MN.018.A Medical Nutritional Support

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Thank you for being a valued provider for members in one or more of our health plans: Jefferson Health Plans Medicare Advantage, Jefferson Health Plans Individual and Family Plans, Jefferson Health Plans CHIP, and/or Jefferson Health Plans EverWell (our Medicaid plan).

PRODUCT VARIATIONS

This policy applies to all Jefferson Health Plans lines of business unless noted below.

POLICY STATEMENT

Our Jefferson Health Plans EverWell /Jefferson Health Plans CHIP/and Jefferson Health Plans Individual and Family Plans:

Enteral nutrition is the provision of nutritional requirements through a tube into the stomach or small intestine.

The short-term methods of enteral tube feedings include nasogastric, nasoduodenal and, less frequently, nasojejunal tubes. Long-term enteral feedings are best administered by a percutaneous gastrostomy or jejunostomy tube.

Specific nutritional support is considered to be a medical item and covered only when it is administered enterally (i.e., by feeding tube) for members that have either of the following:

- A dysfunction of indefinite duration or disease of the structures that normally permit food to reach the small bowel, or

- A disease of the small bowel that impairs digestion and absorption of an oral diet

Both conditions require enteral feedings to provide sufficient nutrients to maintain weight and strength commensurate with the member's overall health status.

The patient must have an impairment that is long-term(ordinarily at least three months) or “permanent”.

The member's condition could be either an anatomic abnormality (e.g., obstruction due to head and neck cancer or reconstructive surgery, etc.) or a motility disorder (e.g., severe dysphagia following a stroke, neuromuscular or disease of the central nervous system that interferes with the ability to chew or swallow, etc.).

Enteral nutrition is not considered medically necessary for members with a functioning gastrointestinal tract whose need for enteral nutrition is due to reasons such as anorexia or nausea associated with mood disorder, end-stage disease, etc. Adequate nutrition must not be possible by dietary adjustment and/or oral supplements.

Enteral nutrition may be considered medically necessary for members with partial impairments (e.g., a member with dysphagia who can swallow small amounts of food or a member with Crohn's disease who requires prolonged infusion of enteral nutrients to overcome a problem with absorption). *If enteral nutrition criteria are met, all tube feeding supplies are covered for the individual.*

When a feeding pump is requested, it must be supported by sufficient medical documentation to establish that the pump is medically necessary (eg, gravity feeding or syringe feeding is not satisfactory due to aspiration, diarrhea, dumping syndrome, or a controlled rate of infusion is required -less than 100 ml/hr. etc.).

Allowance is made for the simplest model that meets the medical needs of the patient as established by medical documentation. More than 3 nasogastric tubes or 1 gastrostomy/jejunostomy tube every 3 months is rarely considered medically necessary.

Specific enteral nutritional support that is taken orally (i.e., by mouth) is not covered unless mandated by state law. Regular food is not considered a medical item.

Regular food products include:
Baby food, gluten-free food products, high protein powders and mixes, low carbohydrate diets, normal grocery items, nutritional supplement puddings, weight-loss foods and formula (products to aid weight loss), or other regular

grocery products that can be mixed in blenders and used with an enteral system regardless of whether these regular food products are taken orally or parenterally.

Total Parenteral Nutrition:
Parenteral nutrition is considered medically necessary if adequate nutritional intake is not possible for members who meet *any* of the following criteria:

1. Documentation of a failure of enteral (i.e., oral or tube feeding) nutrition, as defined by *either* of the following:

2. A non-edematous or post-dialysis documented loss of greater than 10 % of body weight over a 3-month period.

3. Total protein less than 6 g/dL or serum albumin less than 3.4 g/dL.

4. A condition in which it is necessary for the gastrointestinal tract to be totally non-functioning for a period of time.

5. Evidence of structural or functional bowel disease that makes oral and tube feedings inappropriate.

6. Hyperemesis gravidarum (only in cases of failed medical management or when used in a step-therapy program).

7. Member is peri-operative (regardless of disease state) and unable to tolerate oral or tube feedings.

Parenteral nutrition may be either “self-mixed” (i.e., the member or family caregiver is taught to prepare the nutrient solution aseptically) or “pre-mixed”. The physician must justify the need for pre-mixed parenteral nutritional solutions.

Parenteral nutrition is considered not medically necessary for members with a functioning gastrointestinal tract whose need for parenteral nutrition is only due to:

1. Physical disorder impairing food intake such as the dyspnea of severe pulmonary or cardiac disease.

2. Psychological disorder impairing food intake such as depression.

3. A side effect of a medication.

4. A swallowing disorder.

5. A temporary defect in gastric emptying such as a metabolic or electrolyte disorder.

6. Renal failure and/or dialysis. Members receiving intra-dialytic parenteral nutrition must meet the criteria for total parenteral nutrition set forth above.

