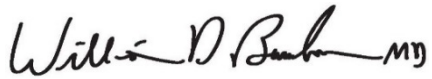


**Prior Authorization Review Panel  
MCO Policy Submission**

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

<b>Plan: AmeriHealth Caritas Pennsylvania</b>	<b>Submission Date:</b> April 28, 2020
<b>Policy Number:</b> CCP.1051	<b>Effective Date:</b> 3/2014 <b>Revision Date:</b> April 7, 2020
<b>Policy Name: Breast pumps</b>	
<b>Type of Submission – Check all that apply:</b>  <input type="checkbox"/> New Policy <input checked="" type="checkbox"/> Revised Policy* <input type="checkbox"/> Annual Review – No Revisions <input type="checkbox"/> Statewide PDL	
<b>*All revisions to the policy <u>must</u> be highlighted using track changes throughout the document.</b>  <b>Please provide any clarifying information for the policy below:</b>  Please see revisions below using tracked changes.	
<b>Name of Authorized Individual (Please type or print):</b>  William D. Burnham, MD	<b>Signature of Authorized Individual:</b>  

# Breast pumps

Clinical Policy ID: CCP.1051

Recent review date: 4/2020

Next review date: 8/2021

Policy contains: Electric breast pumps, hospital breast pumps, manual breast pumps.

*AmeriHealth Caritas Pennsylvania has developed clinical policies to assist with making coverage determinations. AmeriHealth Caritas Pennsylvania's 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's 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's clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, AmeriHealth Caritas Pennsylvania will update its clinical policies as necessary. AmeriHealth Caritas Pennsylvania's clinical policies are not guarantees of payment.*

## Coverage policy

Breast pumps are clinically proven and, therefore, medically necessary when any of the following criteria are met:

- The mother is unable to nurse and provide adequately for her infant(s).
- Temporarily while the mother takes medications that can be found in breast milk and would injure her infant(s).
- Personal-use electric pumps or hospital-grade electric pumps may be necessary if manual breast pumps do not adequately meet maternal or infant needs.
- A new set of breast pump supplies (i.e., initial tubing, shields, and bottles) are necessary with each subsequent pregnancy (American College of Obstetricians and Gynecologists, 2007, United States Breastfeeding Committee and Breastfeeding Center, 2013, American Academy of Family Physicians, 2018).

### Limitations

No limitations were identified during the writing of this policy.

### Alternative covered services

Bright Start® services and lactation specialists as part of hospital delivery.

## Background

The World Health Organization has reiterated its strong support for the exclusive nutrition of infants through breast milk for the first six months of life, and up to and exceeding the first year, citing studies that have demonstrated the benefits of breast milk over other sources of nutrition. Policy statements from various groups (Institute of Medicine, 2011; American Academy of Pediatrics, 2012; American College of Obstetricians and Gynecologists, 2016) arrive at similar conclusions. Benefits to breast feeding found in the medical literature include:

- Improved health to infants. Benefits include reduced risk of otitis media, urinary tract infection, respiratory tract infection, bronchiolitis, necrotizing enterocolitis, atopic dermatitis, gastroenteritis, inflammatory bowel disease, diabetes, childhood leukemia (acute lymphocytic leukemia and acute myeloid leukemia), sudden infant death syndrome, infant mortality, asthma, allergies, and celiac disease.
- Improved health to mothers. Benefits include reduced risk of postpartum blood loss, postpartum depression, risk of subsequent child abuse and neglect (after adjusting for risk factors), and an increase in rapid uterus involution (Ip, 2007).
- The American Association of Pediatrics recommendations also include contraindications against breast feeding, including presence of certain infant metabolic disorders, and maternal conditions, such as tuberculosis, brucellosis, human T-cell lymphotropic virus type I or II, varicella, H1N1 influenza, and presence of particular narcotic drugs. Reductions in smoking, alcohol consumption, and a balanced diet are also recommended for breast feeding mothers (American Academy of Pediatrics, 2012).

