

S3-Guidelines for the Treatment of Inflammatory Breast Disease during the Lactation Period

AWMF Guidelines, Registry No. 015/071 (short version)

S3-Leitlinie „Therapie entzündlicher Brusterkrankungen in der Stillzeit“

AWMF Leitlinien-Register Nr. 015/071 (Kurzfassung)

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Abstract

Breastfeeding is widely acknowledged to be the best and most complete form of nutrition for healthy infants born at term and is associated with numerous benefits in terms of infants' health, growth, immunity and development. However, breastfeeding problems often result in early weaning. Standardized treatment recommendations for breastfeeding-related diseases are necessary to optimize the care offered to breastfeeding women. Evidence and consensus based guidelines for the treatment of puerperal mastitis, sore nipples, engorgement and blocked ducts were developed on the initiative of the National Breastfeeding Committee. These guidelines were developed in accordance with the criteria set up by the *Arbeitsgemeinschaft der Wissenschaftlichen Medizinischen Fachgesellschaften* (AWMF), the Association of Scientific Medical Societies in Germany. The recommendations were drawn up by an interdisciplinary group of experts and were based on a systematic search and evaluation of the literature but also took clinical experience into account. Additionally good clinical practice (GCP) in terms of expert opinion was formulated in cases where scientific investigations could not be performed or were not aimed for. This article presents a summary of the recommendations of the S3-guidelines.

Abbreviation

GCP Good Clinical Practice

Zusammenfassung

Stillen gilt als die optimale Ernährungsform für gesunde reif geborene Säuglinge und ist mit einer Vielzahl an Vorteilen für Gesundheit und Entwicklung verbunden. Jedoch führen Stillprobleme häufig zu einem frühzeitigen Abbruch der Stillbeziehung. Um eine optimale Betreuung von stillenden Frauen zu gewährleisten, sind einheitliche Handlungsempfehlungen für die Therapie der still-assoziierten Brusterkrankungen notwendig. Auf Initiative der Nationalen Stillkommission wurde eine evidenz- und konsensbasierte Leitlinie zur Therapie wunder Brustwarzen, der verstärkten initialen Brustdrüsenanschwellung, der Mastitis puerperalis und des Milchstaus entwickelt. Die Leitlinienentwicklung folgte methodisch den Kriterien der Arbeitsgemeinschaft der Wissenschaftlichen Medizinischen Fachgesellschaften (AWMF). Die Empfehlungen wurden basierend auf systematischen Recherchen und Bewertungen der Literatur und unter Berücksichtigung praktischer Erfahrungen in einer interdisziplinär zusammengesetzten Expertengruppe abgeleitet. Zusätzlich wurden Klinische Konsensuspunkte als Expertenmeinung zu Fragestellungen formuliert, zu denen keine wissenschaftlichen Untersuchungen möglich sind oder angestrebt werden. Im vorliegenden Artikel werden die Empfehlungen der S3-Leitlinie zusammenfassend präsentiert.

Introduction

Breastfeeding is acknowledged to be the natural and best form of nutrition for healthy infants born at term. The recommendation in Germany is for infants to be exclusively breastfed in the first months of life.

However, problems during breastfeeding such as mastitis or sore nipples often lead to early weaning [1–3].

To promote breastfeeding it is crucially important to provide the best treatment to women with breastfeeding-related breast diseases. The National Breastfeeding Committee in cooperation with the German Society for Gynecology and Obstetrics has initiated the development of the evidence- and consensus based guidelines (S3) for the treatment of inflammatory breast disease in the lactation period. The guidelines aim to improve the health-care provided to lactating women who experience breastfeeding problems.

The guidelines were compiled according to criteria drawn up by the Association of Scientific Medical Societies in Germany (*Arbeitsgemeinschaft der Wissenschaftlichen Medizinischen Fachgesellschaften* [AWMF]). An interdisciplinary guidelines group which included representatives from 14 different organizations (Table 1) drew up recommendations for the treatment of the following breast diseases based on both evidence and clinical experience:

- ▶ sore nipples
- ▶ initial engorgement
- ▶ blocked ducts
- ▶ mastitis

Table 1 Participating professional associations, societies and other organizations.

