Specialized infant formula

Clinical Policy ID: CCP.1501

Recent review date: 12/2025

Next review date: 4/2027

Policy contains: Eosinophilic gastroenteropathy; feeding intolerance; food protein-induced enterocolitis syndrome; galactosemia; inborn errors of metabolism; lactase deficiency; milk allergy; specialized infant formula; short bowel syndrome.

AmeriHealth Caritas has developed clinical policies to assist with making coverage determinations. AmeriHealth Caritas' clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of "medically necessary," and the specific facts of the particular situation are considered, on a case by case basis, by AmeriHealth Caritas when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. AmeriHealth Caritas' clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. AmeriHealth Caritas' clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, AmeriHealth Caritas will update its clinical policies as necessary. AmeriHealth Caritas' clinical policies are not guarantees of payment.

Coverage policy

This policy addresses oral specialized infant formula for use in the home setting for children aged 12 months or younger. This policy does not address enteral tube feedings. For children older than 12 months, refer to clinical policy CCP.1524 Oral nutritional supplements; for donor human milk coverage for infants 6 months or younger, refer to clinical policy CCP.1185 Donor human milk.

Specialized infant formula for home use is clinically proven and, therefore, may be medically necessary when all of the following criteria are met:

- Breast milk or standard infant formula is insufficient, not tolerated, or contraindicated.
- Formula is deemed medically necessary by a physician/other licensed health care provider who will supervise the use of the oral formula.

- Formula is exempt from the general requirements for standard infant formula for nutritional labeling under the statutory and regulatory guidelines of the U.S. Food and Drug Administration (2023), and labeling contains a description of the medical condition for which the specialized formula is indicated.

Covered medical conditions

- Documentation supports one of the following medical conditions requiring treatment with specialized infant formula:

- Immunoglobulin E (IgE)-mediated or Non-IgE-mediated Cow's Milk Allergy (Bognanni, 2024).
- Note: Medically necessary formulas for cow's milk allergy must be hypoallergenic (e.g., extensively hydrolyzed formulas, amino acid formulas or hydrolyzed rice formulas).
- Contraindication: Partially hydrolyzed formulas (often marketed as "gentle" or "comfort") are not hypoallergenic and are contraindicated and excluded for the treatment of cow's milk allergy.
- Galactosemia (O'Connor, 2009).
- Phenylalanine hydroxylase deficiency (including Phenylketonuria) (Smith, 2025). Congenital or primary lactase deficiency (O'Connor, 2009).
- Non-immunoglobulin E-mediated food protein allergy (National Institute of Allergy and Infectious Diseases, 2010; Nowak-Węgrzyn, 2017).
- Short bowel syndrome (National Institute of Diabetes and Digestive and Kidney Diseases, undated).
- Inborn errors of metabolism (Genetic Metabolic Dietitians International and the Southeast Regional Newborn Screening and Genetics Collaborative, 2021).
- Homocystinuria (Al-Sadeq, 2020).
- Maple Syrup Urine disease (Hassan, 2022).
- Has documented gastroesophageal reflux disease, defined as pathological reflux associated with symptoms that negatively impact health or wellbeing (e.g., esophagitis, food refusal, significant pain, failure to thrive), and is unresponsive to standard management techniques (including reassurance and feeding adjustments) (Haiden, 2024).
- Functional Infant Regurgitation: Specialized (e.g., Anti-Reflux/thickened) formulas may be considered medically necessary only when all the following are met (Haiden, 2024):
- The infant meets Rome IV criteria for regurgitation (i.e., physiological reflux without signs of gastroesophageal reflux disease); AND
- Documentation supports the failure of non-nutritional interventions (reassurance, feeding adjustments); AND
- Significant parental distress persists despite reassurance.
- Other diagnoses mandated by state law.

Requests for specialized infant formula for conditions not listed above are subject to medical review and approval on a case-by-case basis.

Limitations

Continued coverage for specialized infant formulas is subject to medical review of medical necessity at six months of use or as requested.

