Clinical Policy Title: Lactation specialist/consultant

Clinical Policy Number: 12.02.05

Effective Date: January 1, 2016
Initial Review Date: August 19, 2015
Most Recent Review Date: August 17, 2016
Next Review Date: August 2017

Related policies:
None.

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

Coverage policy

Keystone First considers the use of a lactation specialist/consultant to be clinically proven and, therefore, medically necessary when the following criteria are met:

- Member’s physician requests professional support and breast-feeding education.
- These sessions are in addition to any lactation counseling provided during an inpatient maternity stay.
- Service is rendered by a physician or a registered nurse certified as a lactation specialist/consultant, a Certified Lactation Counselor® (CLC), or an International Board Certified Lactation Consultant® (IBCLC).

A maximum of six counseling sessions are generally sufficient to meet medical necessity. Additional sessions would require prior authorization.

Limitations:

All other uses of lactation specialists/consultant are not medically necessary.

Alternative covered services:
• Bright Start® services.
• Breast pump education.

**Background**

Breast feeding is the feeding of infants or young children with breast milk from female breasts (i.e., through lactation). A child’s sucking reflex enables babies to suck and swallow milk instinctively. Some mothers may elect to express (expel) milk either by hand or by using a breast pump to feed to an infant later. The process of feeding breast milk is also called breast feeding or nursing.

Professional lactation support might soon become more widely available, since private insurers must cover it under the Affordable Care Act (ACA). However, the ACA doesn't stipulate which providers qualify for reimbursement, and states have varied interpretations. Some states interpret the ACA to mean licensed health care providers, such as M.D.s, are reimbursed for lactation support but IBCLCs are not reimbursed.

An IBCLC is a health care professional who specializes in the clinical management of breast feeding. An IBCLC is certified by the International Board of Lactation Consultant Examiners® Inc., under the direction of the U.S. National Commission for Certifying Agencies. An IBCLC works in a variety of health care settings, including hospitals, pediatric and family practice offices, public health clinics, and private practice.

Health professionals who provide lactation support do so in hospitals, birth centers, physicians’ offices, public health clinics, private offices, and a variety of community settings. They are members of the health care team who support the work of physicians and other primary health care providers. Professional breast-feeding experts support breast feeding when they assist mothers and infants, create and administer lactation programs, and educate other health professionals about breast feeding.

The IBCLC certification requires a person to pass the certification exam administered by the International Board of Lactation Consultant Examiners. The eligibility requirements for IBCLC certification vary by professional background. Once certified, all IBCLCs must recertify every five years.

Certified lactation consultants (CLCs) educate and counsel about breast feeding. The CLC certification, accredited by the American National Standards Institute, requires a person to complete the CLC training course and pass the certification exam administered by the Academy of Lactation Policy and Practice. Once certified, all CLCs must recertify every three years.

The Blueprint for Action on Breastfeeding in Europe is a new project to help women feel more positive about breast feeding and to increase the number of mothers who choose to feed their babies this way. The project identified a number of initiatives that can be done locally and nationally to promote, protect, and support breast feeding. The result — the Blueprint — is a model plan that policymakers and health professionals can turn into action plans. The project is supported by the European Commission. Breast-feeding specialists and mothers from 29 countries have been involved in its development.

Several reasons are given to promote breast feeding:
• It is the natural way to feed babies and young children and the ideal start to life for all children.
In the first six months of a baby’s life, breast feeding is the best way to ensure healthy growth and development. Breast feeding provides valuable nutritional benefits, alongside other types of food, beyond the age of six months. Breast feeding has a positive impact on the health of women and children, leading to lower healthcare costs and lower levels of health inequalities.

There are many factors that influence the decision whether to breast feed exclusively or with complementary feeding, and for how long.

Maternal and infant benefits from breast feeding include protection from infections, biologic signals for promoting cellular growth and differentiation, a decrease in maternal postpartum blood loss, and a reduction in the risk of ovarian and breast cancers. Despite the benefits of breast feeding, cultural and societal barriers to breastfeeding exist at all levels, from hospitals to the workplace. Underserved women — those unable to obtain quality health care by virtue of poverty, cultural differences, race and ethnicity, geographic region, or other factors that contribute to health care disparities — may face greater barriers in the initiation and continuation of breast feeding.

Breast feeding has a societal and socioeconomic benefit. One study estimates that $3.6 billion would be saved annually in the cost of treating some childhood illnesses if breast-feeding rates were increased (Weimer 2001). Children breast fed as infants have fewer childhood illnesses and fewer visits to the pediatrician’s office, which leads to decreased parental absenteeism from work. In addition, the estimated cost of formula (up to $1,200 per year) is four times that of breast feeding (approximately $300 per year for increased food for a lactating woman [United States Breastfeeding Committee 2002]).

