Micromedex® policy on compendia drug content

Data Sheet

Micromedex Solutions includes DRUGDEX® which is one of the named drug information compendia in the Centers for Medicare and Medicaid Services program for use in the determination of medically-accepted indications of drugs and biologicals used beyond package labeling in an anticancer chemotherapeutic regimen.

Micromedex contains FDA-approved indications as well as Non-FDA approved or off-label uses, 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-biased, 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.

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. 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.

Independent review

Uses may be vetted by independent reviewers with expertise in a variety of specialties. Micromedex maintains independent off-label reviewers to facilitate the off-label process. Reviewers are health care professionals with board-certification or expertise in applicable specialty areas.

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

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. New uses and revised existing uses with significant changes to the ratings may be subject to independent review.

About Merative

Merative provides data and software for healthcare and government social services. With focused innovation and deep expertise, Merative works with providers, employers, health plans, governments, and life science companies to drive real progress. Merative helps clients orient information and insights around the people they serve to improve decision-making and performance. Merative, formerly IBM Watson Health, became a new standalone company as part of Francisco Partners in 2022. Learn more at merative.com.

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Produced in the United States of America
February 2024

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