Clinical Policy: Enteral Nutrition, Medical Foods, Food Thickeners, and Formula

Reference Number: NH.CP.DME.03
Last Review Date: 1/2021

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
To ensure consistency in the application of medical necessity criteria for members who require enteral nutrition including infant formulas, food thickeners and specialty medical foods that require prior authorization for claims payment.

Policy/Criteria

I. It is the policy of New Hampshire Healthy Families that all requests for prior approval of enteral nutrition services must contain the following *required documentation*, clinical information and is **medically necessary** for the following indications:

- Current height, weight and body mass index
- Growth charts for Pediatric members only
- Nutritional history should list current diet and estimated calories consumed per day
- If foods are suspected of causing allergy alternatives tried should be stated
- There should be a brief description of the clinical problem and why readily available foods will not be able to meet the member's needs. Standard formulas are classified as a regular food.
- If tube fed whether diet is limited to enteral feedings or if regular foods are used either by tube or mouth

Requests not containing the information referenced above may be referred for physician review and denied if there is missing information/information that cannot be confirmed by the requesting or dispensing provider.

1. PROCEDURE (Pediatric – age 20 and under, *see sections A, B,C,and D*):

A. Pediatric-exclusive diagnostic criteria for all enteral nutrition, medical foods, food thickeners, and specialty medical foods (age 20 and under).

1. Verify the request is not currently a formula that can be provided by the state WIC program
2. If for inborn errors of metabolism, e.g. phenylketonuria: APPROVE
3. If for disease conditions associated with a greater caloric need, e.g. Cystic Fibrosis, Cancers under active treatment, AND the request is for a high density beverage: APPROVE

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a. If for the following disease/conditions as listed below: APPROVE
   - Ulcerative colitis
   - Gastrointestinal cancer
   - Abnormal loss of weight
   - Ischemic bowel disease
   - Nausea/vomiting
   - Dysphagia
   - CVA (Cerebrovascular Accident)
   - Short gut syndrome
   - Jaw fracture
   - IUGR (Intrauterine Growth Restriction)

If diagnostic criteria is not met, the Utilization Management Prior Authorization Nurse will review for clinical criteria, as documented in section B.

B. Pediatric clinical criteria for all enteral nutrition, medical foods, and specialty medical foods (age 20 and under).

1. Requests associated with a diagnosis of end stage renal disease, diabetes, and malabsorption syndromes: SECONDARY REVIEW
2. Underweight or Failure to Thrive MAY be approved if:
   a. Body Mass Index is <5th percentile for age or weight for height is <5th percentile for age AND (one of the following)
      i. There is no medical condition such as dwarfism or other syndromes associated with low body mass
      ii. There has been inadequate response to regular foods or formulas
      iii. For diagnosis of underweight or failure to thrive:
         a. The alternatives tried should include readily available high calorie foods such as Carnation Instant Breakfast or other age-appropriate choices.
         b. Estimated caloric needs per day based on age and weight. Estimated caloric gap per day with not met with a standard diet or supplementation.
      iv. If the infant has a diagnosis of Intrauterine Growth Restriction (IUGR) AND weight percentiles lag head circumference and length percentiles, high calorie requests may be approved.
   b. Premature babies need to use formula for higher calories until "catch up" growth is complete. Weight gain ideally is ~ 15 grams per day. However, prematurity is not in of itself a reason for approval for standard formulas such

as Enfamil, Prosobee, Similac or SMA (standard formulas may change over time) MAY be approved if:

i. Babies born <34 weeks gestational age AND with a birthweight below 1800 grams will need supplementation for at least 3 months post conceptual age. Some may need supplemental calories until 9 months of age. If the infant's weight for length is consistently maintained at the 25th percentile high calorie formulas may be discontinued.
ii. Formulas developed specifically for premature infants (not simply high calorie) should be used until the infant reaches 2000 grams.

Cow's Milk Protein Allergy (CMPA), Cow's Milk Intolerance

Information needed - Clinical documentation of the diagnosis of CMPA or symptoms consistent with CMPA, referrals to specialists if made, referral results, test findings, reactions to CMP free diet and when indicated the details of the reaction to the reintroduction of CMP.