Intradialytic parenteral nutrition (IDPN) is considered medically necessary when BOTH of the following criteria are met:

1. The individual is on chronic hemodialysis.

2. The individual is a candidate for total parenteral nutrition (i.e., nutritional status cannot be adequately maintained on oral or enteral feedings).

Specialized intradialytic parenteral nutrition solutions are considered clinically equivalent, but not clinically superior, to standard formulations of intradialytic parenteral nutrition.
There are various intradialytic parenteral nutrition preparations, where one may be significantly more expensive than the other but not proven to be clinically superior.

Special medical foods **that are mandated by state law are covered.**
Special medical foods for the treatment of inborn errors of metabolism for members with an established diagnosis (e.g., phenylketonuria (PKU) homocystinuria, branch chain ketonuria, galactosemia, etc.) and documented failure of conservative dietary interventions are covered as mandated by Act 191. The special oral formulas are designed to restrict intake of one or more amino acids.

Pasteurized Human Donor Breast Milk Inpatient Infant:
Pasteurized donor human milk (PDHM) is covered for an infant who is younger than twelve months of age based on the infant's corrected gestational age, who is receiving care in an inpatient setting and has any of the following health conditions:

1. An infant birth weight equal to or less than one thousand eight hundred grams.

2. An infant gestational age equal to or less than thirty-four weeks.

3. A high risk for development of necrotizing enterocolitis, bronchopulmonary dysplasia, sepsis, or retinopathy of prematurity.

4. A congenital or acquired gastrointestinal condition or other serious medical condition associated with long-term feeding or malabsorption complications.

5. Congenital heart disease requiring surgery in the first year of life.

6. Has had or will have an organ or bone marrow transplant or has an immunologic deficiency.

7. Renal disease requiring dialysis in the first year of life.

8. Infant hypoglycemia or jaundice.

9. Neonatal abstinence syndrome.

10. Any other health condition for which the use of PDHM is medically necessary as determined by the Department.

Outpatient Infant – *Requires Prior Authorization*

PDHM is covered for an infant who is younger than twelve months of age based on the infant's corrected gestational age, who is receiving care in an outpatient setting and has any of the following health conditions:

1. A congenital or acquired gastrointestinal condition or other serious medical condition associated with long-term feeding or malabsorption complications.

2. Congenital heart disease requiring surgery in the first year of life.

3. Has had or will have an organ or bone marrow transplant or has an immunologic deficiency.

4. A history of sepsis.

5. Renal disease requiring dialysis in the first year of life.

6. Any other health condition for which the use of PDHM is medically necessary as determined by the Department. **Donor human milk** may be used for high-risk infants when the mother's milk is not available, or the mother cannot provide milk. Priority will be given to providing donor human milk to infants <1500g birth weight. The donor must be identified and screened using methods such as those currently used by the Human Milk Banking

Association of North America (HMBANA) milk banks or other established commercial milk banks. The donor milk is pasteurized according to accepted standards.

Limitation: The standard formula for newborns or infants is considered to be **not** medically necessary and is therefore **not covered.** The standard infant formula for normal infants or for infants with medical illness or disability is considered to be non-medical in nature as nutrition is a normal need for all infants.

Oral Nutritional Products: For members under age 21 years:
Each case will be determined based on medical necessity. Physician documentation must provide all of the following:

1. A description of the member's clinical condition that clearly outlines why the nutritional needs cannot be met through dietary modification to increase caloric intake (snacks, higher calorie/protein foods).

2. A description of the member's current nutritional status (e.g., height, weight, percentiles for pediatric members).

3. **Pediatric Failure to Thrive:** Pediatric (Neonates, Infants and Children< than 18 yrs. of age) weight loss unresponsive to standard age-appropriate interventions for four weeks with clinical signs and symptoms of malnutrition as indicated by the following:

    - Weight and height, and/or BMI below 10th percentile for age; OR
    - Growth decreased at least 2 percentile lines of weight for age on the growth chart.

4. A prescription or order including the product, administration route and rate of intake.

5. An estimated duration of therapy.

6. For oral nutritional supplementation expected to be required long term (months), documentation of a nutritional assessment needs to be provided that includes an assessment of current caloric intake, caloric needs, and why dietary modification cannot meet those needs.

