

MedStar Health, Inc. POLICY AND PROCEDURE MANUAL

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SUBJECT: Nutritional Support
INDEX TITLE: Medical Management
ORIGINAL DATE: January 2013

This policy applies to the following lines of business: (Check those that apply.)

COMMERCIAL	<input type="checkbox"/> HMO	<input type="checkbox"/> PPO	<input type="checkbox"/> Fully Insured	<input type="checkbox"/> Individual Product	<input type="checkbox"/> Marketplace (Exchange)	<input checked="" type="checkbox"/> All
GOVERNMENT PROGRAMS	<input type="checkbox"/> MA HMO <input type="checkbox"/> MA PPO <input type="checkbox"/> MA C-SNP <input type="checkbox"/> MA D-SNP <input checked="" type="checkbox"/> MA All					
OTHER	<input checked="" type="checkbox"/> Self-funded/ASO					

I. POLICY

It is the policy of MedStar Health, Inc. to cover nutritional products when it is medically necessary and covered under the member's specific benefit plan.

It is the policy of MedStar Health, Inc. to consider coverage of nutritional products when appropriate and consistent with good medical practice, and after review on an individual basis, for the specific indications detailed in this policy.

The coverage and payment of pumps and supplies is considered independent of nutritional product determinations.

All denials are based on medical necessity and appropriateness as determined by a MedStar Health, Inc. Medical Director (Medical Director).

II. DEFINITIONS

Enteral Nutritional Product -- Any product prescribed to be delivered through a tube into the gastrointestinal tract, regardless of the location of the tube or the method of placement, for the purpose of restoring or maintaining nutrition, weight, and strength commensurate with the member's overall health status.

Food Additives -- Commercially available products such as thickeners, vitamins, minerals, fiber supplements, calorie supplements, protein supplements, and products to aid in lactose digestion.

Grocery Items -- Food items widely available for common consumption, including baby foods and food mixtures that are blended after their purchase.

Oral Nutritional Product--Any product prescribed to be ingested by the oral route for the purpose of restoring or maintaining nutrition, weight, and strength commensurate with the member's overall health status.

Permanent Gastrointestinal Impairment -- A documented disease of the gastrointestinal tract which includes:

- A permanent non-function or disease of the structures that normally permit food to reach the small bowel.
- A permanent disease of the small bowel which impairs digestion and absorption of an oral diet. Permanence does not require a determination that there is no possibility that the member's condition may improve in the future. If the judgment of the treating physician, substantiated in the medical record, is that the condition is of long and indefinite duration (ordinarily at least three months), the test of permanence is considered met.

Semi-Synthetic Protein / Protein Isolate Formulas -- Liquid nutritional products designed to provide complete nutritional needs with a common protein base. Such products (including Ensure, Isocal, Boost, Osmolite, and Sustacal) typically meet the needs of most members requiring nutritional replacement. Considering that these products, or reasonable substitutes, are widely available in the local retail and grocery markets, they are considered shelf nutritional products.

Shelf Nutritional Product -- Any product of nutritional value which is widely available in the local retail and grocery markets.

Special-Needs Nutritional Product -- Any nutritional product not available in the local retail or grocery markets which is specifically designed for the special nutritional needs of a member with intake restrictions based on a medical condition/diagnosis.

III. PURPOSE

The purpose of this policy is to define the criteria for coverage of nutritional products.

IV. SCOPE

This policy applies to various departments as indicated by the Benefit and Reimbursement Committee. These include, but are not limited to Medical Management, Benefit Configuration and Claims departments.

V. PROCEDURE

A. Medical Description

There are many physical conditions that cause the inability to eat enough food to maintain health. Some examples are decreased appetite, difficulties in swallowing, or any type of surgery that interferes with eating. If eating is still possible, oral nutritional products can be used with the purpose of restoring or maintaining adequate nutritional status, weight, or strength for the maintenance of overall health. Many oral nutritional products are widely available through commercial retail; however, there are some products that require the prescription of a doctor.