Definitions:

AAF – Amino Acid Formulas (Neocate®, AleCare®)
CMP - Cow's-milk protein
CMPA- Cow's-milk protein allergy (or intolerance)
eHPF - Extensively hydrolyzed protein formulas (Alimentum®, Nutramigen®)

Symptoms – fussiness, gassiness, chronic vomiting, constipation, diarrhea, blood in stool, reflux, colic, wheezing, rhinitis, cough, laryngeal edema, respiratory distress, atopic dermatitis, urticaria, anaphylaxis, poor weight gain, refusal to eat, iron deficiency anemia, enterocolitis syndrome, protein-losing enteropathy with hypoalbuminemia, eosinophilic oesopagogastroenteropathy.

Zero to 12 months of age:

Request if for eHPF

1. Member has documentation of CMPA or symptoms.
    i. Can be approved for up to 6 months coverage of eHPF not to extend beyond 14 months of age.
    ii. After the first 6 month approval they may get up to another 6 month approval (not past the age of 14 months) if:
        1. They fail (symptoms recur) a trial of cow's-milk protein formula AND soy-protein based formula.

Request is for AAF

1. Member's symptoms have failed to clear using eHPF formula, AND
2. This is prescribed in consultation with pediatric gastroenterologist

They can be approved for coverage for 6 months (not to exceed past 14 months of age)
OR

3. Consultation with pediatric gastroenterologist is pending.

They can be approved for coverage for up to 3 months while awaiting evaluation (not to extend beyond 14 months of age)

12 months and older

After the age of 12 months there are alternatives to cow's milk that can be used. Refer to Medical Director Review.

C. Pediatric clinical criteria for all food thickeners (age 20 and under).
All requests for food thickeners must be accompanied by a diagnosis of gastro esophageal reflux, dysphagia or esophagitis and can be approved if accompanying one or more of the following:

1. History of Aspiration Pneumonia AND an abnormal swallowing study
2. Weight loss due to significant vomiting AND failure of thickened feedings or positioning to correct reflux
3. Formulas are generally not considered treatment for reflux unless allergy has been proven
4. Formulas with rice solids added are not superior to standard formula with rice cereal
5. If the diagnosis is Food protein-induced enter colitis, food protein-induced enteropathy, allergic eosinophilic gastroenteritis or food allergy the diagnosis must be supported by relevant history, physical findings and laboratory testing. See appendix below. REFER FOR SECONDARY REVIEW

D. Autism for food texture challenges, poor intake, or food aversions (all ages)

When reviewing a request for formula does:

a. The member (all ages) has a diagnosis of Autism, ***and*** the clinical indicate *any* of the following:
   - food texture issues
   - flavor issues

- poor regular food intake
- food aversion

b. ***And*** clinical notes indicate that formula is the main or only source of nutrition.

1. If all of the criteria above is met the nurse may auto-approve the formula for up to one year.
2. This applies to CPT codes B4150 and B4160 formula (Pediasure, Boost products, Ensure) requests only. *It does NOT apply to requests for Carnation Instant Breakfast.*

For any services that do not meet the above criteria, these requests will be REFER FOR SECONDARY REVIEW by the Medical Director for consideration and final determination.

2. PROCEDURE (Adult – age 21 and older, *see sections D, E, F and G*):

D. Adult-exclusive diagnostic criteria for all enteral nutrition, medical foods, food thickeners, and specialty medical foods (age 21 and older).

1. If for disease conditions associated with a greater caloric need, e.g. Cystic Fibrosis, Cancers under active treatment, AND the request is for a high density beverage - APPROVE
2. If for the following disease/conditions as listed below: APPROVE
   - Ulcerative colitis
   - Gastrointestinal cancer
   - Abnormal loss of weight
   - Ischemic bowel disease
   - Nausea/vomiting
   - Alzheimer's disease
   - Dysphagia
   - CVA (Cerebrovascular Accident)
   - Short gut syndrome
   - Jaw fracture

If diagnostic criteria is not met, the Utilization Management Prior Authorization Nurse will review for clinical criteria, as documented in section B.

E. Adult clinical criteria for all enteral nutrition, medical foods, and specialty medical foods (age 21 and older).

BMI < 18.5 kg/m^2

OR

BMI less than 20 kg/m^2 and unintentional weight loss greater than 5% within the last 3-6 months

OR

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

OR

Diagnosis of chronic renal failure or end stage renal disease and recent albumin level (Within 3 months) < 3.5/dl

OR

Inadequate oral intake or expected inadequate oral intake over a period of 7 to 14 days

OR

Disorders that interfere with nutrient absorption and assimilation, including, but not limited to, phenylketonuria (PKU), homocystinuria, and methyl malonic acidemia.

