BlueCross BlueShield of North Carolina

Medicare Part C Medical Coverage Policy

Investigational (Experimental) Services

Origination: November 2009
Review Date: June 24, 2024
Next Review: June 2025

****** This policy was implemented in the absence of National Coverage Determinations (NCD), Local Coverage Determinations (LCD) coverage criteria. This policy applies to all Blue Medicare HMO, Blue Medicare PPO, Blue Medicare Rx members, and members of any third-party Medicare plans supported by Blue Cross NC through administrative or operational services. ******

DESCRIPTION OF PROCEDURE OR SERVICE

Title XVIII of the Social Security Act SSA 1862(a) (1) (A) prohibits Medicare coverage for items and services which are not "reasonable and necessary" for the diagnosis and treatment of an injury or illness or to improve the functioning of a malformed body part. Medical necessity cannot be established if the safety and effectiveness of a device is unknown.

The Plan defines the terms "investigational" and/or "experimental" as medical, surgical, psychiatric, and other health care services, supplies, treatments, items, procedures, drug therapies, or devices that are determined by the Plan to be either:

A. Not generally accepted or endorsed by health care professionals in the general medical community as safe and effective in treating the condition, illness, or diagnosis in the setting for which their use is proposed; **OR**

B. Not proven by scientific evidence to be safe and effective in treating the condition, illness or diagnosis for which their use is proposed; **OR**

C. Not medically necessary in the particular case; **OR**

D. Furnished at a level of duration that is not medically appropriate; **OR**

E. Not furnished in a setting appropriate to the member's needs and concerns.

Any request for health care services, supplies, treatments, items, procedures, drug therapies, or devices that are not covered in a National Coverage Determination (NCD), or Local Coverage Determination (LCD), or otherwise specified "covered" in the Medicare benefit manuals or other transmittals and/or have an unspecified code will have to be reviewed for medical necessity.

DEFINITIONS

Food Drug Administration (FDA): The FDA is an agency within the U.S. Department of Health and Human Services. It oversees medical products, food and new drugs (among other duties) to protect the public health by assuring safety, effectiveness and quality of these products. Examples are cosmetics, dietary supplements and products that give off radiation, biologics, prescription drugs, veterinary products, medical devices, etc.

Category A (Experimental) Device: This is a classification assigned by the Food and Drug Administration (FDA) in which there are still questions of safety and effectiveness regarding a device. These devices are generally novel, first of-a-kind technologies in which the absolute risk of the device type has not been established.

Category B (Non-experimental/investigational) Device: This is a classification assigned by the Food and Drug Administration in which the initial questions of safety and effectiveness of that device type have been resolved, for example, FDA premarket approval or clearance has been obtained.

Category III codes (or T codes): The American Medical Association (AMA) developed Category III CPT codes to track the utilization of emerging technologies, services and procedures. The assignment of a Category III code description does not establish a service or procedure as safe, effective, or applicable to the clinical practice of medicine, unless there is an NCD, LCD or a Medicare coverage article exist.

POLICY STATEMENT

The Plan will review for medical necessity based on objective-evidenced based data.

BENEFIT APPLICATION

Please refer to the member's individual Evidence of Coverage (EOC) for benefit determination. Coverage will be approved according to the EOC limitations if the criteria are met.

Coverage decisions will be made in accordance with:

- The Centers for Medicare & Medicaid Services (CMS) National Coverage Determinations (NCDs);
- General coverage guidelines included in Original Medicare manuals unless superseded by operational policy letters or regulations; and
- Written coverage decisions of local Medicare carriers and intermediaries with jurisdiction for claims in the geographic area in which services are covered.

Benefit payments are subject to contractual obligations of the Plan. If there is a conflict between the general policy guidelines contained in the Medical Coverage Policy Manual and the terms of the member's particular Evidence of Coverage (EOC), the EOC always governs the determination of benefits.