Arbeitsgemeinschaft freier Stillgruppen (AFS) e. V. [Task group of autonomous breastfeeding groups]
Berufsverband Deutscher Laktationsberaterinnen IBCLC (BDL) e. V. [Professional Association of German Lactation Consultants IBCLC]
Berufsverband der Frauenärzte (BVF) e. V. [German Professional Association of Gynecologists]
Deutsche Gesellschaft für Gynäkologie und Geburtshilfe (DGOG) e. V. [German Society of Gynecology and Obstetrics]
Deutsche Gesellschaft für Hebammenwissenschaft (DGHWi) e. V. [German Midwifery Society]
Deutsche Gesellschaft für Hygiene und Mikrobiologie (DGHM) e. V. [German Society of Hygiene and Microbiology]
Deutsche Gesellschaft für Kinder- und Jugendmedizin (DGKJ) e. V. [German Society of Pediatrics and Adolescent Medicine]
Deutsche Gesellschaft für Perinatale Medizin (DGPM) e. V. [German Society of Perinatal Medicine]
Deutsche Gesellschaft für Psychosomatische Frauenheilkunde und Geburtshilfe (DGPF) e. V. [German Society of Psychosomatic Gynecology and Obstetrics]
Deutsche Gesellschaft für Senologie e. V. [German Senology Society]
Deutscher Hebammenverband e. V. [German Association of Midwives]
La Leche Liga Deutschland e. V. [La Leche League Germany]
Paul-Ehrlich-Gesellschaft für Chemotherapie (PEG) e. V. [Paul Ehrlich Society for Chemotherapy]
WHO/UNICEF Initiative "Babyfreundlich" [WHO/UNICEF Baby-friendly Hospital Initiative]

Each recommendation was given a rating based on the available evidence and other criteria (e.g. patient preference, ethical obligations, applicability) which indicated the strength of the recommendation (A, B or O) (Table 2). In addition to the recommendations, standards of Good Clinical Practice (GCP) were formulated, based on the clinical experience of members of the Guidelines Group, to provide standards for therapies for which no scientific investigations are possible or planned.

Table 2 Grades of recommendation.

Grade of recommendation	Syntax	Symbol
Strongly recommended	"shall"	A
Recommended	"should"	B
Neither recommended nor not recommended	"can"	O

This article is a short version of the S3-guidelines. Interested persons are requested to refer to the long version for further information and, in particular, to the summaries of the body of evidence for individual recommendations. The long version and the methodological report for the guidelines are freely available (in German) online (<http://www.awmf.org/>).

Sore Nipples



Sore nipples are injured nipples with or without infection.

Symptoms of sore nipples

- ▶ fissures
- ▶ skin abrasions
- ▶ rhagades
- ▶ signs of inflammation in the nipple and/or areola:
 - ▶ pain, particularly when the infant latches on
 - ▶ redness
 - ▶ edema
 - ▶ temperatures well above normal
- ▶ scab formation
- ▶ pale or dark blotches on the nipple

If bacterial infection is present, pus or yellowish discharge may be present on the sore, reddened nipple [4–6].

Differential diagnosis

- ▶ Candida infection of the nipple or breast
- ▶ dermatitis
- ▶ traumatic lesion
- ▶ malignancy
- ▶ Paget's disease of the breast

Recommendations for the treatment of sore nipples during the lactation period

Good Clinical Practice

Prior to beginning any treatment of sore nipples, it is important to start by considering the following potential causes (GCP):

- ▶ breastfeeding technique (position and frequency)
- ▶ infant's technique for latching-on and sucking
- ▶ use of breastfeeding aids (pumps, nipple shields)
- ▶ presence of anatomic anomalies in the child or mother
- ▶ psychological factors
- ▶ initial engorgement

Anatomical factors present in the mother (flat or inverted nipples) or the child (malposition of the tongue, too short frenulum of the tongue or lip, (lower) jaw asymmetry, palatal anomalies) can affect latching-on, attachment and sucking [7–10]. In such cases, particular attention has to be devoted on achieving the correct latching-on. The anatomic anomalies listed above are not the

topic of the guidelines; however, it is important to check whether any such anomalies are present prior to initiating therapy. When using aids (pumps, nipple shields) it is important to ensure that they are used correctly. Pumps should be positioned correctly and nipple shields should be used accurately. In addition to positioning the child correctly and getting it to latch on correctly, different maternal positions during breastfeeding and measures to stimulate the let-down reflex (relaxation, massage, moist heat) can assist in treating sore nipples. Breastfeeding means physical and emotional closeness. Conscious and unconscious feelings are communicated and may have a disruptive influence on the interaction between mother and child. Psychosomatic aspects should be taken into account and included in the treatment of sore nipples.

