Enteral Nutrition (Oral and Tube Feeding) (for Tennessee Only)

Policy Number: CS136TN.P
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➲ Instructions for Use

Table of Contents **Page**

Related Policy

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

Application

This Medical Policy applies to Medicaid and CoverKids in the state of Tennessee.

Coverage Rationale

➲ See Benefit Considerations

Enteral Nutrition by Tube Feeding

State-Specific Criteria

For adults (members 21 years of age and older), for medical necessity clinical coverage criteria, refer to the TennCare Medicaid, Chapter 1200-13.13-.10: Exclusions for enteral nutrition administered by tube feeding (e.g., nasogastric, gastronomy, or jejunostomy tube).

Non–State-Specific Criteria

For individuals under the age of 21, enteral nutrition (standard or Specialized Nutrient Formula) administered by tube feeding (e.g., nasogastric, gastrostomy, or jejunostomy tube) is medically necessary in certain circumstances. For medical necessity clinical coverage criteria for individuals under the age of 21, refer to the InterQual® CP: Durable Medical Equipment, Enteral and Parenteral Nutrition Therapy.

Click here to view the InterQual® criteria.

Note: When used for tube feeding, standard formula may be considered medically necessary because standard foods cannot be administered through a tube.

Oral Nutrition

State-Specific Criteria

For adults (individuals age 21 and older), for medical necessity clinical coverage criteria, refer to the TennCare Medicaid, Chapter 1200-13.13-.10: Exclusions for oral liquid nutrition.

Non–State-Specific Criteria

For individuals under the age of 21, Specialized Nutrient Formula administered orally, as a primary or supplementary source of nutrition, is considered medically necessary when **all** the following criteria are met:

- A physician, advanced practitioner (nurse practitioner, certified nurse specialist, or physician assistant), 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, 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 stages 2 to 5 (or on dialysis) for individuals aged less than 24 months; or
  - Crohn disease; or
  - Severe malabsorption syndrome (such as cystic fibrosis, short bowel syndrome, or intestinal failure); or
  - Malnutrition or individual will become malnourished or have severe disorders such as physical disability, Intellectual Disability, or death if the nutritional therapy is not instituted; or
  - Severe food allergies, including eosinophilic esophagitis, other forms of eosinophilic gastrointestinal diseases, food protein-induced allergic proctocolitis, and food protein-induced enterocolitis syndrome, 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 (in children)

Note: Refer to the Benefit Considerations section for additional information on coverage limitations and exclusions.

Definitions

Refer to the federal, state, or contractual definitions that supersede the definitions below.

Inborn Errors of Metabolism: Inborn Errors of Metabolism are a group of disorders that cause a block in a metabolic pathway, leading to clinically significant consequences. Examples include 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).

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

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. A food is a Medical Food only if:

- It is a specially formulated and processed product (as opposed to a naturally occurring foodstuff used in its natural state) for the partial or exclusive feeding of a patient by means of oral intake or enteral feeding by tube.
- It is intended for the dietary management of a patient who, because of therapeutic or chronic medical needs, has limited or impaired capacity to ingest, digest, absorb, or metabolize ordinary foodstuffs or certain nutrients, or who has other special medically determined nutrient requirements, the dietary management of which cannot be achieved by the modification of the normal diet alone.
- It provides nutritional support specifically modified for the management of the unique nutrient needs that result from the specific disease or condition, as determined by medical evaluation.
- It is intended to be used under medical supervision.
- It is intended only for a patient receiving active and ongoing medical supervision wherein the patient requires medical care on a recurring basis for, among other things, instructions on the use of the Medical Food

[Code of Federal Regulations 21 CFR 101.9(j)(8)].

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 individuals. Medical Foods are foods that are specially formulated and processed (as opposed to a naturally occurring foodstuff used in its natural state) for the individual 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 (U.S. Food and Drug Administration, 2006).

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.

Specialized Nutrient Formula: Formula that is produced to meet unique nutrient needs for specific disease conditions (Greer, 2003).

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
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

HCPCS Code	Description
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

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, use of a liquid supplement, or delivery by use of a tube, also referred to as a tube feeding (American College of Gastroenterology, 2021).