1. Requests associated with a diagnosis of end stage renal disease, diabetes, and malabsorption syndromes: SECONDARY REVIEW
2. Underweight or Failure to Thrive MAY be approved if:
    A. Body Mass Index is <5th percentile for age or weight for height is <5th percentile for age AND (one of the following)
        I. There is no medical condition such as dwarfism or other syndromes associated with low body mass
        II. There has been inadequate response to regular foods or formulas
        III. For diagnosis of underweight or failure to thrive:
            i. The alternatives tried should include readily available high calorie foods such as Carnation Instant Breakfast or other age-appropriate choices (see Pediatric Nutrition Handbook, most recent edition, for excellent information on the nutritional content of many foods).
            ii. Estimated caloric needs per day based on age and weight. Estimated caloric gap per day with not met with a standard diet

F. Adult clinical criteria for all food thickeners (age 21 and older).

All requests for food thickeners must be accompanied by a diagnosis of gastro esophageal reflux, dysphagia or esophagitis and can be approved if accompanying one or more of the following:

1. History of Aspiration Pneumonia AND an abnormal swallowing study

2. Weight loss due to significant vomiting AND failure of thickened feedings or positioning to correct reflux
3. Formulas are generally not considered treatment for reflux unless allergy has been proven

I. If the diagnosis is Food protein-induced enter colitis, food protein-induced enteropathy, allergic eosinophilic gastroenteritis or food allergy the diagnosis must be supported by relevant history, physical findings and laboratory testing. See appendix below. REFER FOR SECONDARY REVIEW.

G. Autism for food texture challenges, poor intake, or food aversions (all ages)

When reviewing a request for formula does:

c. The member (all ages) has a diagnosis of Autism, ***and*** the clinical indicate *any* of the following:
   - food texture issues
   - flavor issues
   - poor regular food intake
   - food aversion

d. ***And*** clinical notes indicate that formula is the main or only source of nutrition.

3. If all of the criteria above is met the nurse may auto-approve the formula for up to one year.
4. This applies to CPT codes B4150 and B4160 formula (Pediasure, Boost products, Ensure) requests only. *It does NOT apply to requests for Carnation Instant Breakfast.*

Approvals for Pediatric and Adult specialty medical food may be entered by the reviewing nurse if criteria are met for up to 3 months from the date of the request, for pediatric members, and up to 6 months for adult members. Medical director approvals should also be for no more than 3 months, for pediatric members, and up to 6 months for adult members. If enteral nutrition requests are approved this includes equipment and supplies.

Renewal requests must include current height and weight and interval feeding history. Interval feeding history is defined as response to use of the previously approved enteral nutrition.

- Has the member maintained weight gain on the approved enteral nutrition?
- If the member had symptoms of colitis or esophagitis have they resolved while taking the enteral nutrition.

Appendix

Diagnostic Criteria for Food protein-induced enterocolitis

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Protracted vomiting (generally 1-3 hours after feeding and diarrhea (often bloody to BOTH milk-based or soy-based formula

Food protein-induced proctocolitis

Blood streaked stools to breast milk, milk AND soy formulas

Food protein-induced enteropathy

Protracted diarrhea, often fatty, to cow's milk, soy and other foods. Celiac disease may be a cause- which should be proven

Allergic eosinophilic esophagitis

Chronic GERD, food refusal, abdominal pain, dysphagia. Most is due to cow's milk intolerance. Often associated with asthma and atopic dermatitis. Requirement: allergy testing and an elimination diet trial

Allergic Eosinophilic gastroenteritis

Generally due to cow's milk allergy. Weight loss and FTT are hallmarks. Requirements: history and allergy testing and a trial of an elimination diet

Anaphylaxis, urticarial and angioedema on food challenge is strongly suggestive of allergy to a food which should be confirmed by allergy testing.

Coding Implications

This clinical policy references Current Procedural Terminology (CPT®). CPT® is a registered trademark of the American Medical Association. All CPT codes and descriptions are copyrighted 2018, American Medical Association. All rights reserved. CPT codes and CPT descriptions are from the current manuals and those included herein are not intended to be all-inclusive and are included for informational purposes only. Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

CPT® Codes	Description
B4034	ENTER FEED SUPKIT SYR BY DAY
B4035	ENTERAL FEED SUPP PUMP PER D
B4036	ENTERAL FEED SUP KIT GRAV BY
B4081	NASOGASTRIC TUBING W/STYLET
B4082	NASOGASTRIC TUBING WO STYLET
B4083	STOMACH TUBE LEVINE TYPE
B4087	GASTRO/JEJUNO TUBE STD
B4088	GASTRO/JEJUNO TUBE, LOW-PRO

