







- 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



