- 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



Pharmacy Policy.

## F. Related Policies/Rules

## G. Review/Revision History

	DATE	ACTION
Date Issued	07/22/2022	Original effective date
Date Revised	12/06/2022	Additions to clarify claims submission requirements, responsibility for sourcing of codes, and MSBs not accepted without additional DAW review. Individual drug reimbursement information may be found in a Pharmacy Policy
Date Effective	02/01/2023	
Date Archived		

## H. References

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

The Reimbursement Policy Statement detailed above ha

