EmblemHealth

Reimbursement Policy:

Pharmacy – Medical Claim Edit

POLICY NUMBER	REVIEW DATE:	APPROVED BY
RPC20230049	11/25/2025 *This policy criteria applicable for dates of service on or before 12/31/2025*	**RPC (Reimbursement Policy Committee)**

Reimbursement Guideline Disclaimer: We have policies in place that reflect billing or claims payment processes unique to our health plans. Current billing and claims payment policies apply to all our products, unless otherwise noted. We will inform you of new policies or changes in policies through postings to the applicable Reimbursement Policies webpages on emblemhealth.com. Further, we may announce additions and changes in our provider manual and/or provider newsletters which are available online and emailed to those with a current and accurate email address on file. The information presented in this policy is accurate and current as of the date of this publication.

The information provided in our policies is intended to serve only as a general reference resource for services described and is not intended to address every aspect of a reimbursement situation. Other factors affecting reimbursement may supplement, modify or, in some cases, supersede this policy. These factors may include, but are not limited to, legislative mandates, physician or other provider contracts, the member's benefit coverage documents and/or other reimbursement, and medical or drug policies. Finally, this policy may not be implemented the same way on the different electronic claims processing systems in use due to programming or other constraints; however, we strive to minimize these variations.

We follow coding edits that are based on industry sources, including, but not limited to, CPT® guidelines from the American Medical Association, specialty organizations, and CMS including NCCI and MUE. In coding scenarios where there appears to be conflicts between sources, we will apply the edits we determine are appropriate. We use industry-standard claims editing software products when making decisions about appropriate claim editing practices. Upon request, we will provide an explanation of how we handle specific coding issues. If appropriate coding/billing guidelines or current reimbursement policies are not followed, we may deny the claim and/or recoup claim payment.

Overview:

This policy applies to biologics or drugs for which no specific Plan guideline(s) exists.

Definitions:

Term	Definition
Indication	An indication is defined as a diagnosis, illness, injury, syndrome, condition or other clinical parameter for which a drug may be given.
FDA Approval	Approval for marketing by the Food and Drug Administration (FDA) of drugs/biologics that are considered safe and effective.
FDA-Approved Indication	An indication depicted on the drug/biologic's official label with prescribing instructions, which includes, but is not necessarily limited to, dosage, route of administration, duration and frequency of administration and population to whom the drug would be administered.

Term	Definition
Medically Accepted Indication	1. Usage consistent with FDA-approved indication (labeled indication). 2. Articles or Local Coverage Determinations (LCDs) published by National Government Services. 3. Usage supported by ≥1 citations in at least 1 of the following drug compendia: • American Hospital Formulary Service Drug Information (AHFS-DI) — indication is supportive. *https://www.ahfsdruginformation.com/off_label/levels.aspx* • Clinical Pharmacology — indication is supportive. *https://clinicalpharmacology.com* • NCCN Drugs and Biologics Compendium — indication is a Category 1 or 2A. *https://www.nccn.org* • Micromedex® DrugDex® — indication is Class I, Class IIa, or Class IIb. *www.micromedexsolutions.com* • Lexi-Drugs® — indication is Evidence Level A *https://online.lexi.com/lco/action/home*
Off-label (also referred to as unlabeled or non-FDA-approved) usage	Drug/biologic usage for an indication that is not listed on the official label; further defined as administration of the drug/biologic in a way that deviates significantly from the prescribing information on the official label for a particular indication. This includes, but is not necessarily limited to, dosage, route of administration, duration and frequency of administration and population to whom the drug would be administered. Unapproved uses of drugs include a variety of situations ranging from completely unstudied to thoroughly investigated drug uses where the FDA has not been asked for approval. Many off-label uses are effective, well documented in peer-reviewed literature and widely used.
Phase II Trials	Controlled clinical studies conducted to evaluate the effectiveness of the drug for a particular indication or indications in patients with the disease or condition under study and to determine the common short-term side effects and risks.
Phase III Trials	Expanded controlled and uncontrolled trials after preliminary evidence suggesting effectiveness of the drug has been obtained and are intended to gather additional information to evaluate the overall benefit-risk relationship of the drug and provide an adequate basis for physician labeling.
Length of Authorization	12 months

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Guideline

The medical claim edit prior approval policy requires prior approval for all medical drugs with significant safety, clinical or potential abuse or diversion concerns filled under the medical benefit. The policy is intended to ensure that medications are used safely and will be effective for members.

