

## Statement of Medical Necessity/Prior Authorization Request

Date:

Patient:

DOB:

Diagnosis: **Phenylketonuria (PKU)**

To Whom It May Concern:

\_\_\_\_\_ [PATIENT'S NAME] is being treated for Phenylketonuria (PKU) by \_\_\_\_\_ [CENTER/CLINIC/GENETICIST]. The Camino PRO® Modular Medical Formula System has been prescribed and is medically necessary as the optimum treatment for \_\_\_\_\_ [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 Phenylketonuria (PKU) (ICD.9.CM 270.1), a metabolic disorder affecting approximately 1:10,000 to 1:25,000 live births. This metabolic disorder is due to a defect in the enzyme responsible for the metabolism of phenylalanine, an essential amino acid. As a consequence, blood and tissue concentrations of phenylalanine are greatly elevated, resulting in accumulation of toxic phenylalanine metabolites.

If untreated, those with PKU suffer irreversible and progressive brain damage. Manifestations include profound mental retardation, neurological disorders, and seizures. When PKU is diagnosed during the neonatal period and managed by *life-long* nutrition support, those affected by PKU will achieve normal growth and development and maintain proper mental function throughout life.

The primary treatment for PKU is strict dietary control of phenylalanine intake. A phenylalanine-restricted diet excludes all foods high in protein (i.e., meat, fish, poultry, dairy products, legumes and nuts). The diet includes only prescribed amounts of medical food, low protein packaged food products, vegetables, fruits, fats and simple sugars. Using only natural low protein foods, the degree of protein restriction necessary to reduce plasma phenylalanine concentrations to treatment levels would lead to marked protein malnutrition, failure-to-thrive and death. For this reason, medical foods free of phenylalanine but containing all other essential and nonessential amino acids, minerals and vitamins are required.

***Phenylketonuria is a LIFELONG disease and a permanent condition. There is no cure at this time for PKU.*** 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 PKU. The cost of treatment for PKU is significantly lower than the cost of providing care for untreated PKU patients suffering from brain damage and mental retardation.

Effective treatment of PKU 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 PKU 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 PKU 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 PKU. 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]

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### Camino PRO® Product Information and Reimbursement Codes

Product	Flavor	Packaging (*RTD)	NDC Codes for reimbursement
Camino PRO® AA Drink	Pina Colada	140 ml x 28 pouches*	24359-0310-01
Camino PRO® AA Drink	Fruit Punch	140 ml x 28 pouches*	24359-0310-02
Camino PRO® BetterMilk™ with Glytactin™ Drink		49 g x 28 packets	24359-0350-01
Camino PRO RESTORE™ with Glytactin™ Drink	Lemon-Lime	500 mL x 12 bottles*	24359-0350-03
Camino PRO RESTORE™ with Glytactin™ Drink	Tangerine	500 mL x 12 bottles*	24359-0350-05