Medical Policy Reference Manual
Medical Policy

2.01.080 Pasteurized Donor Human Milk

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Description

Infants less than 1500 grams (g) of weight at birth are at increased risk for growth failure due to unmet high protein and caloric needs. The American Academy of Pediatrics (AAP) recommends and encourages the use of human donor milk in LBW infants < 1500g when mother's milk is inadequate or lacking despite significant lactation support, and provided that donors are properly screened and appropriate measures are taken to collect, store and pasteurize the milk. According to the AAP, there are no clear guidelines for when human donor milk should be discontinued in infants weighing < 1500g, and that postmenstrual ages ranging from 32 to 36 weeks is commonly used in the United States because it covers the highest risk period for necrotizing enterocolitis, an inflammatory disease of the intestine that mostly affects LBW infants. The Human Milk Banking Association of North America (HMBANA), a non-profit organization, has established evidence-based screening and processing measures to ensure the safe distribution of donor milk, and offers accreditation to member milk banks who are required to follow strict guidelines on such measures. HMBANA mostly distributes to hospitals for NICU patients because priority is given to these patients however, in the outpatient settings, a clinician is usually involved in the ordering of donor human milk and supervises use. Donor human milk is also available through for-profit commercial human milk banks that are not associated with HMBANA.

Policy

Use of pasteurized donor human milk is **medically necessary** for low birth weight infants with documented birth weight of less than 1500 grams when the mother's own breast milk is unavailable or insufficient.

Otherwise, use of pasteurized donor human milk for all other indications is considered **experimental/investigational** as it does not meet TEC criteria # 2-5.

Policy Guidelines

Pasteurized donor human milk must be prescribed by a licensed healthcare provider (e.g. neonatologist, pediatrician, nurse practitioner) with documentation supporting medical necessity, and should be obtained from a milk bank that meets state-specific quality standards or from member milk banks certified by the Human Milk Bank Association of North America.

Treating providers should counsel parents or legal guardians on the benefits and risks associated with use of pasteurized donor human milk such as those cited by the Food and Drug Administration (e.g. exposure to infectious diseases, chemical contaminants, illegal and prescription drugs, and improper handling and storage).

Experimental / Investigational

The term "experimental/investigational" describes services or supplies that are in the developmental stage and are in the process of human or animal testing. Services or supplies that do not meet all 5 of the criteria listed below adopted

by the BlueCross BlueShield Association Technology Evaluation Center (TEC) are deemed to be experimental/investigational:

1. The technology* must have final approval from the appropriate U.S. government regulatory bodies; and
2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes; and
3. The technology must improve the net health outcome; and
4. The technology must be as beneficial as any established alternatives; and
5. The improvement must be attainable outside the investigational settings.

* *Technology* includes drugs, devices, processes, systems, or techniques

Rationale:

1. The technology must have final approval from the appropriate U.S. government regulatory bodies:

Currently, there are no federal or state guidelines on the preparation, handling and transfer of donor human milk and donor human milk bank operations lack regulatory oversight. The Food and Drug Administration does not currently provide oversight over the use of donor human milk but recommends potential users consult with a healthcare provider first, and warns against the potential safety risks (e.g., exposure to infectious diseases, chemical contaminants, illegal and prescription drugs; improper handling and storage) associated with inadequately screened products (e.g., donor human milk obtained from the internet).

2. The scientific evidence must permit conclusions concerning the effect on health outcomes:

The more recent studies (Colaizy et al., 2012; Rochow et al., 2013; Hair et al., 2013) on the use of pasteurized human donor milk in LBW infants show improved growth outcomes compared with earlier study findings of relatively slow growth. Improvements in growth outcomes may be attributed to increased availability of donor milk with higher nutrient content and fortification.

A retrospective study by Spatz et al. (2018) found that among 197 patients cared for in the NICU, the average number of days an infant received pasteurized human donor milk was 23 days (range: 1-134 days) and on average, these infants consumed about 195 ml daily (range: 6-1335 ml). The study did not report on growth outcomes of infants who received pasteurized donor human milk compared with those who did not, and indications for use were unclear.

