CABINET FOR HEALTH AND FAMILY SERVICES
DEPARTMENT FOR MEDICAID SERVICES

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July 30, 2013

TO: Hospital Providers (PT 01)
Provider Letter # A-252
Physicians (PT 64)
Provider Letter # A-373

RE: HB366 and "Milk Fortifier"

To All Relevant Parties,

Pursuant to HB 366 (See Attachment: A), the Department for Medicaid Services acknowledges that any product conforming to the referenced description of "Milk Fortifier" is a covered benefit for eligible Medicaid beneficiaries. Currently this "product" is prescribed under very specific clinical circumstances for prevention of Necrotizing Enterocolitis and associated comorbidities and requires administration under the direction of a treating physician.

Reimbursement for this covered benefit has been available *and* continues to be covered under the appropriately billed Newborn Intensive Care Unit (NICU) DRG (See Attachment: B).

Any questions regarding this coverage can be directed to the covered beneficiaries managed care plan (MCO), or the Department for Medicaid Services for individuals not enrolled in a MCO, with specific reference to information reflecting appropriateness of care information referenced above.

Respectfully,

John Langefeld, M.D.
Chief Medical Officer

CABINET FOR HEALTH & FAMILY SERVICES
Department for Medicaid Services

A

KRS 304.17A-139 (Excerpt)

(4) *(a) For the purposes of this subsection:*

1. "Milk fortifier" means a commercially prepared human milk fortifier made from concentrated one hundred percent (100%) human milk.

2. "One hundred percent (100%) human diet" means the supplementation of a mother's expressed breast milk or donor milk with a milk fortifier.

(b) A health benefit plan that provides prescription drug coverage shall provide that coverage for a one hundred percent (100%) human diet, if the one hundred percent (100%) human diet and supplemented milk fortifier products are prescribed for the prevention of Necrotizing Enterocolitis and associated comorbidities, and are administered under the direction of a physician. Coverage under this subsection may be subject to a cap of fifteen thousand dollars ($15,000) per infant, for each plan year, subject to annual inflation adjustments.

B

Applicable Centers for Medicare and Medicaid Services (CMS) DRGs

DRG Versions 18-24

DRG	CMS Neonate DRG Description	Length of Stay
386	Extreme immaturity or respiratory distress syndrome	Review <8 days
387	Prematurity with major problems	Review <6 days
388	Prematurity w/o major problems	Review <5 days
389	Full term w/ major problems	Review <5 days
390	Neonate w/ other significant problems	Review <5 days

DRG Version 25

DRG	CMS Neonate DRG Description	Length of Stay
790	Extreme immaturity or respiratory distress syndrome	Review <8 days
791	Prematurity with major problems	Review <6 days
792	Prematurity w/o major problems	Review <8 days
793	Full term w/ major problems	Review <8 days
794	Neonate w/ other significant problems	Review <5 days

Applicable All Payer (AP) DRGs

DRG	AP DRG Description	Length of Stay
622	Significant OR Procedure w/ multiple major problem	Review <15 days
626	W/o significant OR Procedure w/ multiple major problems	Review <11 days
627	W/o significant OR Procedure w/ major problem	Review <5 days
630	W/o significant OR Procedure w/ other problem	Review <5 days

Press Release

May 7, 2013, 9:09 a.m. EDT

Prolacta Praises Landmark Legislation in Kentucky Mandating Human Milk Diet for Preemies in Jeopardy of Intestinal Disease Legislation is Kentucky's First Health Care Mandate in 21 Years and Becomes First in the Country to Pass a Law Supporting Human Milk Nutrition for Premature Infants

MONROVIA, Calif., May 07, 2013 (BUSINESS WIRE) -- Prolacta Bioscience, the pioneer of human milk nutrition for premature infants in the neonatal intensive care unit (NICU), is applauding the groundbreaking decision by the State of Kentucky in support of a 100% human milk diet for premature infants in the NICU. This will be the first time since 1992 that the State has passed a healthcare mandate. Kentucky now becomes the first state in the country to pass a law that supports exclusive breast milk nutrition for critically ill premature infants. This means that hospitalized preemies will now have the benefit of being fed an exclusive breast milk diet without being exposed to any formula products, which are typically made from cow milk.

