Enteral Nutrition (Oral and Tube Feeding) (for New Jersey Only)

Guideline Number: CS136NJ.L
Effective Date: August 1, 2023

➲ Instructions for Use

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Related Policy

- Durable Medical Equipment, Orthotics, Medical Supplies and Repairs/Replacements (for New Jersey Only)

Application

This Medical Policy only applies to the state of New Jersey.

Coverage Rationale

➲ See Benefit Considerations

Enteral Nutrition by Tube Feeding

Enteral Nutrition administered by tube feeding (e.g., nasogastric, gastrostomy, or jejunostomy tube) is medically necessary in certain circumstances. For medical necessity clinical coverage criteria, refer to the InterQual® CP: Durable Medical Equipment, Enteral and Parenteral Nutrition Therapy.

Click here to view the InterQual® criteria.

Oral Nutrition

Specialized Nutrient Formula administered orally, as a primary or supplementary source of nutrition, is considered medically necessary when all of the following criteria are met:

- A physician, advanced practitioner (NP, CNS, or PA) or registered dietician prescribes the therapy; and
- The condition is chronic and is expected to last for an undetermined or prolonged period of time; and
- Adequate nutrition is not possible by dietary adjustment; and
- The formula used is a Medical Food that is specially formulated for a specific condition; and
- The individual has one of the following conditions:
  - Inborn Errors of Metabolism (such as phenylketonuria (PKU), maple syrup urine disease, homocystinuria, methylmalonic acidemia, propionic acidemia, isovaleric acidemia, and other disorders of leucine metabolism; glutaric aciduria type I and tyrosinemia types I and II; and urea cycle disorders); or

- Chronic kidney disease (CKD) stages 2 to 5 (or on dialysis) for individuals ages less than 24 months; or
- Crohn's disease; or
- Severe malabsorption syndrome (such as cystic fibrosis, short bowel syndrome, or intestinal failure); or
- Malnutrition or individual will become malnourished or suffer from severe disorders such as physical disability, Intellectual Disability or death if the nutritional therapy is not instituted; or
- Severe food allergies, including eosinophilic esophagitis and other forms of eosinophilic gastrointestinal diseases, which, if left untreated, will cause life-threatening allergic reactions, malnourishment, or death (mild and moderate food allergies or food intolerance can usually be treated with formula that is readily available in food stores and pharmacies, or by careful food selection. Formulas for the treatment of such conditions are not considered medically necessary); or
- Gastroesophageal reflux with failure to thrive

Definitions

Check the federal, state or contractual definitions that supersede the definitions below.

Intellectual Disability: Intellectual disability (ID) is a neurodevelopmental disorder that is characterized by deficits in both intellectual functioning and adaptive functioning, whose onset is in the developmental period (Purugganan, 2018).

Inborn Errors of Metabolism: Inborn Errors of Metabolism are a group of disorders that causes a block in a metabolic pathway leading to clinically significant consequences. Examples include: phenylketonuria (PKU), phenylketonuria, maple syrup urine disease, homocystinuria, methylmalonic acidemia, propionic acidemia, isovaleric acidemia, and other disorders of leucine metabolism; glutaric aciduria type I and tyrosinemia types I and II; and urea cycle disorders (National Human Genome Research Institute website, 2013).

Medical Food: A food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation.

Generally, to be considered a medical food, a product must, at a minimum, meet the following criteria:
- The product is a food for oral or tube feeding;
- The product is labeled for the dietary management of a medical disorder, disease, or condition; and
- The product is labeled to be used under medical supervision, and is primarily obtained through hospitals, clinics, and other medical and long term care facilities.

Medical foods are distinguished from the broader category of foods for special dietary use and from foods that make health claims by the requirement that medical foods are to be used under medical supervision. The term "medical foods" does not pertain to all foods fed to sick patients. Medical foods are foods that are specially formulated and processed (as opposed to a naturally occurring foodstuff used in its natural state) for the patient who is seriously ill or who requires the product as a major treatment modality. Typical medical foods are enteral nutrition products, i.e., products provided through the gastrointestinal tract, taken by mouth, or provided through a tube or catheter that delivers nutrients beyond the oral cavity or directly to the stomach (US Food and Drug Administration, 2006).

Specialized Nutrient Formula: Formula that is produced to meet unique nutrient needs for specific disease conditions.

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by federal, state, or contractual requirements and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

HCPCS Code	Description
B4100	Food thickener, administered orally, per oz.

HCPCS Code	Description
*B4102	Enteral formula, for adults, used to replace fluids and electrolytes (e.g., clear liquids), 500 ml = 1 unit
B4103	Enteral formula, for pediatrics, used to replace fluids and electrolytes (e.g., clear liquids), 500 ml = 1 unit
*B4104	Additive for enteral formula (e.g., fiber)
*B4149	Enteral formula, manufactured blenderized natural foods with intact nutrients, includes proteins, fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit
B4150	Enteral formula, nutritionally complete with intact nutrients, includes proteins, fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit
B4152	Enteral formula, nutritionally complete, calorically dense (equal to or greater than 1.5 kcal/ml) with intact nutrients, includes proteins, fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit
B4153	Enteral formula, nutritionally complete, hydrolyzed proteins (amino acids and peptide chain), includes fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit
B4154	Enteral formula, nutritionally complete, for special metabolic needs, excludes inherited disease of metabolism, includes altered composition of proteins, fats, carbohydrates, vitamins and/or minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit
B4155	Enteral formula, nutritionally incomplete/modular nutrients, includes specific nutrients, carbohydrates (e.g., glucose polymers), proteins/amino acids (e.g., glutamine, arginine), fat (e.g., medium chain triglycerides) or combination, administered through an enteral feeding tube, 100 calories = 1 unit
B4157	Enteral formula, nutritionally complete, for special metabolic needs for inherited disease of metabolism, includes proteins, fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit
B4158	Enteral formula, for pediatrics, nutritionally complete with intact nutrients, includes proteins, fats, carbohydrates, vitamins and minerals, may include fiber and/or iron, administered through an enteral feeding tube, 100 calories = 1 unit
B4159	Enteral formula, for pediatrics, nutritionally complete soy based with intact nutrients, includes proteins, fats, carbohydrates, vitamins and minerals, may include fiber and/or iron, administered through an enteral feeding tube, 100 calories = 1 unit
B4160	Enteral formula, for pediatrics, nutritionally complete calorically dense (equal to or greater than 0.7 kcal/ml) with intact nutrients, includes proteins, fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100 calories + 1 unit
B4161	Enteral formula, for pediatrics, hydrolyzed/amino acids and peptide chain proteins, includes fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit
B4162	Enteral formula, for pediatrics, special metabolic needs for inherited disease of metabolism, includes proteins, fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit
Metabolic and Specialized Foods	
*S9432	Medical foods for noninborn errors of metabolism
*S9433	Medical food nutritionally complete, administered orally, providing 100% of nutritional intake
*S9434	Modified solid food supplements for inborn errors of metabolism
*S9435	Medical foods for inborn errors of metabolism