Absolute contraindications:

- Formulas for infant colic ("comfort" formulas): formulas marketed primarily for the management of infant colic (often labeled as "comfort," "sensitive," or "anti-colic"), including those with reduced lactose or partial hydrolyzation, lack sufficient clinical evidence of efficacy (Haiden, 2024).
- Formulas for combined functional gastrointestinal disorders (multi-claim): formulas marketed for the simultaneous treatment of multiple functional gastrointestinal symptoms (e.g., colic and constipation) lack evidence and are not recommended (Haiden, 2024).
- Older Infant-young child formulas for healthy children: These formulas include toddler milks, growing-up milks, and follow-on formulas and they offer no nutritional advantage over a balanced diet and cow milk/human milk for healthy children (Fuchs, 2023).

Alternative covered services

- Enteral tube feedings.
- Parenteral feedings.
- Nutritional counseling.
- Nutritional consultation.

Background

Inborn errors of metabolism are genetic disorders that interfere with the normal metabolism of protein, fat, or carbohydrate and the generation of energy. They are considered present at birth and permanent. Disturbance of these metabolic pathways frequently produces a constellation of nonspecific clinical findings, affecting multiple organ systems with varying severity (Kruszka, 2019).

Newborn screenings have identified multiple inborn errors of metabolism resulting in disorders that remain incurable but treatable with the feeding of medically specialized infant formulas for survival. The inability of the infant's body to breakdown phenylalanine, tyrosine, lysine, tryptophan, and other amino acids can be life threatening and result in poor growth, abnormal motor skill and coordination, slowed development, and learning disabilities. Among those more commonly known and treated are Phenylketonuria, Maple Syrup urine disease, Homocystinuria, Galactosemia (Health Resources and Services Administration, 2023; Nutricia North America, 2023).

Standard infant formula is a manufactured substitute for, or supplement to, human milk for orally feeding term infants younger than 12 months (Martinez, 2011). It is based most commonly on cow's milk fortified with carbohydrates, lipid components, vitamins, minerals, nucleotides, and altered protein content to improve safety and digestibility. Other animal milk and plant-based milk are alternatives to cow's milk for term infants (Milbrandt, 2017).

Bioactive compounds associated with health benefits found in human milk may be added to upgrade the nutritional quality of infant formulas (Almeida, 2021). Common bioactive additives are α-lactalbumin, lactoferrin, taurine, milk fat globule membrane, folates, polyamines, and long-chain polyunsaturated fatty acids. Prebiotics and probiotics, which attempt to mimic the intestinal flora of breast-fed infants, may be beneficial for preventing necrotizing enterocolitis in preterm infants who are formula-fed (Downard, 2012; Bührer, 2020). While these

supplements appear safe and well-tolerated in most instances, there is no consensus on whether they have the same functional effects as human milk or how thermal processing and storage may affect bioactivity (Almeida, 2021).

The U.S. Food and Drug Administration (2023) regulates infant formula as a food supplement. No pre-marketing approval is required, but all formulas marketed in the United States must meet federal nutrient requirements and manufacturers must comply with notification requirements prior to marketing a new formula. These nutrient requirements include minimum amounts for 30 nutrients and maximum amounts for 11 of them (21CFR107.100).

If an infant formula does not meet these nutritional specifications, it is considered an adulterated product. A formula, such as a specialized infant formula, may be considered "exempt" from certain nutrient requirements if it is intended for commercial or charitable distribution and is represented and labeled for use by an infant who has an inborn error of metabolism or low birth weight, or who otherwise has an unusual medical or dietary problem. Recipes for homemade formulas are not regulated (U.S. Food and Drug Administration, 2023).

Preterm formulas have higher caloric density and concentrations of key nutrients (Martinez, 2011). Preterm and enriched formulas are considered the standard of care in the hospital setting, as they may improve short-term growth parameters (O'Connor, 2009). They are usually discontinued at hospital discharge and replaced with transitional formulas for several months. Follow-up formulas are for infants and young toddlers whose solid food intake is not fully adequate to meet age-specific nutritional requirements.

Specialized infant formulas are designed to meet the unique nutritional needs of an infant, when such formulas taken by mouth are the sole source of nutrition, and breast milk or standard infant formula would place the infant at risk for more severe health consequences. These specialized formulas may include added, subtracted, or altered nutrients to ensure adequate nutritional status (Martinez, 2011; Milbrandt, 2017).

