Prior Authorization Review Panel
MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

Plan: AmeriHealth Caritas Pennsylvania	**Submission Date**: 10/27/2023
Policy Number: ccp.1185	**Effective Date:** 1/2016 **Revision Date:** October 1, 2023
Policy Name: Donor human milk	

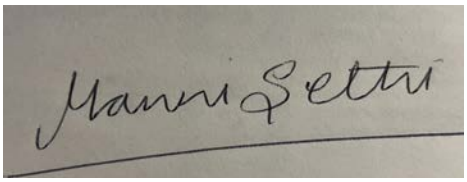
Type of Submission – Check all that apply:

New Policy
x Revised Policy*
Annual Review – No Revisions
Statewide PDL

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any clarifying information for the policy below:

See tracked changes below.

Name of Authorized Individual (Please type or print): Manni Sethi, MD, MBA, CHCQM	**Signature of Authorized Individual:** 

Donor human milk

Clinical Policy ID: CCP.1185

Recent review date: 10/2023

Next review date: 2/2025

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

AmeriHealth Caritas Pennsylvania has developed clinical policies to assist with making coverage determinations. AmeriHealth Caritas Pennsylvania 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 by AmeriHealth Caritas Pennsylvania 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 Pennsylvania 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 Pennsylvania 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 Pennsylvania clinical policies are not guarantees of payment.

Coverage policy

Donor human milk is clinically proven and, therefore, may be medically necessary when any of the following criteria are met:

- 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).
  - Infant was born at or before 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

AND

- Mother's breast milk is contraindicated or otherwise unavailable (Abrams, 2017; Section on Breastfeeding, 2012).

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 at increased risk for necrotizing enterocolitis. This disease results in the necrosis of the digestive system, and 90% of incidence of necrotizing enterocolitis occurs in preterm infants. Necrotizing enterocolitis can require surgery or eventually result in death or multiple comorbidities, and often these infants require lengthy stays in the neonatal intensive care unit. Human milk has been shown to have protective qualities that benefit those at risk for necrotizing enterocolitis in comparison to formula-based diets.

Donor human milk appears not to be in use uniformly across U.S. populations, neither while in the hospital nor on discharge. According to the American Academy of Pediatrics human milk is increasingly recognized for its nutritional and immune effects on neonates, including preterm infants. The Academy recommends donor human milk as an alternative feeding method if the mother's own milk is not available (Zhang, 2020).

As of September, 2022, 17 states and the District of Columbia had enacted legislation to provide coverage of donor human milk through their Medicaid program (Speer, 2022). Of these, over half started coverage since 2018. California was the first to provide coverage, in 1998. Specifications for coverage, such as infant condition, infant age, and mother's ability to breastfeed, vary by state (Rose, 2022).

"Safety net" hospitals, whose proportion of Medicaid patients exceeds 75%, are less likely to offer donor human milk (Rose, 2022). Medicaid covers 40% of U.S. births, and 50% of those born preterm (Markus, 2016). States with coverage of donor human milk account for 55% of U.S. very low-birthweight infants (Shah, 2023). Thus, improving access to donor human milk in the Medicaid population remains a challenge.

A survey of nurses from 97 neonatal intensive care units, covering 6,997 very low birth weight infants, found that most very low birth weight infants are not receiving human milk of any type on discharge (Hallowell, 2016). More than half (52%) were discharged on formula only, 42% on a mix of formula and human milk, and 6% solely on human milk.

The CDC 2020 Maternity Practices in Infant Nutrition and Care survey of 616 U.S. hospitals with level III or IV neonatal intensive care units reported that 13.0% of units did not have available donor milk for very low-birthweight infants. In addition, 54.7% reported that ≥80% of very low-birthweight infants receive donor milk (Boundy, 2022).

There are 572 milk banks worldwide, with Brazil having the largest number (Altobelli, 2020), 29 of which are located in the U.S. (Human Milk Banking Association, 2023a). In 2019, seven million ounces of donor milk were distributed to U.S. hospitals (Chetta, 2021). From 2007 to 2013 in Northern California, the number of hospitals that maintained donor human milk banks rose from 27 to 55, meaning 81.3% of premature infants in the region had such access by 2013 (Kantorowska, 2016). From 2010 to 2022, the amount of human donor milk dispensed in North America rose from 2 million to 10 million ounces (Human Milk Banking Association of North America, 2023b).

A mail survey of 182 U.S. level 3 Neonatal Intensive Care directors revealed that pasteurized human donor milk use is rapidly emerging, and now available in 42% of units. Larger units and those in the West and Midwest were more likely to use donor human milk, while safety-net hospitals were less likely. Lack of knowledge by medical directors of accessibility, safety, and parental receptiveness may be barriers to use (Parker, 2016).

