Clinical Policy: Oral and Enteral Formula

Reference Number: IL.PMN.355
Effective Date: 4.1.26
Last Review Date: 02.10.26
Line of Business: Medicaid

Revision Log

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

Description

Enteral nutrition is feeding provided through the gastrointestinal tract via a tube, catheter, or stoma that delivers nutrients distal to the oral cavity.

Enteral nutrition products may be covered if administered orally or through a feeding tube if medically necessary to prevent serious disability or death in patients with medically diagnosed conditions that preclude the full use of regular food.

Products are grouped by the following product categories:

- Standard: Contain intact macronutrients and be nutritionally complete and a sole source of nutrition where no additional elements, vitamins, minerals, nor macronutrients are additionally required.
- Specialized: Disease-specific with intact macronutrients and modulars
- Elemental and semi-elemental: Nutritionally complete formula which contain extensively hydrolyzed products (EH) (peptide) or fully broken-down (amino acid) protein macronutrients.
- Metabolic: Indicated for inborn errors of metabolism diagnoses for infant, pediatric, and adult members.
- Specialty infant: Indicated for specific diagnosis or conditions for individuals 1 year of age and younger.

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that enteral/oral products medically necessary when the following criteria are met:

I. Initial Approval Criteria

A. Standard Products (must meet all):

1. Request is for Boost Breeze (NDC 43900-0186-29) or Ensure Clear (NDCs 70074-0565-01, 70074-0624-81, 70074-0649-01, or 70074-0648-99)
2. Request does not exceed one of the following maximum daily caloric limits (a, b, or c):
   a. Tube Fed: up to 2,000 calories/day
   b. Orally Fed and 22 years of age and older: up to 1,200 calories/day
   c. Orally Fed and 21 years of age and younger: up to 1,000 calories/day
3. Have severe swallowing or chewing difficulty due to one of the following (a, b, c, d, or e):
   a. Cancer in the mouth, throat or esophagus
   b. Injury, trauma, surgery or radiation therapy involving the head or neck
   c. Chronic neurological disorders
   d. Severe craniofacial anomalies
   e. Transitioning from parenteral or enteral tube feeding to an oral diet

B. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT
   specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.PMN.53 for Medicaid.

II. <u>Continued Approval</u>

A. Standard Products

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Member is responding positively to therapy;

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):

a. For drugs in the PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.PMN.255 for Medicaid; or

b. For drugs NOT in the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.PMN.16 for Medicaid; or

2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – CP.PMN.53 for Medicaid or evidence of coverage documents.

IV. Product Availability

Priduct Name	Availability
Boost Breeze	NDC 43900-0186-29
Ensure Clear	NDCs 70074-0565-01, 70074-0624-81, 70074-0649-01, or 70074-0648-99

Coding Implications

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.

HCPCS Codes	Description
B4102	Enteral formula, for adults, used to replace fluids and electrolytes, 500 ml = 1 unit.
B4103	Enteral formula, for pediatrics, used to replace fluids and electrolytes (e.g., clear liquids), 500 ml = 1 unit

Reviews, Revisions, and Approvals	Date	Approval Date
Policy Created to comply with HFS PDL	2/23/26	

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.
This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

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 and LCDs 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.

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