Claim Edits will be applied during claim processing to validate appropriate drug to therapy based on FDA guidelines. A claim may pend for further review if the ICD-10 code is inappropriate to the drug HCPCs code. If the claim is denied, a notification will be sent to the Provider. The Provider may submit a new or corrected claim for consideration of payment if an error in coding occurred in the original claim submission.

Documentation Requirements

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

Note: For Chemotherapeutic Drugs see Appendix page 7.

Providers may request coverage of off-label usage. Supportive data substantiating usage must be submitted to the Plan (see pp. 3–4 for documentation requirements); the data must include:

- A use supported by clinical research that appears in at least 2 randomized controlled trials on large patient groups (e.g., 300–3,000 or more depending upon the disease/medical condition studied) that definitively demonstrate safety and effectiveness.

OR

- If no evidence is available (per # 1), at least 2 trials with reasonably large patient samples (e.g., 20-300) showing consistent results of safety and efficacy. Greater consideration will be given to higher powered studies with levels of evidence in the following descending order: Randomized or nonrandomized controlled trials, prospective cohort studies, retrospective case control studies, cross sectional studies, surveillance studies, consecutive case series, singe case series.

Studies submitted for Plan review must come from different centers and be published in national or international peer-reviewed journals (with editorial committees comprised of physicians).

Note: Peer-reviewed medical literature includes scientific and medical publications. It does not include in- house publications of pharmaceutical manufacturing companies or abstracts (including meeting abstracts).

OR

- A use that is an accepted standard of medical practice. "Are there published recommendations from specialty societies or in other authoritative evidence-based guidelines" (e.g., a state-of-the-art review article published in a recognized textbook or a reputable publication)?

Note: Acceptance by individual health care practitioners, or even a limited group of health care practitioners, does not typically indicate general acceptance by the medical community. Testimonials indicating such limited acceptance and limited case studies, distributed by sponsors with potential financial conflict of interest in the outcome, are not sufficient evidence of general acceptance by the medical community.

The broad range of available evidence must be considered, and its quality must be evaluated before a conclusion is reached. After such evidence is received, the Plan will, with the appropriate guidance of specialty-specific consultants, as indicated, make a coverage determination for the off-label use of the drug or biological. The Plan may determine usage to be reasonable and necessary for the treatment of illness or injury if, based on available or presented evidence, it is shown to be safe and effective and does not violate national (or in the case of Medicare members) local Medicare determinations and regulations. The approval will include, but is not limited to, diagnosis, dosage, route of administration, duration and frequency of administration and appropriate patient population.

Published Evidence Guidance

In principle, rankings of research design have been based on the ability of each study design category to minimize bias. The following is a representative list of study designs (some of which have alternative names) ranked from most to least methodologically rigorous in their potential ability to minimize systematic bias:

1. Randomized controlled trials
2. Nonrandomized controlled trials
3. Prospective cohort studies
4. Retrospective case control studies
5. Cross-sectional studies
6. Surveillance studies (e.g., using registries or surveys)
7. Consecutive case series
8. Single case reports

The design, conduct and analysis of trials are important factors as well (e.g., a well-designed, well-conducted observational study with a large sample size may provide stronger evidence than a poorly designed and conducted randomized controlled trial with a small sample size).

In determining whether there is supportive clinical evidence for a particular use of a drug or biologic, the quality of the published evidence must be considered. Such consideration involves the assessment of all the following study characteristics:

- Adequate number of subjects.
- Response rate.
- The effect on key status and survival indications; that is, the effect on the patient's well-being and other responses to therapy that indicate effectiveness (e.g., reduction in mortality, morbidity, signs and symptoms).
- The appropriateness of the study design; that is, whether the experimental design (in light of the drugs and conditions under investigation) is appropriate to address the investigative question (e.g., in some clinical studies, it may be unnecessary or not feasible to use randomization, double-blind trials, placebos or crossover).
- The prevalence and life history of the disease when evaluating the adequacy of the number of subjects and the response rate.

