Inclusion Criteria for Medical Foods

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Medical foods that meet the following policy are candidates for inclusion in Micromedex® Medication Management information. Criteria for inclusion in REDBOOK® and other Truven Health Analytics™ products may vary.

What is Medical Food?
Micromedex editorial governance uses the FDA definitions and guidance to define a medical food. The Orphan Drug Act states: "The term "medical food" means a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation."[i]

Additionally, the FDA clarifies that a food is a medical food **only if**:

1. It is a specially formulated and processed product (as opposed to a naturally occurring foodstuff used in its natural state) for the partial or exclusive feeding of a patient by means of oral intake or enteral feeding tube
2. It is intended for the dietary management of a patient who, because of therapeutic or chronic medical needs, has limited or impaired capacity to ingest, digest, absorb, or metabolize ordinary foodstuffs or certain nutrients, or who has other special medically determined nutrient requirements, the dietary management of which cannot be achieved by the modification of the normal diet alone
3. It provides nutritional support specifically modified for the management of the unique nutrient needs that result from the specific disease or condition, as determined by medical evaluation
4. It is intended to be used under medical supervision
5. It is intended only for a patient receiving active and ongoing medical supervision wherein the patient requires medical care on a recurring basis for, among other things, instructions on the use of the medical food[ii]

The FDA uses the statutory definition of "medical food" to narrowly constrain the types of products that fit within this category.[iii] In addition to other criteria, medical foods must be for the dietary management of a specific disorder, disease, or condition for which there are distinctive nutritional requirements and must be intended to be used under medical supervision.[i,iii] Patients with such a disorder, disease, or condition must have a limited capacity to ingest, digest, absorb, or metabolize ordinary foodstuffs or certain nutrients, or have other special medically determined nutrient requirements, which cannot be managed by the modification of the normal diet alone.[ii] Medical foods are not those simply recommended by a physician as part of an overall diet to reduce the risk of a disease or condition.[iii]

Inclusions and Exclusions
The FDA has clarified some conditions which are and are not conditions for which a medical food could be labeled and marketed.

Conditions include, but may not be limited to:
- Inborn errors of metabolism requiring significant restriction of particular amino acids and/or total protein such as in phenylketonuria
- Ornithine transcarbamylase deficiency
- Methylmalonic acidemia, or significant modification of fatty acids/ total fat such as in very long-chain acyl-CoA dehydrogenase

Excluded conditions include, but may not be limited to:
- Pregnancy
- Diabetes mellitus type 1 and type 2
- Essential nutrient deficiencies (e.g., scurvy, pellagra)
- Conventional foods that are low in protein or do not contain protein[iii]

Micromedex Criteria
Micromedex editorial governance takes FDA guidance into consideration when evaluating medical foods for inclusion into content.

To be considered for inclusion in Micromedex solutions, the uses in the medical food product information must be supported by published literature with human trials of sufficient quality to meet the Micromedex evidence-based editorial standards. Submissions for inclusion and policies around those submissions are outlined on the Micromedex website at Micromedex Website.

[i] Orphan Drug Act 21 U.S.C. 360ee 5(b)(3) (1988).
[ii] Regulation of Medical Foods, 21 C.F.R. 101.9(j)(8) (1996).
[iii] Guidance for Industry: Frequently Asked Questions about Medical Foods; second edition. U.S. Food and Drug Administration, August 2013.

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