7. Any case that does not meet the above criteria will be given consideration on a case-by-case basis.

For members age 21 years and older:

Commercial oral nutrition products are covered if such products constitute 50% or more of total patient caloric intake and are found to be medically necessary. The following criteria must be met:

1. Member must have a documented medical condition that limits his or her ability to ingest, digest, or absorb regular food; and

2. Reversible causes have been ruled out; and

3. Severe weight loss unresponsive to standard interventions for four weeks with clinical signs and symptoms of nutritional risk from weight loss as indicated by the following:

    - BMI < 18.5 kg/m2, albumin level of < 3.5 or a cholesterol level of 160 or below; or albumin < 4.0 in end stage renal patients; OR

    - Documented unintentional weight loss >10% over the past 3-6 months, OR

    - Physiologic anorexia and/or cachexia due to disease processes such as cancer, chronic kidney disease, sepsis, liver disease etc.

4. Nutritional assessment has been completed to document current caloric intake, caloric needs, and why dietary modification cannot meet those needs.

Enteral Nutrition: Enteral Nutrition (including administration, supplies, and formula) when ordered by a registered dietician, gastroenterologist or bariatrician may be considered medically necessary in members requiring a feeding tube; and:

1. Central nervous system injury or disease that results in partial or total inability to take nutrients orally and with functional gastrointestinal tract of sufficient absorptive capacity; or

2. Disease or injury (permanent or temporary) that requires the use of a feeding tube in members:

    a) Who are malnourished or are at risk of becoming malnourished; and

    b) Who have inadequate or anticipated inadequate oral intake for at least 7 days; and

    c) In whom the tube feeding provides the primary source of nutrition.

3. Human Immunodeficiency Virus (HIV) /acquired immunodeficiency syndrome (AIDS):

A limit of 960 units per month equating to 96,000 calories per month, or 3,000 calories per day, for 32 days, which will meet the daily caloric needs of the vast majority of members will be considered medically necessary. However, if needed, an exception of the limits may be requested. *A one-month supply will be provided each 32 days.*

Amino acid-based Elemental formula may be considered to be medically necessary in members age 21 years and younger when all of the following criteria are met:

1. Medical record documentation of a laboratory or diagnostic test supported diagnosis of one or more of the following:

    a) Amino acid, organic acid, and fatty acid metabolic and malabsorption disorder.
    b) Cystic fibrosis.
    c) Eosinophilic colitis.
    d) Eosinophilic esophagitis (EE).
    e) Eosinophilic gastroenteritis (EG).
    f) Food protein induced enterocolitis syndrome.
    g) IgE mediated allergies to food proteins.
    h) Short gut syndrome.

2. Documentation of at least two failed formula alternatives.

MEDICARE ADVANTAGE

- See CMS Local Coverage Determination (LCD) (L38955) - Enteral Nutrition.
- See CMS Policy Article (A58833) - Enteral Nutrition.

Oral Nutritional Products: Oral nutritional supplementation is not covered under Medicare Part B. Enteral Nutrition (including administration, supplies, and formula) when ordered by a registered dietician, gastroenterologist or bariatrician may be considered medically necessary in members with: Requirement of a feeding tube; and

1. Central nervous system injury or disease that results in partial or total inability to take nutrients orally and with functional gastrointestinal tract of sufficient absorptive capacity; or

2. Disease or injury (permanent or temporary) that requires the use of a feeding tube in insured individuals:

   - Who are malnourished or are at risk of becoming malnourished; and
   - Who have inadequate or anticipated inadequate oral intake for at least 7 days; and
   - In whom the tube feeding provides the primary source of nutrition.

Enteral formulas consisting of semi-synthetic intact protein/protein isolates (B4150 or B4152) are appropriate for the majority of beneficiaries requiring enteral nutrition.

The medical necessity for special enteral formulas (B4149, B4153, B4154, B4155, B4157, B4161, and B4162) must be justified in each case and supported by documentation of medical necessity. If a special enteral nutrition formula is provided and if the medical record does not document why that item is medically necessary, it will be denied as not reasonable and necessary. (Refer to the LCD-related Policy Article (A58833) for policy specific documentation requirements.)

If a pump (B9002) is ordered, there must be documentation in the beneficiary's medical record to justify its use (e.g., gravity feeding is not satisfactory due to reflux and/or aspiration, severe diarrhea, dumping syndrome, administration rate less than 100 ml/hr, blood glucose fluctuations, circulatory overload, gastrostomy/jejunostomy tube used for feeding).

If the medical necessity of the pump is not documented, the pump will be denied as not reasonable and necessary.