Specific health conditions with unique nutritional needs may include genetic deficiencies, inborn errors of metabolism, food intolerance or allergy, and reflux. Specialized formulas for these conditions may contain partially hydrolyzed proteins, lactose-free or lactose-reduced blends, and thickeners. Hypoallergenic formulas contain hydrolyzed proteins that are less likely to stimulate antibody production. Non-allergenic amino acid-based formulas provide simple protein sources that are easier to digest and tolerate. For those wishing to avoid lactose, soy formulas made with corn-based carbohydrate (without lactose) and lactose-free formulas are alternatives. Anti-regurgitation formulas contain thickeners such as cornstarch or an increased amount of casein to reduce the frequency of overt regurgitation and vomiting (Martinez, 2011; Nutricia North America, 2023).

Findings

Guidelines:

Reviewed guidelines state that breastfeeding remains preferred and standard infant formulas are acceptable when breastfeeding is insufficient. The National Institute of Allergy and Infectious Diseases classifies adverse food reactions as immunoglobulin E mediated, non immunoglobulin E mediated, or mixed and recommends elimination of the offending dietary component as initial management (Milbrandt, 2017; O'Connor, 2009; National Institute of Allergy and Infectious Diseases, 2010).

For functional gastrointestinal disorders in early infancy, the European Society for Pediatric Gastroenterology, Hepatology, and Nutrition advises maintaining breastfeeding and reserving specialized formulas for clinician-supervised indications. Thickened formulas are reasonable for prominent regurgitation; protein hydrolyzation or fermentation does not add benefit beyond thickening; use expressed human milk with appropriate thickeners when needed; avoid commercial thickeners associated with necrotizing enterocolitis; anti regurgitation formula can be considered for severe or persistent regurgitation (Haiden, 2024; O'Connor, 2009; Kwok, 2017).

For suspected cow's milk protein allergy, the European Society for Pediatric Gastroenterology, Hepatology, and Nutrition and the National Institute of Allergy and Infectious Diseases support time-limited elimination with planned oral challenge and use of hypoallergenic hydrolyzed protein formula for confirmed immunoglobulin E mediated disease; evidence for prevention of atopic disease or relief of colic remains low certainty, so decisions should be individualized under clinician supervision (O'Connor, 2009; National Institute of Allergy and Infectious Diseases, 2010; Stróżyk, 2020; Gordon, 2018; Ng, 2019; Osborn, 2018; Vandenplas, 2019; Haiden, 2024).

For inherited metabolic diseases, Genetic Metabolic Dietitians International and the Southeast Regional Newborn Screening and Genetics Collaborative recommend condition-specific medical nutrition therapy for phenylketonuria, maple syrup urine disease, propionic acidemia, very long chain acyl coenzyme A dehydrogenase deficiency, and medium chain acyl coenzyme A dehydrogenase deficiency; infants may require partial or complete replacement of human milk or standard formula with specialized medical formulas tailored to diagnosis, severity, and tolerability. The American College of Medical Genetics and Genomics further recommends lifelong maintenance of phenylalanine at or below 360 micromoles per liter for phenylalanine hydroxylase deficiency and achievement of phenylalanine at or below 360 micromoles per liter before conception, with confirmatory molecular testing at birth to guide therapy (Genetic Metabolic Dietitians International and the Southeast Regional Newborn Screening and Genetics Collaborative, 2021; Smith, 2025).

For products marketed to older infants and toddlers, the American Academy of Pediatrics identifies no nutritional advantage for most children, advises product names that avoid the term formula, and recommends shelf placement distinct from infant formulas; after twelve months, whole cow's milk within a balanced diet is appropriate, with continued vitamin D for breastfed toddlers and attention to iron intake (Fuchs, 2023).

Systematic reviews

Evidence synthesis now includes a large prevention meta-analysis that clarifies where hydrolyzed formulas may help and where they do not. A review by the European Society for Pediatric Gastroenterology, Hepatology, and Nutrition synthesized 72 studies on functional gastrointestinal disorders and continued to advise maintaining breastfeeding and reserving specialized formulas for defined, clinician-supervised indications (Haiden, 2024). A new systematic review and meta-analysis of 24 trials including n=10,950 infants found that, compared with cow's milk formula, extensively hydrolyzed formula reduced risk of cow's milk allergy through age two years, partially hydrolyzed formula reduced risk of eczema through age two years, and extensively hydrolyzed formula reduced risk of eczema after age two years; compared with breast milk, both hydrolyzed strategies increased risk of wheeze in children younger than two years; most signals were supported by low to moderate quality evidence (Li, 2024).

