Donor human milk

Clinical Policy ID: CCP.1185

Recent review date: 10/2024

Next review date: 2/2026

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 both criteria are met (Abrams, 2017):

- Either:
    - Infant is at risk for necrotizing enterocolitis, i.e., fulfills at least one of the following criteria: Very low birth weight (equal to or less than 1,500 grams) or infant ≤ 28 weeks of gestation and is younger than age six months.
    - Infant suffers from gastrointestinal anomaly, metabolic or digestive disorder, or is recovering from intestinal surgery that causes digestive needs to require additional support.
    - Infant is at risk for malabsorption.
- Mother's breast milk is contraindicated or otherwise unavailable.

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, 2013; Shah, 2023).

Findings

Guidelines

Recommendations by the American Academy of Pediatrics call for exclusive breastfeeding until six months of age, as the use of mother's or donor milk for all preterm or low birth weight infants to reduce the risk of developing necrotizing enterocolitis; use of unpasteurized donor milk is not recommended (Abrams, 2017). The Academy recommends donor human milk as an alternative feeding method for high-risk infants if the mother's own milk is not available (Zhang, 2020), and it recommends that access to donor human milk be based strictly on medical necessity, not ability to pay (Committee on Nutrition, 2017).

Evidence review

Feeding the infant with donor human milk entails possible health and safety risks for the infant. These risks include exposure to bacterial contamination, infectious diseases, and chemical contaminants (e.g., toxic metals and illegal and prescription drugs), if the donor has not been adequately screened, and the milk has not been properly handled and stored (Thayagabalu, 2024). The U.S. Food and Drug Administration recommends that, after consultation with a physician, a mother can decide to feed her baby with human milk from other sources, provided milk donors have been screened for safety of the milk (U.S. Food and Drug Administration, 2018).

The following systematic reviews and meta-analyses have examined the efficacy of donor human milk. The majority of studies included in these analyses compared donor human milk to standard or specialized pre-term formula in pre-term infants (≤ 28 weeks gestation) and infants with very low birth weight (< 1,500g). The most

common outcomes were measures of morbidity, such as risk of necrotizing enterocolitis, late-onset sepsis, retinopathy of prematurity, and bronchopulmonary dysplasia; anthropometric measures; and length of hospital stay.

There is strong and consistent evidence that human milk (mother's own milk or donor human milk) significantly reduces the risk of necrotizing enterocolitis in pre-term and very low birth weight infants, whereas formula nutrition is associated with greater increases in physical growth measures and frequency of necrotizing entercolitis. Lower certainty evidence suggests donor human milk may reduce: the risk of bronchopulmonary dysplasia, late onset sepsis, and retinopathy of prematurity; hospital length of stay; the duration of parenteral nutrition; and the time of full enteral feeding. There is insufficient evidence supporting a benefit of donor human milk on other outcomes or in non-preterm or low-risk infants.

A review of 44 studies concluded that human milk (including donor milk) is associated with a 4% reduction in necrotizing enterocolitis, and possibly with reductions in severe necrotizing enterocolitis, retinopathy of prematurity, and length of stay. Higher doses of human milk result in greater protection (Miller, 2018). A review of four studies concluded that donor human milk was not beneficial to preventing surgical necrotizing enterocolitis compared with formula (relative risk 0.45, 95% confidence interval 0.19 to 1.09) (Silano, 2019).

A Cochrane review of nine trials (n = 1,070) included comparisons of donor breast milk with standard formula (four trials), and nutrient-enriched preterm formula (five trials). Formula-fed infants had higher in-hospital weight increase (mean difference = 2.58), length (1.93), and head circumference (1.59), while formula feeding increased frequency of necrotizing enterocolitis (Quigley, 2018). The latest data in the Cochrane review included 12 trials (n = 1,879) showed similar results similar to the prior year. Formula-fed infants had a higher risk of necrotizing enterocolitis, with a significant risk ratio of 1.87 (Quigley, 2019).

A meta-analysis of 17 studies found there was no significant difference in the frequency of bronchopulmonary dysplasia between human milk-fed and donor human milk-fed, very low birth weight premature infants. The frequency of bronchopulmonary dysplasia was significantly reduced in the donor human milk group compared to the preterm formula group (odds ratio = 0.62, 95% confidence interval, $P = .02$) (Lu, 2023). No differences between groups were observed for head circumference gain, sepsis, retinopathy of prematurity, or mortality (Yu, 2019). The evidence for a beneficial effect of donor human milk on hospital length of stay was mixed (Yang, 2020; Yu, 2019).

For other outcomes in premature infants, a large meta-analysis of 11 randomized controlled trials (n = 1,390) donor human milk significantly reduced the duration of parenteral nutrition (mean difference −2.39, $P = .0002$) and the time of full enteral feeding (mean difference −0.33, $P = .0002$), while formula significantly affected physical growth measures, including weight gain, head growth, and body length (all $P < .00001$), and reduced the time for premature infants to regain birth weight ($P < .00001$). The authors suggested adding fortifiers in donated milk could improve the ability to promote the physical growth of premature infants (Li, 2022).

Regarding donor human milk use in populations other than pre-term infants, McCune (2021) found low quality, conflicting evidence of a potential benefit in feeding tolerance and gastrointestinal health, but a lack of evidence on clinical, growth, and breastfeeding outcomes. In moderate-late preterm and early term healthy infants, the benefits of supplementing mother's own milk with donor human milk instead of infant formula were inconclusive, nor was a clear effect observed on exclusive breast feeding duration, any breastfeeding, hypoglycemia, or morbidity (McClintock, 2024).

References

On August 29, 2024, 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.

8/2018: Policy references updated.

10/2019: Policy references updated. Policy ID changed to CCP.1185.

10/2020: Policy references updated.

10/2021: Policy references updated.

10/2022: Policy references updated.

10/2023: Policy references updated.

10/2024: Policy references updated.