More than three nasogastric tubes (B4081, B4082, and B4083), or one gastrostomy/jejunostomy tube (B4087 or B4088) every three months is not reasonable and necessary. In-line digestive enzyme cartridges (B4105) are reasonable and necessary for beneficiaries who:

- Meet the coverage criteria for enteral nutrition; AND
- Have a diagnosis of Exocrine Pancreatic Insufficiency (EPI) More than two in-line digestive enzyme cartridges (B4105) per day will be denied as not reasonable and necessary.

ALL LINES of BUSINESS:

NON-COVERED

- Baby food, and other regular grocery products that can be blenderized and used with the enteral system.
- Enteral nutrition for temporary impairments.
- Enteral products for the diagnosis of "failure to thrive."
- Enteral products for the purpose of augmenting normal dietary sources of nutrition.
- Grocery items and food additives.
- Orally administered enteral nutrition products, related supplies, and equipment.

NOT SEPERATELY REIMBURSED:

Enteral formula additives are Digestive enzyme cartridges (e.g. Relizorb) used in conjunction with enteral nutrition therapy not meeting criteria listed in specific policy (MN.024.A Relizorb® (immobilized lipase) Cartridge®) is considered to be of unproven benefit and therefore not medically necessary and **NOT COVERED**.

The Cystic Fibrosis Foundation does not recommend for or against a specific method of providing pancreatic enzyme therapy during enteral tube feedings in individuals with CF. The North American Society of Pediatric Gastroenterology, Hepatology and Nutrition Pancreas Committee concluded that the current literature reveals a lack of data in the area of nutrition in pediatric pancreatology. This limitation has led to most recommendations being expert recommendations rather than evidence based (Not applicable to Medicare lob)

Low protein modified food products are **NOT COVERED** for inherited errors of metabolism because they do not meet the policy definition of medical foods or nutritional formulas.

This information is in accordance with the state mandate. Pennsylvania Mandate does not require coverage for low-protein modified food products such as breads, pasta, pastry shells, and rice pizza shells that can be purchased commercially without a prescription and are used in the dietary management of rare hereditary genetic metabolic disorders such as PKU, branched chain-ketonuria, galactosemia, and homocystinuria.

Initial approval: Up to a 3-month supply may be authorized. Quantity sufficient to meet the member's nutritional need in accordance with confirmed diagnosis and caloric requirement as ordered by the prescribing physician or clinical nutritionist for a one-month (30-day) supply of the product size or as indicated by applicable State laws.

Jefferson Health Plans EverWell: Any requests for services, which do not meet criteria set in the PARP, may be evaluated on a case-by-case basis.

Coverage requires use of FDA-approved enteral nutrition feeding/infusion kits, pumps, supplies, and related nutritional formulas indicated for treatment of the patient's confirmed diagnosed medical condition.

A non-clinical individual or family member who has received specialized training may provide enteral nutrition safely and effectively at home.

Women, Infants and Children (WIC) Program:

Children who are under age 5 may also obtain enteral products from the WIC Program. Coverage is limited to specific approved enteral products designated on the WIC preferred list.

CONTINUATION OF THERAPY:

Member continues to meet indication for initial therapy.

AND

Documentation of regular interval monitoring and nutritional reassessments, including current nutritional status, evidence of response to the prescribed enteral nutrition, and the continued requirement of enteral nutrition to maintain appropriate body weight and health must be submitted with subsequent requests.

CODING

Note: The Current Procedural Terminology (CPT®), Healthcare Common Procedure Coding System (HCPCS), and the 10th revision of the International Statistical Classification of Diseases and Related Health Problems (ICD-10) codes that may be listed in this policy are for reference purposes only. Listing of a code in this policy does not imply that the service is covered and is not a guarantee of payment. Other policies and coverage guidelines may apply. When reporting services, providers/facilities should code to the highest level of specificity using the code that was in effect on the date the service was rendered. This list may not be all inclusive.

CPT® is a registered trademark of the American Medical Association.

CPT Code	Description
N/A	N/A

HCPCS Code	Description
B4081	Nasogastric tubing with stylet
B4082	Nasogastric tubing without stylet
B4083	Stomach tube – Levine type
B4087	Gastrostomy/jejunostomy tube, standard, any material, any type, each
B4088	Gastrostomy/jejunostomy tube, low-profile, any material, any type, each
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)
B4105	In-line cartridge containing digestive enzyme(s) for enteral feeding, each
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

HCPCS Code	Description
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
B9002	Enteral nutrition infusion pump, any type

ICD-10 Codes	Description
N/A	

BENEFIT APPLICATION

Medical policies do not constitute a description of benefits. This medical necessity policy assists in the administration of the member's benefits which may vary by line of business. Applicable benefit documents govern which services/items are eligible for coverage, subject to benefit limits, or excluded completely from coverage. This policy is invoked only when the requested service is an eligible benefit as defined in the Member's applicable benefit contract on the date the service was rendered. Services determined by the Plan to be investigational or experimental, cosmetic, or not medically necessary are excluded from coverage for all lines of business.

