

***Preemie Parent Medical Necessity NICU sample template (not a guarantee of reimbursement):***

*Hospital name, address and date*

*CC: Your insurance carrier, address, patient's name, date of birth, patient's policy ID/group number and name of patient's policy holder.*

***Dear Hospital Administrator and Coverage Insurer:***

This letter serves as a request for prescription coverage (or appeal – select appropriate) coverage of a human-based human milk fortifier for my child, \_\_\_\_ born at 1,250 grams or below, being cared for in the NICU at \_\_\_\_\_ hospital. My provider and I agree that my child should receive only an exclusive human milk diet (EHMD) using human-based human milk fortifier until or such time as my child is mature enough to tolerate foreign cow milk proteins.

I, HCP (Insert Name) examined the child (*patient's name*) and determined the diagnosis of very low birthweight, and other potential complications constitute the clinical need for an exclusive human milk diet consisting of mom's milk and or qualified donor milk with the addition of human-based human milk fortifier for my child.

Two randomized controlled clinical trials have shown that extremely premature (EP) infants, defined as less than 1250 g birth weight, are at increased risk for developing necrotizing enterocolitis (NEC) and requiring surgical intervention for NEC if their diet, including the fortifier, is not composed of exclusively human milk with a human-based milk fortifier. The first trial published in 2009 showed an almost three-fold increase in cases of NEC in those babies who were exposed to non-human components in their diet. The odds of surgical intervention for NEC were eight-fold higher in the group with non-human components in their diet. <sup>1</sup>

The second trial published in J Pediatrics 2013 demonstrated a similar decrease in both NEC and surgical intervention in a group of EP babies solely receiving donor human milk-based products compared to those getting standard cow milk-based formula. This trial also demonstrated that infants fed

Human milk-based diet vs cow milk-based preterm formula experienced nine fewer days on TPN. <sup>2</sup>

This analysis demonstrated that provision of exclusively human-milk diet during early postnatal period, a diet devoid of cow milk protein, is associated with lower risks of death, NEC, NEC requiring surgery and sepsis in EP infants. The study results also demonstrate decreased mortality and morbidity with EHMD. <sup>3</sup>

The publication referenced below, June 2014, combined data from the two mentioned clinical trials demonstrated a dose response relationship of cow milk protein on greater mortality and morbidity for infants  $\leq 1250$  g compared to an exclusively human milk diet during early postnatal period. An exclusively human milk diet is devoid of cow milk protein and is associated with lower risks of death, NEC, NEC requiring surgery and sepsis in EP infants.<sup>3</sup>

A 2015 published study in the Journal of Perinatology concluded implementing an EHM diet in VLBW infants led to a significant decrease in the incidence of NEC. Other benefits of this diet included: decreased feeding intolerance, shorter time to full feeds, shorter length of stay, and lower hospital and physician charges for extremely premature and VLBW infants. <sup>4</sup>

In 2016 a large multicenter study demonstrated similar results for the EHMD with human milk-based fortifiers resulting in significant reductions in the incidence of NEC, mortality, late onset sepsis, retinopathy, and bronchopulmonary dysplasia.<sup>5</sup>

Further supportive publications from March 2020 addresses quality improvement outcomes and cost avoidance benefits of human-based human milk fortifier on clinical outcomes and cost.<sup>6</sup>

In addition to the improved clinical outcomes a health economics analysis of the acute care costs for EP infants published recently showed a net savings of between \$8000-9000 per EP infant fed a completely human milk-based diet. All the publications are referenced below for your review.<sup>7,8</sup>

Based upon the foregoing, research supports my plan to administer human milk-based fortifier with/without human donor milk is/was medically necessary and that the cost of this product should be covered to reduce mortality and morbidities commonly associated with prematurity and that administering cow milk-based fortifiers/formula or products of vegetable origin for this patient is not medically justifiable.

If you have questions about this patient or would like additional information to assist your review, please contact me at *(insert contact) information*. Thank you for your consideration.

Sincerely,

***Insert Physician or Nurse Practitioner's name and title***

#### References:

1. Sullivan S, Schanler RJ, Kim JH, et al. An exclusively human milk-based diet is associated with a lower rate of necrotizing enterocolitis than a diet of human milk and bovine milk-based products. *J Pediatr*. 2010;156(4):562-567. doi:10.1016/j.jpeds.2009.10.040
2. Cristofalo EA, Schanler RJ, Blanco CL, et al. Randomized trial of exclusive human milk versus preterm formula diets in extremely premature infants. *J Pediatr*. 2013;163(6):1592-1595. doi:10.1016/j.jpeds.2013.07.011
3. Abrams SA, Schanler RJ, Lee ML, Rechtman DJ. Greater mortality and morbidity in extremely preterm infants fed a diet containing cow milk protein products. *Breastfeed Med*. 2014;9(6):281-285. doi:10.1089/bfm.2014.0024
4. Assad M, Elliott MJ, Abraham JH. Decreased cost and improved feeding tolerance in VLBW infants fed an exclusive human milk diet. *J Perinatol*. 2016;36(3):216-220. doi:10.1038/jp.2015.168
5. Hair AB, Peluso AM, Hawthorne KM, et al. Beyond necrotizing enterocolitis prevention: improving outcomes with an exclusive human milk-based diet. *Breastfeed Med*. 2016;11(2):70-74. doi:10.1089/bfm.2015.0134
6. Hannah Ryan Fischer, et al. The Business Case for Quality Improvement. *Journal of Perinatology*: March 2020; doi.org/10.1038/s41372-020-0660-y
7. Ganapathy V, Hay JW, Kim JH. Costs of necrotizing enterocolitis and cost-effectiveness of exclusively human milk-based products in feeding extremely premature infants. *Breastfeed Med*. 2012;7(1):29-37. doi:10.1089/bfm.2011.0002
8. Huston RK, Markell AM, McCulley EA, et al. Decreasing necrotizing enterocolitis and gastrointestinal bleeding in the neonatal intensive care unit: the role of donor human milk and exclusive human milk diets in infants  $\leq$  1500 g birth weight. *ICAN*. 2013;6(2):86-93. doi:10.1177/1941406413519267