

# Clinical UM Guideline

Subject: Electric Breast Pumps Guideline #: CG-DME-35 Status: Reviewed

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# Description

This document addresses the use of standard electric breast pumps (non-hospital grade) or heavy-duty, hospital-grade breast pumps for initiating and maintaining expression of human breast milk in specified situations.

# **Clinical Indications**

#### **Medically Necessary:**

A standard, non-hospital grade, electric breast pump is considered **medically necessary** when there is documentation of ongoing breastfeeding.

An electric, heavy-duty, hospital-grade breast pump is considered medically necessary for any of the following indications:

- A. When a breastfeeding infant is confined to the hospital: or
- B. When a breastfeeding infant has a medical (for example, respiratory, cardiac or genetic condition) or congenital condition (for example, cleft palate) that interferes with breastfeeding; or
- C. When the mother has been unsuccessful expressing sufficient breast milk after a trial using a manual, battery powered or standard electric pump.

### Not Medically Necessary:

An electric breast pump (standard non-hospital grade or heavy-duty hospital grade) is considered **not medically necessary** in the absence of ongoing breastfeeding.

An electric, heavy-duty, hospital grade breast pump is considered not medically necessary when the criteria above are not met.

# Coding

The following codes for treatments and procedures applicable to this guideline are included below for informational purposes.

Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

### When services may be Medically Necessary when criteria are met:

**HCPCS** 

E0603 Breast pump, electric (AC and/or DC), any type

E0604 Breast pump, hospital grade, electric (AC and/or DC), any type

E1399 Durable medical equipment, miscellaneous [when specified as a wireless or wearable breast

pump]

ICD-10 Diagnosis

All diagnoses

### When services are Not Medically Necessary:

For the procedure codes listed above when criteria are not met or for situations designated in the Clinical Indications section as not medically necessary.

# **Discussion/General Information**

The FDA regulates breast pumps as medical devices that extract or "express" breast milk. Breast pumps may be used to increase or maintain a woman's milk supply, relieve engorged breasts and plugged milk ducts, or pull out flat or inverted nipples so a nursing baby can latch-on to its mother's breast more easily (FDA, 2018). There are three main types of breast pumps: manual, battery-powered and electric pumps. Standard manual and electric breast pumps are intended for single person use and are typically sold as a medical device. The standard models may be available from lactation and DME providers as well as select retail stores. Expression of human milk from the breast with standard powered (electric) or non-powered (manual) breast pumps may facilitate ongoing nutritional requirements of infants.

A type of pump which is approved by the FDA for safe use by multiple users, where each individual utilizes their own collection kit (typically includes breast shields and tubing), is the electric, heavy-duty breast pump. These pumps are more durable and powerful to support more frequent pumping of breast milk. The pumps tend to be larger and heavier, and therefore, not as portable as the typical electric personal breast pump. These devices are typically available in the hospital setting for mothers who have infants that are still hospitalized. Lactation consultants, specialty medical supply stores, and durable medical equipment (DME) supply sources may rent or sell hospital-grade breast pumps. The FDA (2018) states on their website "Please note that the term "hospital-grade pump" is not recognized by the FDA and there is no consistent definition for this term, so individual companies could mean different things when they label their breast pumps as hospital-grade."

An electric, heavy-duty, hospital-grade breast pump is recommended for mothers who are dependent on the expression of pumped breast milk (initiation or continuation of milk production) due to circumstances that do not allow for breastfeeding. Expressed breast milk is needed for times when the infant is unable to breastfeed due to medical (for example, confinement in an intensive care unit, prematurity, apnea, etc.) and/or congenital reasons (for example, a cleft lip). During these situations, the mother needs to extract breast milk in order to provide nutrients necessary for healthy growth and development.

The National Association of Neonatal Nurses (NANN, 2016) issued a position statement on the use of human milk and breastfeeding in the neonatal intensive care unit (NICU). Recommendations include use of a hospital-grade electric pump with a double collection kit to initiate lactation and establish an adequate milk supply. NANN states it is critical to monitor early and frequent breast milk supply from pumping during the first 2 weeks to ensure that the mother will have an adequate supply at the time of the infant's discharge.

Breastfeeding and human milk provide natural, normal nutrition for all infants. There are many short- and long-term benefits of breastfeeding for both infant and mother. Exclusive breastfeeding is recommended for the first 6 months of life by the American College of Obstetricians and Gynecologists (ACOG, 2016), American Academy of Pediatrics (AAP, 2012), and the World Health Organization (WHO, 2018). The AAP recommends breast feeding continue through the infant's first year of life or longer. Various groups continue to support promotion of breastfeeding interventions to improve the rate of breastfeeding in the United States. The U.S. Preventive Services Task Force (USPSTF, 2016) recommends interventions during pregnancy and after birth to promote and support the initiation and continuation of breastfeeding.

