Nutritional Support (Infant Formulas, Enteral Nutrition and Total Parenteral Nutrition)

Policy Number: 066
Section: Treatment
Effective Date: 10/03/2022
Last Review Date: 9/13/2022
Status: Current

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Related Policies:

- None

Policy:

(***INFORMATIONAL NOTE:*** *Also refer to a separate policy on* ***Medical Nutritional Therapy*** *(Inherited Metabolic Disease Mandate), Policy #018 in the Treatment Section.)*

For Medicare Advantage, Medicaid and FIDE-SNP, please refer to the Coverage Sections below for coverage guidance.)

I. ***Infant Formulas and Mandated Benefits:***

A. *Administered Orally:*

Please note that currently, all **infant formulas** and **supplements** do not require prescription by a physician; thus, they are ***not eligible for reimbursement***. This is based on contract exclusion language and is not subject to medical necessity review. **However**, coverage is required under the following mandates:

1. **Inherited Metabolic Disease Mandate** - "Medical foods" and "low protein modified food products" are covered in accordance with the New Jersey State Mandate for coverage of treatment of inherited metabolic disease. (Please refer to a separate policy on Medical Nutritional Therapy for Inherited Metabolic Disease - Policy #018 in the Treatment Section of this database.)

2. **Infant Formula Mandate -** "Specialized non-standard infant formulas" are covered in accordance with the New Jersey State Mandate for coverage of certain infant formulas. The mandate requires that benefits be provided "for expenses incurred in the purchase of specialized non-standard infant formulas, when the covered infant's physician has diagnosed the infant as having multiple food protein intolerance and has determined such formula to be medically necessary, and when the covered infant has not been responsive to trials of standard non-cow milk-based formulas, including soybean and goat milk." Note that the mandate requires trial(s) of **any** standard non-cow milk-based formula or any reasonable combination. [An infant is defined as up to 12 months of age. This definition is consistent with information from the National Center for Health Statistics (NCHS) of the Centers for Disease Control and Prevention (CDC), and the United Nations Population Information Network (POPIN).]

   Informational Note: as of 09/13/2022 there are no facilities in the State of New Jersey that are licensed and certified to supply human breast milk. Therefore, this is not in effect at this time.

3. ***Human Breast Milk - DONATED HUMAN BREAST MILK***

   For fully insured, SHBP and ASO groups which have opted in, an Act concerning coverage for donated human breast milk went in to effect January 1, 2019 which provides for insurance coverage for the following:
   i. Expenses incurred in the provision of pasteurized donated human breast milk (including human milk fortifiers) are covered in accordance with the state mandates for individuals enrolled in a New Jersey product subject to New Jersey's insurance law.

   ii. Coverage of pasteurized donated human breast milk, which may include human milk fortifiers, is based on meeting criteria which include the following:

      a. The covered person is an infant under the age of six months

      b. The milk is obtained from a human milk bank that meets quality guidelines established by the Department of Health

      c. The licensed medical practitioner who is prescribing the milk must meet **one** of the following requirements:

         α. The licensed medical practitioner has issued an order for an infant who is medically or physically unable to receive maternal breast milk or participate in breast feeding or whose mother is medically or physically unable to produce maternal breast milk in sufficient quantities or participate in breast feeding despite optimal lactation support; or

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β. The licensed medical practitioner has issued an order for an infant who meets any of the following conditions:

- a body weight below healthy levels determined by the licensed medical practitioner
- a congenital or acquired condition that places the infant at a high risk for development of necrotizing enterocolitis
- a congenital or acquired condition that may benefit from the use of donor breast milk as determined by the Department of Health

iii. Coverage for donated human breast milk is subject to utilization review, including periodic review, of the continued ***medical necessity***.