The U.S. Department of Health and Human Services publication Healthy People 2020 set a target that 81.9% of mothers nurse at least some of the time, with 44.3% continuing exclusive nutritional support for their babies through breast milk until three months, and 23.7% until six months. National figures for 2012 include 76.9%, 36.0%, and 16.3% (Centers for Disease Control and Prevention, 2014). Disparities between racial and ethnic groups have persisted; 80.6% of Latino mothers initiate breast feeding, while only 58.1% of African American mothers do so (U.S. Department of Health and Human Services, 2010).

An estimated five percent of women have insufficient breast milk to be able to provide complete nutrition for their infants, such as women with tubular breasts or hypoplasia. Those women may need to supplement with infant formulas. Anatomic considerations, such as inverted nipples, surgical or infectious disruption of the areola, or other breast surgeries, generally do not preclude a woman from nursing according to the American College of Obstetricians and Gynecologists, but may affect the infant's ability to latch on long enough to obtain adequate nutrition (American College of Obstetricians and Gynecologists, 2007).

Mastitis and pain may require a woman to temporarily discontinue nursing but use a breast pump to continue stimulation of milk production. Some women may prefer to express milk using a breast pump between nursing episodes to supplement their infant's time directly at the breast. Some employers may not allow a woman to nurse at work, so she may need to pump during those periods. Many women may not be able to nurse if traveling or in public areas, so they may find that the use of a breast pump allows greater flexibility.

Breast pumps are devices that extract milk from lactating women. Pumps can be manual, electric, or the hospital type needed to provide breast milk for premature infants. Manual pumps require repetitive use of pressure generated by hand or foot power. Manual pumps allow the woman to adjust the pressure to generate the adequate expression of milk without causing pain. However, they may cause fatigue and are often less efficient than electric pumps. Personal-use electric pumps are larger than manual pumps and generate greater suction.

As such, the time required for expression of milk is shorter. These pumps are intended for a single user and may require more sterilization of the tubing. Hospital-grade electric pumps are intended for multiple users with accessories for each individual. They may provide greater stimulation to maintain adequate lactation than either the manual or personal electric pump (American Association of Family Practitioners, 2018).

Once collected, milk is stored in a container. This “expressed” breast milk can be donated to milk banks. Milk may be kept at room temperature no longer than six hours, refrigerated no more than eight days, and frozen no more than 12 months.

The proportion of mothers who breast feed continues to rise. From 2004 to 2013 births, increases were observed in infants ever breastfed (73.8% to 81.1%), breastfed at six months (41.5% to 51.8%), breastfed at 12 months (20.9% to 28.7%), exclusively breastfed at three months (30.5% to 44.4%) and exclusively breastfed at six months (11.3% to 22.2%) (Centers for Disease Control and Prevention, 2018).

Most breast feeding mothers have used a pump. A national survey from 2005 – 2007 found that the percentage of mothers who pumped milk or tried to do so was 85.8 percent for infants age 0 - 2 months, 77.5% for infants age 3 - 5 months, and 59.9% for infants age 6 - 7 months (Centers for Disease Control and Prevention, 2014).

## Findings

The 2013 policy for electric pumps by the United States Breastfeeding Committee and National Breastfeeding Center recommends that one electric pump purchase per birth event should be considered medically necessary. In addition, electric pump rentals every 36 months should be considered medically necessary to support lactation initiation after mothers and infants are separated and when the mother cannot breastfeed due to complications, congenital anomalies, and other conditions. In addition, two kits per pregnancy are considered necessary to allow double pumping i.e., both breasts simultaneously (United States Breastfeeding Committee and National Breastfeeding Center, 2013). The 2013 policy was similar to that issued by the American College of Obstetricians and Gynecologists several years earlier (American College of Obstetricians and Gynecologists, 2007).

The American Academy of Family Practitioners recommends use of a hand pump when mother and infant are separated briefly, and a hospital-grade electric pump for longer and more frequent separations. When an infant must be bottle fed, it is encouraged to not feed an entire bottle whenever possible, which will add an extra burden on the mother to produce more milk when breastfeeding resumes (American Academy of Family Physicians, 2018).

The Affordable Care Act mandates that insurance plans cover the cost of breast pumps and breastfeeding counseling (American College of Obstetricians and Gynecologists, 2019).