Advice regarding care

The general rules with regard to hand hygiene also apply to the treatment of sore nipples. If nursing pads are used, they should be changed frequently for hygienic reasons, and breathable materials should be preferred.

Treatment of sore nipples

No topical applications are needed if the skin is intact.

Evidence and consensus based recommendation

Based on the existing body of evidence it is currently not possible to issue a recommendation for or against the topical application of highly purified lanolin or maternal breast milk for the treatment of sore nipples (0).

In practice, lanolin or maternal breast milk are often used in the topical treatment of sore nipples, based on the principles of moist wound healing. But existing scientific studies do not permit conclusions to be drawn on the efficacy of lanolin or breast milk for the treatment of sore nipples.

Good Clinical Practice

Based on many years of practical experience, the topical application of maternal breast milk or highly purified lanolin can be recommended (GCP).

Many years' experience with the use of lanolin or breast milk in practice indicate that these forms of treatment are associated with high levels of satisfaction and are well accepted by women. Based on this practical experience but not on scientific studies, we can recommend using breast milk or lanolin as a concomitant application to treat sore nipples.

Evidence and consensus based recommendation

Due to insufficient data and a lack of data about the benefit or harm of the following treatments, the effectiveness of the following applications cannot currently be assessed (0):

- ▶ application of breast compresses for moist wound healing (hydrogel compresses, Multi-Mam compresses)
- ▶ application of tea bags (e.g. filled with sage tea)
- ▶ soft laser therapy (low level laser)
- ▶ use of nursing pads specially layered to prevent abrasion to the nipple

Evidence and consensus based recommendation

The use of nipple shields to treat sore nipples is not required (0).

Good Clinical Practice

If strong pain generated when the infant latches on forces the mother to discontinue breastfeeding with the affected breast for a time, the breast should be drained (as often as previously when breastfeeding) either manually or mechanically (GCP).

When using pumps, it is important to ensure that they are positioned correctly.

Blood in milk is not a sufficient reason to stop breastfeeding.

Good Clinical Practice

After balancing the benefit against the harm, the conclusion is that alcohol-containing solutions, creams and paraffin-based ointments shall not be recommended to women with sore nipples (GCP).

Treatment of infected nipples

Advice regarding care

In addition to standard hand hygiene measures, nipples should be carefully cleaned (using a sterile saline solution, pH-neutral liquid soap or antiseptic).

Evidence and consensus based recommendation

Infected nipples are associated with a high risk of developing mastitis and should be treated using antibiotics (B).

Evidence and consensus based recommendation

The systemic administration of antibiotics is preferable to a topical application (B).

Good Clinical Practice

Prior to starting calculated antibiotic therapy, samples shall be collected for bacteriological investigation (GCP).

Even though it may be necessary to start calculated antibiotic therapy before the bacteriological results are available, it is recommended that samples be obtained for bacteriological assessment. The sensitivity and specificity is much lower if bacteriological samples of pathogens are only collected after the start of antibiotic therapy. Culturing pathogens allows therapy to be adapted to the specific pathogen detected in the antibiogram. This prevents the unnecessary use of broad-spectrum antibiotics and allows drug-resistant pathogens (e.g. MRSA) to be detected and treated accordingly. It also prevents the wrong therapy being administered, particularly at a time where increasing numbers of pathogens are becoming resistant to drugs. Moreover, it provides

information on the epidemiological conditions and presence of pathogens in a facility which will affect the calculated antibiotic therapy.

Initial Engorgement

Initial engorgement refers to the painful swelling and enlargement of breasts at the beginning of the lactation period. The cause of engorgement is lymphedema in the glandular breast tissue; it is important to differentiate engorgement from blocked ducts. The swelling of glandular tissue may be limited to the areola or to the periphery of the breast or comprise both areas [11, 12]. Increased swelling of glandular tissue often begins between the third and the fifth day postpartum.