NOTE*: If there is no supply of human breast milk that meets the above requirements, the insurer shall not be required to provide coverage of expenses pursuant to this section.*

According to UpToDate's review article on the management of milk allergy, most patients with cow's milk allergy (CMA) do not tolerate milk from sheep and goats. Significant amino acid sequence homology and resulting high rate of clinical cross-reactivity between milk from ruminants (e.g., approximately 90 percent of children with IgE-mediated CMA react to goat's milk) makes milk from sheep and goats inappropriate feeding alternatives for most cow's milk-allergic individuals.

A recommendation from the 2010 Diagnosis and Rationale for Action against Cow's Milk Allergy (DRACMA) summary report from the 2nd Milan Meeting on Adverse Reactions to Bovine Proteins suggests extensively hydrolyzed milk formula rather than soy formula in children with IgE-mediated cow's milk allergy (conditional recommendation/very low-quality evidence) and that soy should not be used in the first 6 months of life because of nutritional risk.

iv. When a specialized non-standard infant formula is being given for continued therapy beyond the infancy period (i.e. more than 12 months of age), its eligibility may be extended when there is clear documentation (i.e., copies of original medical records submitted either hard copy or electronically by the treating physician) that a reasonable treatment plan has been implemented to introduce new food sources to wean the child off the formula. In addition, the progress notes must document the type of food(s) being introduced, the quantity, the frequency, and the child's reaction (when appropriate).

B. Administered via an Enteral Feeding Tube:

Infant formulas are ***eligible for reimbursement*** when the medical necessity criteria for enteral nutrition are met. (Refer to policy statement III below.)

II. **Formulas and Supplements for Other than Infants**:

A. Administered Orally:

Formulas and supplements administered orally for other than infants may be considered ***medically necessary*** for certain medical conditions (e.g., elemental formula for eosinophilic esophagitis). However, since these formulas and supplements do not require prescription by a physician, they are not eligible for reimbursement. This is based on contract exclusion language and is not subject to medical necessity review.

B. Administered via an Enteral Feeding Tube:

Formulas and supplements administered via an enteral feeding tube are ***eligible for reimbursement*** when the medical necessity criteria for enteral nutrition are met. (Refer to policy statement III below)

III. **Enteral Nutrition (EN):**

A. Enteral nutrition is ***medically necessary*** when both of the following numbered criteria are met:

1. An anatomical inability to swallow due to, for example, head and neck cancer or an obstructing tumor or stricture of the esophagus (e.g., due to eosinophilic esophagitis) or stomach;
   OR
   A central nervous system disease leading to sufficient interference with the neuromuscular coordination of chewing and swallowing creating a risk of aspiration;

   AND

2. It is the sole source of nutrition. [This means that the member's total daily caloric requirement to maintain body weight (typically around 2000-2200 calories depending on the individual's size and weight) is exclusively provided by the enteral formula given through the feeding tube.]

   (Refer to policy statement I.B. above for eligibility of infant formulas administered through an enteral feeding tube.

   For eligibility of items and services related to a medically necessary enteral nutrition, refer to policy statement VI below.)

B. Relizorb is considered ***medically necessary*** when both of the following criteria are met:

1. used for enteral feeding for treatment of pancreatic insufficiency due to cystic fibrosis; *AND*
2. there is documented failure of pancreatic enzyme replacement therapy (PERT).

IV. **Total Parenteral Nutrition (TPN):**

A. **Total parenteral nutrition** is ***medically necessary*** when both of the following lettered criteria are met:

1. The member has any of the following diseases or conditions that result in impaired intestinal absorption, including but not limited to:

   i. Crohn's disease;

   ii. obstruction secondary to stricture or neoplasm of the esophagus or stomach;

iii. loss of the swallowing mechanism due to a central nervous system disorder, where the risk of aspiration is great;

iv. short bowel syndrome secondary to massive small bowel resection;

v. malabsorption due to enterocolic, enterovesical, or enterocutaneous fistulas (TPN being temporary until the fistula is repaired);

vi. motility disorder (pseudo-obstruction);

vii. newborn infants with catastrophic gastrointestinal anomalies such as tracheoesophageal fistula, gastroschisis, omphalocele, or massive intestinal atresia;

viii. infants and young children who fail to thrive due to systemic disease or secondarily to intestinal insufficiency associated with short bowel syndrome, malabsorption, or chronic idiopathic diarrhea;

ix. patients with prolonged paralytic ileus following major surgery or multiple injuries;