In the policy statement on breast feeding, the American Academy of Pediatrics (AAP) states that any breast feeding is associated with reductions in middle ear infections, gastrointestinal infections, sudden infant death syndrome, and adolescent and adult obesity rates. Therefore the AAP recommends exclusive breast feeding for the first six months after birth, followed by continued breast feeding for one year or longer as other foods are introduced.

Breast-feeding support for new families was spotlighted in the U.S. Surgeon General's “Call to Action to Support Breastfeeding,” issued January 20, 2011. The call to action challenges the nation to work toward removing obstacles that make it difficult for women to achieve their breast-feeding goals, and serves as a model roadmap for governments worldwide to robustly address similar challenges. According to the Centers for Disease Control and Prevention (CDC), fewer than 75 percent of infants nationwide are breast fed, and less than half are still breast fed at six months.

Authorized under provisions of the ACA, the U.S. Department of Health and Human Services (DHHS) released health plan coverage guidelines, developed by an Institute of Medicine committee, that require health insurance plans to cover breast pumps and specific women's preventive services. New health plans and non-grandfathered plans and issuers must provide coverage consistent with these guidelines in the first plan year (in the individual market, policy year) that begins on or after August 1, 2012.

Leaflets, phone support, and other means of providing information that require little or no face-to-face interaction with prospective parents or new mothers is less effective than extended face-to-face contact. The use of printed materials alone is the least effective intervention.
Breast milk is well-established as the best source of nutrition for newborns and infants. Breast feeding has many maternal, infant, and societal benefits. Although national rates of initiating breast feeding are acceptable, the U.S. falls short in breast-feeding continuation, particularly among underserved populations. The American College of Obstetricians and Gynecologists (ACOG) supports efforts to educate patients on the benefits and mechanics of breast feeding and encourages health care providers, nursing staff, and government assistance agencies to remain strong advocates for breast feeding, including lactation programs within hospitals. A multidisciplinary approach that involves community, family, patients, and clinicians will strengthen the support for and feasibility of the desired goals of 2012 Breastfeeding Report Card Healthy People 2020.

Searches

Keystone First 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 evidence-based practice centers.
- The Centers for Medicare & Medicaid Services (CMS).

We conducted searches on July 14, 2016. Search terms were: “lactation consultant” and “breastfeeding.”

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

ACOG strongly supports breast feeding as the preferred method of feeding for newborns and infants and recommends exclusive breast feeding until the infant is approximately six months old. A longer breast-feeding experience, with gradual introduction of iron-enriched solid foods in the second half of the first year of life, is beneficial. ACOG encourages health care professionals, hospitals, and employers to support women who choose to breast feed their infants. Although most women can breast feed, some women will choose not to breast feed or cannot breast feed. Health care providers should be sensitive to the needs of women, regardless of their decision.

According to the 2012 Breastfeeding Report Card, 76.9 percent of infants in the U.S. were ever breast fed. However, 47.2 percent of infants were breast fed at six months, which decreased to 25.5 percent at 12 months. Although breast-feeding rates have increased over the past several years, the goals of U.S. Department of Health and Human Services report Healthy People 2020’s goals include; increasing the rate of continued breast feeding and improving the rate of exclusive breast feeding, according to the DHHS.
Healthy People 2020’s targets for breastfeeding are to:

- Increase the proportion of infants who are:
  - Ever breast fed (81.9 percent).
  - Breast fed at six months (60.6 percent).
  - Breast fed at one year (34.1 percent).
  - Exclusively breast fed through three months (46.2 percent).
  - Exclusively breast fed through six months (25.5 percent).
- Increase the percentage of employers with on-site lactation support (38 percent).
- Reduce the proportion of breast-fed newborns who receive formula supplementation in the first two days of life (14.2 percent).
- Increase the proportion of live births that occur in facilities that provide recommended care for lactating mothers and their babies (8.1 percent).

According to ACOG, the following are benefits of breast feeding:

- Decreased rate of common childhood infections, such as ear infection and infection that causes diarrhea, which results in decreased parental absenteeism from work.
- Decreased rates of childhood obesity in children who were breastfed as infants.
- Decreased rates of hypertension, hyperlipidemia, diabetes, and cardiovascular disease among women who breast fed their infants.
- Decreased rates of ovarian and breast cancer in women who breast fed their infants.
- Increased bonding between mother and infant.
- Lower risk of postpartum depression.
- Increased postpartum weight loss.
- Decreased unintended pregnancy.

The CDC performed a study of 4,000 pregnant women from across the nation to participate in the Infant Feeding Practices Study II (IFPS II) between May and December 2005. The IFPS II was conducted collaboratively by the Food and Drug Administration (FDA) and the CDC, and was co-funded by other agencies in the DHHS.

