

Topic Description and References

June 2017 NY EBBRAC Meeting

Pasteurized Donor Human Milk

Description

Maternal breast milk is the preferred food for almost all infants, regardless of gestational age or weight at birth. However, when babies are born prematurely their mothers often do not have sufficient breast milk for them and supplementation or sole feeding with either donor human milk or preterm infant formula is required. Pursuant to the 2017-18 Enacted Budget, pasteurized donor human milk (PDHM) is a mandated benefit. Therefore, the NY EBBRAC will not make a coverage recommendation, but will review the evidence surrounding the use of PDHM.

References

- Aetna. (2017). *Nutritional support policy*. Retrieved from http://www.aetna.com/cpb/medical/data/1_99/0061.html
- American Academy of Pediatrics. (2012). Breastfeeding and the use of human milk. *Pediatrics*, 129(3), e827-841. doi: 10.1542/peds.2011-3552
- American Academy of Pediatrics. (2017). Donor human milk for the high-risk infant: Preparation, safety, and usage options in the United States. *Pediatrics*, 139(1). doi: 10.1542/peds.2016-3440
- Boyd, C. A., Quigley, M. A., & Brocklehurst, P. (2007). Donor breast milk versus infant formula for preterm infants: Systematic review and meta-analysis. *Archives of Disease in Childhood Fetal and Neonatal Edition*, 92(3), F169-F175. doi: 10.1136/adc.2005.089490
- Cacho, N. T., Parker, L. A., & Neu, J. (2017). Necrotizing enterocolitis and human milk feeding: A systematic review. *Clinics in Perinatology*, 44(1), 49-67. doi: <http://dx.doi.org/10.1016/j.clp.2016.11.009>
- California WIC Association. (2012). *Ramping up for reform: Quality breastfeeding support in preventive care*. Retrieved from http://www.calwic.org/storage/documents/bf/2012/Ramping_up_for_Reform-WIC_Breastfeeding_Toolkit_2012.pdf
- Campbell Collaboration. (2015). Campbell Collaboration systematic reviews: Policies and guidelines. *Campbell Systematic Reviews, Supplement 1*. doi: 10.4073/csrs.2015.1
- Chowning, R., Radmacher, P., Lewis, S., Serke, L., Pettit, N., & Adamkin, D. H. (2016). A retrospective analysis of the effect of human milk on prevention of necrotizing enterocolitis and postnatal growth. *Journal of Perinatology: Official Journal of the California Perinatal Association*, 36(3), 221-224. doi: 10.1038/jp.2015.179
- Cigna. (2016). *Nutritional support medical coverage policy*. Retrieved from https://cignaforhcp.cigna.com/public/content/pdf/coveragePolicies/medical/mm_0136_coveragepositioncriteria_nutritional_support.pdf

Topic Description and References

June 2017 NY EBBRAC Meeting

- Cochrane Collaboration. (2011). *Cochrane handbook for systematic reviews of interventions*. Retrieved from <http://handbook.cochrane.org/>
- Corpeleijn, W. E., de Waard, M., Christmann, V., van Goudoever, J. B., Jansen-van der Weide, M. C., Kooi, E. M., . . . van Zoeren-Grobbe, D. (2016). Effect of donor milk on severe infections and mortality in very low-birth-weight infants: The early nutrition study randomized clinical trial. *JAMA Pediatrics*, *170*(7), 654-661. doi: 10.1001/jamapediatrics.2016.0183
- Guyatt, G. H., Oxman, A. D., Vist, G. E., Kunz, R., Falck-Ytter, Y., Alonso-Coello, P., & Schünemann, H. J. (2008). GRADE: An emerging consensus on rating quality of evidence and strength of recommendations. *British Medical Journal*, *336*(7650), 924-926. doi: 10.1136/bmj.39489.470347.AD
- Herrmann, K., & Carroll, K. (2014). An exclusively human milk diet reduces necrotizing enterocolitis. *Breastfeeding Medicine*, *9*(4), 184-190. doi: 10.1089/bfm.2013.0121
- Human Milk Banking Association of North America. (n.d.). *Donor human milk: Ensuring safety and ethical allocation*. Retrieved from <https://www.hmbana.org/sites/default/files/images/position-paper-safety-ethical.pdf>
- Kantorowska, A., Wei, J. C., Cohen, R. S., Lawrence, R. A., Gould, J. B., & Lee, H. C. (2016). Impact of donor milk availability on breast milk use and necrotizing enterocolitis rates. *Pediatrics*, *137*(3), e20153123. doi: 10.1542/peds.2015-3123
- Lechner, B. E., & Vohr, B. R. (2017). Neurodevelopmental outcomes of preterm infants fed human milk: A systematic review. *Clinics in Perinatology*, *44*(1), 69-83. doi: 10.1016/j.clp.2016.11.004
- Mahon, J., Claxton, L., & Wood, H. (2016). Modelling the cost-effectiveness of human milk and breastfeeding in preterm infants in the United Kingdom. *Health Economics Review*, *6*, 54. doi: 10.1186/s13561-016-0136-0
- Manzoni, P., Stolfi, I., Pedicino, R., Vagnarelli, F., Mosca, F., Pagni, L., . . . Farina, D. (2013). Human milk feeding prevents retinopathy of prematurity (ROP) in preterm VLBW neonates. *Early Hum Dev*, *89 Suppl 1*, S64-68. doi: 10.1016/s0378-3782(13)70019-7
- Martin, J. A., Hamilton, B. E., Osterman, M. L. K., Driscoll, A. K., & Mathews, T. J. (2017). Births: Final data for 2015. *National Vital Statistics Report*, *66*(1).
- Moher, D., Liberati, A., Tetzlaff, J., & Altman, D. G. (2009). Preferred reporting items for systematic reviews and meta-analyses: The PRISMA statement. *PLoS Medicine*, *6*(7), e1000097. doi: 10.1371/journal.pmed.1000097
- National Conference of State Legislatures. (2016). *Breastfeeding state laws*. Retrieved from <http://www.ncsl.org/research/health/breastfeeding-state-laws.aspx>