Benefits of breastfeeding include a lower risk of diarrhea, otitis media and lower respiratory tract diseases than bottle-fed infants during the first year of life (AAP, 2012; Ip, 2007). Additional short- and long-term effects of breastfeeding include additional health benefits

While the benefits of breastfeeding are well documented and the majority of women in the United States initiate breastfeeding, the incidence of continued breastfeeding drops sharply by 3 months. According to a 2016 survey, 81.1% of women initiate breastfeeding following birth. At 6 months of age only 22.3% of infants have been fed breastmilk exclusively (Meeks, 2017). While women initially report intention to breastfeed exclusively for at least 3 months, only 32.4% of the women report achieving this goal (Meeks, 2017).

In an update of the 2008 Cochrane study on the methods of breast milk expression for lactating women, data from a total of 1998 individuals in 34 studies were analyzed (Becker, 2014). The studies were conducted in the U.S. and at international sites which included preterm or ill neonates as well as term and older, healthy infants. Milk expression was achieved by a variety of methods which included hand-expression, manual pumps and electric pumps. The authors concluded the time of birth, and the purpose for expression of breast milk influence the most suitable method for expressing milk. Methods to promote optimal milk expression (such as early initiation of milk expression, relaxation music, hand expression, manual pumps and warming of the breasts) were "As effective or more effective, than large electric pumps for some outcomes." The authors noted caution in interpretation of the results as the interventions and study methodologies varied across the studies.

In 2011, the Institute of Medicine (IOM) Committee on Preventive Services for Women provided the recommendations on preventive services to address health needs specific to women. Under provisions of the Patient Protection and Affordable Care Act, the U.S. Department of Health and Human Services (DHHS) released health plan coverage guidelines, which included recommendations from the IOM, that require health insurance plans cover breast pumps and certain other women's preventive services. Beginning on or after August 1, 2012, new health plans and non-grandfathered plans are required to provide coverage consistent with these guidelines in the first plan year (in the individual market, policy year), when delivered by a network provider. The guidelines recommend coverage of costs for renting breast feeding equipment for each birth.

In 2022 the Academy of Breastfeeding Medicine (ABM) revised their guidelines to include the following recommendations; when the mother is medically ready for hospital discharge, but the newborn is not, or vice versa, the newborn and mother should continue 24-hour rooming in to facilitate breastfeeding. The mother should be encouraged to spend as much time as possible with the hospitalized newborn, regularly breastfeed, and be instructed in techniques to express breast milk so that expressed milk can be given to the hospitalized newborn if separation occurs. It should also be ensured the mother has access to a breast pump or knows how to hand express if a breast pump is not available. High-quality education regarding breast pump use should be provided. Programs should be in place for the mother to borrow a pump for use at home if she does not otherwise have access.

The AAP (2022) policy on breastfeeding and the use of human milk supports policies that protect breastfeeding including universal paid maternity leave, the right of a woman to breastfeed in public, insurance coverage for lactation support and breast pumps, universal workplace break time with a clean, private location for expressing milk, the right to feed expressed milk, and the right to breastfeed in childcare centers and lactation rooms in schools to sustain breastfeeding.

In recent years there have been several advances in breastfeeding equipment which could encourage breastfeeding and continue for a longer period of time. Devices are available which are worn inside the bra which allow a woman to perform activities of daily living while pumping. Other devices support wireless connectivity and allow for tracking of pumping and infant activities. Standard non-hospital grade breast pumps can include these features and can be considered appropriate as a means of promoting infant health.

# **Definitions**

Electric breast pump: A powered breast pump, electrically powered suction device used to express milk from the breast.

Hospital-grade breast pump: Non-standard, electric, heavy-duty breast pump, that is FDA approved for reuse by multiple lactating women (not for single person/personal use).

Manual breast pump: Nonpowered device designed to express breast milk using suction created through a manual process.

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### Index

Ameda Elite Breast Pump<sup>®</sup>
Ameda Finesse Double Breast Pump<sup>®</sup>
Ameda Platinum Breast Pump<sup>®</sup>
Ameda Purely Yours Breast Pump<sup>®</sup>
Hygeia Enjoye
Hygeia EnRiche
Hygeia Q
Lansinoh Smartpump
Lansinoh SignaturePro

Medela<sup>®</sup> Powered Breast Pump Symphony<sup>®</sup> Motif DUO Nurture III Breast Pump<sup>®</sup>

NUK Expressive Single Electric Breast Pump

Spectra Dew 350 Electric Breast Pump<sup>®</sup>
Spectra S1 PLUS Electric Breast Pump<sup>®</sup>

Spectra S2 PLUS Electric Breast Pump<sup>®</sup>

Tomy Quiet Expressions

White River Automatic Breast Pump®

The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

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