The design of the IFPS II was similar to that of the original study (the IFPS I), conducted in 1992 – 1993. In the current longitudinal survey, a large cohort of 4,900 women was enrolled prenatally, and > 2000 were followed through the first year of their infant’s life. See results below:

<p>| Table 3.3. Percent of babies who were fed any breast milk in the past seven days by infant age and selected demographics1 | Infant age in months |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Neonatal | 2 | 3 | 4 | 5 | 6 | 7 | 9 | 10 | 12 |
| All(n) | 3,002 | 2,546 | 2,381 | 2,232 | 2,178 | 2,092 | 2,017 | 1,942 | 1,804 | 1,802 |
| (%) | 72.4 | 63.8 | 60.4 | 56.9 | 53.7 | 49.8 | 45.6 | 41.6 | 37.1 | 25.2 |
| Age |  |  |  |  |  |  |  |  |  |  |
| 18 – 24 | 61.0 | 46.9 | 41.9 | 37.4 | 34.2 | 31.4 | 27.0 | 23.8 | 22.4 | 12.9 |</p>
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1. Table is based on variables: N40A, M2A1A, M3A1A, M4A1A, M5A1A, M6A1A, M7A1A, M9A1A, MXA1A, MWA1A


Fein et al. (2008) examined the association between breast feeding and employment, an aspect of breast feeding that had not been previously documented. Researchers found that any of three strategies that provided milk for the infant during the workday (pumping milk only, breast feeding directly only, pumping and breast feeding directly) were equally effective and superior to the strategies that did not provide milk for the infant during the workday (pumping and dumping the milk or neither pumping nor
breast feeding during the workday) for maintaining breast feeding intensity in the month after the mother returned to work. However, feeding the infant directly from the breast during the workday, either alone or in combination with pumping milk, was associated with longer breast-feeding duration after return to work than pumping only, whereas the shortest duration was observed among those who neither pumped nor breast fed during the workday.

A multipronged approach associated with improved breast milk feeding rates and very low-weight infants of inner-city hospitals found that breast milk feeding has advantages over formula feeding in premature infants, but issues in them is low measures initiated in their inner-city hospital. Some hospitals, started dedicated lactation services counseling mothers prenatally and postdate only educating hospital staff, in advocating with the state's Medicaid insurance to provide free home breast pumps. These measures were associated with improvement in breast milk feeding rates for very low birth-weight infants from 22 percent to 88 percent over five years.

In 2010, the CDC recommended that HIV-infected women in the United States refrain from breast feeding to avoid postnatal transmission of HIV-1 to their infants through breast milk. These recommendations should also be followed by women receiving antiretroviral therapy. Passage of antiretroviral drugs into breast milk has been evaluated for only a few anti-retroviral drugs, such as ZDV, 3TC, and nevirapine.

Both the AAP and the CDC state that maternal infection with hepatitis C is compatible with breast feeding. Though an infant can be infected with hepatitis C during pregnancy or delivery, breast-fed infants do not have higher rates of hepatitis C than formula-fed infants.

Mother’s should check with their obstetrician, family practitioner or pediatrician regarding the safety of breastfeeding when receiving chemotherapy or radiation. Additionally, there are certain over-the-counter and prescription medications that can pass through breast milk and should be avoided if possible when breast feeding. Consultation with a physician is necessary. Mother’s that are actively using prescription or illicit opioids should not breast feed. Mothers using illicit drugs should also refrain from breast feeding.

In addition, the current statement from the AAP 2015 RedBook online is:

“Hepatitis C virus (HCV) RNA and antibody to HCV have been detected in milk from mothers infected with HCV. Transmission of HCV via breast feeding has not been documented in mothers who have positive test results for anti-HCV but negative test results for HIV antibody. Mothers infected with HCV should be counseled that transmission of HCV by breast feeding theoretically is possible but has not been documented. Mothers infected with HCV should consider abstaining from breast feeding from breast with cracked or bleeding nipples. According to current guidelines of the U.S. Public Health Service, maternal HCV infection is not a contraindication to breast feeding. The decision to breast feed should be based on an informed discussion between a mother and her health care professional.”