Codes labeled with an asterisk (*) are not on the State of New Jersey Medicaid Fee Schedule and therefore may not be covered by the State of New Jersey Medicaid Program.

Description of Services

Enteral nutrition refers to any method of feeding that uses the gastrointestinal tract to deliver nutrition and calories including a normal oral diet, using a liquid supplement or delivery by use of a tube also referred to as a tube feeding (ACG, 2021).

Formula for enteral nutrition can be provided by tube feeding or orally, as replacement or supplement to dietary intake. Formula can be standard formula (nutritionally complete with intact nutrients) or specialized nutrient formula. Specialized nutrient formulas are used for conditions requiring specific dietary components, requiring the alteration of specific dietary components, or disorders of the carbohydrate, lipid, vitamin, mineral, amino acid or nitrogen metabolism (Greer 2003).

Benefit Considerations

The following are generally not covered (for exceptions, refer to state or contractual requirements for coverage):

- Specialized enteral formula when the criteria above are not met;
- Standard enteral formula for oral intake;
- Self-blenderized formulas for oral intake;
- Commercial food thickeners;
- Enteral formula additive for oral intake;
- Electrolyte-containing fluids used for oral intake used to replace fluids and electrolytes;
- Nutritional or cosmetic therapy using high-dose or mega quantities of vitamins, minerals or elements and other nutrition-based therapy. Examples include supplements, electrolytes, and foods of any kind. This includes, but is not limited to: high protein foods, low protein foods, and low carbohydrate foods;
- Formulas for the treatment of mild and moderate food allergies or food intolerance;
- Oral Nutrition for lack of appetite or cognitive conditions (e.g., lack of appetite secondary to stimulant medications

Some services (refer to the Coverage Rationale) may not be covered. Refer to the state or contractual requirements for benefit plan coverage.

Clinical Evidence

Inborn Errors of Metabolism

Jameson and Remmington (2020) conducted a systematic review to assess individuals with phenylketonuria that were started with of a low-phenylalanine diet early in life and assess the possible effects of relaxing or terminating the diet on neuropsychological performance and intelligence, and a number of other outcomes. The review included randomized controlled trials (RCTs), both published and unpublished using Cochrane Central Register of Controlled Trials (CENTRAL), Group's Inborn Errors of Metabolism Trials Register, Medline, Society for the Study of Inborn Errors of Metabolism, and SHS Inborn Errors Review Series. Four studies with a total of 251 participated were identified. The authors indicate that due to the lack of good quality RCTs, no firm conclusions could be drawn about the effectiveness of initiating specific dietary interventions in PKU. However, based on results of non-randomized studies have concluded that a low-phenylalanine diet is effective in reducing blood phenylalanine levels and improving intelligence quotient and neuropsychological outcomes. Current recommendations to commence a low-phenylalanine diet at diagnosis should continue to be observed to address concerns about learning disability and neurological damage in untreated PKU. In reviewing RCTs of diet interruption in older individuals, the authors found that intelligence quotient was significantly higher in participants who continued the diet than in those who stopped the diet after 12 months. The authors also concluded that there is a lack of evidence about the precise level of phenylalanine restriction or when, if ever, the restricted diet could be relaxed and suggest a large, well-designed, adequately-powered RCT is necessary to provide further recommendations.

Ney et al (2016) conducted a randomized, controlled, crossover trial to investigate the safety and efficacy of a low-phenylalanine (Phe) diet combined with glycomacropeptide medical foods (GMP-MFs) or traditional amino acid medical foods (AA-MFs) providing the same quantity of protein equivalents in free-living subjects with phenylketonuria (PKU). This was a 2-stage study that included 30 early treated PKU individuals (18 females and 12 males) ranging in age from 15-49 years. The inclusion criteria for subject participation include the following: 1) individuals with PKU aged ≥ 12 y treated shortly after birth with a low-Phe diet; 2) diagnosis with classical or variant PKU based on plasma Phe concentration of > 600 μmol/L; 3) current prescribed diet

