Donor human milk

Clinical Policy ID: CCP.1185

Recent review date: 11/2025

Next review date: 3/2027

Policy contains: Human milk, infant nutrition, necrotizing enterocolitis, very low birth weight infants.

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Coverage policy

Donor human milk is clinically proven and, therefore, may be medically necessary when any of the following criteria are met (Abrams, 2017; Embleton, 2022; World Health Organization, 2022):

- Infant is 6 months of age or younger.
- Mother's own milk is contraindicated or unavailable despite lactation support.
- At least one clinical indication is present:
    - Risk for necrotizing enterocolitis, defined by very low birth weight (≤1,500 g) or gestational age ≤32 weeks.
    - Infant suffers from a condition that impairs nutrient absorption (malabsorption), including but not limited to: gastrointestinal anomalies, metabolic or digestive disorders, recovery from intestinal surgery, short bowel syndrome, or exocrine pancreatic insufficiency.

Limitations

No limitations were identified during the writing of this policy.

Alternative covered services

Lactation specialists within network.

Background

Breast-feeding and human milk are the standard of care for all infant feeding. Exclusive breast-feeding is recommended for the first six months of life as human milk is the ideal form of nutrition for newborn infants. Human milk, unlike infant formula, provides active enzymes that enhance maturation of the infant's gut and protect against infection related to the immune system. There are many advantages of an infant diet of human milk, including lifelong developmental benefits.

Breast-feeding and mother's milk are the best options for feeding all infants, as they provide the highest level of benefits. Human milk's composition changes over time post-delivery to provide the optimal nutritional mix to the developing infant. However, many infants most in need of the optimal nutritional benefits provided by human milk are not able to receive an adequate supply, as 30% of mothers of premature infants are unable to produce sufficient quantities of milk for their children. Donor human milk provides an alternative to formula feeding that delivers many of the benefits of a mother's own milk (Steele, 2018).

Very low birth weight infants are more likely than normal birth weight infants to have difficulty eating, gaining weight, and fighting infection, and to have health problems at birth that can affect their health later in life. For example, necrotizing enterocolitis, which occurs in preterm infants, results in the necrosis of the digestive system. Necrotizing enterocolitis can require surgery, lengthy stays in the neonatal intensive care unit, or eventually result in death and multiple comorbidities (Ginglen, 2023).

According to the American Academy of Pediatrics, human milk is increasingly recognized for its nutritional and immune effects on neonates, including preterm infants (Zhang, 2020). Yet, donor human milk is not used uniformly across U.S. populations, neither while in the hospital nor on discharge (Hallowell, 2016). Larger neonatal intensive care units and those in the West and Midwest were more likely to use donor human milk, while safety-net hospitals that serve large segments of the Medicaid population were less likely. Variable regulatory requirements, availability of human milk banks, and provider and parental receptiveness are contributing barriers to use (Boundy, 2022; Parker, 2016; Shah, 2023).

Findings

Across guidelines, systematic reviews, and meta-analyses, the evidence base converges on a clear clinical picture: donor human milk is a clinically useful intervention for preterm and very low birth weight infants when mother's own milk is unavailable. Its primary benefit is a significant reduction in necrotizing enterocolitis, a finding that is weighed against the trade-off of slower short-term, in-hospital growth. The evidence shows little to no effect on mortality or late-onset infection. To meet growth goals, fortification of donor human milk is often necessary. The safety of this intervention depends on regulated milk banking protocols, including donor screening and pasteurization. For populations outside of high-risk infants, the evidence for routine clinical use remains limited.

Guidelines

Major pediatric and health organizations consistently prioritize mother's own milk, with pasteurized donor human milk as the recommended next choice for high-risk infants. The World Health Organization and the European Society for Pediatric Gastroenterology, Hepatology and Nutrition issue conditional recommendations, judging the harm of necrotizing enterocolitis from formula to be more clinically significant than the small advantages in growth rate (World Health Organization, 2022; Embleton, 2022). The American Academy of Pediatrics and the Canadian Paediatric Society more strongly recommend pasteurized donor human milk over formula for very low birth weight and other high-risk infants when mother's milk is unavailable or contraindicated, and they emphasize

routine fortification to meet nutrient requirements (Canadian Paediatric Society, 2022; Meek, 2022). All guidelines underscore that safety hinges on regulated milk banking for donor screening and pasteurization, and several highlight equitable access based on medical need, not ability to pay (Committee on Nutrition, 2017; World Health Organization, 2022).