AND

2. The member is in a stage of wasting with any of the following:

i. weight is significantly less than normal body weight for a patient's height and age in comparison with pre-illness weight;

ii. serum albumin is less than 2.5 gm;

iii. blood urea nitrogen (BUN) is below 10 mg (but this is not a good marker in patients receiving dialysis due to protein catabolism);

iv. phosphorus level is less than 2.5 mg (normal phosphorus is 3–4.5 mg);

v. the patient can receive no more than 30% of his/her caloric needs orally or the patient cannot benefit from tube feedings as a result of a malabsorptive disorder.

(NOTE: BUN and phosphorous levels may not be good markers of wasting in members with chronic kidney disease.)

B. Long-term PN is ***medically necessary*** for members with prolonged gastrointestinal tract failure that prevents the absorption of adequate nutrients to sustain life.

(For eligibility of items and services related to a medically necessary total parenteral nutrition, refer to policy statement VI below.)

V. **Supplemental EN**:

In general, a daily caloric intake of 2000-2200 calories is sufficient to maintain body weight. If 750 calories or less are being administered by EN, they are considered supplemental and are ***not medically necessary***.

VI. Eligible items and services associated with a medically necessary EN* (please refer to exception noted below) or TPN include, but are not limited to, the following:

A. cost of nutrients that require a physician's prescription (enteral formulas and parenteral nutritional solutions); *(Refer to policy statement I.B. above for eligibility of infant formulas administered through an enteral feeding tube.)*

B. cost of rental or purchase of an infusion pump and heparin lock;

C. supplies and equipment necessary for the proper functioning and effective use of a EN or TPN system (e.g., catheters, dressings, IV stand, needles, filters, extension tubing, and concentrated nutrients);

D. home visits by a physician;

E. home visits by a registered nurse (R.N.) or licensed practical nurse (L.P.N.) under the order and supervision of a physician;

F. placement of gastrostomy or jejunostomy feeding tubes and central venous catheters.

*** Exception** An enteral pump (B9000-B9002) and associated supplies are ***medically necessary*** for administration of medication and/or an enteral product (when criteria are not met) if the member is at risk of or experiences:

1. complications associated with syringe or gravity method of administration, and

2. documentation in the member's medical record submitted either hard copy or electronically that supports 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).

VII. Ineligible items and services include, but are not limited to, the following:

A. blenderized baby food and regular shelf food used with an enteral system;

B. substances to increase protein or caloric intake in addition to the member's daily diet;

C. member with a stable nutritional status in whom only short-term parenteral nutrition might be required (i.e., for less than 2 weeks);

D. routine pre- and/or post-operative care;

E. over-the-counter enteral nutritional substances.

Policy Guidelines:

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N/A

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Medicare Coverage:

Per LCD L38955, Enteral Nutrition is covered for a beneficiary who requires feedings via an enteral access device and who has a permanent non-function or disease of the structures that normally permit food to reach the small bowel or disease that impairs digestion and/or absorption of an oral diet when LCD L38955 and Article A58833 criteria are met.

Limited coverage of in-line digestive enzyme cartridges are reasonable and necessary for the management of Medicare beneficiaries with a diagnosis of Exocrine Pancreatic Insufficiency (EPI) to maintain weight and strength commensurate with their overall health status.

