

Coverage Determination Process for Medicare Part B Drugs and Biologics:

Upon receiving an organization determination request for Medicare Part B drugs and biologics, Care N' Care (CNC) conducts a comprehensive review to evaluate coverage appropriateness based on current evidence in widely used treatment guidelines or clinical literature.

The following outlines CNC's stepwise approach to ensure that coverage is medically necessary and reasonable:

- 1- **National Coverage Determinations (NCDs) and Local Coverage Determinations (LCDs):** CNC adheres to NCDs and LCDs established by the Centers for Medicare & Medicaid Services (CMS) as outlined in the ([Medical Coverage Database](#))
- 2- **Milliman Care Guidelines (MCG):** When coverage criteria are not fully established in NCD or LCD, CNC refers to criteria outlined in [MCG](#).
- 3- **FDA Drug Labeling:** in cases where criteria is not defined by MCG, CNC refers to FDA-approved labeling for the medication including indications, patient age requirements, dosing recommendations, contraindications, and clinical trial inclusion criteria (e.g., genetic testing, comorbid conditions) ([FDA drug labeling](#))
- 4- **Off-Label Use:** For off-label use CNC refers to:
 - **CMS Defined Compendia*:** These may include resources such as the National Comprehensive Cancer Network (NCCN) guidelines, Micromedex, Lexi-Drugs, and others.
 - **Peer-Reviewed Medical Journals:** CNC also considers information published in peer-reviewed medical journals for evaluating off-label use.

* Care N' Care adheres to CMS guidelines for utilizing compendia, which ensure transparency and thorough evaluation of therapies, including:

- Summaries of pharmacologic characteristics and potential uses in specific diseases
- Indexed information by drug or biological
- A publicly transparent process for evaluating therapies and identifying potential conflicts of interest

Reference: [Medicare Benefit Policy Manual Chapter 15 – Covered Medical and Other Health Service](#)