Clinical Policy Title: Breast pumps

Clinical Policy Number: 12.02.01

Effective Date: March 1, 2014
Initial Review Date: Sept. 18, 2013
Most Recent Review Date: May 18, 2016
Next Review Date: May 2017

Related policies:

CP # 15.02.03  Nutritional support

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

Coverage policy

Prestige Health Choice considers the use of breast pumps to be clinically proven and, therefore, medically necessary when the following criteria are met:

- Expression of human milk by a pump is medically necessary when the mother is unable to nurse and provide adequately for her infant(s).
- Temporarily when the mother takes medications, if found in breast milk, would be injurious to her infant(s).
- Personal-use electric pumps or hospital-grade electric pumps may be covered 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 eligible for coverage with each subsequent pregnancy.

Limitations:

Policy contains:

- Electric breast pumps.
- Manual breast pumps.
- Hospital breast pumps.
Coverage determinations are subject to benefit limitations and exclusions as delineated by the state Medicaid authority. The Florida Medicaid website can be accessed at http://ahca.myflorida.com/Medicaid/.

All other uses of breast pumps are not medically necessary. Prestige Health Choice covers health care service/items when they are a plan benefit, medically necessary and not prohibited from coverage by state or federal laws and/or regulatory requirements.

The use of a breast pump by another lactating woman to provide her milk to an infant who is not her dependent is not a benefit.

Breast pumps are not covered if there are contraindications to breast feeding, including but not limited to:
- HIV-positive mothers.
- Licit or illicit drugs being taken by the mother for extended periods of time, including cocaine, heroin, radioactive isotopes, antimetabolites, chemotherapy for cancer treatment, some psychotropic medications and other drugs known to cause injury to infants when found in human breast milk.

Because lactation services are not specifically mentioned in the Medicaid statute or federal Medicaid regulations, not all states separately reimburse lactation services as pregnancy-related services. States vary widely in the amount and scope of coverage they provide for lactation services as a part of prenatal, postpartum and infant care.

Breast pumps services not covered by Florida Medicaid and/or Prestige.

Some state Medicaid programs do not cover breast pumps, members may be eligible for a free breast pump through the Special Supplemental Nutrition Program for Women, Infants, and Children — better known as “WIC.” For specific state’s information contact: WIC Breastfeeding Coordinator.

Only one manual or electric breast pump purchase per delivery will be covered, depending on plan coverage per Line of Business.

Alternative covered services:

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

Background

Importance of human breast milk:

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, citing studies that have demonstrated the benefits of breast milk over other sources of nutrition, including:

- There is a reduced incidence of acute infections, especially otitis media, urinary tract infections, and H. influenza meningitis in infants who are exclusively breast fed.
- There is a lower incidence of asthma and allergies in breast fed infants compared to those on external formulas.
- Breast feeding and longer duration of nursing are inversely proportional to the latter development of childhood obesity.
- Low-birth-weight infants who exclusively receive breast milk have, in one study, shown a five-point mean higher score on IQ testing than those on artificial formulas.
- Mothers receive protective benefits as well, with reductions in postpartum hemorrhage and early evidence to suggest lower rates of breast and ovarian cancer in women who nursed their babies.
- Postpartum depression in mothers can be mitigated by breast feeding.
- In developing nations, there are additional benefits to the infants with lower rates of diarrhea and improved mortality rates.
- Mothers’ body mass index (BMI), below or over, can determine the affect milk production.

The American Academy of Pediatrics (AAP), in its 2012 Policy Statement, reinforced the value articulated by the World Health Organization, and further noted a reduction in necrotizing enterocolitis in premature infants, sudden infant death syndrome, childhood leukemia and a 30 percent reduction in the incidence of type 1 diabetes mellitus. The AAP strongly recommended that pediatricians should promote as the normal expectation, that mothers nurse their infants at least for the first six months. The AAP further cites baby, mother and general economic factors. The American College of Obstetricians and Gynecologists (ACOG) has also encouraged its members to promote breast feeding.

Healthy People 2020 targets 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 3 months, and 23.7 percent at 6 months.

While the CDC reports that 75 percent of mothers initiate nursing, there is a large disparity in rates by race, culture and ethnicity. The CDC reports the highest levels of breast feeding occur in Hispanic and non-Hispanic white populations, with breast feeding 10 percent to 17 percent lower in non-Hispanic black populations. Higher socioeconomic status was positively associated with higher rates of breast feeding.