DESCRIPTION OF SERVICES

Enteral nutrition refers to any method of feeding that uses the gastrointestinal (GI) tract to deliver nutrition to the body and includes a normal oral diet, the use of liquid supplements, and/or delivery by tube feeding. Enteral tube feeding is the deliverance of nutrition via a prepyloric or post pyloric tube for temporary or permanent use. Enteral tube feeds may be administered by gravity or enteral infusion pump on a continuous or intermittent schedule. Enteral nutrition is indicated in individuals who are unable to meet adequate caloric and metabolic needs to maintain health via dietary adjustments and/or oral supplementation (Ley et al. 2023). Enteral nutrition can be curated to individual needs and come in an array of different formulas. Each formula differs in its macro and micronutrient composition. *There are four major types of formulas (Church et al. 2023):*

1. **Standard/Polymeric formulas** contain whole proteins, complex carbohydrates, and long chain triglycerides (LCTs) which require full digestive function to break down the intact nutrients. Most standard formula contain neither gluten nor lactose in clinically relevant amounts. Normal or near normal digestive and absorptive functions are necessary for the use of polymeric formulas.

2. **Elemental formulas** contain individual amino acids and medium chain triglycerides (MCTs) broken down or pre-digested to their simplest form requiring minimal digestive function for those patients who have compromised digestive systems or nutrient absorption problems.

3. **Semi-elemental formulas** contain amino acids of varying length, simple carbohydrates, and MCTs. These formulas are partially pre-digested or partially hydrolyzed.

4. **Specialized/disease-specific formulas** are designed for a variety of clinical conditions or disease states.

Enteral Nutrition

Nutritional support is essential for Individuals who are unable to meet their daily caloric or fluid requirements orally. Enteral delivery (into the stomach or intestine) is the preferred delivery method as it is most similar to the normal physiologic method of nutrient delivery. Enteral delivery is less expensive than parenteral (intravenous) nutritional support and, additionally, there are fewer complications. Enteral nutrition is provided by inserting a tube into the stomach or small intestine for delivery of the required dietary supplements. The nutritional formula can be delivered by gravity or by pump. Feeding may be either intermittent or continuous throughout the day and/or night. Enteral nutrition may range from supplementing a patient's oral intake to supplying all of the patient's daily nutrition. Special formulas are available to meet different nutritional needs. Enteral nutrition may be provided safely and effectively in the home by a nonprofessional person or family member who has received specialized training. Enteral nutrition is an option when a patient is unable to maintain a caloric intake sufficient to maintain weight and overall health.

According to the U.S. Food and Drug Administration, "the term medical food, as defined in section 5(b) 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 2 nutritional requirements, based on recognized scientific principles, are established by medical evaluation.'" "Medical foods do not have to undergo premarket review or approval by FDA and individual medical food products do not have to be registered with FDA".

The FDA regulates infant formulas developed for Inborn Errors of Metabolism (IEM) and categorizes these formulas as "exempt." An exempt infant formula is an infant formula intended for commercial or charitable distribution that is represented and labeled for use by infants who have IEM or low birth weight, or who otherwise have unusual medical or dietary problems. Infant formulas have special nutritional labeling requirements and must contain certain nutrients within a specified range; however, some deviations from these nutritional labeling requirements and nutrient specifications are permitted for "exempt" infant formulas. The FDA will consider, for example, whether a deviation from the nutritional requirements and regulations is necessary to provide an exempt infant formula that is appropriate for the dietary management of a specific disease, disorder, or medical condition. These formulas must meet the same regulatory requirements as standard infant formulas for the dietary management of specific diseases, disorders, or medical conditions without the offending nutrient(s). While infant formulas for IEM are also considered to be medical foods, they are regulated as infant formulas.

Parenteral Nutrition/Total Parenteral Nutrition (TPN)
Parenteral nutrition involves the delivery of micronutrients and macronutrients through catheters in central or peripheral veins. In most instances, the central

venous route is utilized; for long-term total parenteral nutrition (TPN), a central catheter (e.g., Hickman, Broviac, PIC) is burrowed through a subcutaneous tunnel on the anterior chest.

Intradialytic Parenteral Nutrition (IDPN) is the most costly and least efficient nutritional supplement.It often costs twice as much as dialysis itself and only 70% of the nutrients are actually delivered to the patient because of lost into dialysis.