Symptoms

- ▶ generalized swelling
- ▶ pain
- ▶ diffuse edema
- ▶ redness
- ▶ shiny skin
- ▶ decreased flow of milk
- ▶ usually bilateral presentation
- ▶ slight increase in temperature ($< 38.4^{\circ}\text{C}$) [11, 12]

Differential diagnosis

- ▶ blocked ducts
- ▶ mastitis
- ▶ (inflammatory) breast cancer
- ▶ erysipelas
- ▶ neurodermatitis
- ▶ dermatoses
- ▶ allergic skin reactions (e.g. to jewelry, piercings, bra fasteners)
- ▶ mechanical, physical, drug-related or toxic exogenous skin changes (causes: bra, manipulation, trauma, temperature, creams, etc.)
- ▶ Paget's disease of the breast

Recommendation for the treatment of initial engorgement

Good Clinical Practice

Despite swelling of the breast, the breast shall be emptied regularly. It is important to avoid injury to the nipple (GCP).

Regular emptying of the breast improves venous and lymphatic flow and stimulates milk production. It is important to ensure that the baby is placed at the breast at least 8–12 times in 24 hours in the first days after giving birth. This breastfeeding rhythm should also be continued at night [12]. If the mother cannot breastfeed, the breast should be regularly emptied manually or mechanically [13].

Good Clinical Practice

Reverse Pressure Softening can be used if there is strong swelling in the area of the areola to make it easier for the child to latch on correctly (GCP).

Reverse Pressure Softening is done directly prior to placing the infant at the breast. The goal is to use gentle pressure to create a ring of dimples around the nipple which will make it easier for the infant to latch on [14]. The technique should only be used after being shown how to do so by trained staff or breastfeeding consultants. Painful massage and all forms of forceful pressure must be avoided as they increase the risk of injury to tissue with subsequent mastitis.

Good Clinical Practice

Non-steroidal anti-inflammatory drugs (e.g. ibuprofen) can be used for pain relief (GCP).

Only very low levels of ibuprofen or its metabolites are excreted into breast milk after maternal ingestion. If ibuprofen is only used for a limited period, it is generally not necessary to discontinue breastfeeding.

Evidence and consensus based recommendation

Due to insufficient data or a lack of data about the benefit or harm of the following treatments, the effectiveness of the following applications cannot currently be assessed (0):

- ▶ application of cabbage leaves
- ▶ application of cooling pads
- ▶ application of curd cheese (topical)
- ▶ application of Retterspitz (topical)
- ▶ acupuncture
- ▶ deep tissue massage
- ▶ Plata Rueda or Marmet massage
- ▶ therapeutic ultrasound

Given the current lack of scientific studies on cabbage leaves and cooling pads, it is not possible to infer that one method is superior to another. At the same time, the effectiveness of cabbage leaves or cooling pads has been neither proven nor disproven. It is not possible to estimate the impact of natural recovery over time on the observed effects of breast applications. There are no studies comparing these forms of treatment with placebo or control groups who had no intervention.

No studies verifying the efficacy of a topical application of curd cheese or Retterspitz or the use of acupuncture to treat initial breast engorgement could be identified. In practice, deep tissue massage is used to reduce the swelling and pressure in the breast. The massage shall drain accumulated lymph through the lymphatic pathways. There is no scientific evidence available on its efficacy. In practice, warmth is applied to stimulate the let-down reflex together with massage (Plata Rueda or Marmet) prior to breastfeeding to improve milk flow and make it easier to drain the breast [13]. No scientific studies investigating this form of treatment could be identified.

In a randomized controlled double-blind study where 85% of patients suffered from engorgement, ultrasound treatment was compared with sham ultrasound treatment; it was shown that pain and hardened breasts improved similarly with both interventions. This study indicates that the improvement obtained was not due to the ultrasonic waves applied but to a placebo effect [15]. Other data on the benefit or harm of ultrasound to treat initial engorgement are lacking.

Good Clinical Practice

Based on many years' practical experience, symptoms can be treated by applications to the breast in the form of cooling pads, cabbage leaves or curd cheese or by deep tissue massage (GCP).

In practice, cooling pads, cabbage leaves and the application of curd cheese have been used for years to treat initial breast engorgement. There are also many years' experience with the use of deep tissue massage. Women's rating of these methods is individually different. Even if there is no scientific evidence underpinning the efficacy of the methods, based on practical experience, the application of cabbage leaves, cooling pads or curd cheese and the use of deep tissue massage to treat the symptoms of initial breast engorgement can be recommended; the choice of application is an individual decision.

