

Statement of Medical Necessity/Prior Authorization Request

Date:

Patient:

DOB:

Diagnosis: **Maple Syrup Urine Disease (MSUD)**

To Whom It May Concern:

_____ [PATIENT'S NAME] is being treated for Maple Syrup Urine Disease (MSUD) by _____ [CENTER/CLINIC/GENETICIST]. The Camino PRO® Modular Medical Formula System has been prescribed and is medically necessary as the optimum treatment for [ENTER PATIENT'S NAME]. This letter is being submitted to justify _____ [HIS/HER] need for insurance coverage of the Camino PRO® Modular Medical Formula System.

_____ [PATIENT'S NAME] was diagnosed at birth with Maple Syrup Disease (MSUD) (ICD.9.CM 270.3), a metabolic disorder affecting approximately 1: 100,000 to 1:300,000 live births. This metabolic disorder is due to several defects that affect the enzyme branch chain alpha-ketoacid dehydrogenase complex, which is responsible for the metabolism of the branch chain amino acids (leucine, isoleucine, and valine). As a consequence, blood and tissue concentrations of leucine, isoleucine and valine are greatly elevated, resulting in accumulation of branch-chain ketoacids, their amino acid precursors and alloisoleucine in blood, urine, and cerebrospinal fluid.

If untreated, those with MSUD suffer irreversible and progressive brain damage, seizures, apnea, and likely death. The treatment for MSUD includes consumption of medical food to provide appropriate amino acids while eliminating those that are toxic. In addition, strict dietary control of natural protein intake is necessary, meaning elimination of all foods high in protein (i.e., meat, fish, poultry, dairy products, legumes, and nuts). Even grains and starches are limited or excluded altogether. Specially prepared low protein packaged food products are required to meet dietary protein restrictions. Some vegetables, fruits, fats, and simple sugars are allowed. Restricting protein without the use of medical food would lead to marked protein malnutrition, failure-to-thrive and death. For this reason, medical foods free of leucine, isoleucine, and valine, but containing all other essential and nonessential amino acids, minerals and vitamins are required.

MSUD is a LIFELONG disease and a permanent condition. There is no cure at this time for MSUD. It is recognized that medical foods are the major source of essential amino acids necessary for life and that they constitute the principal medical treatment for individuals with MSUD. The cost of treatment for MSUD is significantly lower than the cost of providing care for untreated MSUD patients suffering from brain damage and mental retardation.

Effective treatment of MSUD requires that medical food be consumed every day, is taken in small doses several times (at least 3; more is preferred) throughout the day, and is taken with meals/snacks. Historically, medical formulas were developed as infant formulas, following a scoop-and-mix format, meaning powder from a can was scooped out and mixed with water. However, research shows that as those with MSUD begin to take responsibility for their own diets, the traditional powdered formula is not an effective treatment. Lack of compliance due to social stigma and offensive taste, as well as inability to accurately measure, weigh, and mix formula accurately leads to poor metabolic control. Poor metabolic control can lead to a host of medical and psychological issues that may require rigorous and costly treatment. In addition, patients who are not compliant with medical food intake are at extreme risk for severe

nutritional deficiencies. To ensure adequate dosing and compliance, patients with MSUD need a ready-to-feed product that does not require them to weigh, measure, and calculate. Using a pre-measured ready-to-feed medical formula eliminates human error and reduces waste.

The Camino PRO® System is a nutritionally superior, ready-to-feed version of outmoded powdered formulas. The system improves compliance by allowing patients to meet their protein needs in a variety of ways, depending on their schedules, taste preferences, and calorie needs. It also offers many nutritional benefits, such as fiber, prebiotics, and omega-3 fats. No other medical formula available today meets all of these nutritional needs. *Though Camino PRO® products are designed to be consumed with meals, as this is required for good metabolic control; Camino PRO® products are not to be confused with low protein foods.*

_____ [PATIENT'S NAME] requires ____ [NUMBER OF GRAMS] grams of protein equivalent from Camino PRO® to manage ____ [HIS/HER] condition. With appropriate nutrition support, we are confident that [PATIENT'S NAME] will continue to achieve ____ [HIS/HER] growth and development potential and avoid the devastating consequences of untreated MSUD. The Camino PRO® System is designed to mix and match modules to meet nutritional needs and promote the level of dietary compliance necessary to achieve this goal. Please see below the following page for individual product information and reimbursement codes. It is important that _____ [PATIENT'S NAME] has access to all products within the system for it to function effectively. Per gram of protein, there is no price difference across the range of modules. Therefore, we respectfully request insurance reimbursement/coverage for all modules in the Camino PRO® Modular Medical Formula System.

If you have further questions, please do not hesitate to contact us _____
_____ [METABOLIC CLINIC CONTACT INFO].
Thank you for your assistance in this matter.

Sincerely,

_____ [PHYSICIAN OR DIETITIAN]

Camino PRO® Product Information and Reimbursement Codes

Product	Flavor	Packaging (all RTD)	NDC Codes for reimbursement
Camino PRO® AA Drinks	Pina Colada	140 ml x 28 pouches	24359-0610-01
Camino PRO® AA Drinks	Fruit Punch	140 ml x 28 pouches	24359-0610-02