



Clinical Policy Title: Breast pumps

Clinical Policy Number: CCP.1051

Effective Date: March 1, 2014
Initial Review Date: September 18, 2013
Most Recent Review Date: April 2, 2019
Next Review Date: April 2020

Policy contains:

- Electric breast pumps.
- Hospital breast pumps.
- Manual breast pumps.

Related policies:

CCP.1185 Donor human milk
CCP.1052 Nutritional support

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

Coverage policy

AmeriHealth Caritas considers the use of breast pumps to be 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:

All other uses of breast pumps are not medically necessary.

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 arrive at similar conclusions (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 percent of mothers nurse at least some of the time, with 44.3 percent continuing exclusive nutritional support for their babies through breast milk until three months, and 23.7 percent until six months. National figures for 2012 include 76.9 percent, 36.0 percent, and 16.3 percent (Centers for Disease Control and Prevention, 2014). Disparities between racial and ethnic groups have persisted; 80.6 percent of Latino mothers initiate breast feeding, while only 58.1 percent 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, percent 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, 2017).

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 percent for infants age 3 - 5 months, and 59.9 percent for infants age 6 - 7 months (Centers for Disease Control and Prevention, 2014).

Searches

AmeriHealth Caritas searched PubMed and the databases of:

- UK National Health Services Centre for Reviews and Dissemination.
- Agency for Healthcare Research and Quality.
- The Centers for Medicare & Medicaid Services.
- Cochrane reviews.

We conducted searches on February 14, 2019. Search terms were: “breast pump” and “electric breast pump.”

We included:

- **Systematic reviews**, which pool results from multiple studies to achieve larger sample sizes and greater precision of effect estimation than in smaller primary studies. Systematic reviews use predetermined transparent methods to minimize bias, effectively treating the review as a scientific endeavor, and are thus rated highest in evidence-grading hierarchies.
- **Guidelines based on systematic reviews.**
- **Economic analyses**, such as cost-effectiveness, and benefit or utility studies (but not simple cost studies), reporting both costs and outcomes — sometimes referred to as efficiency studies — which also rank near the top of evidence hierarchies.

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 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 percent 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 percent to 80 percent, 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 percent 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 percent reported pump-related problems, the

most common of which was the pump did not extract sufficient milk. Another 15 percent 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 percent) and exclusive breastfeeding (17.8 versus 50.0 percent). The African-American rate of exclusive breastfeeding was similar with and without a breast pump (19.4 and 16.3 percent); rates of any breastfeeding were higher for those with no breast pump (46.9 and 31.4 percent, $P = .004$). Authors concluded available breast pumps were not linked with more exclusive breastfeeding (Bream, 2017).

Policy updates:

A total of one guideline/other and three peer-reviewed articles were added to, and four peer-reviewed references removed from this policy in February 2019.

The policy number was changed from CP#12.02.01 to CCP.1051 in February, 2019.

References

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Centers for Medicare & Medicaid Services National Coverage Determinations:

No National Coverage Determinations identified as of the writing of this policy.

Local Coverage Determinations

No Local Coverage Determinations identified as of the writing of this policy.

Commonly submitted codes

Below are the most commonly submitted codes for the service(s)/item(s) subject to this policy. This is not an exhaustive list of codes. Providers are expected to consult the appropriate coding manuals and bill accordingly.

CPT Code	Description	Comment
N/A		

ICD-10 Code	Description	Comment
O91.03	Infection of nipple associated with lactation	
O91.13	Abscess of breast associated with lactation	
O91.23	Nonpurulent mastitis associated with lactation	
O92.13	Cracked nipple associated with lactation	
O92.20-O92.4	Other and unspecified disorders of breast associated with pregnancy and the puerperium	
O92.70-O92.79	Other and unspecified disorders of lactation	

HCPCS Level II Code	Description	Comment
A4281-A4286	Breast pump parts and supplies, replacement	
E0602	Breast pump, manual, any type	
E0603	Breast pump, electric (AC and/or DC), any type	
E0604	Breast pump, hospital grade, electric (AC and/or DC), any type	