If a physical illness or injury causes the inability to eat, nutrition must be supplied in a different way. One method is enteral nutrition which is commonly known as tube feeding. Enteral nutrition is a special liquid food mixture containing protein, carbohydrates (sugar), fats, vitamins and minerals which is administered through a tube into the stomach or small bowel. There are two different types of tubes used for this procedure. One type is a tube that is placed through the nose into the stomach or bowel called a nasogastric or nasoenteral feeding tube. The other which is placed directly through the skin into the stomach is called a gastrostomy or jejunostomy tube. Enteral nutrition is delivered through the tube by syringe, gravity, or pumps either at one time or at a continuous designated rate. The amount, duration, and rate depend on the physical condition or illness, tolerance of the patient, and type of enteral formula.

A. Specific Indications

Criteria for nutritional product coverage varies according to any of the following:

- a. Insurance coverage
- b. State and federal mandates addressing nutritional products
- c. Prescription of oral use versus enteral use

Refer to Section G-Variations for indications related to specific MedStar Health products.

Regardless of insurance coverage, the following applies to all products and all conditions that follow:

Nutritional products which are medically necessary for the management of certain inborn errors of metabolism and inherited metabolic disorders are covered as defined in Act 2014 – 158 and Act 1996 - 191. Coverage is independent of whether the product is administered orally or enterally. These conditions include any of the following disorders:

- a. Phenylketonuria
- b. Branch-chain ketonuria
- c. Galactosemia
- d. Homocysteinuria
- e. Allergic reaction or malabsorption syndromes, specifically hemorrhagic colitis



Amino acid-based elemental medical formula (made of 100% free amino acids as the protein source) are covered as defined in Act 2014- 158 when ordered/prescribed by a physician for documented medical necessity to infants or children (under 18 years old) administered orally or enterally for food protein allergies, food protein-induced enterocolitis syndrome, eosinophilic disorders, and short-bowel syndrome.

C. Limitations

1. Food additives, as defined in Section II- Definitions above, are a non-covered service in all cases.
2. Grocery Items, as defined in Section II- Definitions above, are a non-covered service in all cases.
3. The medical necessity for special-needs enteral formulas must be justified and documented.
4. The feeding supply kit must correspond to the method of administration.
5. Not medically necessary and not covered:
 - a. Multiple kit types used on the same date of service.
 - b. More than three nasogastric tubes (NG), or one gastrostomy/jejunostomy tube every three months.

D. Information Required for Review

The following information and documentation should be submitted, in accordance with the requirements listed above and in Section G - Variations, with any request for coverage of a nutritional product to assess medical necessity:

1. An attending physician's order or prescription which includes the product, the administration rate, and the route of administration,
2. An account of the member's current nutritional status, including height and weight, and current percentiles for pediatric members,
3. A complete description of the clinical circumstance which justifies the requested product and the intended route of administration,
4. Documentation of permanent gastrointestinal impairment in cases where this applies as outlined above in Section II- Definitions,
5. Documentation of the presence of an inborn error of metabolism, or an inherited metabolic disorder, when such a justification exists,
6. For amino acid-based elemental medical formula, documentation supporting medical necessity and reason for physician prescription,
7. An explanation of why shelf products will not meet nutritional needs in any request for a special-needs nutritional product,
8. An attestation that the member's nutritional needs cannot be met using dietary modifications, including trials and failure,
9. An estimated duration of therapy.

Note: A Durable Medical Equipment (DME) Information Form (DIF) should be completed, signed and dated by the supplier and kept on file by the supplier and

made available upon request.

E. Review Period

1. A request for a nutritional product will be authorized, at the Medical Director's or Nurse Reviewer's discretion, for duration commensurate with the chronicity and stability of the member's clinical circumstance. No request will be approved for duration of greater than 180 days.
2. A request for renewal of a nutritional product must be submitted by the treating physician prior to expiration of the current authorization.

F. Review Process

1. The Medical Management ancillary service staff reviews the request according to the established criteria. If the case does not meet the established criteria, it is referred to a Medical Director.
2. If referred, the Medical Director determines if the requested service is medically necessary and appropriate.
3. The Medical Management ancillary service staff completes the review process and communicates the review decision according to the Timeliness of UM Decisions policy for the member's benefit plan.

G. Variations

Medicare Criteria for Coverage

Oral Nutritional Products (those prescribed products that are intended for oral consumption) are a non-covered service. An exception might be made in the rare case that a Medicare insured member might meet criteria under Act 158 and 191.