Formula for enteral nutrition can be provided either by tube feeding or orally, as a replacement for or supplement to dietary intake. Enteral formulas may be standard formulas, which are nutritionally complete products containing intact nutrients, or Specialized Nutrient Formulas. Specialized Nutrient Formulas are designed for individuals requiring specific dietary components or altered nutrient composition due to unique metabolic, digestive, or disease-related needs; these may include conditions involving disturbances in carbohydrate, lipid, vitamin, mineral, amino acid, or nitrogen metabolism (COC, 2026). They are used when standard formulas cannot meet an individual's distinctive nutritional requirements. Specialized Nutrient Formulas are classified as Medical Foods, specially formulated products intended to be consumed or administered enterally under the supervision of a physician and designed for the specific dietary management of a disease or condition with distinctive nutritional requirements established by medical evaluation [as defined in 21 U.S.C. § 360ee(b)(3)].

Benefit Considerations

For individuals of any age, the following are generally not covered:

- Specialized formula when the criteria in the Coverage Rationale (*Oral Nutrition* section) above are not met
- Standard formula for oral intake when state specific criteria in the Coverage Rationale (*Oral Nutrition* section) above are not met
- 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 doses or mega quantities of vitamins, minerals, or elements and other nutrition-based therapy (examples include supplements, electrolytes, and foods of any kind; these include but are 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)

Refer to the TennCare Medicaid, Chapter 1200-13-13.

Inborn Errors of Metabolism

Adams et al. (2023) conducted a systematic evidence review to examine the body of literature on phenylalanine hydroxylase (PAH) deficiency and evaluate the effect of treatment on neurological and physiological outcomes. Elevated serum phenylalanine (PHE) levels due to biallelic pathogenic variants in PAH may cause neurodevelopmental disorders or birth defects from maternal phenylketonuria (PKU). New PHE reduction treatments have been approved in the last decade, but uncertainty of the optimal lifespan goal for PHE levels in individuals with PAH deficiency remains. Results included a total of 350 studies. The risk of bias was moderate. Lower PHE was consistently associated with better outcomes. Achieving PHE of ≤ 360 µmol/L before conception substantially lowered the risk of a negative effect to offspring in pregnant individuals (odds ratio, 0.07; 95% CI, 0.04-0.14; p < 0.0001). Adverse events due to pharmacological treatment were common, but medication reduced PHE levels, enabling reductions in dietary restrictions. The reduction of PHE levels to ≤ 360 µmol/L through diet or medication represents effective interventions to treat PAH deficiency.

Jameson and Remmington (2020) conducted a systematic review to assess individuals with PKU who were started with a low-PHE 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 CENTRAL (Cochrane Central Register of Controlled Trials), the Group's Inborn Errors of Metabolism Trials Register, MEDLINE, the Society for the Study of Inborn Errors of Metabolism, and the SHS Inborn Errors Review Series. Four studies, with a total of 251 individuals, were identified. The authors indicated 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, results of nonrandomized studies have shown that a low-PHE diet is effective in reducing blood PHE levels and improving intelligence quotient and neuropsychological outcomes. Current recommendations to commence a low-PHE 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 the intelligence quotient was significantly higher in individuals 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 on the precise level of PHE restriction or when, if ever, the restricted diet could be relaxed and suggested that 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-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 participants with PKU. This was a two-stage study that included 30 early-treated participants with PKU (18 female and 12 male), who ranged in age from 15 to 49 years. The inclusion criteria for participant participation included the following: (1) those with PKU aged ≥ 12 years treated shortly after birth with a low-PHE diet; (2) a diagnosis of classical or variant PKU based on a plasma PHE concentration of > 600 µmol/L; (3) a current prescribed diet that included > 50% of daily protein needs from AA-MFs; and (4) the ability to consume both AA-MFs and GMP-MFs. Potential participants 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 participant elected to wash out to enroll in the study. Participants 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. The exclusion criteria were pregnancy or other concerns deemed to interfere with participation in the study protocol. Overall, 20 participants 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 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 in individuals with PKU. However, some limitations to the study include a relatively short dietary treatment