includes > 50% of daily protein needs from AA-MFs; and 4) ability to consume both AA-MFs and GMP-MFs. Potential subjects consuming GMP-MFs before the study were eligible to participate if they returned to AA-MFs for 3 weeks before the first study visit to allow for a washout of any effects from consuming GMP-MFs before the study; one subject elected to washout to enroll in the study. Individuals taking sapropterin dihydrochloride, a synthetic form of the tetrahydrobiopterin cofactor for PAH (KUVAN; BioMarin Pharmaceutical Inc.), were eligible to participate if their Phe tolerance was stable and they remained on the same dose of KUVAN throughout the study. Optimal control of plasma Phe concentrations was not required for participation in the study. Exclusion criteria were pregnancy or other concerns deemed to interfere with participation in the study protocol. Twenty individuals had classical PKU and 10 had a variant PKU. The participants consumed, in random order for 3 weeks each, their usual low-Phe diet combined with AA-MFs or GMP-MFs. Equal randomization of the diet treatment order was achieved by using a computer-generated scheme. The treatments were separated by a 3-week washout with AA-MFs. Fasting plasma amino acid profiles, blood Phe concentrations, food records, and neuropsychological tests were obtained. The trial findings included that the frequency of medical food intake was higher with GMP-MFs than with AA-MFs. Study participants rated GMP-MFs more acceptable than AA-MFs and noted improved gastrointestinal symptoms and less hunger with GMP-MFs. Analysis of covariance (ANCOVA) indicated no significant mean ±SE increase in plasma Phe (62 ±40 μmol/L, p = 0.136), despite a significant increase in Phe intake from GMP-MFs (88 ±6 mg Phe/d, p = 0.026). AA-MFs decreased plasma Phe (−85 ±40 μmol/L, p = 0.044) with stable Phe intake. Blood concentrations of Phe across time were not significantly different (AA-MFs = 444 ±34 μmol/L, GMP-MFs = 497 ±34 μmol/L), suggesting similar Phe control. Results of the Behavior Rating Inventory of Executive Function were not significantly different. The authors concluded that GMP-MFs provide a safe and acceptable option for the nutritional management of PKU. The greater acceptability and fewer side effects noted with GMP-MFs than with AA-MFs may enhance dietary adherence for individuals with PKU. However, some limitations to the study included relatively short dietary treatment period of 3 week, evidence of subject bias toward a preference for AA-MFs, and inclusion of 15 different brands of AA-MFs to accommodate subject preferences.

MacDonald et al (2006) conducted a randomized, crossover study to determine if a lower dose of protein substitute could achieve the same or better degree of blood phenylalanine control when compared to the dosage recommended by the United Kingdom Medical Research Council (UK MRC) guidelines which recommend children over 2 years should be maintained on a level of 2 g/kg/day. The study included 25 children (14 girls and 11 boys) with well controlled PKU, ages 2-10 years (median 6 years). In a six week randomized, crossover study, two doses of protein substitute (Protocol A: 2 g/kg/day of protein equivalent; Protocol B: 1.2 g/kg/day protein equivalent) were compared. Each dose of protein substitute was taken for 14 days, with a 14 day washout period in between. Twice daily finger prick blood samples (fasting pre-breakfast and evening, at standard times) for plasma phenylalanine were taken on day 8-14 of each trial period to determine any day to day variability in protein substitute dosages. The results of the study revealed that higher dosage of protein substitute was associated with lower blood phenylalanine concentrations in PKU. When compared with control values, median plasma phenylalanine on the low dose of protein substitute increased at pre-breakfast by 301 μmol/l (95% CI 215 to 386) (p < 0.001) and in the evening by 337 μmol/l (95% CI 248 to 431) (p < 0.001) (fig 11).). On the high dose of protein substitute, when compared to control values, the median plasma phenylalanine concentrations remained unchanged (they decreased at pre-breakfast by 4.5 μmol/l (95% CI −34 to 23) and in the evening by 6 μmol/l (95% CI −46 to 31). There was wide variability in changes in blood phenylalanine concentrations between individual subjects. It was not correlated with age, phenylalanine tolerance, or total energy intake. The authors concluded that a high dose of protein substitute appeared to lower blood phenylalanine concentrations in PKU. However, it did have a variable and individual impact on overall phenylalanine control. Furthermore, the authors recommended additional controlled studies maintaining a constant intake of carbohydrates and fat are necessary but the results of the study do suggest that dosage of protein substitute may have an important role in overall blood phenylalanine control.

Clinical Practice Guidelines

American College of Medical Genetics and Genomics

The American College of Medical Genetics and Genomics evidence based guidelines on the nutrition management of phenylalanine hydroxylase deficiency make the following recommendations (Singh et al., 2014):

- Provide the same nutrient intakes as those of the general population, except for PHE, TYR, and protein.
- Assess the need for vitamin/mineral supplementation when a medical food without complete vitamins and minerals is used or when there is insufficient adherence with medical food intake.
- Monitor nutrition status by assessing anthropometrics, clinical signs and symptoms, nutrient intake, and laboratory indexes of metabolic control and nutrition adequacy.

Galactosemia Network (GalNet)

GalNet published evidence-based and internationally applicable guidelines for the diagnosis, treatment, and follow-up of classical galactosemia, one of the inborn errors of galactose metabolism. The following recommendation addressed dietary management for infants (Welling et al., 2017):

- Clinicians should immediately commence a galactose-restricted diet (e.g., soy-based, casein hydrolysate or elemental formula) if classical galactosemia is suspected in an infant, without waiting for confirmation of the diagnosis.

Chronic Kidney Disease

In a case series with historical controls, Van Dyck, et al (1998) reported on the growth of infants with chronic kidney failure (CKD) who underwent aggressive nutritional management. Twenty infants diagnosed with CKD in the first weeks of life (congenital renal disease or bilateral renal vein thrombosis) received a diet consisting of between 1.8 and 2.2 g of protein kg body weight and 110% ±130% of the recommended calories. Supplements of essential amino acids were given to account for 20% of the protein intake. The infants also received additional plain water when thirsty and supplements of sodium chloride, sodium bicarbonate, calcium, and vitamin D. Some also received erythropoietin injections. At 12 months of age, their length (z-score = -1.6 compared favorably to that of a group of historical controls (-3.3). Their weight for age (-1.5) and head circumference for age (-1.1) at 12 months were also documented. The findings suggest that infants with CKD fed a modified diet can achieve improved growth, as compared to no nutritional management. The findings are limited by lack of contemporary controls or randomization.

