



MEDICAL POLICY STATEMENT

Indiana Medicaid

Policy Name & Number	Date Effective
Infant Formula-IN MCD-MM-1357	03/01/2024-03/31/2025
Policy Type	
MEDICAL	

Medical Policy Statement prepared by CareSource and its affiliates are derived from literature based on and supported by clinical guidelines, nationally recognized utilization and technology assessment guidelines, other medical management industry standards, and published MCO clinical policy guidelines. Medically necessary services include, but are not limited to, those health care services or supplies that are proper and necessary for the diagnosis or treatment of disease, illness, or injury and without which the patient can be expected to suffer prolonged, increased or new morbidity, impairment of function, dysfunction of a body organ or part, or significant pain and discomfort. These services meet the standards of good medical practice in the local area, are the lowest cost alternative, and are not provided mainly for the convenience of the member or provider. Medically necessary services also include those services defined in any Evidence of Coverage documents, Medical Policy Statements, Provider Manuals, Member Handbooks, and/or other policies and procedures.

Medical Policy Statements prepared by CareSource and its affiliates do not ensure an authorization or payment of services. Please refer to the plan contract (often referred to as the Evidence of Coverage) for the service(s) referenced in the Medical Policy Statement. If there is a conflict between the Medical Policy Statement and the plan contract (i.e., Evidence of Coverage), then the plan contract (i.e., Evidence of Coverage) will be the controlling document used to make the determination. According to the rules of Mental Health Parity Addiction Equity Act (MHPAEA), coverage for the diagnosis and treatment of a behavioral health disorder will not be subject to any limitations that are less favorable than the limitations that apply to medical conditions as covered under this policy.

Table of Contents

A. Subject.....	2
B. Background.....	2
C. Definitions	2
D. Policy	2
E. Conditions of Coverage.....	3
F. Related Policies/Rules.....	3
G. Review/Revision History.....	3
H. References.....	3

A. Subject

Infant Formula

B. Background

Infant formula may be provided through medical insurance when the member is unable to tolerate standard formula or breast milk due to a variety of conditions, including, but not limited to, gastrointestinal disorders, malabsorption, and inborn errors of metabolism. These products must be Food and Drug Administration (FDA)-approved and prescribed appropriately by a qualified physician.

While the member is awaiting authorization, the Women, Infants and Children (WIC) program will provide a supplemental amount of exempt infant formula or medical food. Pursuant to Code of Federal Regulations 7 C.F.R. § 246.10(d)(1)(iii) and § 246.10(d)(1)(iv), to receive this WIC benefit, members must obtain documentation of a qualifying condition from a healthcare professional licensed to write medical prescriptions. Members should be referred to WIC only as a secondary provider. Medicaid becomes the primary provider after approval as a covered benefit is granted.

C. Definitions

- **Inborn Errors of Metabolism (IEM) (eg, Inherited Metabolic Disease)** – A disease caused by inborn errors of amino acid, organic acid, or urea cycle metabolism and treatable by the dietary restriction of one or more amino acids.
- **Medical Food** – A formula intended for the dietary treatment of a disease or condition for which nutritional requirements are established by medical evaluation and formulated to be consumed or administered under the direction of a physician.
- **Standard Food** – Regular grocery products including typical, not specially formulated infant formulas available without a prescription.

D. Policy

I. Prior authorization is required.

II. CareSource considers infant nutritional formula medically necessary when **ALL** the following criteria are met:

- A. Formula is being dispensed to treat an illness, including (but not limited to):
 - 1. inborn errors of metabolism/metabolic disorders
 - 2. severe food allergies that require an elemental formula
 - 3. gastrointestinal disorders/malabsorption syndrome
- B. Inability of member to maintain body weight and nutritional status (initial and ongoing treatment) with standard food/formula
- C. No other means of nutrition is feasible or reasonable
- D. Convenience of the member or the member's caretaker is not the primary reason for the request for the service
- E. Formula is not being dispensed for routine or ordinary nutritional needs

E. Conditions of Coverage
NA

F. Related Policies/Rules
NA

G. Review/Revision History

DATE		ACTION
Date Issued	10/12/2022	
Date Revised	10/11/2023	Annual review: updated references, approved at Committee.
Date Effective	03/01/2024	
Date Archived	03/31/2025	This Policy is no longer active and has been archived. Please note that there could be other Policies that may have some of the same rules incorporated and CareSource reserves the right to follow CMS/State/NCCI guidelines without a formal documented Policy.

H. References

1. Burris A, Burris J, Jarvinen KM. Cow's milk protein allergy in term and preterm infants: clinical manifestations, immunologic pathophysiology, and management strategies. *NeoReviews*. 2020;21(12):e795-e808. doi:10.1542/neo.21-12-e795
2. Cederholm T, Barazzoni R, Austin P, et al. ESPEN guidelines on definitions and terminology of clinical nutrition. *Clin Nutr*. 2017;36(1):49-64. doi:10.1016/j.clnu.2016.09.004
3. Food Supplements, Nutritional Supplements, and Infant Formulas, 405 IND. ADMIN. CODE 5-24-9 (2023).
4. *Guidance for Industry: Frequently Asked Questions about Medical Foods*. 3rd ed. US Dept of Health and Human Services; 2023. Accessed September 20, 2023. www.fda.gov
5. Inherited Metabolic Disease Coverage, IND. CODE § 27-13-7-18 (2023).
6. *Provider Reference Module: Durable and Home Medical Equipment and Supplies*. Indiana Health Coverage Programs; 2022. Accessed September 20, 2023. www.in.gov
7. Supplemental Foods, 7 C.F.R. § 246.10 (2022).

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Approved OMPP 12/04/2023

The MEDICAL Policy Statement detailed above has received due consideration as defined in the MEDICAL Policy Statement Policy and is approved.