Findings

A panel of experts from the United Kingdom and India recommend that donor pasteurized human milk is the second choice (expressed breast milk is the first choice) to feed preterm infants. Both types of milk should be fortified with human milk factor to meet the nutritional needs of premature infants (Kumar, 2017). 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 reduces the risk of developing necrotizing enterocolitis (Abrams, 2017; Section on Breastfeeding, 2012). Use of unpasteurized donor milk is not recommended (Abrams, 2017).

The American Academy of Pediatrics also supports use of donor human milk for high-risk infants when quantity of available mother's milk is insufficient and recommends access to donor human milk be based strictly on medical necessity, not ability to pay (Committee on Nutrition, 2017).

The U.S. Food and Drug Administration recommends that, after consultation with a physician, a mother can decide to feed her baby with milk from other sources, provided milk donors have been screened for safety of the milk (U.S. Food and Drug Administration, 2018).

Meta-Analyses

- A systematic review/meta-analysis of 32 studies (six of which were randomized controlled trials) found significant reductions in the risk of necrotizing enterocolitis only if premature infants are given both their own and donated breast milk (Altobelli, 2020).
- A systematic review/meta-analysis of seven randomized controlled trials of very low birth weight infants (n = 876) compared outcomes of formula with donated breast milk. Formula showed more advantages in increasing infant weight and length than donated breast milk. Formula could also significantly increase the risks of necrotizing enterocolitis and length of hospital stay (Xie, 2019).
- 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 (Silano, 2019).
- An increase in donor human milk use was associated with a statistically significant increase of any breast feeding at discharge (relative risk = 1.19) but rises in exclusive maternal breast feeding (1.12) or exclusive administration of a mother's own milk (1.08) were not significant (Williams, 2016).

- Three randomized studies (n = 814) found that supplementing mother's milk with pasteurized donor human milk did not significantly reduce bronchopulmonary dysplasia risk when compared to preterm formula (*P* = .56), but significantly reduced days on a mechanical ventilator (n = 433, *P* = .02) (Villamor-Martinez, 2018).
- 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 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 higher risk of necrotizing enterocolitis, with a significant risk ratio of 1.87 (Quigley, 2019).
- Four randomized controlled trials (n = 725) showed a significantly lower rate of necrotizing enterocolitis from donor human milk compared to formula; and no reduction in length of hospital stay for either group. Eight observational studies (n = 2,496) showed a significant reduction in length of stay in the donor human milk group (Yang, 2020).
- Seven randomized controlled trials (n = 876) compared very low birth weight infants given formula or donor milk. Formula was superior in increasing weight, but significantly increased risk of necrotizing enterocolitis and hospital stay. No differences between groups were observed for head circumference gain, sepsis, retinopathy of prematurity, or mortality (Yu, 2019).

Systematic Reviews

- A review of 31 articles identified 26 factors that act as barriers to milk donation, and 38 factors that act as facilitators. The most important facilitators include having excess milk, altruism, and helping other babies, while religious and cultural concerns are the most important barriers (Doshamangir, 2019).
- A review of the literature analyzed efficacy of donor milk for indicators (all of which mother's own milk showed positive outcomes). Improvements from donor milk were found for bronchopulmonary dysplasia and necrotizing enterocolitis, but no effect found for all-cause mortality, neurodevelopment impairment, sepsis, long term growth, and retinopathy of prematurity (Chetta, 2021).
- A review of 11 studies of neonatal outcomes concluded that donor human milk was beneficial, but not equivalent to mother's own milk (Cartagena, 2022).

Surveys

- Among 22 Northern California hospitals with a clear transition to availability of donor human milk, breast-feeding at neonatal intensive care unit discharge rose 10% (Kantorowska, 2016).
- In a survey of 83 Italian neonatal intensive care units treating 4,277 very low birth weight infants, those facilities with a human milk bank had a much greater rate of discharges with exclusive breast-feeding than did those with no milk bank (29.6% versus 16%) (Arslanoglu, 2013).

