- **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