



# Medical Coverage Policy

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## Breast Pumps

### Table of Contents

Overview .....	1
Coverage Policy.....	1
General Background.....	2
Coding/Billing Information.....	4
References .....	5

### Related Coverage Resources

- [Pediatric Intensive Feeding Programs](#)
- [Preventive Care Services](#)
- [Speech Therapy](#)

#### **INSTRUCTIONS FOR USE**

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

### Overview

This Coverage Policy addresses breast pumps which are medical devices used by breastfeeding women to extract or express their breast milk.

### Coverage Policy

**Coverage for a breast pump and supplies varies across plans. Refer to the customer's benefit plan document for coverage details.**

**If coverage is available for breast pumps, the following conditions of coverage apply.**

**A manual or standard electric breast pump is considered medically necessary for the initiation or continuation of breastfeeding.**

**Rental of a heavy duty electrical/hospital grade breast pump is considered medically necessary for the initiation or continuation of breastfeeding when a standard electric breast pump has been tried and failed, and ANY of the following indications is in effect:**

- Direct breastfeeding is not possible because of a separation due to the prolonged or repeat hospitalization of either the infant or the mother.
- The infant has a medical condition or congenital anomaly that prevents effective breastfeeding.
- The mother has a medical condition or anatomical anomaly that prevents effective breastfeeding.

**NOTE: Trial of a standard electric pump is not required if the infant is in the neonatal intensive care unit (NICU).**

**Rental of a heavy duty electrical/hospital grade breast pump when requested solely for convenience is considered not medically necessary.**

**A wireless breast pump (e.g., Willow Wearable Breast Pump) is considered experimental, investigational or unproven.**

## General Background

It is recommended that most infants, with some exceptions, be breast-fed and/or receive expressed human milk exclusively for the first six months of life and continue breastfeeding with complementary foods for at least one year. Breast milk is widely acknowledged as the ideal source of nutrition for infants, with compelling advantages such as a decreased incidence of a number of acute and chronic diseases, widely documented in the literature. Also, preterm infants who receive breast milk have been reported to experience greatly reduced rates of sepsis and necrotizing enterocolitis compared to infants who receive milk substitutes. Breast milk has also been associated with enhanced retinal development and visual acuity in preterm infants (American Academy of Family Physicians [AAFP], 2014).

Infants with anomalies such as cleft lip and/or cleft palate, Down syndrome, or congenital heart disease may have difficulty with breastfeeding. A breast pump may be needed to support the breastfeeding process. Medical conditions such as breast abscess or mastitis may require frequent mechanical pumping of the affected breast until antibiotic therapy is completed. Anatomical abnormalities of the breast (e.g., flat or inverted nipples), may impact breastfeeding in a small percentage of cases. Treatment has historically included Hoffman's exercises and nipple cups however the effectiveness of these treatments has been questioned. In the early neonatal period, a breast pump may be of help in women with flat or inverted nipples (Newton, 2012). There are conditions for which breastfeeding is contraindicated such as, infants with galactosemia, mothers infected with human immunodeficiency virus, mothers with human T-cell lymphotropic virus type I or II and mothers with active untreated tuberculosis (American Academy of Pediatrics [AAP], 2012).

### Breast Pumps

Breast pump devices may be manual, battery-powered, or electric. Manual breast pumps are designed to use the strength of the hand or arm muscles for pumping one breast at a time. Some manual pumps use tubes to create a vacuum that express milk into an attached container. There are bicycle horn pumps, which consist of a rubber ball attached to a breast shield. This type can be difficult to keep dry and clean (FDA, 2018). Battery-powered pumps use batteries for creating suction, thus minimizing muscle fatigue. Most are designed for pumping one breast at a time and are suggested for occasional use. For most women, electric pumps stimulate the breast more effectively than manual expression or hand pumps. Electric pumps are used mainly to continue breastfeeding when a mother is not able to breastfeed for several days or more. Hospital grade models are recommended and typically used during an extended separation of mother and infant due to hospitalization caused by illness or prematurity.

The newest type of breast pump is one that is wireless. An example of this device is the Willow Wearable Wireless Breast Pump. The wireless breast pump has no external tubes or cords which allows the device to attach to the breast and be concealed in a bra, while pumping the milk into an internal disposable bag. Since the pump is completely hidden, a concern regarding a wireless pump is that it would be difficult to assess the effectiveness of milk expression, the amount of milk collected, and/or if the device was malfunctioning or needed to be charged. There is insufficient evidence in the published peer-reviewed literature to support the safety and effectiveness of the wireless breast pump.

## **U.S. Food and Drug Administration (FDA)**

Manual breast pumps are considered Class I medical devices, requiring manufacturers to register the device with the FDA. Powered breast pumps are considered Class II medical devices, requiring that manufacturers submit a premarket 510(k) notification to the FDA.

## **Literature Review**

The safety and effectiveness of breast pumps, primarily standard electric and hospital grade pumps, have been demonstrated by several randomized controlled trials (RCTS) (Hopkinson and Heird, 2009; Hayes, et al., 2008; Meier, et al., 2008; Slusher, et al., 2007).