Documentation:

For Plan consideration of off-label usage, copies of relevant full-text articles from the peer-reviewed literature must be submitted to the Plan if all of the following situations are applicable:

1. An unlabeled use of the drug/biologic does not appear in at least 1 of the 4 major compendia mentioned (see # 3; p. 1).

2. The FDA has previously determined that there was insufficient data to approve the drug/biologic or that the drug/biologic is investigational and no new determination from the FDA is anticipated.

3. At least 2 articles exist, reporting research that appears in at least 2 Phase II trials from different centers, that are published in national or international peer-reviewed journals (with editorial committees comprised of physicians) supporting the indication/s requested.

4. Regardless of the evidence supporting coverage and the determination of the Plan regarding the general off-label use of a drug/biologic, individual patient medical records may be required to determine if an off-label use is reasonable and necessary for treatment of a patient's illness or injury. These records must be available to the Plan upon request.

Limitations/Exclusions

Off-label drugs/biologics are not considered medically necessary when the following circumstances are applicable:

- If a use is identified as not indicated by CMS (in the case of Medicare members) or the FDA, or if a use is specifically identified as not indicated in at least one of the 2 major compendia, or it is determined (based on peer-reviewed literature) that the drug/biologic is not safe and effective, then the off-label usage is not supported and therefore not covered.
- Coverage will not be provided for off-label usage, regardless of the supporting evidence submitted to the Plan, if is not reasonable and necessary.
- If the drug use is not on the FDA label, does not appear on the AHFS or USPDI compendia, or (in the case of Medicare members) National Government Services has not published an Article covering the off-label usage, then coverage will not be provided.

Note: Services related to noncovered services are not covered (e.g., administration services).

References:

Medicare Coverage General Information Compendia 1861 (t)(2) - Anti-cancer. https://www.cms.gov/medicare/coverage/determination-process/basics/compendia-1861-t2-anti-cancer. Accessed January 17, 2018.

NGS. LCD Drugs and Biologicals, Coverage of, for Label and Off-Label Uses. December 2017. https://www.cms.gov/medicare-coverage-database/errors/StatusCodeError?statusCode=404; Accessed January 17, 2018;
Updated by NGS. LCD Drugs and Biologicals, Coverage of, for Label and Off-Label Uses. July 2025. https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdId=33394; Accessed January 17, 2018; updated CMS link 11/25/2025.

Appendix:

The following sections of the New York State insurance law mandate coverage for chemotherapy. The specific provisions (A) and (B) are also included below.

1. New York Insurance Law § 3216. Individual accident and health insurance policy provisions.
2. New York Insurance Law § 3221. Group or blanket accident and health insurance policies; standard provisions.

3. New York Insurance Law § 4303. Definition of benefits under non-profit medical and dental indemnity or health and hospital service corporations.
   A. Every policy which provides coverage for prescribed drugs approved by the Food and Drug Administration of the United States government for the treatment of certain types of cancer shall not exclude coverage of any such drug on the basis that such drug has been prescribed for the treatment of a type of cancer for which the drug has not been approved by the Food and Drug Administration. Provided, however, that such drug must be recognized for treatment of the specific type of cancer for which the drug has been prescribed in one of the following established reference compendia:
      i. National Comprehensive Cancer Network (NCCN) Drugs & Biologics Compendium™; or
      ii. United States Pharmacopeia Drug Information; or recommended by review article or editorial comment in a major peer-reviewed professional journal.
   B. Notwithstanding the provisions of this paragraph, coverage shall not be required for any experimental or investigational drugs or any drug which the Food and Drug Administration has determined to be contraindicated for treatment of the specific type of cancer for which the drug has been prescribed. The provisions of this paragraph shall apply to cancer drugs only and nothing herein shall be construed to create, impair, alter, limit, modify, enlarge, abrogate or prohibit reimbursement for drugs used in the treatment of any other disease or condition.

Revision History

Company	DATE	REVISION
EmblemHealth	11/25/2025	• *This policy criteria applicable for dates of service **on or before 12/31/2025.*** • CMS reference links updated
EmblemHealth	11/25/2025	• Transferred policy content to individual company-branded template. No changes to policy title or policy number.
EmblemHealth	12/2023	• Reformatted and reorganized policy, transferred content to new template with new Reimbursement Policy Number