Topic Description and References

June 2017 NY EBBRAC Meeting

- National Institute for Health and Care Excellence. (2014). *Developing NICE guidelines: The manual*. Retrieved from <https://www.nice.org.uk/media/default/about/what-we-do/our-programmes/developing-nice-guidelines-the-manual.pdf>
- O'Connor, D. L., Gibbins, S., Kiss, A., Bando, N., Brennan-Donnan, J., Ng, E., . . . Unger, S. (2016). Effect of supplemental donor human milk compared with preterm formula on neurodevelopment of very low-birth-weight infants at 18 Months: A randomized clinical trial. *Journal of the American Medical Association*, *316*(18), 1897-1905. doi: 10.1001/jama.2016.16144
- Parker, M. G., Burnham, L., Mao, W., Philipp, B. L., & Merewood, A. (2016). Implementation of a donor milk program is associated with greater consumption of mothers' own milk among VLBW infants in a US, level 3 NICU. *Journal of Human Lactation: Official Journal of International Lactation Consultant Association*, *32*(2), 221-228. doi: 10.1177/0890334415598305
- Quigley, M., & McGuire, W. (2014). Formula versus donor breast milk for feeding preterm or low birth weight infants. *Cochrane Database of Systematic Reviews*(4). doi: 10.1002/14651858.CD002971.pub3
- Schünemann, H., Brozek, J., Guyatt, G., & Oxman, A. (2014). *GRADE handbook for grading quality of evidence and strength of recommendations. Updated October 2013. The GRADE Working Group, 2013*. Retrieved from <http://gdt.guidelinedevelopment.org/app/handbook/handbook.html>
- Scottish Intercollegiate Guidelines Network. (2009). *Critical appraisal: Notes and checklists*. Retrieved from <http://www.sign.ac.uk/methodology/checklists.html>
- Texas Medicaid & Healthcare Partnership. (2017). *Texas Medicaid provider procedures manual*. Retrieved from http://www.tmhp.com/HTMLmanuals/TMPPM/Current/index.html#t=TMPPM-PDF%2F2_Childrens_Services%2F2_Childrens_Services.htm&rhsearch=donor%20milk&rhhlterm=donor%20milk&rhsyns=%20
- Tufts Health Plan. (2016). *Medical necessity guidelines: Oral formula*. Retrieved from <https://tuftshealthplan.com/documents/providers/guidelines/medical-necessity-guidelines/oral-formula-massachusetts-products-m>
- Unger, S., Gibbins, S., Zupancic, J., & O'Connor, D. L. (2014). DoMINO: Donor milk for improved neurodevelopmental outcomes. *BMC Pediatrics*, *14*, 123. doi: 10.1186/1471-2431-14-123
- Verd, S., Porta, R., Botet, F., Gutierrez, A., Ginovart, G., Barbero, A. H., . . . Plata, II. (2015). Hospital outcomes of extremely low birth weight infants after introduction of donor milk to supplement mother's milk. *Breastfeeding Medicine: The Official Journal of the Academy of Breastfeeding Medicine*, *10*(3), 150-155. doi: 10.1089/bfm.2014.0138
- Williams, T., Nair, H., Simpson, J., & Embleton, N. (2016). Use of donor human milk and maternal breastfeeding rates: A systematic review. *Journal of Human Lactation: Official Journal of*

Topic Description and References

June 2017 NY EBBRAC Meeting

International Lactation Consultant Association, 32(2), 212-220. doi:
10.1177/0890334416632203

Zhou, J., Shukla, V. V., John, D., & Chen, C. (2015). Human milk feeding as a protective factor for retinopathy of prematurity: A meta-analysis. *Pediatrics*, 136(6), e1576-1586. doi:
10.1542/peds.2015-2372