Becker et al. (2016) conducted an updated Cochrane review on methods of milk expression for lactating women. The review consisted of 41 trials for inclusion (n=2293), with 22 trials (n=1339) contributing data for analysis. The included studies were published and unpublished randomized or quasi-randomized controlled trials that compared one method of milk expression (e.g., pumping) with another method any time after birth. The objectives were to assess maternal satisfaction with the method of expression, bacterial contamination, effectiveness of expression method, effect on milk composition, and cost implication (related to infant length of stay in a neonatal unit). The risk of bias was variable. The content was updated without any changes to the conclusions. The most suitable method of milk expression may depend on the time since birth and mother/infant preference. There was reported satisfaction with relaxation and greater milk expression when mothers listened to music, warmed and massaged the breast, and pumped frequently. Hand expression and lower cost pumps may be as effective, or more effective than larger breast pumps for some outcomes. There were no differences in the contamination of milk and the level of breast pain across methods of expression. There was some variation in nutrient content across methods, this may be relevant to some infants. Small sample sizes, large standard deviations, and the diversity of the interventions argue caution in applying these results. Furthermore, the authors concluded that more research is needed for trials on hand expression, relaxation and other techniques that do not have a commercial potential.

Despite the lack of evidence comparing the different types of breast pumps and demonstrating superiority of one over another, health professionals typically recommend the use of a hospital grade electric breast pump with a double collection system for mothers of neonates in special care nurseries, in order to create and sustain an adequate milk supply (Slusher, et al., 2007; Meier, 2001).

Studies comparing wireless breast pumps to standard electric or hospital grade breast pumps are lacking. Data supporting the safety and effectiveness of the wireless pumps are lacking.

## **Professional Societies/Organizations**

**Academy of Breastfeeding Medicine (ABM):** In the clinical protocol regarding peripartum breastfeeding management for the healthy mother and infant at term, the ABM stated that if the infant needs to be separated from the mother, the mother should be instructed on how to maintain lactation through instruction on manual and mechanical expression. According to the ABM, there is evidence that the use of an electric breast pump produces more milk compared to manual expression. Furthermore, a combination of the two methods may produce optimal milk production (Holmes et al., 2013).

In the clinical protocol on supplementary feedings in the healthy term breastfed neonate the ABM recommended method for extra feeding supplementation for the infant is expressed breast milk. In the first few days following birth, hand expression may elicit larger volumes and increase supply. However, the combination of massage, compression, with mechanical pump expression may also increase available milk (Kellams, et.al, 2017).

**American Academy of Family Physicians (AAFP):** The AAFP position paper on breastfeeding states that the optimal method for expressing milk varies with the length of the mother's absence from the infant and maternal preference. For occasional brief absences, hand expression and/or the use of a hand pump is usually sufficient. The longer and more frequent the separations, the more important it is for the mother to use a hospital grade double-pumping electric pump. This is especially important in cases of maternal-infant separation caused by illness or prematurity (AAFP, 2014).

**American Academy of Pediatrics (AAP):** The AAP reaffirmed in 2012 that an infant be exclusively breastfed for the first six months of life. Breastfeeding should be continued as complimentary past six months for the first year of life and beyond for as long as mutually desired by mother and child. It is recommended that all preterm infants receive human milk. Training for manual and mechanical milk expression must be available so the infant can receive the mother's own milk (AAP, 2012).

**American College of Obstetricians and Gynecologists (ACOG):** The ACOG committee opinion on optimizing support for breastfeeding as part of obstetric practice stated that exclusive breastfeeding is recommended for the first six months of life. It is also recommended that women continue breastfeeding to one year of age or longer with the addition of complementary foods (ACOG, 2018).

**U.S. Preventive Services Task Force (USPSTF):** According to an USPSTF recommendation statement, there is convincing evidence that breastfeeding provides substantial health benefits for children and adequate evidence that breastfeeding provides moderate health benefits for women. As such, the USPSTF recommends interventions during pregnancy and after birth to promote and support breastfeeding (USPSTF, et al., 2016; USPSTF, 2008).

**Centers for Medicare & Medicaid Services (CMS)**

- National Coverage Determinations (NCD): No NCD found
- Local Coverage Determination (LCD): No LCD's found

**Use Outside of the US**

The WHO recommends that mothers worldwide exclusively breastfeed infants for the child's first six months to achieve optimal growth, development and health. Colostrum, the yellowish, sticky breast milk produced at the end of pregnancy, is recommended by the organization as the perfect food for the newborn. Feeding should be initiated within the first hour after birth. Continued breastfeeding along with appropriate complementary foods is recommended up to two years of age or beyond (WHO, 2017).

**Coding/Billing Information**

- Note:** 1) This list of codes may not be all-inclusive.  
 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

**Considered medically necessary when criteria in the applicable policy statements listed above are met:**

HCPCS Codes	Description
A4281	Tubing for breast pump, replacement
A4282	Adapter for breast pump, replacement
A4283	Cap for breast pump bottle, replacement
A4284	Breast shield and splash protector for use with breast pump, replacement
A4285	Polycarbonate bottle for use with breast pump, replacement
A4286	Locking ring for breast pump, 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

**Considered Experimental/Investigational/Unproven when used to report a wireless breast pump (e.g., Willow Wearable Breast Pump):**

CPT® Codes	Description
E1399	Durable medical equipment, miscellaneous

\*Current Procedural Terminology (CPT®) ©2018 American Medical Association: Chicago, IL.

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