CLINICAL EVIDENCE

The **National Kidney Foundation Kidney Disease Outcomes Quality Initiative (KDOQI)** and the European Best Practice guidelines recommend the following diet:

- 1.2 g/kg protein per day; at least 50 percent should be of high biologic value.
- 30 to 35 kcal/kg of calories per day

The recommended protein allowance is higher than the recommended daily allowance for healthy adults (which is 0.8 g/kg/day).

Immune-enhancing nutritional supplements: The role for immune-enhancing nutritional supplements, also referred to as immunonutrition (i.e., enteral or parenteral supplementation with arginine, glutamine, nonessential fatty acids, branched chain fatty acids, nucleotides, or RNA), remains unclear. There is insufficient high-quality evidence to suggest any specific supplementation for all surgical patients.

Exclusive Enteral Nutrition (EEN) in the Treatment of Crohn's Disease- Narula et al. (2018), in a systematic review by the Cochrane Collaboration, evaluated the safety and effectiveness of exclusive EN as primary therapy to induce remission in Crohn's Disease (CD) and examined the importance of formula composition on effectiveness. This Cochrane review suggests that EEN is superior to corticosteroids in pediatric CD, but slightly inferior in adult CD for the induction of remission. It is noted that corticosteroids are often preferred over EN as induction therapy for CD. The authors conducted a large meta-analysis of 27 randomized trials (1,011 participants). The systematic review concluded very low-quality evidence suggesting that corticosteroids therapy may be more effective than EN for induction of clinical remission in adults with active CD. Very low-quality evidence also suggests that EN may be more effective than steroids for induction of remission in children with active CD. Furthermore, protein composition-elemental, semi-elemental, or polymeric formulas does not appear to influence the effectiveness of EN for the treatment of active CD, therefore the need for specialty formulas is unclear.

Intradialytic parenteral nutrition (IDPN) — For patients who continue to lose weight or have very low serum albumin (<3.2 g/dL) despite oral supplementation and for patients such as those with severe gastroparesis who may be unable to tolerate oral supplementation, IDPN may be needed. IDPN is convenient because it is delivered during dialysis and is likely to be beneficial in some patients. However, although a number of case reports and studies suggest that IDPN provides substantial benefit, the studies were mostly retrospective or poorly designed. *IDPN is the costliest and least efficient nutritional supplement*.

Nutritional supplements Indications -The following are indications for treatment with dietary supplements:

- An unintentional loss of 5 percent of nonedematous weight within three months or 10 percent of nonedematous weight over six months

or

- An albumin <3.8 g/dL

These thresholds for treatment with supplements are based on clinical judgement and experience. The effect of nutritional supplementation on clinically important outcomes is unclear. There has been only one randomized trial that examined the effects of protein supplementation on mortality in patients on dialysis. However, that study compared intradialytic parenteral nutrition with oral protein supplement and did not include a usual care arm. In both groups, there was increase in body weight and serum albumin, but there were no differences between the two groups regarding the primary endpoint of mortality.

A 2020 Cochrane review including 22 randomized trials that examined oral protein-based nutritional supplements in patients on maintenance dialysis concluded that supplementation likely increased serum albumin, especially in patients on hemodialysis and those with malnutrition, and may have increased serum prealbumin and mid-arm muscle circumference.

Two large, observational studies of oral nutritional supplement suggested better survival associated with nutritional supplement. Protein supplementation was associated with a 29 percent decreased mortality over a mean follow-up of 14 months (hazard ratio [HR] 0.71, 95% CI 0.58-0.86). However, in both studies, residual confounding related to patient, or facility-related factors cannot be excluded. In addition, an obvious effect of supplementation on the serum albumin concentration, muscle mass, or protein anabolism has not been conclusively demonstrated.

For most patients' oral supplements are suggested rather than intravenous supplements. For most patients on hemodialysis, intradialytic parenteral

nutrition (IDPN) and oral supplements are equally effective. In one comparative study, 186 patients on hemodialysis patients with malnutrition were randomly assigned to oral nutritional supplements, with or without one year of IDPN. At two years, there was no difference in mortality, hospitalization rate, and nutritional status between the two groups.

However, for patients who continue to lose weight or have very low serum albumin (<3.2 g/dL) despite oral supplementation for three months, IDPN can be used, providing the patient can consume at least 50 percent of the prescribed caloric intake.

If this degree of oral intake cannot be reached, a nasoenteral feeding tube with nighttime enteral nutrition can be tried or, if oral intake is not tolerated, total *parenteral nutrition* (TPN) is an option.