For additional information and enteral nutrition *eligibility*, refer to Local Coverage Determination (LCD): Enteral Nutrition (L38955) and Local Coverage Article: Enteral Nutrition - Policy Article (A58833). Available at: https://med.noridianmedicare.com/web/jadme/policies/lcd/active

Per LCD L38953 and Article A58836, Parenteral Nutrition is covered when the treating practitioner documents that enteral nutrition has been considered and ruled out and the beneficiary has a permanent condition that which significantly impairs the absorption or transport of nutrients by the gastrointestinal (GI) system. For additional information and *eligibility* for parenteral nutrition, refer to Local Coverage Determination (LCD): Parenteral Nutrition (L38953) and Local Coverage Article: Parenteral Nutrition (A58836). Available at: https://med.noridianmedicare.com/web/jadme/policies/lcd/active

For criteria for *test of permanence* for enteral and parenteral nutrition, refer to Articles A58833 and A58836.

Local Coverage Article: Standard Documentation Requirements for All Claims Submitted to DME MACs (A55426). Available at: https://med.noridianmedicare.com/web/jadme.

Also, see, National Coverage Determination (NCD) for Medical Nutrition Therapy (180.1). Available to be accessed at CMS National Coverage Determinations (NCDs) Alphabetical Index search page:https://www.cms.gov/medicare-coverage-database/indexes/ncd-alphabetical-index.aspx.

Medicaid Coverage:

The metabolic disease mandate, as codified at N.J. Stat. § 26:2J-4.17, does not apply to Medicaid MCOs. Similarly, the infant formula mandate, codified at N.J. Stat. § 26:2J-4.25, does not apply to Medicaid MCOs.

Please confirm Medicaid benefit.

FIDE-SNP Coverage:

For members enrolled in a Fully Integrated Dual Eligible Special Needs Plan (FIDE-SNP): (1) to the extent the service is covered under the Medicare portion of the member's benefit package, the above Medicare Coverage statement applies; and (2) to the extent the service is not covered under the Medicare portion of the member's benefit package, the above Medicaid Coverage statement applies.

Description:

An **infant formula** is defined by the United States Federal Food, Drug and Cosmetic Act (FFDCA) as "a food which purports to be or is represented for special dietary use solely as a food for infants by reason of its simulation of human milk or its suitability as a complete or partial substitute for human milk". Food and Drug Administration (FDA) regulations define infants as persons not more than 12 months old. Commercial infant formulas are regulated by the FDA. According to information from the Mayo Clinic, infant formula can be a practical and safe alternative to breast milk. Breast milk is the best source of infant nutrition. However, providing breast milk for the entire first year of life may not be feasible for all mothers. Infant formulas offer another option.

There are three (3) main types of infant formulas:

- Cow's milk formulas - most infant formula is made with cow's milk that has been altered to resemble human breast milk. This gives the formula the right balance of nutrients and makes it easier to digest. Although most infants do well on cow's milk formula, some need other types of infant formula including, but not limited to, infants who are allergic to the proteins in cow's milk.
- Soy-based formulas - this may be an option for infants who are intolerant or allergic to cow's milk formula or to lactose, a sugar naturally found in cow's milk. Some infants who are allergic to cow's milk may also be allergic to soy milk.
- Protein hydrolysate formulas - these hypoallergenic formulas are meant for infants who have allergies to cow's and soy-based milk. Protein hydrolysate formulas are easier to digest and less likely to cause allergic reactions than other types of formula.

In addition, specialized infant formulas are available for premature infants and those who have specific medical conditions.

Enteral nutrition (EN) is used for patients with a functioning intestinal tract, but with disorders of the pharynx, esophagus, or stomach that prevent nutrients from reaching the absorbing surfaces in the small intestine. The patient is at risk of severe malnutrition. EN involves administering non-sterile liquids directly into the gastrointestinal tract through nasogastric, gastrostomy, or jejunostomy tubes. An infusion pump may be used to assist the flow of liquids. Feedings may be either intermittent or continuous (infused 24 hours a day).

Total parenteral nutrition (TPN), also known as parenteral hyperalimentation, is used for patients with medical conditions that impair gastrointestinal absorption to a degree incompatible with life. It is also used for variable periods of time to bolster the nutritional status of severely malnourished patients with medical or surgical conditions. TPN involves percutaneous transvenous implantation of a central venous catheter into the vena cava or right atrium. A nutritionally adequate hypertonic solution consisting of glucose (sugar), amino acids (protein), electrolytes (sodium, potassium), vitamins and minerals, and sometimes fats is administered daily. An infusion pump is generally used to assure a steady flow of the solution either on a continuous (24-hour) or intermittent schedule. If intermittent, a heparin lock device and diluted heparin are used to prevent clotting inside the catheter.