Systematic Reviews

Across high-quality syntheses, the prevention signal for necrotizing enterocolitis is consistent while growth effects favor formula unless donor human milk is fortified. A 2024 Cochrane review of 12 randomized controlled trials (N = 2,296) found with high certainty that, compared with formula, donor human milk reduces necrotizing enterocolitis by about one-half, with little or no effect on late-onset invasive infection or all-cause mortality before discharge; in-hospital weight, length, and head growth were slower with donor human milk (Quigley, 2024). Complementing those findings, a comprehensive systematic review demonstrated dose–response patterns: higher human milk exposure is associated with lower necrotizing enterocolitis risk. That review's meta-analyses included 4 randomized trials (N = 1,116) and 22 observational studies (N = 8,778), all showing reduced necrotizing enterocolitis with higher human milk intake (Miller, 2018). In contrast, evidence for other outcomes is mixed. A 2020 systematic review of 12 studies (N = 3,221) found that while observational cohorts tended to show shorter hospital stays with donor human milk, randomized trials showed no difference (Yang, 2020). In populations outside of the very preterm or very low birth weight groups, systematic reviews highlight significant uncertainty. A 2024 review of 11 studies (N = 10,147) in moderate-late preterm and early-term healthy infants found no clear effect of supplementing with donor human milk versus formula on exclusive breastfeeding or clinical morbidities (McClintock, 2024). A scoping review of 26 studies similarly found small, heterogeneous samples and inconsistent endpoints, limiting conclusions on growth or morbidity in non-preterm populations (McCune, 2021).

Meta-analyses

Meta-analyses clarify the expected clinical trade-offs and quantify secondary outcomes. One meta-analysis of randomized trials reported that donor human milk led to shorter parenteral nutrition duration by 2.39 days and earlier achievement of full enteral feeds by 0.33 days compared with formula. The same analysis confirmed that formula produced faster in-hospital gains in weight, head circumference, and length, supporting the common practice of targeted fortification when donor human milk is used (Li, 2022). Regarding specific morbidities, respiratory outcomes show a selective benefit. Meta-analyses have found lower rates of bronchopulmonary dysplasia with donor human milk compared to preterm formula (Lu, 2023; Yu, 2019). However, for other outcomes, a meta-analysis of 7 randomized trials (N = 876) reported no statistically significant differences between donor human milk and formula for late-onset sepsis, retinopathy of prematurity, or mortality (Yu, 2019). Furthermore, a focused meta-analysis of 4 trials found no clear protective effect of donor human milk for surgically treated necrotizing enterocolitis, despite the consistent reduction in the overall incidence of the condition (Silano, 2019).

Other evidence

The clinical utility of donor human milk is conditional on safe sourcing and processing. Informal milk sharing poses avoidable risks of infectious and chemical contamination (Thayagabalu, 2024). National regulatory guidance advises that any human milk used from outside the mother be obtained through milk banks that apply rigorous donor screening, pasteurization, and validated handling protocols (U.S. Food and Drug Administration, 2018). Implementation and equity remain limiting factors, as regulated milk banking is concentrated in high-resource settings, which constrains the translation of trial-level efficacy into routine practice in many regions (World Health Organization, 2022).

In 2025, we reorganized the findings section thematically and we revised coverage criteria based on systematic reviews and meta-analyses of randomized controlled trials (Quigley, 2024), international guidelines (World

Health Organization, 2022; Embleton, 2022), and national policy statements (Meek, 2022), and added an additional guideline Canadian Paediatric Society, 2022.

References

On September 16, 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 "human donor milk" "donor human milk." 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

8/2015: initial review date and clinical policy effective date: 1/2016

8/2016: Policy references updated.

8/2017: Policy references updated.

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