In another case series, Tom, et al (1999) documented the growth of 12 infants and children (ages 4 to 81 months) on hemodialysis. The participants received individualized nutritional management with 90.6% and 155.9% of their recommended energy and protein nutritional intake, respectively. Where necessary, caloric supplements (Ross-Abbott Laboratories, Montreal, Quebec, Canada) included Similac PM 60/40, Nepro, Suplena, or Ensure with added polycose, microlipid, and protein. In addition to oral feeding, five participants received tube feeding and six parenteral nutrition. Over the course of dialysis treatment, the improvement in height SD score was + 0.31 SD/y. The findings are limited by lack of comparison group but suggest that growth of infants and young children can be improved with nutritional management that may require oral supplement of specialized formula, tube feeding, or parenteral nutrition.

Clinical Practice Guidelines

National Kidney Foundation Kidney Disease Outcomes Quality Initiative (KDOQI) Pediatric Renal Nutrition Taskforce (PRNT)

In a 2020 sets of clinical practice recommendations on energy and protein requirements for children with CKD stages 2-5 and on dialysis from the Pediatric Renal Nutrition Taskforce of the National Kidney Foundation Kidney Disease Outcomes Quality Initiative (Shaw 2020), the taskforce members provided, among others, the following recommendations:

- We suggest that the initial prescription for energy intake in children with CKD2–5D should approximate that of healthy children of the same chronological age. Level B; moderate recommendation.
- To promote optimal growth in those with suboptimal weight gain and linear growth, we suggest that energy intake should be adjusted towards the higher end of the suggested dietary intake (SDI).
- We suggest that the target protein intake in children with CKD2–5D is at the upper end of the SDI to promote optimal growth. The protein intake at the lowest end of the range is considered the minimum safe amount and protein intake should not be reduced below this level.
- We suggest that the protein intake in children on dialysis may need to be higher than the SDI for non-dialysis patients to account for dialysate protein losses.
- In children with persistently high blood urea levels, we suggest that protein intake may be adjusted towards the lower end of the SDI, after excluding other causes of high blood urea levels.

In another 2020 sets of clinical practice recommendations on the dietary management of calcium (Ca) and phosphate (P) in children with CKD stages 2-5 and on dialysis from the Pediatric Renal Nutrition Taskforce of the National Kidney Foundation Kidney Disease Outcomes Quality Initiative (McAlister 2020), the taskforce members provided, among others, the following recommendations:

- We suggest that the total Ca intake from diet and medications, including P binders, should be within the SDI, and be no more than twice the SDI, unless in exceptional circumstances.

- In special circumstances, such as for infants with CKD or those with mineral depleted bone, a higher Ca intake may be considered with careful monitoring.
- We suggest that the dietary P intake of children with CKD should be within the SDI for age, without compromising adequate nutrition.
- We suggest that intake of Ca and P is adjusted to maintain serum Ca and P levels within the age-appropriate normal range, without compromising nutrition. Changes in management should be based on trends of serial results rather than a single result, with integration of serum Ca, P, PTH, alkaline phosphatase and 25-vitamin D levels. C (weak)
- We suggest that children with CKD who have hyperphosphatemia or hyperparathyroidism will require further dietary restriction of P, potentially to the lower limit of the SDI, without compromising adequate nutrition. Advice to limit the P contribution from phosphate additives should be given. Use of P binders for further control of serum P and PTH levels is often required, in addition to dietary restriction. C (weak)
- We suggest that children with persistent hypocalcaemia or a high PTH may require a Ca intake above 200% of the SDI for calcium for short periods and under close medical supervision. Calcium can be provided through Ca supplementation, together with vitamin D (usually both native and active forms), as well as other sources of Ca such as a high Ca dialysate. C (weak)
- We suggest that children with persistent hypophosphatemia should have their dietary P intake increased. P supplements may be necessary in some patients, particularly those on intensified dialysis or with renal wasting of P.

American Academy of Pediatrics (AAP) Committee on Nutrition

In the 2020 AAP Committee on Nutrition Pediatric Nutrition textbook (American Academy of Pediatrics, 2019), the authors make the following statements, among others:

- Nutritional renal prescriptions [for children with chronic kidney disease (CKD)] can be complex, and it is often necessary to increase the intake of some nutrients (for example, higher protein-energy needs).
- For young children and infants [with CKD], supplemental enteral nutrition may be required to meet nutritional goals if energy intakes are otherwise inadequate to prevent further growth delays.
- A variety of specialized formulas exists for infants, children, and young adults with renal disease and should be used with the assistance of an experienced renal dietitian.
- In pediatric patients, there is no evidence that restricting protein intake is effective at delaying progression of renal disease or time to dialysis initiation.
- With the progression of CKD to more severe stages, the use of dietary enteral feeding in combination with protein powder supplementation may be required for children who are unable to meet recommended daily goals for age with spontaneous food or enteral/fluid intake, and tube feeding may be necessary to provide full nutrition for growth.
- When serum phosphate concentrations are elevated, restriction to 80% of the [Dietary Reference Intake (DRI)] is suggested.

Crohn's Disease

Levine A et al. (2019) completed a randomized controlled trial comparing exclusive enteral nutrition (EEN) to Crohn's disease (CD) exclusion diet (CDED) which is a whole-food diet coupled with partial enteral nutrition for children with mild to moderate CD. The participants were randomly assigned to group A (n = 40) who received CDED plus 50% calories from Modulen Nestle formula for 6 weeks (stage 1) then followed by CDED with 25% partial enteral nutrition for the next 7 to 12 weeks (state 2). Group B (n = 38) received EEN for 6 weeks followed by a free diet with 25% partial enteral nutrition from weeks 7 to 12. The children in both groups were evaluated at baseline and weeks 3, 6 and 12 with 16S ribosomal RNA gene (V4V5) sequencing performed on stool samples. Four children withdrew from the study due to intolerance within 48 hours. Seventy four patients with a mean age of 14.2 ±2.7 years were included for remission analysis. The combination of CDED and partial enteral nutrition was tolerated in 39 children (97.5%), whereas EEN was tolerated by 28 children (73.6%) (p = .002; odds ratio for tolerance of CDED and partial enteral nutrition, 13.92; 95% confidence interval [CI] 1.68–115.14). At week 6, 30 (75%) of 40 children given CDED plus partial enteral nutrition were in corticosteroid-free remission vs 20 (59%) of 34 children given EEN (p = .38). At week 12, 28 (75.6%) of 37 children given CDED plus partial enteral nutrition were in corticosteroid-free remission compared with 14 (45.1%) of 31 children given EEN and then partial enteral nutrition (p = .01; odds ratio for remission in children given CDED and partial enteral nutrition, 3.77; CI 1.34–10.59). In children given CDED plus partial enteral nutrition, corticosteroid-free remission was associated with sustained reductions in inflammation (based on serum level of C-reactive protein and fecal level of calprotectin) and fecal proteobacteria. The authors concluded that CDED plus partial enteral nutrition was better tolerated than EEN in children with mild to moderate CD and although both diets were effective in inducing remission by week 6, the

combination CDED plus partial enteral nutrition induced sustained remission in a significantly higher proportion of patients than EEN.