Data from the world literature have been analyzed to test whether low BMI: kg/m2 is a useful indicator of functional impairment of lactation performance. Forty-one databases containing 1,726 measurements have been identified as having reliable estimates of breast milk quantity and/or quality. There is no detectable relationship between maternal BMI and the volume of milk produced by mothers when analyzed according to the mean BMI of different populations, or of different subgroups stratified
by BMI within populations. This conclusion holds even at BMIs < 18.5. The most remarkable feature of the data is the very high milk volumes produced by very thin mothers. It is accepted that the composition of breast milk is relatively unaffected by general under-nutrition of the type that would be indicated by a low BMI with the possible exception of milk fat levels and hence the energy content. Analysis of the available data reveals studies in which there are weak, but significant, correlations between maternal BMI and milk fat. However, other studies show no association or even a negative relationship. Inter-country analysis fails to reveal any detectable association between BMI and milk energy. Milk energy levels seem adequate even at BMIs < 18.5. It is concluded that human lactation performance is extremely robust and that BMI does not provide a useful indicator of function at the levels studied so far. Lactation performance must become compromised when under nutrition is sufficiently severe, but it appears that this must occur only in famine or near-famine conditions.

Nursing with skin-to-skin contact between mother and baby has gained increasing recognition as bringing benefits to mother and baby. An infant is more likely to latch on to the mother’s breast and enjoy successful nursing if there is skin-to-skin contact. There is evidence that both mother and baby relax more.

Prestige Health Choice strongly encourages the use of breast feeding, when possible.

**Reasons for using a breast pump:**

**Physiologic/anatomic issues** — An estimated 5 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. There are some reasons that a lactating woman may not be able to nurse and may require the use of a breast pump. 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 ACOG, but may affect the infant’s ability to latch on long enough to obtain adequate nutrition. 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.

**Social/cultural issues** — 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 are in public areas, so may find the use of a breast pump allows greater flexibility.

**Types of breast pumps:**

Breast pumps can be manual, electric or the hospital-type needed to provide breast milk for premature infants.

**Manual breast pumps** — These 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, manual pumps may cause fatigue and are often less efficient than electric pumps.

**Personal-use electric pumps** — These 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** — These 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.

The following provides examples of different codes that states use for billing and receiving federal matching funds for coverage of lactation services:

- Manual breast pump purchase, CPT code E0602.
- Hospital-grade electric breast pump rental, CPT code E0604.
- Individual electric breast pump purchase, CPT code E0603.

Example of a state benefit package:
Rhode Island provides the following benefit package for breast feeding mothers enrolled in Medicaid. None of the services are associated with copayments.

<table>
<thead>
<tr>
<th>Equipment</th>
<th>Coverage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manual breast pump purchase</td>
<td>Covered benefit for medical necessity or for mother returning to work or school (up to child’s first birthday). Requires prescription.</td>
</tr>
<tr>
<td>Hospital-grade electric breast pump rental</td>
<td>Covered benefit for medical necessity or for mother returning to work or school (up to child’s first birthday). Requires prescription.</td>
</tr>
<tr>
<td>Individual electric breast pump purchase</td>
<td>Covered benefit for medical necessity or for mother returning to work or school (up to child’s first birthday). Requires prescription.</td>
</tr>
<tr>
<td>Pump kits purchase</td>
<td>Covered benefit — authorized with electric pump (one maximum).</td>
</tr>
</tbody>
</table>

**Searches**

Prestige Health Choice searched PubMed and the databases of:
- UK National Health Services Centre for Reviews and Dissemination.
- Agency for Healthcare Research and Quality’s National Guideline Clearinghouse and other
We conducted searches on April 28, 2016. 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 Affordable Care Act (2010) requires most health insurance plans to cover the cost of a breast pump as part of women’s preventative health services.

Prestige Health Choice considers breastfeeding as the preferred method of providing nutrition to infants and the use of breast pumps, when nursing is not possible, to be clinically proven as the effectiveness of its use has been established in 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, are considered by Prestige Health Choice when making coverage determinations.

**Policy updates:**

Under coverage added #4. A new set of breast pump supplies i.e., initial tubing, shields, and bottles) are eligible for coverage with each subsequent pregnancy.

Under limitation added – additional limitations

Under types of breast bump added - The following provides examples of different codes that States use for billing and receiving federal matching funds for coverage of lactation services and an example of a state benefit package.

