**Letter of Medical Necessity**

**MODULEN® Nutritionally Complete Powdered Formula**

Date: Month, Day, Year

TO: Insurance company

FROM: Physician Name

SUBJECT: Request for Coverage/Reimbursement for Modulen® Nutritionally Complete Powdered Formula

I am requesting insurance coverage and reimbursement on behalf of my patient, *Name/Date of Birth*. I have prescribed Modulen® formula as partial enteral nutrition (PEN), as part of the Crohn’s Disease Exclusion Diet (CDED).

The CDED, which is for the dietary management of Crohn’s Disease (CD), is a whole-food diet coupled with partial enteral nutrition (PEN), designed to reduce exposure to dietary components that have adverse effects on the microbiome and intestinal barrier.1

In a randomized controlled trial, the CDED plus PEN was shown to be better accepted than an exclusive enteral nutrition regimen in children with mild to moderate CD, and demonstrated superior

sustained remission and reduction in inflammation by week 12 on the diet.1

*Verify medical necessity for formula, including date of birth, diagnosis, height/weight, weight history, brief documentation of failure or intolerance to other medical management strategies for Crohn’s Disease.*

Modulen® formula is for the special dietary use of individuals age 5+ years with CD who have been prescribed the CDED that includes partial enteral nutrition, under medical supervision. Modulen® meets the criteria for partial enteral nutrition as part of the CDED.

Modulen® formula is recognized by the Centers for Medicare and Medicaid Services (CMS) in HCPCS Category B4160 for pediatrics.

Thank you for taking the time to review this request. Please contact me should you require any additional information.

Sincerely,

Signature

Name, Title

1. Levine A et al. Crohn’s Disease Exclusion Diet Plus Partial Enteral Nutrition Induces Sustained Remission in a Randomized Controlled Trial. *Gastroenterology* 2019;157:440-450.