Takagi S, et al. (2009) reported secondary outcomes of a randomized controlled trial (RCT) regarding the quality of life (QoL) and medical cost of half elemental diet (ED) (defined as one in which half of the patient's caloric needs are met with an elemental diet while the remaining are met with tolerated whole foods) as maintenance therapy for individuals with Crohn's Disease (CD). The primary outcome measure of this RCT was the occurrence of relapse during a 2-year period and the secondary outcomes were QoL and medical costs. 51 participants with CD in remission were randomly assigned to Group A (n = 26) who received half ED and Group B (n = 25) who received a free diet. No statistically significant differences between groups were detected. The authors concluded that half-ED contributed to keep patients in a clinically stable state, without affecting their QOL, nor leading to additional medical expenses. The study is limited by the small sample size that may have not allowed detection of clinically important group differences.

O'Morain C, et al. (1984) conducted a randomized controlled trial to assess the safety and efficacy of replacing the normal diet by a protein free elemental diet as a way to induce remissions in individuals with acute exacerbations of Crohn's disease (CD. Acute exacerbations are generally treated with prednisolone or potentially more toxic immunosuppressive drugs or surgery. Twenty one patients acutely ill with exacerbations of CD were randomized with either prednisolone 0 75 mg/kg/day or an elemental diet (Vivonex) for four weeks. Participants were assessed at 4 and 12 weeks. The trial findings showed that participants treated with elemental diet had improved as much as and by some criteria more than the steroid treated group. The authors concluded that elemental diet is a safe and effective treatment for acute CD.

Severe Food Allergies

Arias et al. (2014) conducted a systematic review and meta-analysis of 33 studies to assess the efficacy of different diet therapies to treat patients with eosinophilic esophagitis (EoE) in inducing disease remission. A total of 1317 patients (1128 children and 189 adults) were represented in the data. Thirteen studies from this review included 429 EoE patients (411 children and 18 adults) that evaluated the efficacy of exclusive feeding with an amino acid-based elemental diet. Results demonstrated amino acid-based elemental formulas were effective for 90.8% of cases. Seven studies evaluated six-food elimination diet (SFED) in 197 patients (75 children and 122 adults). The combined efficacy documented was 72.1%. The authors concluded that amino acid-based elemental formulas and SFEDs were the most effective dietary intervention by achieving < 15 eosinophils/high-power field.

Clinical Practice Guidelines

Meyer et al. (2018) published an evidence based practical guide on the use of amino-acid formulas (AAF) for treating children with cow's milk protein allergy (CMPA). The following topics were included in the review as possible reasons for using AAFs:

- Symptoms not fully resolved on extensively hydrolyzed formula
- Faltering growth/failure to thrive
- Multiple food eliminations
- Severe complex gastrointestinal food allergies
- Eosinophilic esophagitis
- Food protein-induced enterocolitis syndrome
- Severe eczema
- Symptoms while breastfeeding.

Severe Malabsorption Syndrome

Clinical Practice Guidelines

The Cystic Fibrosis (CF) Foundation The Subcommittee on Growth and Nutrition of the CF Foundation provides the following evidence based guidelines (Stallings et al., 2008):

- For children aged 1 to 12 years with growth deficits, the CF Foundation recommends that intensive treatment with behavioral intervention in conjunction with nutrition counseling be used to promote weight gain. (B recommendation)
- For children with growth deficits and adults with weight deficits, the CF Foundation recommends the use of nutritional supplements (oral and enteral) in addition to usual dietary intake to improve the rate of weight gain. (B recommendation)

- For children aged 13 years and older with growth deficits and for adults with weight deficits, the CF Foundation has insufficient evidence to make a recommendation regarding intensive treatment with behavioral intervention in conjunction with nutrition counseling to promote weight gain.
- For children with growth deficits and adults with weight deficits, the CF Foundation recommends the use of nutritional supplements (oral and enteral) in addition to usual dietary intake to improve the rate of weight gain. (B recommendation)
- For children aged 13 years and older with growth deficits and for adults with weight deficits, the CF Foundation has insufficient evidence to make a recommendation regarding intensive treatment with behavioral intervention in conjunction with nutrition counseling to promote weight gain.
- For children and adults, the CF Foundation has insufficient evidence to amend the existing guidelines regarding PERT dosing and the CFA or growth response, and, therefore, recommends that the current consensus-based guidelines be used for care (7). These include: 500 to 2,500 units lipase per kilogram body weight per meal; or 10,000 units lipase per kilogram body weight per day; or 4,000 units lipase per gram dietary fat per day.

