



REIMBURSEMENT POLICY STATEMENT NORTH CAROLINA MARKETPLACE

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Policy Name		Policy Number	Effective Date
Standard Medical Billing Guidance		PY-PHARM-0134-NC-MP	02-01-2023
Policy Type			
Medical	Administrative	Pharmacy	REIMBURSEMENT

Reimbursement Policy Statement: Reimbursement Policies prepared by CareSource and its affiliates are intended to provide a general reference regarding billing, coding and documentation guidelines. Coding methodology, regulatory requirements, industry-standard claims editing logic, benefits design and other factors are considered in developing Reimbursement Policies.

In addition to this Policy, Reimbursement of services is subject to member benefits and eligibility on the date of service, medical necessity, adherence to plan policies and procedures, claims editing logic, provider contractual agreement, and applicable referral, authorization, notification and utilization management guidelines. Medically necessary services include, but are not limited to, those health care services or supplies that are proper and necessary for the diagnosis or treatment of disease, illness, or injury and without which the patient can be expected to suffer prolonged, increased or new morbidity, impairment of function, dysfunction of a body organ or part, or significant pain and discomfort. These services meet the standards of good medical practice in the local area, are the lowest cost alternative, and are not provided mainly for the convenience of the member or provider. Medically necessary services also include those services defined in any federal or state coverage mandate, Evidence of Coverage documents, Medical Policy Statements, Provider Manuals, Member Handbooks, and/or other policies and procedures.

This Policy does not ensure an authorization or Reimbursement of services. Please refer to the plan contract (often referred to as the Evidence of Coverage) for the service(s) referenced herein. If there is a conflict between this Policy and the plan contract (i.e., Evidence of Coverage), then the plan contract (i.e., Evidence of Coverage) will be the controlling document used to make the determination.

CareSource and its affiliates may use reasonable discretion in interpreting and applying this Policy to services provided in a particular case and may modify this Policy at any time.

According to the rules of Mental Health Parity Addiction Equity Act (MHPAEA), coverage for the diagnosis and treatment of a behavioral health disorder will not be subject to any limitations that are less favorable than the limitations that apply to medical conditions as covered under this policy.

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A. Subject

Standard Medical Billing Guidance

B. Background

Reimbursement policies are designed to assist you when submitting claims to CareSource. They are routinely updated to promote accurate coding and policy clarification. These proprietary policies are not a guarantee of payment. Reimbursement for claims may be subject to limitations and/or qualifications. Reimbursement will be established based upon a review of the actual services provided to a member and will be determined when the claim is received for processing. Health care providers and their office staff are encouraged to use self-service channels to verify member's eligibility.

It is the responsibility of the submitting provider to submit the most accurate and appropriate CPT/HCPCS/ICD-10 code(s) for the product or service that is being provided. The inclusion of a code in this policy does not imply any right to reimbursement or guarantee claims payment.

This reimbursement policy applies to all health care services reported using the CMS1500 Health Insurance Professional Claim Form (a/k/a HCFA), the CMS 1450 Health Insurance Institutional Claim Form (a/k/a UB04) or its electronic equivalent or any successor form. This policy applies to all products, all network and non-network physicians and other qualified health care professionals, including, but not limited to, non-network authorized and percent of charge contract physicians and other qualified health care professionals. Additionally, this policy applies to drugs and biologicals being used for FDA-approved indications or labels. Drugs and biologicals used for indications other than those in the approved labeling may be covered if it is determined that the use is medically accepted, taking into consideration the major drug compendia, authoritative medical literatures and/or accepted standards of medical practice.

C. Definitions

- **Indication** is defined as a diagnosis, illness, injury, syndrome, condition, or other clinical parameter for which a drug may be given.
- **FDA approved Indication/Label** is the official description of a drug product which includes indication (what the drug is used for); who should take it; adverse events (side effects); instructions for uses in pregnancy, children, and other populations; and safety information for the patient. Labels are often found inside drug product packaging.
- **Off-label/Unlabeled use of a drug** is defined as a use for a non-FDA approved indication, that is, one that is not listed on the drug's official label/prescribing information.
- **Off-label use** is further defined as giving the drug in a way that deviates significantly from the labeled prescribing information 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.



- **Unlabeled use** of a drug is a use that is not included as an indication on the drug's label as approved by the FDA. FDA approved drugs used for indications other than what is indicated on the official label.
- **Drug compendia**, defined as summaries of drug information that are compiled by experts who have reviewed clinical data on drugs. CMS (Center for Medicare and Medicaid Services) recognizes the following compendia: American Medical Association Drug Evaluations (AMA-DE), United States Pharmacopoeia-Drug Information (USP-DI) or its successor publication and American Hospital Formulary Service-Drug Information (AHFS-DI) as authoritative sources for use in the determination of a "medically-accepted indication" of drugs and biologicals used off-label in an anticancer chemotherapeutic regimen. The USP DI is a database of drug information developed by the U.S. Pharmacopoeia but maintained by Micromedex, which contains medically accepted uses for generic and brand name drug products.

