



## PEDIATRIC PATIENT ACCESS TO MEDICAL FOODS

Pediatric patients with diseases and disorders of the gastrointestinal system and liver frequently require medical foods; yet, insurers routinely deny coverage of these health-promoting nutrients. **The North American Society for Pediatric Gastroenterology, Hepatology and Nutrition (NASPGHAN) believes that legislation is needed requiring private and public health insurance plans to provide for the coverage of medically necessary food for these patients.**

### WHAT ARE MEDICAL FOODS?

Medical foods are foods or dietary supplements that are specially formulated and processed (as opposed to a naturally occurring food used in its natural state) for a patient who requires the food as a major treatment modality. Medical foods are not foods that are part of regular diet given to patients, nor foods or supplements that purport to improve health or function of otherwise healthy individuals. The Food and Drug Administration (FDA) defines medical foods as:

“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.” (section 5(b) of the Orphan Drug Act (21 U.S.C. 360ee (b) (3))).

### MEDICAL FOODS FOR THE TREATMENT OF DISEASES OF THE DIGESTIVE SYSTEM

For many diseases of the digestive system, medical foods constitute the prescribed medical treatment and may be essential to survival, yet are not covered benefits. These diseases include:

- chronic gastrointestinal diseases, complicated by malabsorption and malnutrition, (e.g. short bowel syndrome/intestinal failure, Crohn’s disease, chronic pancreatitis);
- chronic serious liver disease (e.g. biliary atresia, the most common indication for liver transplantation in children); and
- chronic allergic syndromes (e.g. eosinophilic esophagitis).

Medical foods, including expensive vitamin formulations, used to treat these disorders are essential and, in a majority of cases, the only route of safe and effective therapy available.

Often times, insurers will cover a medical food, such as a special formula, but only if it is administered through a tube placed in the nose, stomach or intestine, even though the patient is fully capable of oral consumption. This practice is more costly to the health care system and is fundamentally unfair to the patient. Administration of medical foods by tube should only be used in situations where the child is unable to consume sufficient quantities of needed foods orally. Feeding through devices can be associated with its own potential complications and can be cumbersome to the family and the patient. For example, a gastrostomy tube can leak, cause ulcerations, or in severe cases, cause a perforation in the intestinal tract.

### WHY FEDERAL LEGISLATION REQUIRING MEDICAL FOODS COVERAGE IS NEEDED

No federal law exists to mandate consistent coverage and payment for medical foods. Thirty-seven states and the District of Columbia have laws mandating that health insurance cover medical foods for special dietary use, but these laws are variable and do not apply to plans governed by the Employee Retirement Income Security Act (ERISA). For many insured children, medical foods are an essential component of their medical treatment; however, because they are not a covered benefit, they incur the tremendous cost of medical foods or forgo their physician’s recommended treatment, which, in turn, can lead to less favorable medical outcomes.

**Bottom Line:** Pediatric patients with diseases of the digestive system should not be denied access to medical foods that are essential to their medical treatment. Federal legislation is needed to ensure consistent coverage requirements across public and private health insurance plans.