A 2015 Cochrane review of 17 studies (n = 961) comparing pumping methods, hand expression, and pump type generally found no differences in milk contamination, volume, and energy content. Initiating milk pumping within 60 minutes of birth for a very low birth-weight baby obtained greater milk quantity than for those who initiated pumping 1 – 6 hours after birth. Most studies had low risk of bias (Becker, 2015).

A 2016 follow-up to this study included 22 trials with 1,339 mothers of infants in neonatal units to evaluate efficacy of pumps, and 14 trials of 730 mothers with healthy infants at home. Studies were often heterogeneous or not

comparable, and suffered from small sample sizes. However, authors found that low-cost interventions such as initiating milk expression even before breast feeding, relaxation, massage, warming the breasts, hand expression, and lower cost pumps may be as or more effective than large electric pumps (Becker, 2016).

A systematic review of healthy term infants reviewed seven studies on the association between expressing and successful breast feeding. Results were mixed: some studies found expression resulted in successful breast feeding for long periods, while some did not (Johns, 2013).

A systematic review of 10 studies showed mothers using breast pumps for at least one year significantly increased the average duration of exclusively breastfed cases (8.3 months versus 4.7 months) (Kim, 2018).

A systematic review of 48 studies determined that expression using simultaneous pumping with an electric pump has health advantages in the infant's first two weeks of life (Renfrew, 2009).

Breast pumps may be needed more frequently in special needs populations. In a study of 157,187 mothers (8.8% of which had gestational diabetes mellitus), the percent of mothers with diabetes utilizing breast pumps was significantly greater (odds ratio 1.28) compared to those without diabetes (Oza-Frank, 2017).

A review notes that the majority of new U.S. mothers use breast pumps in the first four months after births to achieve milk-feeding goals. It also notes that there are few guidelines to aid mothers and their providers in choosing the most appropriate type of pump, and using it in the most appropriate manner. The review assesses means of selecting pumps and their use by the extent to which the pump replaces the infant for milk removal, and the stage of lactation (Meier, 2016).

A quality-improvement project at Cincinnati Children's Hospital Medical Center added several interventions, including a loaner breast pump program for uninsured and underinsured mothers, to neonatal intensive care unit infants < 1500 grams at birth. Within 11 months, the percent of infants receiving at least 500 milliliters of human milk per kilogram rose from 50% to 80%, with the most recent average 1,111 mL/kg (Ward, 2012).

Providing free home breast pumps, which the Tennessee Medicaid program does, was one factor in improving breast milk-feeding rates from 22% to 88% over five years, for very low birth-weight infants at an inner-city hospital (Dereddy, 2015).

There have been no randomized controlled trials comparing efficiency of hand and electric pump expression for mothers of very low birth-weight infants. A study (n = 12 hand, n = 14 electric) documented during the first seven days after birth, and continuing to 28 days after, mothers using electric pump expression had twice the cumulative milk production than those using hand expression (Lussier, 2015). Another review found different results; after two months, hand expression improved eventual breast feeding rates compared to electric pumping (Flaherman, 2012).

A study of 1,844 mothers who used breast pumps found 62% reported pump-related problems, the most common of which was the pump did not extract sufficient milk. Another 15% reported an injury, typically sore nipples. Learning from written or video instructions, using a battery-operated pump and intending to breast feed less than 12 months were associated with elevated risk of problems (Qi, 2014).

A 2017 review found that donor high-dose human milk does not reduce risks to Neonatal ICU infants as that from the mother (Meier, 2017).

A review of 355 inner-city infants given free breast pumps at birth with a visit 1.5-3.5 months after birth showed African-Americans, versus other races, had significantly lower rates of any breastfeeding (38.9% versus 93.8%) and exclusive breastfeeding (17.8% versus 50.0%). The African-American rate of exclusive breastfeeding was similar with and without a breast pump (19.4% and 16.3%); rates of any breastfeeding were higher for those with no breast pump (46.9% and 31.4%,  $P = .004$ ). Authors concluded available breast pumps were not linked with more exclusive breastfeeding (Bream, 2017).

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On January 8, 2020, 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 “breast pump” and “electric breast pump.” 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

9/2013: initial review date and clinical policy effective date: 3/2014

2/2019: References updated. The policy number was changed from CP#12.02.01 to CCP.1051.

1/2020: References updated.