Blocked Ducts and Mastitis

Both in the international scientific literature and in practice, the terms "blocked ducts" and "mastitis" are understood to mean different things. Mastitis is either defined exclusively as an infection of the breast or as an inflammation of the breast which may or may not be accompanied by infection [16]. The following definitions were used in the guidelines:

Puerperal mastitis is an inflammation of the breast occurring during the lactation period and is caused by blockage of the milk flow or by infection.

Symptoms of puerperal mastitis

- ▶ locally limited redness, warmth and swollen areas in the breast
- ▶ strong local pain in the breast
- ▶ systemic reactions such as generalized discomfort and fever (> 38.4 °C)
- ▶ local, commonly unilateral, symptoms, in rarer cases bilateral symptoms [11]

Blocked ducts describes a condition in which the blockage of a milk duct results in insufficient drainage of the milk duct. The resulting increase in pressure in the lactiferous duct leads to local discomfort in the breast but without detriment to the mother's general state of health.

Symptoms of blocked ducts

- ▶ local pain
- ▶ local hardening ("lump")
- ▶ no or only slightly increased warmth in affected areas
- ▶ no fever (< 38.4 °C)
- ▶ good general condition
- ▶ unilateral
- ▶ occasionally presents with a small white blister on the nipple [11, 12]

Differential diagnosis

- ▶ Breast abscess
- ▶ (inflammatory) breast cancer

Recommendation for the treatment of blocked ducts and mastitis

Good Clinical Practice

Prior to beginning treatment of blocked ducts or mastitis, the following causes shall be assessed (GCP):

- ▶ breastfeeding technique
- ▶ frequency of breastfeeding
- ▶ sore nipples
- ▶ initial engorgement
- ▶ mechanical blockage of the milk flow
- ▶ increased milk flow
- ▶ traumatic lesions
- ▶ lack of let-down reflex (stress, sleep deprivation)
- ▶ psychological factors
- ▶ inadequate hygiene

There are no controlled studies which explicitly examine the impact of lactation counseling and emotional support in the treatment of blocked duct or inflammation of the breast. Many years of experience indicate that for therapy to be successful, an integrated approach is necessary when treating affected women. For information on psychosomatic aspects, interested persons are referred to the specialist literature on psychosomatic gynecology.

Evidence and consensus based recommendation/ Good Clinical Practice

Regular drainage of the breast is essential in women with mastitis (A) or blocked ducts (GCP) to relieve pressure in the glandular tissue.

If necessary, the breast should be drained manually or mechanically (GCP).

Practical experience suggests that efficient drainage of the breast is promoted by stimulating the let-down reflex. Plata Rueda or Marmet massage is used for this. There are no scientific studies available on the efficacy of this technique.

Sufficient drainage of the breast to provide relief to the glandular tissue can be supported by starting breastfeeding using the affected breast. If the pain is too strong, it may be helpful to put the infant first to the unaffected breast and then switch to the affected breast once the let-down reflex has occurred [12, 17].

Good Clinical Practice

Various physical measures can be taken (GCP):

- ▶ apply warmth prior to starting breastfeeding/prior to manual or mechanical drainage of the breast
- ▶ cool the breast after breastfeeding/after manual or mechanical drainage of the breast

The alternating application of warmth and cooling to the affected breast can encourage milk flow and reduce discomfort. The application of warmth prior to commencing breastfeeding, e.g. in the form of warm compresses or poultices, stimulates milk flow. The measures taken after breastfeeding to cool the breast reduce swelling and pain [12, 17, 18].

Good Clinical Practice

Therapy of blocked ducts or mastitis can include massaging the blocked areas in the breast in the direction of the nipple. It is important to avoid all pressure which could be experienced as painful by the mother (GCP).

The flow of milk can be encouraged through gently massaging blocked areas in the direction of the nipple during breastfeeding [17]. There is no scientific evidence to support this.

Evidence and consensus based recommendation

Due to insufficient data or a lack of data about the benefit or harm of the following treatments, the effectiveness of the following applications cannot currently be assessed (0):

- ▶ acupuncture
- ▶ homeopathy
- ▶ vibration

Good Clinical Practice

Non-steroidal anti-inflammatory drugs can be used for analgesia (GCP).

If use of these conservative treatment methods does not lead to a significant clinical improvement within 24–48 hours or if, despite consistent therapy, a clear deterioration occurs, it must be assumed that bacterial mastitis is present, which has an increased risk of abscess formation.