Excluded on Full-Text Review

Boyd, C. A., Quigley, M. A., & Brocklehurst, P. (2007). Donor breast milk versus infant formula for preterm infants: Systematic review and meta-analysis. *Archives of Disease in Childhood Fetal and Neonatal Edition*, 92(3), F169-F175. doi: 10.1136/adc.2005.089490

Cacho, N. T., Parker, L. A., & Neu, J. (2017). Necrotizing enterocolitis and human milk feeding: A systematic review. *Clinics in Perinatology*, 44(1), 49-67. doi:
<http://dx.doi.org/10.1016/j.clp.2016.11.009>

Chowning, R., Radmacher, P., Lewis, S., Serke, L., Pettit, N., & Adamkin, D. H. (2016). A retrospective analysis of the effect of human milk on prevention of necrotizing enterocolitis and postnatal growth. *Journal of Perinatology: Official Journal of the California Perinatal Association*, 36(3), 221-224. doi: 10.1038/jp.2015.179

Herrmann, K., & Carroll, K. (2014). An exclusively human milk diet reduces necrotizing enterocolitis. *Breastfeeding Medicine*, 9(4), 184-190. doi: 10.1089/bfm.2013.0121

Kantorowska, A., Wei, J. C., Cohen, R. S., Lawrence, R. A., Gould, J. B., & Lee, H. C. (2016). Impact of donor milk availability on breast milk use and necrotizing enterocolitis rates. *Pediatrics*, 137(3), e20153123. doi: 10.1542/peds.2015-3123

Lechner, B. E., & Vohr, B. R. (2017). Neurodevelopmental outcomes of preterm infants fed human milk: A systematic review. *Clinics in Perinatology*, 44(1), 69-83. doi:
10.1016/j.clp.2016.11.004

Mahon, J., Claxton, L., & Wood, H. (2016). Modelling the cost-effectiveness of human milk and breastfeeding in preterm infants in the United Kingdom. *Health Economics Review*, 6, 54. doi: 10.1186/s13561-016-0136-0

Manzoni, P., Stolfi, I., Pedicino, R., Vagnarelli, F., Mosca, F., Pugni, L., . . . Farina, D. (2013). Human milk feeding prevents retinopathy of prematurity (ROP) in preterm VLBW neonates. *Early Hum Dev*, 89 Suppl 1, S64-68. doi: 10.1016/s0378-3782(13)70019-7

Parker, M. G., Burnham, L., Mao, W., Philipp, B. L., & Merewood, A. (2016). Implementation of a donor milk program is associated with greater consumption of mothers' own milk among VLBW infants in a US, level 3 NICU. *Journal of Human Lactation: Official Journal of International Lactation Consultant Association*, 32(2), 221-228. doi:
10.1177/0890334415598305

Verd, S., Porta, R., Botet, F., Gutierrez, A., Ginovart, G., Barbero, A. H., . . . Plata, II. (2015). Hospital outcomes of extremely low birth weight infants after introduction of donor milk to

Topic Description and References

June 2017 NY EBBRAC Meeting

supplement mother's milk. *Breastfeeding Medicine: The Official Journal of the Academy of Breastfeeding Medicine*, 10(3), 150-155. doi: 10.1089/bfm.2014.0138

Zhou, J., Shukla, V. V., John, D., & Chen, C. (2015). Human milk feeding as a protective factor for retinopathy of prematurity: A meta-analysis. *Pediatrics*, 136(6), e1576-1586. doi: 10.1542/peds.2015-2372

Included Studies

Corpeleijn, W. E., de Waard, M., Christmann, V., van Goudoever, J. B., Jansen-van der Weide, M. C., Kooi, E. M., . . . van Zoeren-Grobbe, D. (2016). Effect of donor milk on severe infections and mortality in very low-birth-weight infants: The early nutrition study randomized clinical trial. *JAMA Pediatrics*, 170(7), 654-661. doi: 10.1001/jamapediatrics.2016.0183

O'Connor, D. L., Gibbins, S., Kiss, A., Bando, N., Brennan-Donnan, J., Ng, E., . . . Unger, S. (2016). Effect of supplemental donor human milk compared with preterm formula on neurodevelopment of very low-birth-weight infants at 18 Months: A randomized clinical trial. *Journal of the American Medical Association*, 316(18), 1897-1905. doi: 10.1001/jama.2016.16144

Quigley, M., & McGuire, W. (2014). Formula versus donor breast milk for feeding preterm or low birth weight infants. *Cochrane Database of Systematic Reviews*(4). doi: 10.1002/14651858.CD002971.pub3

Williams, T., Nair, H., Simpson, J., & Embleton, N. (2016). Use of donor human milk and maternal breastfeeding rates: A systematic review. *Journal of Human Lactation: Official Journal of International Lactation Consultant Association*, 32(2), 212-220. doi: 10.1177/0890334416632203