For allergic disease management, prior systematic reviews remain directionally consistent: benefits from hydrolyzed formulas for colic or prevention of atopic disease are small or uncertain and overall certainty is low (Gordon, 2018; Ng, 2019; Osborn, 2018; Vandenplas, 2019). For infants and toddlers with cow's milk allergy who cannot be breastfed, a separate systematic review analyzed 14 randomized controlled trials and seven observational studies with total n=2,430 participants and suggested that extensively hydrolyzed cow's milk–based formula might increase outgrowth of cow's milk allergy versus amino acid formula and might reduce severe vomiting and development of food protein–induced enterocolitis syndrome, with very low certainty (Bognanni, 2024).

Meta analysis

A quantitative synthesis of four randomized controlled trials with (n = 410) infants with confirmed immunoglobulin E mediated and nonimmunoglobulin E mediated cow's milk protein allergy showed that an amino acid formula containing a specific synbiotic blend was associated with fewer infections, lower antimicrobial medication use,

and fewer hospital admissions compared with unsupplemented amino acid formula; effects are not generalizable to other synbiotic compositions (Sorensen, 2021).

New growth-focused meta-analysis adds context for formula selection in cow's milk allergy. A review of eight clinical trials including (n = 469) participants reported that amino acid formula and extensively hydrolyzed formula both improved weight and weight-for-age z-scores versus soy formula, with no meaningful effect on length-for-age; pooled estimates suggested a larger gain in weight-for-age z-score with amino acid formula than with extensively hydrolyzed formula; study quality and heterogeneity limit certainty (Harijani, 2025).

Other evidence

For confirmed immunoglobulin E mediated cow's milk protein allergy, hypoallergenic hydrolyzed protein formulas are indicated and appear safe and well tolerated (O'Connor, 2009; Stróżyk, 2020). Short trials may be reasonable in refractory colic, but systematic reviews report low-quality support for this approach (Gordon, 2018; Ng, 2019; Osborn, 2018; Vandenplas, 2019).

In rare situations of intolerance to intact or hydrolyzed proteins or in malabsorptive conditions such as food protein-induced enterocolitis syndrome, eosinophilic gastroenteropathies, and short bowel syndrome, nonallergenic amino acid-based elemental formulas may be required (National Institute of Diabetes and Digestive and Kidney Diseases, undated; Nowak-Węgrzyn, 2017; O'Connor, 2009).

In 2025 we revised the specialized infant formula policy to clarify coverage for cow's milk allergy, separate physiologic regurgitation from gastroesophageal reflux disease, add explicit contraindications, and align phenylalanine hydroxylase deficiency terminology. New citations and guidelines include American College of Medical Genetics and Genomics guidance for phenylalanine hydroxylase deficiency (Smith 2025), the American Academy of Pediatrics report on toddler milks (Fuchs 2023), and meta-analyses quantifying effects of hydrolyzed formulas on allergy prevention and growth (Li 2024; Harijani 2025). These led to policy changes: hypoallergenic formulas are required for confirmed cow's milk allergy and partially hydrolyzed products are excluded; anti-regurgitation formulas are covered for Rome IV regurgitation only after failure of non-nutritional measures while coverage for reflux disease requires documented disease with failed conservative care; formulas marketed for colic or for multiple functional symptoms are contraindicated; and toddler or follow-on milks confer no advantage for healthy children.

References

On October 20, 2025, we searched PubMed and the databases of the Cochrane Library, the U.K. National Health Services Centre for Reviews and Dissemination, the Agency for Healthcare Research and Quality, and the Centers for Medicare & Medicaid Services. Search terms were "Metabolism, Inborn Errors/diet therapy" (MAJR), "eosinophilic enteropathy," "galactosemia," "lactase deficiency," "food intolerance", "milk hypersensitivity" (MeSH), "phenylketonuria" (MeSH), "homocystinuria" (MeSH), and "maple syrup urine disease". We included the best available evidence according to established evidence hierarchies (typically systematic reviews, meta-analyses, and full economic analyses, where available) and professional guidelines based on such evidence and clinical expertise.

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Policy updates

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