Randomized Trials and Other Large Studies

- A study of 2,804 preterm newborns with enteral milk feeding was randomized by daily rate of feeding, i.e., 30 versus 18 milliliters per kilogram of body weight. No significant differences were observed between the two groups for survival without moderate or severe neurodevelopmental disability at 24 months (65.5% versus 68.1%, *P* = .16). Rates for the two groups were similar for late-onset sepsis (29.8% and 31.1%) and necrotizing enterocolitis (5.0% and 5.6%) (Dorling, 2019).
- A study of 1,791 very low weight births were divided into those before (n = 1,334) and after (n = 457) the introduction of probiotics and donor human milk. Significantly lower mortality (7.6% versus 2.4%, *P* < .001) and incidence of sepsis (6.2% versus 3.5%, *P* = .028) were observed in the after-donor

milk/probiotic group. The after-donor group was also associated with an insignificantly lower rate of necrotizing enterocolitis (2.8% versus 1.5%, *P* = .14) and borderline significant rate of associated gastrointestinal perforation (1.6% versus 0.4%, *P* = .052) (Sharpe, 2018).

- After an increase in necrotizing enterocolitis and subsequent initiation of a protocol of enteral feeding (in the absence of hemodynamic problems), tropic feeding of five to seven days, and 20 to 30 ml/kg/day of breast or donor milk among very low birth weight infants, one hospital observed a fall in necrotizing enterocolitis rates from 7.7% (12/155 infants pre-protocol) to 0.9% (1/115 infants), significant at *P* = .008, and a reduction in mortality from 17.4% to 7.8%, significant at *P* = .02, with no increase in length of hospital stays or sepsis (Sanchez-Tamayo, 2016).
- A retrospective study of a cohort of 550 very low birth weight infants found that those given either maternal breast milk or donor human milk on more than 50% of their days in the neonatal intensive care unit had a lower rate of necrotizing enterocolitis (3.4% versus 13.5%) and lower mortality (1.0% versus 4.2%), compared with those given maternal or donor milk less than 50% of their days in the neonatal intensive care unit (Chowning, 2016).
- In a multisite study in Ontario, Canada, of children who as infants had very low birth weight and were treated with either donor milk or preterm formula, rates of necrotizing enterocolitis (measured at 90 days post-enrollment or at hospital discharge) were lower in the donor milk group, both for all stages of necrotizing enterocolitis (risk difference -7.1%, *P* = .01), and for necrotizing enterocolitis stage > II (risk difference -4.9%, *P* = .02) (O'Connor, 2016).
- Among 22 northern California hospitals that had a marked transition to availability of donor human milk, necrotizing enterocolitis rates declined by 2.6% (Kantorowska, 2016). Alternative measures to necrotizing enterocolitis incidence and mortality may demonstrate the benefits of donor human milk. Among 201 neonatal intensive care unit infants born under 1,000 g, the median hours of oxygen use were lower (24 versus 63) for infants fed donor milk versus formula-fed infants, as were hours of mechanical ventilation (60 versus 192), which researchers interpret as supporting the safety of donor milk (Verd, 2015).
- A study of infants <32 weeks gestation and <1500 grams between 2017-2022 (n = 351) revealed no significant differences between those fed mother's own milk >50% versus human donor milk >50% for fat-free mass, fat mass, and median growth velocity (Thajer, 2023).
- A cohort study of infants born <33 weeks gestation or <1500 grams (n = 1,069) showed that after the introduction of donor human milk until discharge, growth did not decrease significantly; energy and protein intake increased by 5% and frequency of zinc and vitamin D supplementation increased by >30% (Sanchez-Rosado, 2023).
- A single-institution study of births over two years (n = 7,097) determined that in those admitted to neonatal critical care, compared to white non-Hispanic mothers, lower rates of feeding only with pasterurized donor human milk were lower for black non-Hispanics (Odds Ratio 0.47), Hispanics (0.65), and other races (0.63). Similar patterns were found among well infants (Palmquist, 2022).

In addition to the observation noted above that human milk may be associated with lower growth suggesting a need for fortification, some other outcome measures may not improve with greater use of donor human milk (Chowning, 2016).

In a multisite comparison of neurocognitive measures at 18 months between children in Ontario Canada, who as infants with very low birth weight were fed with either human donor milk or formula; no significant differences were found in neurodevelopment as assessed by Bayley-III cognitive composite score, language composite score, or motor composite score, or for morbidity and mortality index, or changes in growth Z scores. However, more children in the donor milk group than in the formula group had cognitive composite scores indicative of neurological impairment, a finding which was statistically significant. Language trended in this same direction, but was not statistically significant (O'Connor, 2016).

A scoping review of 1,083 articles of donor human mik from milk banks identified few that assessed effects of infant outcomes from different milk types (Siziba, 2023).

A cross-sectional survey of 99 U.S. parents, three-fourths of whom were recipients of the Special Supplemental Nutritional Program for Women Infant Children, found that during an infant formula shortage of May 2022, the proportion of mothers using donor human milk rose from 2% to 28%, significant at $P > .0005$ (Cernioglo, 2023)

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On July 12, 2023, 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 “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.

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