D. Policy

CareSource requires that the use of a drug or biological must be safe and effective and otherwise reasonable and necessary. Drugs or biologicals approved for marketing by the Food and Drug Administration (FDA) are considered safe and effective for purposes of this requirement when used for indications specified on the labeling. Therefore, reimbursement may be provided for the use of an FDA approved drug or biological, if:

- It was administered on or after the date of the FDA's approval;
- It is reasonable and necessary for the individual patient; and
- All other applicable coverage requirements are met.

An unlabeled use of a drug is a use that is not included as an indication on the drug's label as approved by the FDA. FDA approved drugs used for indications other than what is indicated on the official label may be covered if it is determined that the use is medically necessary, taking into consideration the major drug compendia, authoritative medical literature and/or accepted standards of medical practice. The following guidelines identify three categories in which medications would not be reasonable and necessary according to accepted standards of medical practice.

- **Not for Particular Illness** – Medications given for a purpose other than the treatment of a particular condition, illness, or injury are not covered (except for certain immunizations.)
- **Route of Administration Not Indicated** – Medication given by injection (parenterally) is not covered if standard medical practice indicates that the administration of the medication by mouth (orally) is effective and is an accepted or preferred method of administration.
- **Excessive Medications** – Medications administered for treatment of a disease which exceed the frequency or duration of dosing indicated by accepted standards of medical practice are not covered.

Effective January 1, 1994, off-label, medically accepted indications of Food and Drug Administration (FDA) approved drugs and biologicals used in an anti-neoplastic chemotherapeutic regimen are identified under the indications described below:



- A regimen is a combination of anti-neoplastic agents clinically recognized for the treatment of a specific type of cancer.
- Off-label, medically accepted indications are supported in either one or more of the compendia or in peer-reviewed medical literature.

E. Conditions of Coverage

A medically accepted indication is one of the following:

- An FDA approved, labeled indication or a use supported in the American Hospital Formulary Service Drug Information (AHFS-DI), NCCN Drugs and Biologics Compendium, Truven Health Analytics Micromedex Drug Dex®, Elsevier/Gold Standard Clinical Pharmacology and Wolters Kluwer Lexi-Drugs® as the acceptable compendia based on CMS' Change Request 6191 (Compendia as Authoritative Sources for Use in the Determination of a "Medically Accepted Indication" of Drugs and Biologicals Used Off-Label in an Anti-Cancer Chemotherapeutic Regimen); or
- Articles of Local Coverage Determinations (LCDs) published by CMS.

In general, a use is identified by a compendium as medically accepted if the:

- Indication is a Category 1 or 2A in NCCN, or Class I, Class IIa, or Class IIb in DrugDex; or,
- Narrative text in AHFS-DI or Clinical Pharmacology is supportive, or
- Indication is listed in Lexi-Drugs as "Use: Off-Label" and rated as "Evidence Level A"

A use is not medically accepted by a compendium if the:

- Indication is a Category 3 in NCCN or a Class III in DrugDex; or,
- Narrative text in AHFS or Clinical Pharmacology is "not supportive," or
- Indication is listed in Lexi-Drugs as "Use: Unsupported"

If a use is identified as not indicated by CMS or the FDA, or if a use is specifically identified as not indicated in one or more of the compendia listed, or if it is determined, based on peer-reviewed medical literature, that a particular use of a drug is not safe and effective, the off-label use is not supported and the drug will not be covered.

Reimbursement is dependent on, but not limited to claims submissions reported using CMS 1500/HCFA, CMS 1450/UB 04 or electronic equivalent, and must include the following:

- 11-digit NDC (National Drug Code)
- HCPCS/CPT Code
- Correct HCPCS units (*not* NDC units)
- Correct NDC unit of measure

PLEASE NOTE THE FOLLOWING:

- Providers are responsible for sourcing and submitting accurate codes.
- Multi-source brands are not accepted without an additional medical necessity review for Dispense as Written (DAW). Medical Necessity for DAW policies can be found at [CareSource.com](https://www.caresource.com) under the applicable market's administrative policies tab.



- If applicable, individual drug reimbursement information may be found in a drug’s Pharmacy Policy.

F. Related Policies/Rules

G. Review/Revision History

	DATE	ACTION
Date Issued		
Date Revised		
Date Effective	02/01/2023	
Date Archived		

H. References

1. Drugs@FDA Glossary of Terms <https://www.fda.gov/drugs/drug-approvals-and-databases/drugsfda-glossary-terms>
2. Centers for Medicare and Medicaid Services, CMS Manual System and other CMS publications and services <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals>
3. United States Federal Food, Drug and Cosmetic Act <https://www.fda.gov/regulatory-information/laws-enforced-fda/federal-food-drug-and-cosmetic-act-fdc-act>

The Reimbursement Policy Statement detailed above has received due consideration as defined in the Reimbursement Policy Statement Policy and is approved.