period of 3 weeks, evidence of participant bias toward a preference for AA-MFs, and inclusion of 15 different brands of AA-MFs to accommodate participant 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 PHE control compared with the dosage recommended by the United Kingdom Medical Research Council guidelines, which recommend that children over 2 years of age 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 and who were aged 2 to 10 years (median, 6 years). In a 6-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 of 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 prior to breakfast and evening, at standard times) for plasma PHE were taken on days 8 to 14 of each trial period to determine any day-to-day variability in protein substitute dosages. The results of the study revealed that a higher dosage of protein substitute was associated with lower blood PHE concentrations in PKU. Compared with control values, median plasma PHE on the low dose of protein substitute increased prior to breakfast by 301 µmol/l (95% CI, 215-386 µmol/l; $p < 0.001$) and by 337 µmol/l (95% CI, 248-431 µmol/l; $p < 0.001$) in the evening. On the high dose of protein substitute, compared with control values, the median plasma PHE concentrations remained unchanged, and they decreased prior to breakfast by 4.5 µmol/l (95% CI, -34 to 23 µmol/l) and by 6 µmol/l (95% CI, -46 to 31 µmol/l) in the evening. There was wide variability in changes in blood PHE concentrations between individual participants. It was not correlated with age, PHE tolerance, or total energy intake. The authors concluded that a high dose of protein substitute appeared to lower blood PHE concentrations in PKU. However, it did have a variable and individual impact on overall PHE control. Furthermore, the authors recommended that additional controlled studies that maintain a constant intake of carbohydrates and fat are necessary, but the results of the study do suggest that the dosage of protein substitute may have an important role in overall blood PHE control.

Clinical Practice Guidelines

American College of Medical Genetics and Genomics (ACMG)

The ACMG evidence-based guidelines on the nutrition management of PAH deficiency make the following recommendations (Singh et al., 2014):

- Provide the same nutrient intakes as those for the general population, except for PHE, tyrosine (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.

Southeast Regional Genetics Network – HRSA Region 3 (SERN)/Genetic Metabolic Dietitians International (GMDI)

In an effort to standardize care, the *PKU Nutrition Management Guidelines* (2022) were created as part of a larger project undertaken by SERN and the GMDI to develop guidelines for inherited metabolic disorders.

- Meet the patient's recommended PHE intake (for anabolism and maintaining an appropriate blood PHE concentration) by adjusting intact protein intake based on the recommended intake ranges by age.
- Provide a total protein intake (from a combination of intact protein and amino acid–based medical food) approximately 50% higher than the daily recommended intake (DRI) for infants and children from birth to 4 years of age and 20% to 40% higher than the DRI for those over 4 years of age. The amount of medical food prescribed is based on the difference between the total protein recommendation and the intact protein allowance.
- Provide supplemental TYR if blood TYR concentrations are consistently below the normal range.
- With the exception of recommended intake for protein, PHE, and TYR, patients with PKU should meet the same DRI for age- and gender-specific nutrient/micronutrients and energy as healthy patients in the general population.

Note: Detailed intake recommendations can be found at: Nutrition Management Guidelines for PKU | Southeast Regional Genetics Network.

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 addresses 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 who underwent aggressive nutritional management. Overall, 20 infants diagnosed with chronic kidney failure 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 per kg of 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 of -1.6 compared favorably to that in 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 chronic kidney failure who are fed a modified diet can achieve improved growth compared with no nutritional management. The findings are limited by the lack of contemporary controls and randomization.

Clinical Practice Guidelines

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

In a 2020 set of clinical practice recommendations on energy and protein requirements for children with stage 2 to 5 chronic kidney disease (CKD), who are on dialysis, from the PRNT of the KDOQI (Shaw et al., 2020), the task force members provide, among others, the following recommendations:

- We suggest that the initial prescription for energy intake in children with CKD 2 to 5D should approximate that in 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 toward the higher end of the suggested dietary intake (SDI).
- We suggest that the target protein intake in children with CKD 2 to 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 nondialysis patients to account for dialysate protein losses.
- In children with persistently high blood urea levels, we suggest that protein intake may be adjusted toward the lower end of the SDI, after excluding other causes of high blood urea levels.