CPT® Codes	Description
B4100	FOOD THICKENER ADMINED ORALLY-OUNCE
B4104	ADDITIVE FOR ENTERAL FORMULA
B4105	ENZYME CARTRIDGE ENTERAL
B4149	ENTRAL F BLENDERIZD NAT FOODS W/INTACT NUTRIENTS
B4150	ENTRL FRMLA CATEG I SEMI-SYN PROTEIN 100 CAL=1U
B4152	ENTRL FRMLA CATEG II INTACT PROT ISO 100 CAL=1U
B4153	ENTRL FRMLA CATEG III HYDROLIZE PROT 100 CAL-1U
B4154	ENTRL FRMLA CATEG IV DEFINED FORMULA 100 CAL=1U
B4155	ENTRL FRMLA CATEG V MODULAR COMPONENT 100 CAL=1U
B4157	ENTRAL F NUTRITION CMPL INHERITED DZ METAB
B4158	ENTRAL F PED NUTRITION CMPL W/INTACT NUTRNTS
B4159	ENTRAL F PED NUTRITN CMPL SOY BASD INTCT NUTRNTS
B4160	ENTRAL F PED NUTRITION CMPL CAL DENSE NUTRNTS
B4161	EF PED HYDROLYZED/AMINO ACID
B4162	ENTRAL F PED SPCL METAB NEEDS INHERITED DZ METAB
B4164	PARENTERAL NUTRITION CARBO 50% /LESS HOMEMIX
B4168	PARENTERAL NUTRITION AMINO ACID 3.5% HOMEMIX
B4172	PARENTERAL NUTRITION AMINO ACID 5.5-7% HOMEMIX
B4176	PARENTERAL NUTRITION AMINO ACID 7-8.5% HOMEMIX
B4178	PARENTERAL NUTRITION AMINO ACID 8.5% MIN HOMEMIX
B4180	PARENTERAL NUTRITION CARBO MORE 50% HOMEMIX
B4185	PARENTERAL NUTRITION SOLUTION /10 GRAMS LIPIDS
B4189	PARENTERAL NUTRITION COMPOUND 10-51 GMS PROTEIN
B4193	PARENTERAL NUTRITION COMPOUND 52-73 GMS PROTEIN
B4197	PARENTERAL NUTRITION COMPOUND 74-100 GMS PROTEIN
B4199	PARENTERAL NUTRITION COMPOUND OVER 100 GM PROT
B4216	PARENTERAL NUTRITION ADDITIVES HOMEMIX PER DAY
B4220	PARENTERAL NUTRITION SUPPLY KIT PREMIX PER DAY
B4222	PARENTERAL NUTRITION SUPPLY KIT HOME MIX PER DAY
B4224	PARENTERAL NUTRITION ADMIN KIT PER DAY
B5000	PARENTERAL NUTRITION CMPD ANY STRENGTH RENAL
B5100	PARENTERAL NUTRITION CMPD ANY STRENGTH HEPATIC
B5200	PARENTERAL NUTRITION CMPD ANY STRENGTH STRESS
B9002	ENTERAL NUTRITION INFUSION PUMP W/ALARM
B9004	PARENTERAL NUTRITION INFUSION PUMP PORTABLE
B9006	PARENTERAL NUTRITION INFUSION PUMP STATIONARY
B9998	NOC ENTERAL SUPPLIES
B9999	NOC PARENTERAL SUPPLIES

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HCPCS Codes	Description
N/A	

ICD-10-CM Diagnosis Codes that Support Coverage Criteria
+ Indicates a code requiring an additional character

ICD-10-CM Code	Description
n/a	

Reviews, Revisions, and Approvals	Date	Approval Date
Original approval date	2/17	2/17
Annual Review, No Substantive Changes	3/18	3/18
Annual Review, No Substantive Changes	7/19	7/19
Annual Review, No Substantive Changes	7/20	7/20
Annual Review, Addition of Cow's Milk Protein Allergy (CMPA) added	1/21	1/21

References

1. Koletzko, S. et. al., (2012). Diagnostic Approach and Management of Cow's-Milk Protein Allergy in Infants and Children: ESPGHAN GI Committee Practical Guidelines, Journal of Pediatric Gastroenterology and Nutrition, (55, #2), pp221 to 229

https://www.healthychildren.org/English/healthy-living/nutrition/Pages/Milk-Allergy-Foods-and-Ingredients-to-Avoid.aspx

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering

benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

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Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

Note: For Medicare members, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs, and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at http://www.cms.gov for additional information.