Category III CPT Codes

Medicare Advantage Medical Policy #MA-120
Original Effective Date: 09/01/2025
Current Effective Date: 09/01/2025

Applies to all products administered or underwritten by the Health Plan, unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

In the absence of a National Coverage Determination (NCD), Novitas Local Coverage Determination (LCD), or Blue Advantage medical policy, the Health Plan considers all services and procedures listed in the current and future Category III CPT Code list to be **investigational.***

Background/Overview

Current Procedural Terminology (CPT) Codes

The American Medical Association (AMA) develops (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).

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

Section 1862(a)(1)(A) of the Social Security Act (SSA) 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.

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. Novitas Solutions. Non-covered services. Accessed at https://www.novitas-solutions.com/webcenter/portal/MedicareJL/pagebyid?contentId=00027359.

Policy History

Original Effective Date: 09/01/2025
Current Effective Date: 09/01/2025
06/17/2025 Utilization Management Committee review/approval. New policy.
Next Scheduled Review Date: 06/2026

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
    1. Consultation with technology evaluation center(s);
    2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
    3. Reference to federal regulations.

NOTICE: If the Patient's health insurance contract contains language that differs from the Health Plan's Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Health Plan recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.

Medicare Advantage Members
Established coverage criteria for Medicare Advantage members can be found in Medicare coverage guidelines in statutes, regulations, National Coverage Determinations (NCD)s, and Local Coverage Determinations (LCD)s. To determine if a National or Local Coverage Determination addresses coverage for a specific service, refer to the Medicare Coverage Database at the following link: https://www.cms.gov/medicare-coverage-database/search.aspx. You may wish to review the Guide to the MCD Search here: https://www.cms.gov/medicare-coverage-database/help/mcd-benehelp.aspx.

When coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs, internal coverage criteria may be developed. This policy is to serve as the summary of evidence, a list of resources and an explanation of the rationale that supports the adoption of this internal coverage criteria.

InterQual®
Interqual® is utilized as a source of medical evidence to support medical necessity and level of care decisions. InterQual® criteria are intended to be used in connection with the independent professional medical judgment of a qualified health care provider. InterQual® criteria are clinically based on best practice, clinical data, and medical literature. The criteria are updated continually and released annually. InterQual® criteria are a first-level screening tool to assist in determining if the proposed services are clinically indicated and provided in the appropriate level or whether further evaluation is required. The utilization review staff does the first-level screening. If the criteria are met, the case is approved; if the criteria are not met, the case is referred to the medical director.