

Micromedex Policy on Off-Label Indications

Micromedex® Solutions from Truven Health Analytics™ contain FDA-approved or “labeled” indications as well as unapproved or “off-label” indications for drug therapy. Discovery and adoption of new uses for marketed drugs often precedes FDA approval of such uses. Furthermore, some manufacturers fail to seek FDA approval of new indications. Nonetheless, this information is critical to clinicians in day-to-day practice. Micromedex understands the importance of including information on off-label indications in its products.

To continue the long-standing reputation of Micromedex as a leading provider of unbiased information and to support best practices in drug therapy, Micromedex adheres to its policy for inclusion of off-label indications in its databases and products.

Micromedex strives to achieve representation in the following areas:

- Cardiology and Nephrology
- Clinical Toxicology and Substance Abuse
- Critical Care and Emergency Medicine
- Dermatology
- Endocrinology
- Gastroenterology
- Hematology and Oncology
- Infectious Diseases
- Neurology
- Nuclear Medicine and Radiology
- Nutrition and Electrolytes
- Obstetrics and Gynecology
- Ophthalmology
- Otorhinolaryngology
- Pediatrics
- Psychiatry
- Pulmonology
- Rheumatology and Clinical Immunology
- Urology

Identification of Off-Label Indications

At Micromedex, there are two mechanisms for identifying off-label indications. First and foremost, off-label indications are identified through routine monitoring of the primary literature and other accepted sources of medical information such as the FDA, NIH, and CDC. Second, off-label indications may be identified through the consideration of external requests or suggestions for inclusion in Micromedex databases and products. Patient safety and breakthrough therapies are considered in prioritization of indication review.

Research of Off-Label Indications

Regardless of how the off-label indication is identified, members of the Micromedex editorial staff — in conjunction with the medical librarian — conduct a thorough search of the primary literature and other accepted sources of information to identify additional relevant, published information, including negative or inconclusive findings. This ensures all pertinent articles are considered in the analysis.

Clinical Review

Once identified, the evidence is reviewed and evaluated for statistical and methodological validity. If the documentation is deemed sufficient to warrant inclusion, the off-label indication is added to the Micromedex database. In addition to thorough analysis of supporting documentation and internal clinical review, off-label indications meeting the following criteria are reviewed by an internal panel comprising members of the senior clinical staff:

- Rare diseases
- New indications with a Strength of Recommendation rating of “Recommended” or “Recommended in Most Cases,” or an Acceptance rating of “Accepted”
- Existing indications for which the associated ratings significantly change

Outside Expert Review

Occasionally, the internal panel determines documentation to be debatable or controversial. In these cases, the indications are sent to an external Editorial Board maintained by Micromedex. This board is made up of external experts with expertise in a variety of specialties. Additionally, a separate board, the Oncology Advisory Board — made up of oncology experts — reviews new off-label indications related to oncology as well as revisions that result in a significant change in the associated ratings. The board members 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, board members 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. All board members must comply with the Micromedex Conflict of Interest Policy.

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ABOUT TRUVEN HEALTH ANALYTICS

Truven Health Analytics delivers unbiased information, analytic tools, benchmarks, and services to the healthcare industry. Hospitals, government agencies, employers, health plans, clinicians, pharmaceutical, and medical device companies have relied on us for more than 30 years. We combine our deep clinical, financial, and healthcare management expertise with innovative technology platforms and information assets to make healthcare better by collaborating with our customers to uncover and realize opportunities for improving quality, efficiency, and outcomes. With more than 2,000 employees globally, we have major offices in Ann Arbor, Mich.; Chicago; and Denver. Advantage Suite, Micromedex, ActionOI, MarketScan, and 100 Top Hospitals are registered trademarks or trademarks of Truven Health Analytics.

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