Oral supplementation — A systematic review that focused on preoperative nutrition in patients undergoing gastrointestinal surgery included three studies comparing preoperative liquid oral supplementation with usual care or dietary advice.

No significant differences were found in the overall incidence of complications, infectious complications, or length of stay. Each of the trials evaluated a different oral supplement.

Oral supplements —Several supplements are formulated specifically for patients with end-stage kidney disease (ESKD) and are low in potassium and dense in nutrients, which provides adequate calories and protein and minimizes the risk of hyperkalemia and fluid overload. However, they are most expensive.

- Patients who have no history of interdialytic hyperkalemia or volume overload (and are able to tolerate the increase in potassium and fluid intake) in general can use supplements such as Ensure or Boost Nutritional Drink because of their low cost.
- Patients who have a history of hyperkalemia or volume overload on dialysis (due, for example, to heart failure), should use specific "kidney failure" supplement, such as Novasource Renal or Nepro.
- Oral essential amino acids are not routinely used, although some evidence suggests that the administration of essential amino acids may be modestly beneficial to patients with significant hypoalbuminemia. Further study is needed prior to any recommendation concerning their use.

Parenteral nutrition — Patients who are unable to tolerate enteral nutrition support will require intravenous fluid and parenteral nutrition at the discretion of the treating team until such time as they can be transitioned to enteral nutrition.

Parenteral nutrition — Most randomized trials of perioperative parenteral nutrition have been designed as "disease modifying," which is to say that all patients with a particular condition were randomly assigned to receive parenteral nutrition or no artificial nutrition. As a result, much of the data is not helpful to guide decisions related to the individual patient who cannot receive nourishment in any manner other than parenterally. Several meta-analyses have evaluated preoperative parenteral nutrition but have reached inconsistent conclusions.

One systematic review found that preoperative parenteral nutrition (13 randomized trials) decreased postoperative complications by 10 percent, while postoperative parenteral nutrition alone (8 randomized trials) resulted in a 10 percent increase in complication rates. These findings were not verified by a subsequent larger meta-analysis that included 41 trials of parenteral nutrition provided before and/or after surgery.

The VA Cooperative study randomly assigned patients to parenteral nutrition for seven days preoperatively and three days postoperatively or to control groups who either received no nutrition or were fed enterally. Overall, patients who received parenteral nutrition had a higher rate of infectious complications (14.1 versus 6.4 percent), but mortality rates were not significantly different (7.3 and 4.9 percent at 30 days). In a post hoc analysis of the subgroup with the most severe malnutrition, approximately 5 percent of the total cohort, those treated with parenteral nutrition had fewer major postoperative complications than controls (20 to 25 percent versus 40 to 50 percent).

Perioperatively, enteral support is recommended over parenteral support because of its relative simplicity, safety, reduced complications, and lower cost.

The surgical outcomes are less favorable in patients with malnutrition. A multicenter cohort study evaluated the effect of preoperative nutrition support in 512 patients undergoing abdominal surgery who were at nutritional risk as defined by the Nutritional Risk Screening Tool 2002 (NRS-2002).

Of the 120 patients with an NRS score ≥5, the complication rate was significantly lower in the preoperative nutrition group compared with the control group (25.6 versus 50.6 percent). The length of hospital stay was significantly shorter in the preoperative nutrition group than in the control group (13.7 versus 17.9±11.3 days). No significant differences were seen for lesser NRS scores.

Postoperative nutrition support — For many postoperative patients, early oral or enteral nutrition (<24 hours) is possible and is associated with beneficial effects.

Enteral nutrition (oral or tube feeds) rather than parenteral nutrition should be instituted whenever possible. For patients with a delayed return of intestinal function, postoperative parenteral nutrition is indicated only if return of bowel function is not anticipated for more than 10 days. Earlier intervention may be appropriate in patients who have severe malnutrition at baseline, or who have a complicated postoperative course.

Early enteral feeding — Early postoperative enteral nutrition support may decrease the incidence of infectious complications but does not impact other outcomes. Early nutrition is a component of most enhanced recovery after surgery (ERAS) protocols.

A Cochrane review and meta-analysis updated in 2019 identified 17 trials that included 1427 patients undergoing lower gastrointestinal surgery. Early enteral nutrition within 24 hours of surgery compared with later commencement may reduce postoperative length of stay; however, findings were inconclusive for all other outcomes (e.g., postoperative complications, mortality, adverse events, and quality of life). A meta-analysis of seven of the trials found a slightly increased risk of vomiting (risk ratio 1.23, 95% CI 0.96-1.58). The higher incidence of vomiting reported in the early feeding group did not appear to be related to oral intake compared with tube feeding.