Enteral Nutritional Products are covered in cases where adequate nutrition cannot be delivered by the oral route, and where the indication for enteral feeding is one of permanent gastrointestinal impairment as defined by Center for Medicare and Medicaid Services (CMS) and as outlined in Section II- Definitions. In these cases, coverage is provided for shelf nutritional products as well as special needs products, but not for grocery items such as blended foods.

The following requests for a nutritional product will be denied under Medicare:

- a. Any product prescribed for oral consumption, with the rare exception of members with inborn errors of metabolism (see above).
- b. Any enteral product prescribed for a gastrointestinal condition which is not permanent, as defined in Section II- Definitions.
- c. Any enteral product prescribed in the presence of a functioning and intact gastrointestinal tract, such as to treat anorexia or nausea associated with a mood disorder, an end-stage disease, etc.



- d. Any circumstance where the member's nutritional needs can be met using orally consumed foods, orally ingested formulas, or other types of dietary adjustment.

Commercial and CHIP Criteria for Coverage

Oral Nutritional Products will be approved for coverage in the cases of inborn errors of metabolism and hereditary metabolic disorders as described in Act 158 and 191 and as outlined in Section B - Specific Indications. Nutritional products are covered in this instance regardless of whether intake is by the oral or enteral route.

Oral Nutritional Products are covered when clinical circumstance demonstrates that nutritional needs cannot be met without a special-needs nutritional product as outlined in Section II - Definitions and the special-needs nutritional product requested is not available as a shelf item in local retail or grocery markets. Oral nutritional requests for nutritional needs that can be met using shelf nutritional products (including semi-synthetic protein isolate formulas) as described in Section II - Definitions commonly available in the retail or grocery markets will not be covered.

Enteral Nutritional Products will be covered only when a special-needs formula is demonstrated to be medically necessary which will be assessed on a case by case basis. The circumstance requiring tube administration is not a consideration - rather, the need for a product or formula which is unavailable as a shelf nutritional product must be demonstrated. Enteral nutritional products prescribed to meet nutritional needs that can be met using shelf nutritional products (including semi-synthetic protein isolate formulas) as described in Section II - Definitions commonly available in the retail or grocery markets will not be covered.

The following requests for nutritional product will be denied under the Commercial and CHIP plans:

- Any request for a nutritional product, whether prescribed for oral or enteral administration, when the member's nutritional needs can be met by a product which is commonly available in the local retail and grocery market.

Medicaid Criteria for Coverage

Members age 21 and younger:

- All requests are reviewed for medical necessity on a case by case basis.

Members older than 21 years:

Oral Nutritional Products will be covered in the case of inborn errors of metabolism and hereditary metabolic disorders as described in Act 191 and as outlined Section B - Specific Indications. Nutritional products are covered in this instance regardless of whether intake is by the oral or enteral route.

Oral Nutritional Products will be covered when clinical circumstance demonstrates that nutritional needs cannot be met without a special-needs product as outlined above in Section II- Definitions. This presumes that the special-needs nutritional product is not



available as a shelf item in the local retail and grocery markets. As such, oral nutritional requests for needs that can be met using shelf nutritional products (including semi-synthetic protein isolate formulas) as described above, to the extent that they are commonly available in the retail market, will not be covered.

Enteral Nutritional Products will be covered in all cases where the member's nutritional needs cannot be met by oral ingestion. The medical necessity of enteral feeding must be established, although the strict criteria of "permanent gastrointestinal impairment" need not be met. In circumstances where medical necessity is established and documented, the enteral feeding will be covered in accordance with the Medicaid Program Fee Schedule.

The following requests for nutritional product will be reviewed for medical necessity under the Medicaid plan:

- a. Any request for an oral nutritional product when the member's nutritional needs can be met by dietary adjustment, including the use of grocery products/items and shelf nutritional products.
- b. Any request for an enterally administered nutritional product in the case where the member's nutritional needs can be met entirely by the oral route.
- c. Members over age 21 who are under the Acquired Immune Deficiency Syndrome (AIDS) Waiver or other waivers that allows for nutritional products.

H. Records Retention

Records Retention for documents, regardless of medium, are provided within the MedStar Health, Inc. Policy and Procedure for Records Retention.

Unless otherwise mandated by Federal or State law, or unless required to be maintained for litigation purposes, any communications recorded pursuant to this Policy are maintained for a minimum of ten (10) years from the date of recording.

