Clinical Policy: Enteral and Formula Authorization Request

Reference Number: IN.CP.DME.03 Coding Implications
Last Review Date: 01/2025 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 enterals including infant formulas that require prior authorization for claims payment.

Policy/Criteria

All requests for prior approval of enteral services must contain the following information:

- Current height, weight and body mass index
- Growth charts
- 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 may be referred for physician review and denied as "information insufficient".

1. Infant/Child PROCEDURE:

A. Diagnosis review

1. If for inborn errors of metabolism, e.g. phenylketonuria: APPROVE
2. 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 caloric density beverage, e.g., Pediasure: APPROVE
3. Requests associated with a diagnosis of end stage renal disease, diabetes, and malabsorption syndromes: SECONDARY REVIEW
4. 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
        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 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). Estimated caloric needs per day based on age and weight (refer to nutrition review worksheet from OMPP). Estimated caloric gap per day with not met with a standard diet (refer to nutrition review worksheet from OMPP).

iv. IF the infant has a diagnosis of Intrauterine Growth Retardation IUGR) AND weight percentiles lag head circumference and length percentiles, THEN high calorie may be approved

5. 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).
    a. 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.
    b. Formulas developed specifically for premature infants (not simply high calorie) should only be used until the infant reaches 2000 grams.
6. Food Thickeners must be accompanied by a diagnosis of gastro esophageal reflux, dysphagia or esophagitis and one or more of the following
    a. History of Aspiration Pneumonia AND an abnormal swallowing study
    b. Weight loss due to significant vomiting AND failure of thickened feedings or positioning to correct reflux
    c. Formulas are generally not considered treatment for reflux unless allergy has been proven
    d. Formulas with rice solids added are not superior to standard formula with rice cereal
7. IF the diagnosis is Food protein-induced enterocolitis, 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.
8. **Medicaid Only:**

    PA is required for all digestive enzyme cartridges **(**B4105 – *In-line cartridge containing digestive enzyme(s) for enteral feeding, each*) for use with enteral tube feeding. For IHCP approval and coverage of initial requests up to 3 months, the following criteria must be met:
    a. Diagnosis of Cystic fibrosis and Exocrine pancreatic insufficiency

b. Evidence of failed standard pancreatic enzyme therapy (defined as not meeting target weight gain for a minimum period of 6 weeks)
c. Requires nightly continuous tube feedings through gastrostomy tube no less than three times weekly to achieve goal caloric intake

For the initial PA or extensions of initial PA, providers must include additional documentation to support medical necessity of the following orders:

a. The need for special nutrients
b. The need for a pump (see the Parenteral and Enteral Nutrition Pumps for Home Infusion section)

2. Adult PROCEDURE:

A. Diagnosis Review:

I. Ulcerative colitis
II. Gastrointestinal cancer
III. Abnormal loss of weight
IV. Ischemic bowel disease
V. Nausea/vomiting
VI. Alzheimer's disease
VII. Dysphasia
VIII. CVA
IX. Short gut syndrome
X. Jaw fracture
XI. IUGR

B. Adult criteria

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 methylmalonic acidemia.

Approvals 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 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.

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

APPENDIX

Diagnostic Criteria for Food protein-induced enterocolitis

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
B4105	*In-line cartridge containing digestive enzyme(s) for enteral feeding, each*

Reviews, Revisions, and Approvals	Date	Approval Date
Original approval date	03/2013	03/2013
Deleted Note Policy and procedure- clarification of language	2/18/2014	2/18/2014
Added Procedure 2	6/17/2014	6/17/2014
Policy information expanded and redefined Updates to this policy include: 1.Procedure: A. Diagnosis Review: Changed: 4.a.iii: "6th" to "most recent" edition Added 4.a.iv Added 5: "Weight gain ideally is ~ 15 grams per day." Added 5.i and 5.ii. Added 6.c and 6.d 2. Procedure: Diagnosis Review: added IUGR Minor format changes	6/2015	6/2015
Annual Review with changes. Approval time frame for adult members changed to 6 months, instead of 3 months. Added if enteral request approved, this includes equipment and supplies.	6/2016	6/2016
Annual Review with changes. Approval time frame for adult members changed to 6 months, instead of 3 months. Added if enteral request approved, this includes equipment and supplies.	6/2016	6/2016
Annual Review with no changes RB	6/2017	6/2017

Reviews, Revisions, and Approvals	Date	Approval Date
Annual Review with no content changes, changed approver	8/2018	8/2018
Annual Review with no content changes	8/2019	8/2019
Annual review with changes. #1 Procedure – "Infant/Child" added in front of Procedure 2A under Infant/Child Procedure – "Caloric" added in front of density beverage #2 Procedure – Adult added in front of Procedure Compliance 360was changed to Archer	9/2020	9/2020
Added section for Medicaid B4105 review	4/2021	4/2021
Annual Review with no content Changes	04/2023	04/2023
Annual Review with no Changes	01/2025	01/2025

References

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.