Malnutrition

Botran et al. (2011) completed a prospective randomized controlled trial in critically ill children. All of the children received enteral nutrition exclusively and were randomly assigned to a standard diet or a protein-enriched diet (1.1 g protein/100 mL of feeding formula). The level of protein delivery required to enhance protein accretion is higher in critically ill children than in healthy children. 51 children were originally randomized but only 41 completed the study. The inclusion criteria were age between 1 month and 16 years, admission to the pediatric intensive care unit (PICU), receipt of mechanical ventilation with an estimated duration of > 72 hours, and receipt of enteral nutrition exclusively. The exclusion criteria were parenteral nutrition requirement and perceived or confirmed milk protein allergy or intolerance. 21 patients received standard formula and 20 received a protein-enriched formula. The median patient age was 7 months (IQR, 3 to 13 months), and 75% of the children were under 1 year of age. The mean weight was 7.7 kg (median, 6.5 kg; IQR, 4.5 to 9 kg); 75.6% were below the 10th percentile for age and sex and 63.4% were below the 3rd percentile according to national standard references. Both diets were well tolerated; no cases of hyperproteinemia were detected, and no differences in enteral tolerance were noted between the 2 groups. There was a greater positive trend in levels of prealbumin, transferrin, retinol-binding protein, nitrogen balance, and total protein in the protein-enriched diet group. These differences were significant only for retinol-binding protein. The authors concluded that enteral protein supplementation is safe and improves some biochemical parameters of protein metabolism in these patients, and may reduce protein hypercatabolism and improve recovery in critically ill children without producing any adverse effects. The study does have the following limitations: sample size is small; the study was not blinded to the intervention and the composition analysis of the diet used in the study was not performed.

Clinical Practice Guidelines

Academy of Nutrition and Dietetics (Academy) and the American Society for Parenteral and Enteral Nutrition (ASPEN)

The Academy and ASPEN published a consensus statement on characteristics recommended to identify and document adult malnutrition in routine clinical practice. The identification of two or more of the following six characteristics is recommended for diagnosis (White et al., 2012):

- Insufficient energy intake
- Weight loss
- Loss of muscle mass
- Loss of subcutaneous fat
- Localized or generalized fluid accumulation that may sometimes mask weight loss
- Diminished functional status as measured by hand grip strength

The Academy and ASPEN published a consensus statement that provides the following recommendation of standardized set of indicators to be used with assessing and diagnosing pediatric malnutrition in routine clinical practice (Becker et al., 2015):

Primary Indicators When Single Data Point Available			
	Mild Malnutrition	Moderate Malnutrition	Severe Malnutrition
Weight-for-height *z* score	-1 to -1.9 *z* score	-2 to -2.9 *z* score	-3 or greater *z* score
BMI-for-age *z* score	-1 to -1.9 *z* score	-2 to -2.9 *z* score	-3 or greater *z* score

Primary Indicators When Single Data Point Available			
	Mild Malnutrition	Moderate Malnutrition	Severe Malnutrition
Length/height-for-age *z* score	No data	No data	-3 *z* score
Mid-upper arm circumference	Greater than or equal to -1 to -1.9 *z* score	Greater than or equal to -2 to -2.9 *z* score	Greater than or equal to -3 *z* score

Primary Indicators When 2 or More Data Points Available			
	Mild Malnutrition	Moderate Malnutrition	Severe Malnutrition
Weight gain velocity (< 2 years of age)	Less than 75% of the norm for expected weight gain	Less than 50% of the norm for expected weight gain	Less than 25% of the norm for expected weight gain
Weight loss (2 – 20 years of age)	5% usual body weight	7.5% usual body weight	10% usual body weight
Deceleration in weight for length/height *z* score	Decline of 1 z score	Decline of 2 z score	Decline of 3 z score

National Institute for Health and Clinical Excellence (NICE)

A NICE (2017) guideline provides the following recommendations:

- Nutrition support should be considered in people who are malnourished, as defined by any of the following:
  - A BMI of less than 18.5 kg/m^2
  - Unintentional weight loss greater than 10% within the last 3-6 months
  - A BMI of less than 20 kg/m^2 and unintentional weight loss greater than 5% within the last 3-6 months
- Nutrition support should be considered in people at risk of malnutrition who, as defined by any of the following:
  - Have eaten little or nothing for more than 5 days and/or are likely to eat little or nothing for the next 5 days or longer
  - Have a poor absorptive capacity, and/or have high nutrient losses and/or have increased nutritional needs from causes such as catabolism
- Healthcare professionals should consider using oral, enteral or parenteral nutritional support, alone or in combination, for people who are either malnourished or at risk of malnutrition as noted above
- Healthcare professionals should consider oral nutrition support to improve nutritional intake for people who can swallow safely and are malnourished or at risk of malnutrition

Gastroesophageal Reflux with Failure to Thrive

Clinical Practice Guidelines

North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition (NASPGHAN) and the European Society for Pediatric Gastroenterology, Hepatology, and Nutrition (ESPGHAN)

NASPGHAN and ESPGHAN provides recommendations based on comprehensive and systematic review of the medical literature combined with expert opinion. The work group suggests a 2 – 4 week trial of formula with extensively hydrolyzed protein (or amino-acid based formula) in formula fed infants suspected of gastroesophageal reflux (GERD) after optimal non-pharmacological treatment has failed and should be reserved for patients with severe symptoms not responsive to a protein hydrolysate formula (Rosen et al., 2019).

Additional Clinical Practice Guidelines

American Academy of Pediatrics

American Academy of Pediatrics (2006) makes the following recommendations in their policy statement on reimbursement for foods for special dietary use:

- All foods for special dietary use with accepted benefit for treatment of a medical condition should be reimbursed as a medical expense, provided the costs are over and above usual foods. Individual and family financial barriers to obtaining these foods should be removed.

- All states should enact legislation that would require health insurance policy providers to reimburse all foods for special dietary use with accepted medical benefit recommended by a physician to prevent death and serious disability or to foster normal growth and development.
- All expenses for medical equipment and medical supplies necessary for the delivery of foods for special dietary use should be reimbursed.
- Reimbursement for foods for special dietary use should be mandatory for the following:
  - Any medical condition for which specific dietary components or the restriction of specific dietary components is necessary to treat a physical, physiologic, or pathologic condition resulting in inadequate nutrition.
- An inherited metabolic disorder, including but not limited to disorders of carbohydrate metabolism, lipid metabolism, vitamin metabolism, mineral metabolism, or amino acid and nitrogen metabolism.
- A condition resulting in impairment of oral intake that affects normal development and growth.