CRITERIA REQUIRED FOR COVERAGE APPROVAL

A. Preauthorization by the Plan; **AND**

B. Medical director review.

C. The Medical Director may base coverage on the following:

1. Review objective-evidenced based literature based on:
    a. Studies from government agencies, i.e., the FDA;
    b. Evaluations completed by independent technology assessment groups, i.e., BCBSA;
    c. Well-designed controlled clinical studies that have appeared in peer review journals;
    d. Review for like treatments or alternatives that are supported by peer review and the community pattern of medical practice.
    e. An internal technology assessment may be completed.

WHEN COVERAGE WILL NOT BE APPROVED

The Plan does not cover investigational or experimental medical and surgical procedures, equipment, medications, or cosmetic procedures that are not medically necessary **and** have not been strongly supported in research **and** for which there is a safe and medically accepted alternative available.

Medical devices established by the FDA as Category A are considered investigational by the Plan. Generally, their safety and effectiveness have not yet been established and are not covered.

BILLING/ CODING/PHYSICIAN DOCUMENTATION INFORMATION

This policy may apply to the following codes. Inclusion of a code in the section does not guarantee reimbursement.

Applicable Codes: See procedure code(s) for specific procedure or service. List is located at 2024 Blue Medicare CPT Codes Requiring Prior Authorization (bluecrossnc.com)

The Plan may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Special Notes:

A. Category III codes that are covered in an NCD/ LCD may be considered for coverage based on medical necessity. When there is lack of a Medicare coverage statement or policy or applicable codes, then the Plan will review for medical necessity based on objective-evidenced based data such as but not limited to: Studies from government agencies (as FDA); Evaluations performed by independent technology assessment groups (i.e., BCBSA or BCBSNC); or well-designed controlled clinical studies that have appeared in peer review journals.

Medical and Scientific Evidence is defined by the Plan as one of the following:

1. Peer-reviewed scientific studies published in or accepted for publication by medical journals that meet nationally recognized requirements for scientific manuscripts and that submit most of their published articles for review by experts who are not part of the editorial staff.

2. Peer-reviewed literature or biomedical compendia from such sources as the National Institute of Health's National Library of Medicine or The Cochrane Library.

3. An accepted indication for treatment in one of the following standard reference compendia:

    - The American Hospital Formulary Service-Drug Information
    - The American Medical Association Drug Evaluations
    - The American Dental Association Accepted Dental Therapeutics
    - The United States Pharmacopoeia Drug Information

4. Findings, studies, or research conducted by or under the auspices of federal government agencies and nationally recognized federal research institutes including the:
    - U.S. Department of Health and Human Services
    - Federal Agency for Healthcare Research and Quality
    - National Institutes of Health
    - National Cancer Institute
    - National Academy of Sciences
    - Center for Medicare and Medicaid Services, and

- Any national board recognized by the National Institutes of Health for the purpose of evaluating the medical value of health services.
    - The Plan is responsible for routine care of items and services in CMS- approved Category A and Category B IDE studies.
- Routine care items and services refers to items and services that are otherwise generally available to members (that is, a benefit category exists, it is not statutorily excluded, and there is not a national non-coverage decision) that are furnished during a clinical study and that would be otherwise furnished even if the member were not enrolled in a clinical study.

The local Medicare Administrative Contractor with jurisdiction over the Plan's service area determines coverage of IDE studies.

Effective January 1, 2015, a listing of all CMS-approved Category A IDE studies and Category B IDE studies will be published in the Federal Register and posted on the CMS Coverage webpage site located at: http://www.cms.gov/Medicare/Coverage/IDE/index.html

