

Advancing Access to Medical Nutrition Therapy for Pediatric IBD Patients:

Summary of February 2025 Medical Nutrition Meeting, Berlin



Objective: To create a clear and actionable path to improve access to medical nutrition therapy (MNT) for pediatric IBD patients in the United States. This includes addressing barriers such as high out-of-pocket costs, limited insurance coverage, and regulatory challenges through targeted research, legislative advocacy, and stakeholder collaboration. By implementing this six-point strategic action plan, the goal is to ensure MNT becomes an accessible and affordable treatment for the IBD community.

Background: Barriers to Medical Nutrition Therapy (MNT) in the U.S.

In the United States, access to medical nutrition therapy for IBD faces significant barriers, including lack of insurance coverage and high out-of-pocket costs ranging from \$3,000 to \$4,000 per month. Despite evidence showing that medical nutrition can be as effective as steroids—often serving as a standalone therapy—it is rarely covered unless administered via a nasogastric tube.

To address these challenges, the Crohn's & Colitis Foundation convened experts and clinicians specializing in IBD, along with patients, caregivers, researchers, industry representatives, insurers, and regulatory authorities, to develop a strategic action plan aimed at improving access to medical nutrition therapy in the U.S. This effort culminated at the February 2025 Medical Nutrition Meeting in Berlin, Germany, where a six-point strategic action plan was created. Key strategies include narrowing legislative efforts to pediatric patients to achieve initial success.

Six-Point Strategic Action Plan

Developed by the Crohn's & Colitis Foundation with support from The Leona M. and Harry B. Helmsley Charitable Trust and global stakeholders, this plan aims to drive legislative and policy reforms to improve access to medical nutrition:

Breaking Barriers: A 6-Point Strategic Action Plan for Medical Nutrition Therapy Access in Pediatric IBD

1



Develop an Economic Cost Analysis

Medical nutrition therapy (MNT) costs patients \$3,000–\$4,000/month out-of-pocket, while steroids and surgeries drive long-term expenses through complications like hospitalizations. This strategy will analyze data to compare MNT with traditional therapies, emphasizing cost-effectiveness of MNT. For example, studies show MNT can reduce pediatric hospitalization rates by 40%. The findings will target policymakers and insurers to justify coverage expansions.

2



Focus on Pediatric IBD to Advance Key Legislation

Focusing on pediatric IBD streamlines the legislative process, increasing the likelihood of passage. The plan prioritizes state-level bills (e.g., California's 2024 Assembly Bill 1644), ensuring MNT is classified as medically necessary. Narrowing the scope avoids overreach and aligns with bipartisan support for child health initiatives.

3



Carve Out New Opportunities for Working with the FDA

Advocates will push the Food and Drug Administration (FDA) to clarify regulatory pathways for IBD-specific formulas, such as expanding labels for existing medical foods. Collaborating with the FDA's Office of Orphan Products could fast-track approvals, mirroring successes in rare disease therapies. This would also enable clearer insurance coding for reimbursement.

4



Create a Payor Strategy

Partnering with insurers to pilot MNT coverage programs to demonstrate reduced costs. For example, early data shows MNT cuts steroid use by 60% in pediatric patients, lowering complications like growth delays. Highlighting these outcomes could incentivize payors to adopt permanent coverage models.

5



Engage Pharmaceutical Stakeholders

Pharma companies will be urged to include MNT in clinical trials for new therapies, positioning nutrition as a complementary treatment. This collaboration could lead to FDA-approved combo therapies, boosting MNT's availability and improving patient outcomes.

6



Generate Real-World Evidence Supporting the Use of Medical Nutrition Therapy

Create a path where real-world evidence and cost savings are integral to the development process. This includes generating data on the use of medical nutrition as a treatment and its role in reducing side effects. Efforts will also focus on educating healthcare professionals and patients about medical nutrition in IBD, highlighting gaps in care and barriers to access.

Sources: Crohn's & Colitis Foundation, The Helmsley Charitable Trust, Mathematica, Gastroenterology Advisor