European Society for Parenteral and Enteral Nutrition (ESPEN)

The European Society for Parenteral and Enteral Nutrition (ESPEN) published a practical guideline of 61 recommendations (Bischoff et al., 2022) based on the previously published scientific guideline on home enteral nutrition (Bischoff et al., 2020).

ESPN practice guidelines on home enteral nutrition (HEN) are based on current evidence and expert opinion and consist of 61 recommendations that address indications, contraindications, relevant access devices and their use, recommended products, implementation, monitoring and criteria for termination (Bischoff et al., 2020).

Most of the recommendations contained in this document address tube feeding, but ESPEN makes the following recommendation relevant to oral formula: prior to discharge from hospital of patients at risk of malnutrition (e.g., patients with neurological disease, head injury, head and neck cancer, gastrointestinal and other malignancies, non-neoplastic gastrointestinal disease including malabsorptive syndromes), either oral nutritional supplements or HEN should be considered.

The American Society for Parenteral and Enteral Nutrition (ASPEN)

The American Society for Parenteral and Enteral Nutrition (ASPEN) published practice recommendations addressing all aspects of enteral nutrition including formulas, access devices, administration and monitoring. Due to the absence of research or limited strength of the evidence, the recommendations combine clinical evidence with a consensus of expert opinion. Most of the recommendations contained in this document address tube feeding.

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

A medical food, as defined in section 5(b)(3) of the Orphan Drug Act (21 U.S.C. 360ee(b)(3)), is “a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation.” Medical foods are not drugs and, therefore, are not subject to any regulatory requirements that specifically apply to drugs. However, manufacturers of medical foods must comply with all applicable FDA requirements for foods. For additional information, refer to the following guidance document: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-frequently-asked-questions-about-medical-foods-third-edition. Accessed April 13, 2023.

References

American Academy of Family Physicians (AAFP). Failure to Thrive: A Practical Guide. GRETCHEN J. HOMAN, MD, University of Kansas School of Medicine, Wichita, Kansas *Am Fam Physician.* 2016 Aug 15;94(4):295-299. Available at: http://www.aafp.org/afp/2016/0815/p295.html. Accessed January 24, 2023.

American Academy of Pediatrics Committee on Nutrition. Chapter 40 Nutrition in Renal Disease. In: Kleinman RE, Greer FR, eds. Pediatric Nutrition. 8th ed. Itasca, IL: American Academy of Pediatrics; 2019:1123-1150.

American Academy of Pediatric Consensus Statement 2002 Reaffirmed 2006. Reimbursement for Foods for Special Dietary Use. Available at: http://pediatrics.aappublications.org/content/111/5/1117. Accessed January 24, 2023.

American Academy of Pediatrics. Pediatrics in Review. https://pedsinreview.aappublications.org/content/39/6/299. Accessed January 24, 2023.

American College of Gastroenterology [Internet]. Bethesda; c2011 [updated 2021]. Available at: https://gi.org/topics/enteral-and-parenteral-nutrition/. Accessed January 24, 2023.

Arias A, Gonzalez-Cervera J, Tenias JM, et al. Efficacy of dietary interventions for inducing histologic remission in patients with eosinophilic esophagitis: a systematic review and meta-analysis. 0Gastroenterology. 2014;146(7):1639-1648.

Becker P, Carney LN, Corkins MR, et al.; Academy of Nutrition and Dietetics; American Society for Parenteral and Enteral Nutrition. Consensus statement of the Academy of Nutrition and Dietetics/American Society for Parenteral and Enteral Nutrition: indicators recommended for the identification and documentation of pediatric malnutrition (undernutrition). Nutr Clin Pract. 2015 Feb;30(1):147-61. Epub 2014 Nov 24.

Bischoff SC, Austin P, Boeykens K, et al. ESPEN guideline on home enteral nutrition. Clin Nutr. 2020 Jan;39(1):5-22.

Hendricks KM. Ready-to-use therapeutic food for prevention of childhood undernutrition. Nutrition Reviews, Volume 68, Issue 7, 1 July 2010, Pages 429–435.

Jameson E, Remmington T. Dietary interventions for phenylketonuria. Cochrane Database Syst Rev. 2020 Jul 16;7(7):CD001304.

Lehmann S, Ferrie S, Carey S. Nutrition management in patients with chronic gastrointestinal motility disorders: A systematic literature review. Nutr Clin Pract. 2020 Apr;35(2):219-230.

Levine A, Wine E, Assa A, et al. Crohn's disease exclusion diet plus Partial Enteral Nutrition Induces Sustained Remission in a Randomized Controlled Trial. Gastroenterology, 2019-08-01, Volume 157, Issue 2, Pages 440-450.e8.

MacDonald A, Chakrapani A, Hendriksz A, et al. Protein substitute dosage in PKU: how much do young patients need? Arch Dis Child. 2006 Jul; 91(7): 588–593. Published online 2006 Mar 17.

Matilsky D, Meleta K, Castleman T, et al. Supplementary feeding with fortified spreads results in higher recovery rates than with a corn/soy blend in moderately wasted children. J Nutr. 2009 Apr; 139(4): 773–778.

McAlister L, Pugh P, Greenbaum L, et al. The dietary management of calcium and phosphate in children with CKD stages 2-5 and on dialysis-clinical practice recommendation from the Pediatric Renal Nutrition Taskforce. Pediatr Nephrol. 2020 Mar;35(3):501-518.

Meyer R, Groetch M, Venter C. When should infants with cow's milk protein allergy use an amino acid formula? A Practical Guide. J Allergy Clin Immunol Pract. 2018 Mar-Apr;6(2):383-399. Epub 2017 Nov 3.

National Human Genome Research Institute website. About inborn errors of metabolism. Available at: https://www.genome.gov/Genetic-Disorders/Inborn-Errors-of-Metabolism. Accessed January 24, 2023.

