MEDICAL POLICY STATEMENT
Indiana Medicaid

Policy Name & Number	Date Effective
Infant Formula-IN MCD-MM-1357	09/01/2026
Policy Type	
MEDICAL	

Medical Policy Statements are developed from a review of the available evidence-based, clinical information based on and supported by clinical guidelines from medical specialties, peer-reviewed medical and scientific studies, nationally recognized utilization and technology assessment guidelines, and other medical management industry standards to aid in determining the medical necessity of a service. Medically necessary services are defined in the plan-specific Evidence of Coverage, Member Handbooks, Provider Manuals, Medical Policy Statements, and/or other plan policies and procedures.

Medical Policy Statements do not guarantee an authorization or payment of services. Please refer to the plan contract (e.g., Evidence of Coverage, Member Handbook) for the service(s) referenced in the Medical Policy Statement. Except as otherwise required by law, if there is a conflict between the Medical Policy Statement and the plan contract and/or provider agreement, then the plan contract and/or provider agreement will be the controlling document. Reasonable discretion may be used in interpreting and applying this Policy Statement to services provided in a particular case, and the policy may be modified at any time. Medical Policy Statements may be superseded by federal and state laws and regulations, as applicable. In the case of a discrepancy between the Policy Statement's effective date and any applicable legal or regulatory requirement, the law or regulation will govern.

Coverage for mental health and substance use disorder (MH/SUD) benefits are provided at the same level as coverage for medical and surgical (M/S) benefits, as required by the Mental Health Parity and Addiction Equity Act (MHPAEA). MH/SUD benefits are not subject to limits or requirements that are more restrictive than those that apply to M/S benefits.

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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. The member is unable to maintain body weight and nutritional status (initial and ongoing treatment) with standard food/formula.
   C. There is no other means of nutrition that are 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. 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 09/25/2024 07/16/2025 05/20/2026	Annual review: updated references, approved at Committee. Review: removed D.II.E, updated references, approved at Committee. Review: updated references, approved at Committee. Review: updated references, approved at Committee.
Date Effective	09/01/2026	
Date Archived		

H. References

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2. 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
3. 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
4. Food Supplements, Nutritional Supplements, and Infant Formulas, 405 IND. ADMIN. CODE 5-24-9 (2025).
5. *Guidance for Industry: Frequently Asked Questions about Medical Foods*. 3rd ed. US Dept of Health and Human Services; 2023. Accessed March 24, 2026. www.fda.gov
6. Inherited Metabolic Disease Coverage, IND. CODE § 27-13-7-18 (2024).
7. *Provider Reference Module: Durable and Home Medical Equipment and Supplies*. Indiana Health Coverage Programs; 2026. Accessed March 24, 2026. www.in.gov
8. Supplemental Foods, 7 C.F.R. § 246.10 (2024).