References

1. Medicare Claims Processing Manual 100-4, Chapter 32, Sections 68 & 69; Effective date: 1/1/15; Accessed via Internet site Medicare Claims Processing Manual (cms.gov); viewed on 06/03/2024.
2. Medicare Managed Care Manual; Chapter 4; Section 90.5; Effective 01/01/2015; Creating new Guidance; Viewed on line at MCM Chapter 4 (cms.gov); viewed on 06/03/2024.
3. Medicare Managed Care Manual Ch 4, Section 10.7.2, Effective 04/22/2016; accessed via MCM Chapter 4 (cms.gov) on 06/03/2024.
4. Medicare Benefit Manual Ch 14, Section 20, Effective 1/1/2015; accessed via Medicare Benefit Policy Manual (cms.gov) on 06/03/2024.
5. CMS Manual System: Pub 100-02 Transmittal 198, Change Request 8921. Effective Date 1/1/15; accessed via http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R198BP.pdf online on 06/03/2024.
6. MLN Matters MM8921; CR Release Date 11/6/2014, Effective Date 1/1/2015, accessed via Medicare Coverage of Items and Services in Category A and B Investigational Device Exemption (IDE) Studies (cms.gov) on 06/03/2024.
7. Blue Medicare "Evidence of Coverage", 2023; Chapter 4: Medical Benefits Chart (What is covered and what you pay), Section 3.1- Services we do not cover (exclusions). Accessed via Forms library | Members | Medicare | Blue Cross NC viewed on 06/03/2024.
8. BCBSNC Corporate Medical Coverage Policy: Investigational (Experimental) Services; last reviewed on 03/2023; Medical and Scientific Evidence; viewed online at http://www.bcbsnc.com/content/services/medical-policy/index.htm; viewed on 06/03/2024.
9. Social Security; Exclusions from Coverage; viewed online at http://www.socialsecurity.gov/OP_Home/ssact/title18/1862.htm, viewed on 06/03/2024.
10. 2014 Medicare Explained; Wolters Kluwer, Law and Business; 2014 CCH Incorporated. ISBN: 978-0-8080-3738-5; page 273-276—old reference.
11. Medicare Local Coverage Determination for Category III CPT Codes – Palmetto GBA Part A/B (L34555); Effective date: 10/01/2015; accessed via LCD - Non-Covered Category III CPT Codes (L34555) (cms.gov). LCD retired on 3/23/2020.

Policy Implementation/Update Information

Original Date of Administrative Policy: December 5, 1997
Revision Date: November 2009: Converted from Healthcare Services Administrative Policy to Medical Coverage Policy
Revision Date August 2012: Language from EOC and LCD added to policy.
Revision Date July 16, 2014: Edited Description of Investigational services or items to include SSA law and other criteria; Added any request for services not specifically covered by Medicare or have an unspecified code will be reviewed for medical necessity; Added definitions for staff; Edited language from "When coverage will not be approved"; Added a special note regarding Category III codes; updated references.

Revision Date February 6, 2015: Added Category B definition under Definition section; added site location for all CMS-approved Category A and B IDE studies effective 1/1/2015 under When Coverage Will Be Approved section; added #5 under Special Notes referencing MA plans responsibility for routine care items and services for Category A and B IDE studies, along with the Category B device. Added bullet for language referencing routine care items and services. October 29, 2015 updated LCD due to ICD-10 update only.
Revision Date: February 15, 2017: No criteria changes. Minor revisions only.
Revision Date: July 12, 2017: Merged Policy with Investigational (Experimental) Job Aid to prevent accessing multiple documents for these reviews. Definitions Section: Added definition of FDA. Under Criteria for Coverage Approval; Added C, and D.
Revision Date: July 17, 2019: No CMS Updates. Minor Revisions Only.
Revision Date: August 18, 2021; CMS retired LCD L34555-Removed: Criteria for Coverage Approval: D. to remain consistent with CMS.
Revision Date: August 16, 2023; Annual Review; No CMS Updates. Minor Revisions only
Revision Date: November 14, 2023: Added the following statement to the beginning of policy: "This policy was implemented in the absence of National Coverage Determinations (NCD) or Local Coverage Determinations (LCD) coverage criteria." Statement added to align with the 2024 CMS Final Rule.
Revision Date: June 24, 2024: Annual Review. Link under "Applicable Codes" updated. Minor Revisions only

Approval Dates
Medical Coverage Policy Committee: June 24, 2024

Physician Advisor Group/UM Committee: November 14, 2023

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