A Cochrane review of early enteral nutrition in critically ill patients was unable to come to any conclusions on whether early enteral nutrition, compared with delayed enteral nutrition, had any effect on mortality within 30 days, feeding intolerance or gastrointestinal complications, or pneumonia.

National and Specialty Organizations

The American Society for Parenteral and Enteral Nutrition (ASPEN) published a consensus statement in 2022 outlining comprehensive practice guidelines for the indications for enteral nutrition. In congruence with ESPEN's guidelines ASPEN indicated enteral nutrition is a vital component of nutrition around the world and is indicated in those who cannot maintain adequate nutrition via standard oral intake alone. Among the disease states addressed were oncologic in nature, GI diseases, and specific non-GI diseases.

The ESPEN-ESPGHAN-ECFS published Guidelines on Nutrition Care for Infants, Children, and Adults with Cystic Fibrosis which address nutritional management of patients with CF. A summary of recommendations on enteral tube feeding for CF patients include the following:

(a) Recommendation of a progressive approach to intensification of nutrition interventions as needs increase. Preventive nutritional counseling, dietary

modification and/or oral nutrition supplements, and enteral tube feeding (Grade of evidence: low).

(b) Recommendation for clinicians to consider the use of polymeric enteral tube feeding when oral interventions have failed to achieve acceptable rates of growth and nutritional status. (Grade of evidence: high).

(c) Recommendation for the use of parenteral nutrition be reserved for exceptional cases when enteral feeding is not possible. (Grade of evidence: low).

The European Society for Parenteral and Enteral Nutrition (ESPEN) published practice guidelines in 2022 that states there are a multitude of disease processes that necessitate home enteral nutrition including, but not limited to, swallowing disorders due to neurologic disease, obstructions due to malignancies, cachexia due to cancer, chronic obstructive pulmonary disease, heart disease, chronic infections, and malabsorption due to diseases of the liver/pancreas/small intestine. ESPEN's guideline states home enteral nutrition should be offered to malnourished patients or those at nutritional risk who cannot meet their nutrient requirement by normal dietary intake and have a functional GI tract.

The European Society for Parenteral and Enteral Nutrition (ESPEN) guidelines on clinical nutrition in inflammatory bowel disease (IBD) indicates that "there is no 'IBD diet' that can be generally recommended to promote remission in IBD patients with active disease." However, due to serious concerns over corticosteroid use and aiming for optimal growth in children, EN is often first-line therapy for pediatric patients with active Crohn's disease. In adults with Crohn's disease, the guidelines noted that while EN as primary therapy in adults has been effective "the data is not robust" and the "meta-analyses do not support the use of EN as primary treatment for acute exacerbations of CD in adults. Patchy clinical conviction and the data, which appear better than might be expected with placebo, ensure continuing controversy over its role in adults." (Forbes, et al., 2017).

The National Institute for Health and Clinical Excellence (NICE) published guidelines titled Nutrition Support for Adults: Oral Nutrition Support, Enteral Tube Feeding and Parenteral Nutrition.

A summary of the guidelines is below and includes the following recommendations (in relevant part) regarding nutrition support and enteral tube feeding:

(a) Nutrition support should be considered in people who are malnourished, as defined by any of the following:

- BMI of less than 18.5 kg/m2.

- BMI of less than 20 kg/m2 and unintentional weight loss greater than 5% within the last 3–6 months.

- Unintentional weight loss greater than 10% within the last 3–6 months.

(b) Nutrition support should be considered in people at risk of malnutrition as defined by the following:

- Have a poor absorptive capacity, and/or

- 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, and/or

- Have high nutrient losses, and/or

- Have increased nutritional needs from causes such as catabolism.

(c) Healthcare professionals should consider enteral tube feeding in people who are malnourished or at risk of malnutrition and have inadequate or unsafe oral intake, and a functional, accessible gastrointestinal tract. This intervention should be stopped when patient is established on adequate oral intake.

DISCLAIMER

Approval or denial of payment does not constitute medical advice and is neither intended to guide nor influence medical decision making. Policy Bulletins are developed to assist in administering plan benefits and constitute neither offers of coverage nor medical advice. This Policy Bulletin may be updated and therefore is subject to change.

For Jefferson Health Plans EverWell and Jefferson Health Plans CHIP products: Any requests for services that do not meet criteria set in PARP will be evaluated on a case-by-case basis.

POLICY HISTORY

This section provides a high-level summary of changes to the policy since the previous version.

Summary	Version	Version Date
2026 Annual review. References updated. Codes updated.	A	11/20/2024
2025 Annual review. References updated.	A	11/20/2024
This is a new policy.	A	11/20/2024

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