National Institute for Health and Clinical Excellence (NICE). Clinical Guideline 32 Nutrition support in adults: oral nutrition support, enteral tube feeding and parenteral nutrition. February 2006, updated August 2017. January 24, 2023. Available at http://www.nice.org.uk/guidance/CG32.

Ney D, Stroup B, Clayton M, et al. Glycomacropeptide for nutritional management of phenylketonuria: a randomized, controlled, crossover trial. Am J Clin Nutr. 2016 Aug; 104(2): 334–345. Published online 2016 Jul 13.

O'Morain C, Segal AW, Levi AJ. Elemental diet as primary treatment of acute Crohn's disease: a controlled trial. British Medical Journal Volume 288, 23 June 1984.

Purugganan O. Intellectual Disabilities. Pediatr Rev. 2018 Jun;39(6):299-309.

Rigaud D, Brondel A, Poupard T, et al. A randomized trial on the efficacy of a 2-month tube feeding regimen in anorexia nervosa: A 1-year follow-up study. Clinical Nutrition, 2007-08-01, Volume 26, Issue 4, Pages 421-429.

Rosen R, Vandenplas Y, Singendonk M, et al. Pediatric Gastroesophageal Reflux Clinical Practice Guidelines: Joint Recommendations of the North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition and the European Society for Pediatric Gastroenterology, Hepatology, and Nutrition. J Pediatr Gastroenterol Nutr. 2018 Mar;66(3):516-554.

Shaw V, Polderman N, Renken-Terhaerdt J, et al. Energy and protein requirements for children with CKD stages 2-5 and on dialysis-clinical practice recommendations from the Pediatric Renal Nutrition Taskforce. Pediatr Nephrol. 2020 Mar;35(3):519-531.

Singh RH, Rohr F, Frazier D, Cunningham A, et al. Recommendations for the nutrition management of phenylalanine hydroxylase deficiency. Genet Med. 2014 Feb;16(2):121-31. Epub 2014 Jan 2.

Stallings VA, Stark LJ, Robinson KA, et al. Clinical Practice Guidelines on Growth and Nutrition Subcommittee; Ad Hoc Working Group. Evidence-based practice recommendations for nutrition-related management of children and adults with cystic fibrosis and pancreatic insufficiency: results of a systematic review. J Am Diet Assoc. 2008 May;108(5):832-9.

Takagi S, Utsunomiya S, Kuriyama H. et al. Quality of life of patients and medical cost of "half elemental diet" as maintenance therapy for Crohn's disease: Secondary outcomes of a randomised controlled trial. Digestive and Liver Disease, 2009-06-01, Volume 41, Issue 6, Pages 390-394.

Tom A, McCauley L, Bell L, et al. Growth during maintenance hemodialysis: impact of enhanced nutrition and clearance. J Pediatr. 1999 Apr;134(4):464-71.

U.S. Food and Drug Administration. Chapter 21 – Food Composition, Standards, Labeling and Economics. 2006. Compliance Program Guidance Manual. Available at: https://www.fda.gov/media/71685/download. Accessed January 24, 2023.

Van Dyck M, Sidler S, Proesmans W. Chronic renal failure in infants: effect of strict conservative treatment on growth. Eur J Pediatr. 1998 Sep;157(9):759-62.

Welling L, Bernstein LE, Berry GT, et al. Galactosemia Network (GalNet). International clinical guideline for the management of classical galactosemia: diagnosis, treatment, and follow-up. J Inherit Metab Dis. 2017 Mar;40(2):171-176. Epub 2016 Nov 17.

White JV, Guenter P, Jensen G, Malone A, Schofield M; Academy Malnutrition Work Group; A.S.P.E.N. Malnutrition Task Force; A.S.P.E.N. Board of Directors. Consensus statement: Academy of Nutrition and Dietetics and American Society for Parenteral and Enteral Nutrition: characteristics recommended for the identification and documentation of adult malnutrition (undernutrition). JPEN J Parenter Enteral Nutr. 2012 May;36(3):275-83.

World Health Organization (WHO). Available at: https://www.who.int/health-topics/malnutrition#tab=tab_1. Accessed January 24, 2023.

Yuanli L, Yang J, Shunxia S, et al. Effects of intermittent feeding versus continuous feeding on enteral nutrition tolerance in critically ill patients. Medicine (Baltimore). 2020 Dec 11; 99(50): e23528.

Policy History/Revision Information

Date	Summary of Changes
08/01/2023	**Title Change** ● Previously titled *Oral and Enteral Nutrition (for New Jersey Only)* **Applicable Codes** ● Removed HCPCS code B9002 **Benefit Considerations** ● Added language (relocated from the *Coverage Rationale* section) to indicate the following are generally not covered (for exceptions, refer to federal, state, or contractual requirements for coverage): ○ Specialized formula when the criteria for Oral Nutrition in the *Coverage Rationale* [section of the policy] are not met ○ Standard formula for oral intake ○ Self-blenderized formulas for oral intake ○ Commercial food thickeners ○ Enteral formula additive for oral intake ○ Electrolyte-containing fluids for oral intake used to replace fluids and electrolytes ○ Nutritional or cosmetic therapy using high-dose or mega quantities of vitamins, minerals or elements and other nutrition-based therapy; ▪ Examples include supplements, electrolytes, and foods of any kind ▪ This includes, but is not limited to: high protein foods, low protein foods, and low carbohydrate foods ○ Formulas for the treatment of mild and moderate food allergies or food intolerance

Date	Summary of Changes
	○ Oral Nutrition for lack of appetite or cognitive conditions (e.g., lack of appetite secondary to stimulant medications) **Supporting Information** • Archived previous policy version CS136NJ.K

Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the federal, state or contractual requirements for benefit plan coverage must be referenced as the terms of the federal, state or contractual requirements for benefit plan coverage may differ from the standard benefit plan. In the event of a conflict, the federal, state or contractual requirements for benefit plan coverage govern. Before using this guideline, please check the federal, state or contractual requirements for benefit plan coverage. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

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