**Summary of clinical evidence:**
<table>
<thead>
<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>World Health Organization</td>
<td><strong>Key points:</strong></td>
</tr>
<tr>
<td></td>
<td>• Breast milk should be the only source of nutrition for the first six months of a child’s life.</td>
</tr>
<tr>
<td></td>
<td>• Breast milk reduces risks (but does not eliminate them) for a number of infectious and immune-related diseases in the baby, and provides hormonally derived benefits to the mother.</td>
</tr>
<tr>
<td></td>
<td>• There are contraindications to nursing, such as HIV-positive mothers; and illicit or illicit drugs being taken by the mother for extended periods of time, including cocaine, heroin, radioactive isotopes, antimetabolites, cancer chemotherapy, some psychotropic medications, and other drugs known to cause injury to infants when found in human breast milk.</td>
</tr>
<tr>
<td>American Academy of Pediatrics</td>
<td><strong>Key points:</strong></td>
</tr>
<tr>
<td></td>
<td>• Added to the World Health Organization’s list of benefits is reduction of obesity risk.</td>
</tr>
<tr>
<td>Department of Labor (August 2013)</td>
<td><strong>Key points:</strong></td>
</tr>
</tbody>
</table>
| Break Time for Nursing Mothers under the Fair Labor Standards Act (FLSA). | • “Employers are required to provide a reasonable amount of break time to express milk as frequently as needed by the nursing mother. The frequency of breaks needed to express milk, as well as the duration of each break, will likely vary.”  
• The FLSA requirement of break time for nursing mothers to express breast milk does not preempt State laws that provide greater protections to employees (for example, providing compensated break time, providing break time for exempt employees, or providing break time beyond 1 year after the child’s birth). |
| U.S. Food and Drug Administration | **Key points:**                                                                                                                                                                                                                                                                                                                                                                          |
|                               | • Consumer guidelines on breast pumps.  
| La Leche League                | **Key points:**                                                                                                                                                                                                                                                                                                                                                                          |
|                               | • Support group for nursing mothers.  
| Becker (2011)                  | **Key points:**                                                                                                                                                                                                                                                                                                                                                                          |
|                               | • Cochrane Database review of 23 studies.  
• The most suitable method for milk expression may depend on the time since birth, purpose of expression and the individual mother and infant.  
• Low-cost interventions, including early initiation when not feeding at the breast, relaxation, hand expression and lower-cost pumps may be as effective, or more effective, than large electric pumps for some outcomes.  
• Small sample sizes, large standard deviations, small number of studies reviewed, and
the diversity of the interventions argue caution in applying these results beyond the specific method tested in the specific settings.

**Glossary**

**Body mass index (BMI)** — A measure for human body shape based on height and weight (height in meters/ weight in kilograms squared). It can also be calculated and assigned to categories (underweight, normal, overweight, obese) using a chart with weight (kilograms or pounds) and height (meters, or feet and inches on horizontal and vertical axes), respectively.

**Breast pump** — A durable medical equipment device that assists the lactating woman in expressing breast milk. Breast pumps may be manual, dual-electric or hospital-electric.

**Healthy People 2020** — Developed by the Department of Health and Human Services with the Federal Interagency Workgroup (FIW). Health People 2020’s vision is a society in which all people live long, healthy lives. Its mission is to identify nationwide health improvement priorities; increase public awareness and understanding of the determinants of health, disease, and disability and the opportunities for progress; provide measurable objectives and goals that are applicable at the national, state, and local levels; engage multiple sectors to take actions to strengthen policies and improve practices that are driven by the best available evidence and knowledge; and identify critical research, evaluation, and data collection needs.

**References**

**Professional society guidelines/other:**


American College of Obstetricians and Gynecologists, Policy statement breastfeeding. 2004


Center for Disease Control, National Center for Chronic Disease Prevention and Health Promotion.


Peer-reviewed references:


Clinical trials:

Searched clinicaltrials.gov on May 5, 2016, using terms electric and manual breast pumps | Open Studies. 22 studies found, 9 relevant. Two documented below:

Others can be found at: ClinicalTrials.gov website:

Metformin to Augment Low Milk Supply (MALMS) Study. ClinicalTrials.gov Identifier: NCT02179788. Children's Hospital Medical Center, Cincinnati. Published: June 30, 2014. Last updated: February 2, 2016 “This study is a preliminary, small scale randomized trial designed to test for an encouraging trend in the hypothesis that metformin is safe and potentially effective in treating low milk supply in pre-diabetic mothers.”

Trial of Two Electric Breast Pumps in Mothers of Term Infants. ClinicalTrials.gov Identifier: NCT02128295. University College, London. This is a comparison of the effectiveness between two types of breast pumps. Published: April 29, 2014. Updated: December 2, 2015.

CMS National Coverage Determinations (NCDs):

No NCDs for breast pumps.

Local Coverage Determinations

No LCDs for breast pumps.

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.

<table>
<thead>
<tr>
<th>HCPCS Code</th>
<th>Description</th>
<th>Comment</th>
</tr>
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<tbody>
<tr>
<td>E0602</td>
<td>Breast pump, manual, any type</td>
<td></td>
</tr>
<tr>
<td>E0603</td>
<td>Breast pump, electric (AC and/or DC), any type</td>
<td></td>
</tr>
<tr>
<td>E0604</td>
<td>Breast pump, hospital grade, electric (AC and/or DC), any type</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ICD-10 Code</th>
<th>Description</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Z38.00-Z38.8</td>
<td>Newborn</td>
<td></td>
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<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Description</th>
<th>Comment</th>
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