H. Codes

The following codes for treatments and procedures applicable to this policy are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Applicable HCPCS Coding:

HCPCS Code:	Description:
B4100	Food thickener, administered orally, per ounce
B4102	Enteral formula, for adults, used to replace fluids and electrolytes (e.g. clear liquids), 500ml = 1 unit
B4103	Enteral formula, for pediatrics, used to replace fluids and electrolytes (e.g. clear liquids), 500ml = 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 fat, 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 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 minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit
- B4158 Enteral formula, for pediatrics, 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, 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 fat, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit
- B4162 Enteral formula, for pediatrics, for special metabolic needs for

inherited disease of metabolism, includes proteins, fats, carbohydrates, vitamins minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit

I. References

Medical Literature/Clinical Information:

1. American Society for Parenteral and Enteral Nutrition (ASPEN). What is Enteral Nutrition? Copyright 2013. Available from: <https://www.nutritioncare.org/wcontent.aspx?id=266>
2. NHIC Corp. Bulletin: Specialty Enteral Formulas. Posted: January 13, 2011. <http://www.medicarenhic.com/viewdoc.aspx?id=395>
3. Greer FR, American Academy of Pediatrics Committee on Nutrition. Reimbursement for foods for special dietary use. Pediatrics. 2003 May; 111(5 – Pt 1): 1117-1119. <http://pediatrics.aappublications.org/content/111/5/1117.full.pdf+html>
4. Heyland DK. Nutritional support in the critically ill patient. A critical review of the evidence. Crit Care Clin. 1998 Jul; 14(3):423-440. http://www.mdconsult.com/das/article/body/437667405-2/jorg=journal&source=&sp=10322761&sid=0/N/116369/1.html?issn=0749-0704&issue_id=7534
5. The Veterans Affairs Total Parenteral Nutrition Cooperative Study Group. Perioperative total parenteral nutrition in surgical patients. N Engl J Med. 1991 Aug; 325(8):525-532. <http://www.nejm.org/doi/pdf/10.1056/NEJM199108223250801>

Regulatory/Government Source:

1. Centers for Medicare and Medicaid Services (CMS). Local Coverage Determinations (LCD) No. L5041- Enteral Nutrition. (Contractor-NHIC, Corp.), Effective: 05/01/2013. [http://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=5041&ContrId=137&ver=47&ContrVer=1&CntrctrSelected=137*1&Cntrctr=137&name=NHIC%2c+Corp.+\(16003%2c+DME+MAC\)&s=45&DocType=All&bc=AggAAAIAAAAAAAA%3d%3d&](http://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=5041&ContrId=137&ver=47&ContrVer=1&CntrctrSelected=137*1&Cntrctr=137&name=NHIC%2c+Corp.+(16003%2c+DME+MAC)&s=45&DocType=All&bc=AggAAAIAAAAAAAA%3d%3d&)
2. Centers for Medicare and Medicaid Services (CMS). Local Coverage Determinations (LCD) No. L5063 – Parenteral Nutrition. (Contractor-NHIC, Corp.) Effective: 02/04/2011. <http://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=5063&ContrId=137&ver=34&ContrVer=1&Date=02%2f04%2f2011&DocId=L5063&SearchType=Advanced&bc=KAAAAAqAAAAAAAA%3d%3d&>
3. Centers for Medicare and Medicaid Services, National Coverage Determination (NCD) No. 180.2 - for Enteral and Parenteral Nutritional Therapy. Effective July 11, 1984. <http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=242&ncdver=1&bc=AAAAQAAAAAAAA&>
4. Center for Medicare and Medicaid Services (CMS). Medicare Claims Processing Manual. Chapter 20 - Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS). Rev. 2687, 04-19-13. Section 30.7 – Payment for Parenteral and Enteral Nutrition (PEN) Items and Services. <http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c20.pdf>



Disclaimer:

MedStar Health, Inc medical payment and prior authorization policies do not constitute medical advice and are not intended to govern or otherwise influence the practice of medicine. The policies constitute only the reimbursement and coverage guidelines of MedStar Health, Inc and its affiliated managed care entities. Coverage for services varies for individual members in accordance with the terms and conditions of applicable Certificates of Coverage, Summary Plan Descriptions, or contracts with governing regulatory agencies.

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