The legislation states that a health insurance plan with a prescription drug benefit will be required to provide that coverage for a 100% human milk diet, if it is prescribed by a physician in order to prevent necrotizing enterocolitis (NEC) and associated comorbidities. NEC is an acute, dangerous intestinal disease that often times leads to surgery, and sometimes death in preemies. It is one of the leading causes of death in premature infants.
Critically ill premature infants in the NICU will now be eligible for the health insurance benefit of Prolacta's 100% human milk-derived human milk fortifier (HMF) Prolact+ H(2)MF(R), if the neonatologist believes that the preemie is at risk for developing NEC. Kentucky's legislature passed the bill into law after studying the clinical trials which have demonstrated that when Prolact+ H(2)MF was added to human milk, the odds of developing NEC was reduced by 77% in premature infants weighing between 500g and 1250g at birth, when compared to infants receiving human milk fortified with cow milk-based HMF, or compared to preterm infant formula, when the supply of mother's own milk was insufficient.

Additionally, the analysis and Fiscal Impact Statement by the State's actuary indicated that the legislation would not increase administrative expenses of the insurer, nor would it increase premiums. This complements a 2011 study conducted by Dr. Joel Hay with the department of clinical pharmacy & pharmaceutical economics & policy, from the University of Southern California, Los Angeles, California, demonstrating that a 100% breast milk diet which included a fortifier made exclusively from human milk for extremely premature infants may result in a net savings of medical care resources by reducing the incidence of NEC, when compared to feeding these infants HMF produced from cow milk.

The bill was co-sponsored by Representative Joni Jenkins and Senator Julie Denton, and newly elected Senator Morgan McGarvey helped in this accomplishment as a result of a personal experience. Prior to becoming Senator, he and his wife had premature infants in the NICU, born at 26 weeks. The NICU in which their newborns were hospitalized did not have 100% human milk-based HMF available, so Senator McGarvey and his wife had to make the request to hospital administration. They saw the benefits of the human milk diet themselves, and as a result, when he became Senator, he decided that this legislation would be one of the first he wanted to help bring to fruition.

"My wife and I know firsthand how fragile extremely premature babies are when they enter this world," said Senator McGarvey. "Thanks to advances in neonatology, babies born at a pound and a half now have a chance, as a result of a fortified diet made exclusively from breast milk. Our children are thriving today because of the human milk nutrition they received, and we knew we wanted to do all we could to make sure every Kentucky family struggling with premature birth has access to that same standard of care."
HMF is often needed to provide the added nutrition necessary for extremely premature infants in the NICU since they have extra nutritional needs above what can be provided by their mother's milk or donor milk alone. Prolacta's HMF, Prolact+ H(2)MF,can only be administered in a hospital setting by prescription and cannot be purchased directly by consumers.

Dr. David Adamkin, Director of Neonatology, neonatologist at University of Louisville for the McGarvey twins reinforced the importance of a human milk-based diet. "I want to thank Senator McGarvey and congratulate the Kentucky Legislature and Governor for taking this bold step to help premature babies in the Commonwealth of Kentucky. The state is now unique and the first to make this commitment to improving outcomes and decreasing medical risk for these fragile infants."

"Kentucky's decision to pass this legislation underscores their undeniable support of the best care and well-being for NICU preemies," said Scott Elster, CEO of Prolacta. "Studies show that premature infants who are fed exclusive human milk diets have a better chance of survival. Quality of life is improved for these fragile infants without increasing costs to the state. Kentucky's leadership has now enabled doctors to provide the best standard of care for its most vulnerable population."

The use of Prolact+ H(2)MF has grown considerably over the past few years in NICUs across the country, as data continues to underscore the benefits of exclusive human milk nutrition over cow milk-based nutrition. Prolact+ H(2)MF is the only HMF made exclusively from human milk, as opposed to cow milk. Additionally, there was a revised policy statement released by the American Academy of Pediatrics in 2012 recommending that all preterm infants receive human milk, whether their mother's own milk or pasteurized donor breast milk if mother's own milk was unavailable.

About Prolacta Bioscience Prolacta Bioscience, Inc. (http://www.prolacta.com) is a life science company dedicated to improving quality of life by Advancing the Science of Human Milk(TM). Prolacta creates specialty formulations made exclusively from human milk for the nutritional needs of critically ill, premature infants in neonatal intensive care units. It is the first and only company to provide a human milk fortifier made from 100% human milk, Prolact+ H(2)MF. They operate a pharmaceutical grade processing plant and have designed and patented processes that enable them to make their one-of-a-kind life-saving products. Prolacta is committed to making a meaningful difference in the lives of the most vulnerable infants through world-class research and innovative products.

http://cts.businesswire.com/ct/CT?id=bwnews&sty=20130507005810r1&sid=cmtx4&distro=nx **SOURCE: Prolacta Bioscience**