Policy updates:

2016:
Summary of clinical evidence:

<table>
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<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
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<tbody>
<tr>
<td><strong>Henshaw, et al. (2015)</strong></td>
<td>Key points:</td>
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</table>
| Breast-feeding self-Efficacy, mood, and breast-feeding outcomes among primiparous women | - High breast-feeding self-efficacy (BSE) at two days postpartum predicted positive emotional adjustment and fewer depressive symptoms at six weeks postpartum, and more exclusive breast feeding at six months postpartum.  
- Among distressed mothers, breast-feeding concerns were among the most commonly named reasons for stress, along with lack of sleep, lack of social support, and overwhelming learning demands involved with being a new parent.  
- Breast-feeding perceptions are associated with emotional health and breast-feeding outcomes. Bolstering women’s early BSE may be an important goal for multiple dimensions of postpartum health.  
- Declaration of conflicting interests: The authors declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.  
- Funding: This research was funded by the Denison University Research Foundation, as well as the Denison University Sharfstein and Anderson Summer Scholar programs. No conflict of interest exists for any of the authors. |
| **Rosenblatt, et al. (1993)** | Key points:                        |
| Lactation and the risk of epithelial ovarian cancer: the WHO Collaborative Study of Neoplasia and Steroid Contraceptives | - The relationship between lactation and the development of epithelial ovarian cancer was assessed in data from seven countries collected for a multinational hospital-based case-control study conducted from 1979 to 1988.  
- Three hundred and ninety-three cases of ovarian cancer were compared to 2,565 controls matched on age, hospital, and year of interview.  
- A non-significant reduction in risk with short-term lactation was observed, but no further reduction in risk was seen with long-term lactation.  
- The reduction in risk associated with months of lactation was not as great as the reduction with months of pregnancy, which may be a result of lactation being a less effective form of ovulation suppression than pregnancy.  
- The short-term lactation that takes place in developed countries may provide as great a reduction in risk as the long-term lactation practiced in the developing countries included in this study. |

Glossary

**Breast milk substitutes** — Infant formula, follow-on formula, and other foods given instead of breast milk while breast feeding continues.
Complementary feeding — A baby has both breast milk and other foods (including breast milk substitutes).

Exclusive breast feeding — A baby is fed only with breast milk and receives no other liquids, including water, or solids, except medicine or vitamin supplements if necessary.

Lactation — The process of milk production. Human milk is secreted by the mammary glands, which are within the fatty tissue of the breast. The hormone oxytocin is produced in response to the birth of a new baby, and it both stimulates uterine contractions and begins the lactation process. For the first few hours of nursing, a special fluid called colostrum is delivered. Colostrum is especially high in nutrients, fats, and antibodies, to protect the newborn from infection. Thereafter, the amount of milk produced is controlled primarily by the hormone prolactin, which is produced in response to the length of time the infant nurses at the breast.

Predominant breast feeding — A baby is fed mainly with breast milk, but also receives water, tea, or fruit juice.

References

Professional society guidelines/other:


**Peer-reviewed references:**


**Clinical trials:**

Searched clinicaltrials.gov on July 14, 2016, using lactation, consultant, and support | Open Studies. 47 studies found, two relevant.


**CMS National Coverage Determinations (NCDs):**

No NCDs identified as of the writing of this policy.

**Local Coverage Determinations (LCDs):**
No LCDs 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.

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Description</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>99211</td>
<td>Office or other outpatient visit for evaluation &amp; management of an established patient that may not require the presence of a physician</td>
<td></td>
</tr>
<tr>
<td>99212</td>
<td>Office or other outpatient visit for evaluation &amp; management of an established patient. Counseling and/or coordination of care.</td>
<td></td>
</tr>
<tr>
<td>99213</td>
<td>Office or other outpatient visit for evaluation &amp; management of an established patient. Presenting problems low to moderate.</td>
<td></td>
</tr>
<tr>
<td>99214</td>
<td>Office or other outpatient visit for evaluation &amp; management of an established patient. Presenting problems moderate to high severity.</td>
<td></td>
</tr>
<tr>
<td>99215</td>
<td>Office or other outpatient visit for evaluation &amp; management of an established patient. Presenting problems low to moderate to high severity, up to 40 min.</td>
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</tr>
<tr>
<td>99391</td>
<td>Periodic comprehensive preventative medicine, established patient; infant.</td>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>ICD-10 Code</th>
<th>Description</th>
<th>Comment</th>
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</thead>
<tbody>
<tr>
<td>092.3</td>
<td>Agalactia</td>
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</tr>
<tr>
<td>092.4</td>
<td>Hypogalactia</td>
<td></td>
</tr>
<tr>
<td>092.6</td>
<td>Galactorrhea</td>
<td></td>
</tr>
<tr>
<td>092.79</td>
<td>Other disorders of lactation</td>
<td></td>
</tr>
<tr>
<td>R63.3</td>
<td>Infant feeding difficulties</td>
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</tr>
<tr>
<td>Z39.1</td>
<td>Encounter for care and exam of lactating woman</td>
<td></td>
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</table>

<table>
<thead>
<tr>
<th>HCPCS Level II</th>
<th>Description</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>N/A</td>
<td></td>
<td></td>
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</table>