category III CPT code.[1-3]

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

**Internal Molina associates can reference the Corporate Molina Clinical Policy SharePoint site for a list of current medical and pharmacy MCPs and MCRs at https://molinahealthcare.sharepoint.com/sites/CPS-MCPMCR/default.aspx.

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

No applicable codes.

APPROVAL HISTORY

4/5/2021	Policy reviewed, no changes.
4/23/2020	Policy reviewed, no changes.
9/18/2019	Policy reviewed, no changes.
7/10/2018	New policy.

REFERENCES

1. Centers for Medicare and Medicaid Services (CMS). Medicare coverage database (search: category III CPT® codes L34370, L33392, L34995). https://www.cms.gov/medicare-coverage-database/new-search/search.aspx.
2. American Medical Association (AMA). Category III codes. https://www.ama-assn.org/practice-management/category-iii-codes.
3. Optum360. EncoderPro Current Procedural Terminology (CPT®), professional addition: American Medical Association AMA CPT® section guidelines on category III codes.

APPENDIX

Reserved for State specific information *(to be provided by the individual States, not Corporate). Information includes, but is not limited to, State contract language, Medicaid criteria and other mandated criteria.*