

# IBM Micromedex Solutions Policy on DrugDex® Compendia Drug Content

IBM® Micromedex® Solutions contains FDA-approved indications as well as Micromedex® DrugDex®, on the list of statutorily named compendia in the Medicaid program, for use in the determination of certain non-FDA approved indications or “medically-accepted indications” of drugs and biologicals used off-label in an anticancer chemotherapeutic regimen, based on peer reviewed, publicly available clinical or literature evidence. Discovery and adoption of new uses for marketed drugs often precedes FDA approval of such uses. US Food and Drug Administration (FDA) recognizes that these uses or treatment regimens may be important therapeutic options and may even constitute a medically recognized standard of care, as are available in qualified Centers for Medicare and Medicaid Services (CMS) Compendia. Micromedex understands the importance of including such information in a truthful, non-misleading, and accurate manner for the consideration of health care professional individuals seeking information about a medical product.

To continue the long-standing reputation of Micromedex as a leading provider of unbiased information and to support robust and current information in drug therapy, Micromedex adheres to its policy for inclusion of non-promotional, scientific or medical information on these drug uses in its databases and products.

## Identification of Non-FDA Approved Uses

At Micromedex, there are two mechanisms for identifying these uses. First and foremost, such uses may be identified through routine monitoring of the primary literature. Second, uses may be identified through the consideration of external requests for inclusion in Micromedex databases and products.

Patient safety issues, breakthrough therapies, major treatment guideline updates, or other urgent situations are considered in prioritization of reviews. Public Health Agencies, such as CMS and FDA recognize that it may be in the best interest of public health for a firm to respond to unsolicited requests for information about Non-FDA approved uses.

## Research of Non-FDA Approved Uses

Regardless of how the use is identified, members of the Micromedex editorial staff conduct a thorough search of the primary literature and other accepted sources of information to identify additional relevant evidence, including negative or inconclusive findings. This ensures all pertinent articles are considered in the analysis.

## Clinical Review

Once identified, the evidence is critically evaluated for clinical relevance and statistical validity. If the body of evidence is deemed sufficient to warrant inclusion, the medical content about the drug is added to the Micromedex database. All new uses and revised existing uses with significant changes to the ratings require review from external reviewers.

## Independent External Review

Uses are vetted by independent reviewers with expertise in a variety of specialties. All reviewers must be practicing physicians with board certification in applicable specialty areas or practicing pharmacists with board certification and/or advanced training in applicable specialty areas. In addition, reviewers must have at least five years of clinical experience in the applicable specialty area and possess current knowledge of standard practices of care and established clinical guidelines related to drug therapy.

Reviewers must comply with the Micromedex Conflict of Interest Policy. Ratings are applied according to the editorial policy using a consensus methodology.

## Transparency

The Centers for Medicare and Medicaid Services (CMS) require compendia to provide transparency of processes used to evaluate therapies and to identify potential conflicts of interest. In order to meet these requirements, documents detailing transparency information for each drug/non-FDA approved use pair are posted at the Micromedex website. Information is organized by drug name, with the document title indicating the use.

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## Get connected

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## About IBM Watson Health

Each day, professionals throughout the health ecosystem make powerful progress toward a healthier future. At IBM Watson Health, we help them remove obstacles, optimize efforts and reveal new insights to support the people they serve. Working across the landscape, from payers and providers to governments and life sciences, we bring together deep health expertise; proven innovation; and the power of artificial intelligence to enable our customers to uncover, connect and act — as they work to solve health challenges for people everywhere.

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