In another 2020 set of clinical practice recommendations on the dietary management of calcium and phosphate in children with stage 2 to 5 CKD, who are on dialysis, from the PRNT of the KDOQI (McAlister et al., 2020), the task force members provide, among others, the following recommendations:

- We suggest that the total calcium intake from diet and medications, including phosphate 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 calcium intake may be considered with careful monitoring.
- We suggest that the dietary phosphate intake in children with CKD should be within the SDI for age, without compromising adequate nutrition.
- We suggest that intake of calcium and phosphate is adjusted to maintain serum calcium and phosphate 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 calcium, phosphate, parathyroid hormone (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 phosphate, potentially to the lower limit of the SDI, without compromising adequate nutrition. Advice to limit the phosphate contribution from phosphate additives should be given. Use of phosphate binders for further control of serum phosphate and PTH levels is often required, in addition to dietary restriction. C (weak).
- We suggest that children with persistent hypocalcemia or a high PTH may require a calcium intake of above 200% of the SDI for calcium for short periods and under close medical supervision. Calcium can be provided through calcium supplementation, together with vitamin D (usually both native and active forms), as well as other sources of calcium such as a high calcium dialysate. C (weak).
- We suggest that children with persistent hypophosphatemia should have their dietary phosphate intake increased. Phosphate supplements may be necessary in some patients, particularly those on intensified dialysis or with renal wasting of phosphate.

American Academy of Pediatrics (AAP) Committee on Nutrition

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

- Nutritional renal prescriptions (for children with 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 the 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 is suggested.

Crohn Disease

Zhu et al. (2023), in a systematic review, evaluated the Crohn disease exclusion diet (CDED) on remission in individuals with Crohn disease (CD). The authors' aim was to summarize the current evidence on the effectiveness of CDED and provide scientific, effective, and professional dietary support for its use in individuals with CD. A total of 1,120 studies were identified, and seven studies were finally included in the analysis. The study was reported according to the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) statement. The authors concluded that the use of CDED seemed to be effective for the induction and maintenance of remission in children and adults with mild to moderate CD. All studies reported a decrease in disease activity, with improved C-reactive protein and fecal calprotectin levels. However, heterogeneity and limitations existed among the studies included. Further robust studies are needed to validate the present findings. (Levine et al., 2019, below, is included in this study.)

Levine et al. (2019) completed an RCT comparing exclusive enteral nutrition (EEN) with 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), which 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. Overall, 74 participants, 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 = 0.002; odds ratio for tolerance of CDED and partial enteral nutrition, 13.92; 95% CI, 1.68-115.14). At week 6, 30 of 40 children (75%) given CDED plus partial enteral nutrition were in corticosteroid-free remission vs 20 of 34 children (59%) given EEN (p = 0.38). At week 12, 28 of 37 children (75.6%) given CDED plus partial enteral nutrition were in corticosteroid-free remission compared with 14 of 31 children (45.1%) given EEN and then partial enteral nutrition (p = 0.01; 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 of CDED plus partial enteral nutrition induced sustained remission in a significantly higher proportion of participants than EEN.

Takagi et al. (2009) reported the secondary outcomes of an RCT regarding the quality of life (QOL) with a half elemental diet (defined as one in which half of the individual's caloric needs are met with an elemental diet, while the remaining are met with tolerated whole foods) as maintenance therapy in participants with 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. Overall, 51 participants with CD in remission were randomly assigned to group A (n = 26), which received a half elemental diet, and group B (n = 25), which received a free diet. No statistically significant differences between groups were detected. The authors concluded that a half elemental diet contributed to keeping participants in a clinically stable state, without affecting participants' QOL. The study is limited by the small sample size that may have not allowed detection of clinically important group differences.

O'Morain et al. (1984) conducted an RCT to assess the safety and efficacy of replacing the normal diet with a protein-free elemental diet as a way to induce remission in participants with acute exacerbations of CD. Overall, 21 participants who

were acutely ill with exacerbations of CD were randomized to either prednisolone 0.75 mg/kg/day or an elemental diet (Vivonex) for 4 weeks. Participants were assessed at 4 and 12 weeks. The trial findings showed that participants treated with an elemental diet had improved as much as and, by some criteria, more than the steroid-treated group. The authors concluded that an elemental diet is a safe and effective treatment for acute CD.

