



HOW COVERAGE OF MEDICAL FOODS CAN SAVE LIVES & COSTS

CROHN'S DISEASE

Crohn's disease is a lifelong illness that causes intestinal inflammation, leading to abdominal pain, diarrhea, anemia, and poor growth in children. The incidence of Crohn's disease is rising in the United States and there is no existing cure for this condition.

There are many different types of medications for the treatment for Crohn's. When the disease is moderate/severe, a consideration is to use the biologic class of medications for treatment of Crohn's disease. These are highly effective therapies, which are generally covered by commercial insurance, but there are a couple of significant downsides:

Once a specific biologic therapy is started, the patient has to remain on that treatment for the drug to work - forever. If the patient stops it, in all likelihood they will lose response. That is a major consideration especially for pediatric patients who have many decades of treatment ahead of them;

These medications suppress the immune system and increase the patient's risk of infection as well as other side effects of the medication; and

1. Biologics are very expensive. The average annual costs for two most common biologic treatments range from approximately \$25,000 to \$33,000 for the first year of treatment (note that these are the costs for the drugs only, not for infusion costs).
2. Crohn's disease is a lifelong disease. Patients need to be receiving some type of ongoing therapy for their disease to stay in remission. Luckily, biologics are not the only option.
3. Studies in children have demonstrated that "enteral therapy" (the delivery of nutritional formulas into the intestine as a primary treatment) is as effective as conventional and biologic medication options in achieving remission in Crohn's disease. While enteral therapy is not medically appropriate for all Crohn's patients, there are significant benefits:

There are few side effects

- The treatment can typically be delivered at home by the patient/family
- It is far cheaper than biologics

	BIOLOGIC		FORMULA	
	Remicade	Humira	Standard	Pre-digested
Average cost per month for 1st year	\$2,083	\$2,750	\$300	\$1,500

Unfortunately, many commercial insurance carriers will not cover the cost of enteral therapy because the commercial pediatric formula is considered a "medical food," effectively limiting the patient's treatment options to the more expensive and more toxic pharmacologic option. The Patient & Providers for Medical Nutrition Equity Coalition calls on Congress to address this issue by co-sponsoring the bi-partisan Medical Nutrition Equity Act (S. 3657/H.R. 2501).

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CASE STUDY

Jane is a happy and energetic 7-year-old child who lives with her parents and two siblings in Chicago, IL. She was diagnosed with Crohn's Disease when she was 2 years old and owes her life to medical nutrition.

When Jane was 2 years old she had presented to gastroenterology service for malnutrition, fatigue, anemia and diarrhea of six to seven times per day. Jane's parents reported a 5-pound weight loss in the last 6 weeks, and her intake included rice, toast, soup and almond milk. Her weight was 20 pounds, which plots less than the 3rd percentile on Centers for Disease Control and Prevention's (CDC) growth charts, and her height was 33.5 inches, which plots on the 31st percentile for age. Her body mass index (BMI) was 12.6kg/m² which plots less than the 3rd percentile for age. Her anthropometrics (or measurement of the human body) reflected severe acute malnutrition.

Based on her current nutritional status and severity of Crohn's disease, the family, along with a gastroenterologist and inflammatory bowel disease (IBD) team, recommended Exclusive Enteral Nutrition (EEN) therapy for induction therapy. Jane was prescribed to drink a standard polymeric formula to provide 100% of estimated nutritional needs for 8 weeks. The IBD team explained to the family that if Jane was unable to drink the prescribed volume, a naso-gastric tube could be placed so Jane could get the required nutrients without having to drink the prescribed amount. Jane was able to drink the formula, so a naso-gastric tube was not necessary. Jane's formula cost out of pocket for EEN was approximately \$300 per month. Her team of health care providers attempted to obtain insurance coverage but was denied even after appeals were attempted.

At her appointment 2 months later, Jane continued on EEN which was meeting her nutrition needs. She had gained 5.5 pounds, grew .41 of an inch and her BMI improved to 15.4kg/m². Her anthropometrics reflected nutritional rehabilitation and she is no longer malnourished. EEN had successfully induced remission with mucosal healing and improved her nutritional status. The family and IBD team then weaned the EEN and put her on maintenance drug therapy, with a gradual food reintroduction with concomitant decrease of formula over a two-to-three week period.

Over the next few years, EEN was successfully used to treat Jane when she had a flare of her Crohn's disease. Jane's anthropometrics reflect a well-nourished 7-year-old who enjoys playing soccer and is thriving.

Jane depends on medical nutrition to keep her healthy and growing. She, and children like her across the country, are depending on YOU to co-sponsor the Medical Nutrition Equity Act (S. 3657/H.R. 2501). Please contact the offices of Senator Ernst, Senator Casey, Representative Herrera Beutler or Representative McGovern today.