Rationale:

N/A

References:

1. New Jersey State Mandate (P.L. 1997, c. 338) approved January 12, 1998, which mandates health benefits coverage for therapeutic treatment of inherited metabolic disease, including coverage for certain foods and food products.
2. New Jersey State Mandate (P.L. 2001, c. 361) approved January 6, 2002, which requires benefits for expenses incurred in the purchase of certain infant formulas.
3. National Center for Health Statistics (NCHS) of the Centers for Disease Control and Prevention.(www.cdc.gov/nchs/) (accessed 04/11/2002)
4. United Nations Population Information Network (POPIN). (www.un.org/popin/) (accessed 05/14/2002)
5. Centers for Medicare & Medicaid (CMS). National Coverage Determinations (NCDs): NCD for Enteral and Parenteral Nutritional Therapy. Manual Section Number: 180.2; Effective Date: 10/8/2019 7/11/1984. [Available at http://www.cms.hhs.gov/mcd/viewncd.asp?ncd_id=180.2&ncd_version=1&basket=ncd%3A180%2E2%3A1%3AEnteral+and+Parenteral+Nutritional+Therapy (last accessed 9/19/2006).]
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16. Anker SD, Laviano A, Filippatos G, et al. ESPEN Guidelines on Parenteral Nutrition: On Cardiology and Pneumology. Clinical Nutrition 28 (2009):455-460.
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Codes:

(The list of codes is not intended to be all-inclusive and is included below for informational purposes only. Inclusion or exclusion of a procedure, diagnosis, drug or device code(s) does not constitute or imply authorization, certification, approval, offer of coverage or guarantee of payment.)

CPT*

HCPCS

B4102

B4103

B4104

B4105

B4149

B4150

B4152

B4153

B4154

B4155

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B5100

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B5200

B9002

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S9340

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Important Note

The purpose of this policy is to provide information applicable to the administration of health benefits that Horizon Blue Cross Blue Shield of New Jersey, Horizon Healthcare of New Jersey, Inc., Horizon Insurance Company and Healthier New Jersey Insurance Company (collectively "Horizon BCBSNJ") insures or administers. If the member's contract benefits differ from the medical policy, the contract prevails. Although a service, treatment, procedure, equipment, device, supply, or drug may be medically necessary, it may be subject to terms, conditions, limitations and/or exclusions under a member's benefit plan. If a service, treatment, procedure, equipment, device, supply, or drug is not covered, and if the member nevertheless proceeds to obtain any of them, the member may be responsible for the cost to the extent permitted under the member's benefit plan and applicable law. For information about their benefits and payment of those benefits, the member should consult their plan document.

This policy does not replace a physician's or other health care professional's independent clinical judgment or duty to exercise special knowledge and skill in the treatment of Horizon BCBSNJ members. Decisions regarding treatment and treatment plans are the responsibility of physicians and other health care professionals. Horizon BCBSNJ is not responsible for, does not provide, and does not hold itself out as a provider of medical care. Physicians and other health care professionals remain responsible for the quality and type of health care services provided to a Horizon BCBSNJ member.

Horizon BCBSNJ medical policies do not constitute medical advice, authorization, certification, approval, explanation of benefits, offer of coverage, a contract or guarantee of payment.

Medical policies can be highly technical and are written for use by the Horizon BCBSNJ professional staff in making coverage determinations and by other health care professionals. A member referring to this policy should discuss it with their treating health care professional, and should refer to their specific benefit plan for the terms, conditions, limitations and exclusions of their coverage.

Horizon Blue Cross Blue Shield of New Jersey is an independent licensee of the Blue Cross Blue Shield Association.