Severe Food Allergies

Food allergies are immune-mediated diseases that can significantly impact individuals' QOL, sometimes leading to severe morbidity and even mortality. These allergies are characterized by symptoms that can appear shortly after ingesting a relevant food allergen or may be delayed or chronic, which complicates diagnosis. Symptoms can range from mild to severe, with rare cases leading to anaphylaxis, which is a life-threatening reaction. Food allergies involve an immune response to specific foods that can be triggered multiple times. These allergies can be classified based on their pathophysiology into immunoglobulin E (IgE)-mediated, non-IgE-mediated, or mixed IgE disorders. While most food allergies are IgE-mediated, newborns and young children are particularly susceptible to non-IgE-mediated gastrointestinal food allergies. Al-Iede et al. (2023) published a review and focused on the non-IgE-mediated food allergies, apart from cow's milk allergy, which is not well established, with incidence rates between 0.13% and 0.72%. Disorders classified under non-IgE-mediated food allergies primarily affect the gastrointestinal tract and include conditions such as food protein-induced enterocolitis syndrome (FPIES), food protein-induced allergic proctocolitis (FPIAP), food protein-induced allergic enteropathy, and food protein-induced dysmotility disorders such as gastroesophageal reflux disease and constipation. Eosinophilic esophagitis (EoE) is also included in this group, although it is thought to involve both IgE- and cell-mediated immune responses. The most common non-IgE-mediated food allergies are FPIES and FPIAP, typically presenting in infancy and often triggered by cow's milk protein. Individuals with FPIES experience severe vomiting and dehydration, while individuals with FPIAP experience blood in their stool but are otherwise healthy. Diagnosis is usually clinical, based on symptom improvement after removing the offending food, since there are no specific noninvasive tests. Reintroducing the food and documenting symptom recurrence can confirm the diagnosis. Management involves elimination of the trigger food from the infant's diet, supportive treatment for accidental exposures, and nutritional counseling. In mild to moderate cases in which breastfeeding is no longer an option, extensively hydrolyzed formulas for the first 2 weeks are recommended, and if symptoms fail to resolve, an amino acid formula is introduced. In more severe cases such as failure to thrive, an amino acid formula is the formula of choice. When managing complex cases, it is recommended to involve a multidisciplinary team that includes general pediatricians, dietitians, speech pathologists, and allergists/gastroenterologists.

Meyer et al. (2018) published a literature review of multiple practice guidelines on the use of amino acid formulas for treating children with cow's milk protein allergy. This review provides a practical guide that is evidence based for providers to use when suggesting the use of amino acid formulas. The following were included as possible indications for using amino acid formulas:

- Symptoms not fully resolved on extensively hydrolyzed formula
- Faltering growth/failure to thrive
- Multiple food eliminations
- Severe complex gastrointestinal food allergies
- EoE
- FPIES
- Severe eczema
- Symptoms while breastfeeding

Arias et al. (2014) conducted a systematic review and meta-analysis of 33 studies to assess the efficacy of different diet therapies to treat individuals with EoE in inducing disease remission. A total of 1,317 individuals (1,128 children and 189 adults) were represented in the data. Overall, 13 studies from this review included 429 individuals with EoE (411 children and 18 adults) and evaluated the efficacy of exclusive feeding with an amino acid-based elemental diet. The results demonstrated that amino acid-based elemental formulas were effective for 90.8% of cases. Seven studies evaluated a six-food elimination diet in 197 individuals (75 children and 122 adults). The combined efficacy documented was 72.1%. The authors concluded that amino acid-based elemental formulas and six-food elimination diets were the most effective dietary interventions by achieving < 15 eosinophils/high-power field.

Clinical Practice Guidelines

American Gastroenterological Institute (AGA)/Joint Task Force on Allergy-Immunology Practice Parameters (JTF)

Hirano et al. (2020) published an evidence-based guideline from the AGA Institute and the Joint Task Force on Allergy-Immunology Practice Parameters Clinical Guidelines for the Management of Eosinophilic Esophagitis. The dietary recommendations are as follows:

- In patients with EoE, the AGA/JTF suggests using an elemental diet over no treatment (conditional recommendation, moderate-quality evidence).
- In patients with EoE the AGA/JTF suggests using an empiric six-food elimination diet over no treatment (conditional recommendation, low-quality evidence).
- In patients with EoE, the AGA/JTF suggests an allergy testing-based elimination diet over no treatment (conditional recommendation, very low-quality evidence).