Evidence and consensus based recommendation

Bacterial mastitis shall be treated with antibiotics (A).

When choosing the antibiotic, consideration should be given to compatibility with breastfeeding. First and second generation cephalosporins or penicillins with beta-lactamase-inhibitor combinations which are safe for both mother and infant have become the antibiotic of choice. An antibiotic therapy which lasts less than 10 to 14 days is associated with an increased risk of recurrence [12, 17]. Women allergic to penicillin or beta-lactam antibiotics can be treated using clindamycin if the pathogen has been shown to be sensitive to clindamycin.

Good Clinical Practice

The most important pathogens (*S. aureus*, beta-hemolytic *Streptococcus*) have to be considered when planning calculated antibiotic therapy (GCP).

Although studies from outside Germany report an increasing number of patients with mastitis caused by methicillin-resistant *S. aureus* (MRSA), mastitis caused by MRSA in outpatients is still rare in Germany [19]. Penicillins, 1st to 4th generation cephalosporins and carbapenem antibiotics are not effective to treat MRSA. Therapy should be prescribed after close consultation with the microbiologist investigating the pathogen and after considering the antibiogram-resistogram and should take account of

pharmacokinetic criteria (e.g. tissue penetration) and the restrictions on their use. According to the recommendations for calculated antibiotic therapy to treat skin and soft tissue infections made by the Paul Ehrlich Society for Chemotherapy, antibiotics which can be used to combat MRSA-induced infection include linezolid, daptomycin, tigecycline, glycopeptides (all Strength of Recommendation A) and cotrimoxazole (Strength of Recommendation B) combined with fosfomycin or rifampicin, where necessary [20]. For information on dealing with MRSA, please refer to the recommendations on the prevention and control of MRSA in hospitals and other medical facilities issued by the Robert Koch Institute and the updates of these recommendations.

Good Clinical Practice

Samples for microbiological investigation shall be obtained prior to initiating calculated antibiotic therapy (GCP).

Clinical Consensus

Mastitis caused by infection does not constitute a reason for weaning (GCP).

For mothers with infection-related mastitis caring for infants born at term, it is an individual decision whether to interrupt breastfeeding for a short period but continue to express breast milk regularly and discard it or whether to continue to feeding their infant with the milk. Mothers with rare infections caused by group B β -hemolytic *Streptococcus* and bilateral mastitis should discontinue breastfeeding for a period; the infant may also require simultaneous treatment with antibiotics. Premature infants should not receive breast milk if the mother has mastitis caused by bacterial infection.

If mastitis has resulted in abscess formation, the first option for treatment consists of aspiration of the abscess, followed, where necessary, by surgical intervention (e.g. incision of the abscess, drainage), always in combination with antibiotic therapy. Weaning is usually not necessary. Further recommendations on how to treat breast abscesses will be included in the update of these guidelines.

Discussion

▼ These guidelines provide recommendations on the treatment of inflammatory breast disease during the lactation period. These recommendations aim to improve the care of lactating women experiencing breastfeeding problems and help overcome barriers to breastfeeding.

All in all, there was only limited data available on which to base recommendations. There are very few studies with a high level of evidence on these areas of care. The limited availability of such data is due to both economic and ethical reasons. As the maternal and infant benefits of breastfeeding are well known, carrying out prospective controlled studies with randomized allocation of test persons into either one of the two groups “continue breastfeeding” and “discontinue breastfeeding” cannot be justified. Moreover, there is virtually no economic interest in the issue, resulting in a low number of overall studies due to a lack of financial support for investigations.

Because of the limited data, it was not possible to provide only evidence-based consensus recommendations in the guidelines. In order to be able to draw up recommendations even for areas where no investigations are possible, the contributing specialists drew up Good Clinical Practice recommendations based on their own practical experience.

In view of the benefits of breastfeeding for prevention and healthcare economics, it would be important to promote research in this field which could reduce the gaps in evidence concerning the therapy of breastfeeding-associated breast disease as this could generate data which could be incorporated in the guideline's evidence base.

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Conflict of Interest

There are no significant conflicts of interest (see Guidelines Report at www.awmf.org/leitlinien/detail/ll/015-071.html).

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References of studies evaluated systematically as part of the evidence base for these guidelines are obtainable from the long version.