Villamor-Martinez et al. (2018) conducted a systematic review and meta-analysis of randomized control trials and observational studies on the effects of pasteurized donor human milk (DHM) on bronchopulmonary dysplasia (BPD), a common complication of preterm birth, and other respiratory outcomes. The meta-analysis of the RCTs did not establish that supplementing mother's own milk (MOM) with DHM reduces BPD, however, meta-analysis of observational studies showed that supplementing MOM with DHM reduced BPD. Additionally, exclusive use of DHM reduced the risk of BPD compared to preterm formula and/or bovine milk-based fortifier. Mother's own milk (raw) offered the most protection against BPD compared to pasteurized MOM.

Sharpe et al. (2018) retrospectively assessed whether introducing pasteurized human milk and probiotics in infants born < 32 weeks gestational age or < 1500g birthweight was associated with a reduction in mortality and the incidence of necrotizing enterocolitis NEC and sepsis (N=1791). The infants were split into two groups, the pre-donor milk/probiotic cohort (n=1334) or post-donor milk/probiotic cohort (n=457). The authors found that mortality (7.6 vs. 2.4%, $P < 0.001$) and the incidence of sepsis (6.2 vs. 3.5%, $P < 0.05$) were significantly lower in the post-donor milk/probiotic group versus the pre-donor milk/probiotic group. NEC and non-NEC associated perforating gastrointestinal perforation was higher in the pre-donor milk/probiotic group although this finding was statistically insignificant.

A double-blind randomized clinical trial of LBW infants (N=373) reported by Corpeleijn et al. (2016) sought to determine whether providing donor milk in place of formula as a supplemental feeding when mother's milk is insufficient/unavailable during the first 10 days of life results in reduced incidence of serious infection, NEC and mortality. The mean gestational age was 28.4 weeks and the median birthweight was 1,066g. The authors reported similar short-term outcomes in LBW (< 1500g) infants with regard to safety and efficacy when mother's milk was insufficient and concluded that further studies investigating the impact of longer duration of use of human donor milk on short and long-term outcomes are needed.

A survey of U.S.-based NICU Medical Directors (Hagadorn et al., 2016) found that criteria for initiating and continuing donor human milk (DHM) varied among level 3 and 4 NICU's, and that LBW (<1500g to <1800g) was a common

indication for the use of DHM. The authors concluded that short and long-term outcomes for indications other than NEC warrants further study.

3. The technology must improve the net health outcome:

Trials evaluating the use of pasteurized donor human milk in LWB infants (<1500g) have covered a range of indications including growth outcomes, NEC, infection rates and mortality. Overall, the findings have been mixed with regard to these outcomes with some trials showing improved outcomes when using pasteurized donor human milk versus formula. A retrospective study (N=171) by Colaizy et al. (2012) found that LBW infants can grow appropriately when fed predominantly fortified human milk however, risk for poor growth was reported if LWB infants were fed > 75% human milk and that risk is higher when infants were fed predominantly donor human milk. Another study (prospective observational) by Hair et al. (2013) found that exclusive use of human milk-based diet with early and rapid advancement of fortification leads to meeting growth targets with a low rate of extrauterine restriction. Future trials should have well-defined indication-specific parameters around the use of donor human milk to offer consistency in evaluating the efficacy associated with use in LBW infants for key indications such as growth/neurodevelopmental status, NEC and infection/sepsis.

4. The technology must be as effective as any established alternatives:

Use of pasteurized donor human milk in LBW infants < 1500g is increasing and recommended by the American Academy of Pediatrics as an acceptable alternative to mother's own milk when it is insufficient or unavailable. The 2016 RCT by Corpeleijn et al. found that short-term outcomes (infection, NEC and mortality) were similar for LBW infants whose diet was supplemented with donor human milk versus formula when mother's own milk was insufficient or unavailable. A meta-analysis by Silano et al. (2018) found that donor milk did not provide any additional risk prevention for surgical NEC over formula and that mother's milk is the best choice when available.

5. The improvement must be attainable outside the investigational settings:

Improvements have not been established in the investigational settings and therefore, it is unknown whether improvements are attainable outside the investigational settings.

Benefit Applications

Note: For **FEP**, Check the member's contract for benefits

References

The following were among the resources reviewed and considered in developing this policy. By reviewing and considering the resources, CareFirst does not in any way endorse the contents thereof nor assume any liability or responsibility in connection therewith. The opinions and conclusions of the authors of these resources are their own and may or may not be in agreement with those of CareFirst.

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