European Society for Paediatric Gastroenterology, Hepatology, and Nutrition (ESPGHAN)

Amil-Dias et al. (2023) published a position statement on the diagnosis and management of EoE in children. The dietary recommendations are as follows:

- Empiric elimination diets should be the first-line dietary treatment of EoE in childhood; the choice of eliminated foods should be individualized, based on patients' specific needs.
- Cow's milk, wheat-containing cereals, and eggs should be the first foods to consider for elimination when implementing a step-up empirical elimination diet.
- Against the routine use of targeted elimination diets in the treatment of childhood EoE; amino acid–based formulas are highly effective in children with EoE and induce histological remission in up to 90% of patients, but drawbacks include high cost and poor adherence and palatability that limit their use to a second-choice treatment.
- The use of amino acid formulas as an option in patients with multiple food allergies, failure to thrive, or severe disease who do not respond or are unable to follow highly restricted diets.

Severe Malabsorption Syndrome

Clinical Practice Guidelines

Cystic Fibrosis Foundation

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

- For children aged 1 to 12 years with growth deficits, the Cystic Fibrosis 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 Cystic Fibrosis 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 or older with growth deficits and for adults with weight deficits, the Cystic Fibrosis 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 Cystic Fibrosis 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 or older with growth deficits and for adults with weight deficits, the Cystic Fibrosis 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 Cystic Fibrosis Foundation has insufficient evidence to amend the existing guidelines regarding pancreatic enzyme replacement therapy dosing and the coefficient of fat absorption or growth response and, therefore, recommends that the current consensus-based guidelines be used for care. These include 500 to 2,500 units of lipase per kg of body weight per meal; 10,000 units of lipase per kg of body weight per day; or 4,000 units of lipase per gram of dietary fat per day.

Malnutrition

Botran et al. (2011) completed a prospective RCT in critically ill children. All 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. Overall, 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; receipt of mechanical ventilation, with an estimated duration of > 72 hours; and receipt of enteral nutrition exclusively. The exclusion criteria were a parenteral nutrition requirement and perceived or confirmed milk protein allergy or intolerance. Overall, 21 participants received standard formula, and 20 received a protein-enriched formula. The median participant age was 7 months (IQR, 3-13 months), and 75% of the children were under 1 year of age. The mean weight was 7.7 kg (median, 6.5 kg; IQR, 4.5-9 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 two 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, improved some biochemical parameters of protein metabolism in these participants, and may reduce protein hypercatabolism and improve recovery in critically ill children, without producing any adverse effects. The study has limitations: the sample size was small, the study was not blinded to the intervention, and a composition analysis of the diet used in the study was not performed.

Clinical Practice Guidelines

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

The Academy and ASPEN published a consensus statement on the 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 a 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
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 Two 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 one *z* score	Decline of two *z* scores	Decline of three *z* scores

National Institute for Health and Care 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 body mass index of less than 18.5 kg/m^2

- Unintentional weight loss greater than 10% within the last 3 to 6 months
- A body mass index of less than 20 kg/m^2 and unintentional weight loss greater than 5% within the last 3 to 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, have high nutrient losses, and/or have increased nutritional needs from causes such as catabolism
- Health care professionals should consider using oral, enteral, or parenteral nutritional support, alone or in combination, in people who are either malnourished or at risk of malnutrition, as noted above.
- Health care professionals should consider oral nutrition support to improve nutritional intake in people who can swallow safely and are malnourished or at risk of malnutrition.

Gastroesophageal Reflux With Failure to Thrive (in Children)

Clinical Practice Guidelines

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

The NASPGHAN and ESPGHAN provide recommendations based on a comprehensive and systematic review of the medical literature combined with expert opinion. The work group suggests a 2- to 4-week trial of formula with extensively hydrolyzed protein (or amino acid-based formula) in formula-fed infants suspected of gastroesophageal reflux after optimal nonpharmacological treatment has failed; this should be reserved for patients with severe symptoms that are not responsive to a protein hydrolysate formula (Rosen et al., 2018).

Additional Clinical Practice Guidelines

European Society for Parenteral and Enteral Nutrition (ESPEN)

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., 2022).

ESPEN practice guidelines on home enteral nutrition 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 the 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 home enteral nutrition should be considered.

American Society for Parenteral and Enteral Nutrition (ASPEN)

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 (Bankhead et al., 2009).

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 January 13, 2026)

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Policy History/Revision Information

Date	Summary of Changes
06/01/2026	**Supporting Information** • Updated *Description of Services*, *Clinical Evidence*, and *References* sections to reflect the most current information • Archived previous policy version CS136TN.O

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 policy, check the

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