

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Guideline scope

Lymphoedema: prevention and management in people with early, locally advanced, and advanced breast cancer (update)

New evidence about preventing and managing lymphoedema in people with breast cancer suggests that the recommendations in the guideline sections on lymphoedema for people with breast cancer may need updating. Full details are set out in the [June 2023 surveillance review decision](#).

This update will apply to the NICE guidelines on:

- [early and locally advanced breast cancer: diagnosis and management \(NG101\)](#)
- [advanced breast cancer: diagnosis and treatment \(CG81\)](#).

The guideline will be developed using the methods and processes outlined in [developing NICE guidelines: the manual](#).

1 Why the update is needed

New evidence that could affect recommendations was identified through the surveillance process. Topic experts, including those who helped to develop the existing guideline, advised NICE on whether areas should be updated or new areas added. Full details are set out in the [surveillance review decision](#).

Why the guideline is needed

Background information

Breast cancer is the most common cancer in women of all ages. In 2020, 2.3 million women were diagnosed with breast cancer ([World Health Organization](#), 2021). Men account for 0.5 to 1% of breast cancers ([World Health Organization](#), 2021). It is a distressing diagnosis because of the nature of the disease itself, and the potential for the treatment to have a severe, permanent impact on the person (for example, if mastectomy is needed). One of the most common complications that arises in people with breast cancer is lymphoedema ([Fu](#), 2014). The risk factors for developing lymphoedema can be treatment related (for example, because of the number of lymph nodes surgically removed and radiation to the axilla), or disease related (because of the stage and location of the tumour). There are also patient related risk factors such as younger age, obesity and comorbid conditions ([Nassif et al.](#), 2020).

Lymphoedema is a chronic condition, and most management strategies focus on lifestyle changes for the individual and alleviating symptoms and pain. The efficacy of these strategies can be influenced by factors such as the severity of lymphoedema, the timing of intervention, and individual patient variability ([Borman](#), 2018). As most lymphoedema treatments are not curative, it is important to determine what the most effective treatments are to improve the quality of life in patients.

Current practice

There are a variety of approaches for reducing the risk of someone developing lymphoedema, and managing the condition if it does occur in people who have or

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have had breast cancer. Reducing the risk of lymphoedema usually includes early identification of at-risk individuals, education on self-management techniques, and recommending the use of exercise programmes. Regular monitoring and tailored interventions are key components for managing the risk of lymphoedema in the UK ([Donahue et al.](#), 2023). For treatment, a combination of lymphatic drainage techniques, compression therapy, skin care and exercise are commonly used.

2 Who the guideline is for

This guideline is for:

- All healthcare professionals involved in the care of people who have, or have had, breast cancer
- People using breast cancer services, their family members and carers, and the public
- NHS managers and commissioners of breast cancer services (including Integrated Care Services and NHS England Specialising Commissioning).

NICE guidelines cover health and care in England. Decisions on how they apply in other UK countries are made by ministers in the [Welsh Government](#), [Scottish Government](#) and [Northern Ireland Executive](#).

Equality considerations

The [equality impact assessments for the 2018 guideline](#) list equality issues identified during its development and how they have been addressed.

The equalities and health inequalities assessment (EHIA) in [appendix B](#) provides details of equality and health inequalities issues that were identified during the [2023 surveillance review](#). The EHIA form will replace the equality impact assessment form which was used previously. The equality impact assessment for the 2018 guideline will be checked and any issues relevant to the current update that were not identified in the surveillance review will be included in the EHIA for this review question.

This update will look at equality and health inequality issues relating to protected characteristics (age, disability, gender reassignment, pregnancy and maternity, race, NICE guideline update: Early, locally advanced, and advanced breast cancer - lymphoedema

religion or belief, sex, and sexual orientation), socioeconomic status and deprivation, geographical area variation, and inclusion health and vulnerable groups. The issues that have been identified during scoping are summarised in the scoping stage ERIA. In addition, there is a [health inequalities briefing](#) for breast cancer that will be used during development of this update. Consideration will also be given to where health inequality issues arise (for example access to and quality of care) and how that can impact the recommendations made, as well as groups affected.

3 What the updated guideline will cover

3.1 Who is the focus?

Groups that will be covered

- Adults (18 and over) who have, or have had, breast cancer and who have, or are at risk of, lymphoedema of the upper limb (including axilla, hands and fingers), chest wall or breast.

3.2 Settings

Settings that will be covered

- All settings in which NHS-commissioned care is provided.

3.3 Activities, services or aspects of care

Key areas that will be covered in this update

We will look at evidence in the areas below when developing this update. We will consider making new recommendations or updating existing recommendations in this area only:

- Lymphoedema for all people who have, or have had, breast cancer

For all other areas of the guideline:

- There will be no evidence review

- We will retain the existing recommendations, but we may revise them to ensure consistency. In some cases, minor changes may be made without changing the intent of the recommendation.

Proposed outline for the guideline

The table below outlines all the areas that will be included in the guideline. It sets out what NICE plans to do for each area in the guidelines NG101 and CG81.

Proposed outline for the guideline

Area in the guideline	What NICE plans to do
Preoperative Assessment	
Preoperative assessment of breast and axilla	No review of evidence: retain existing recommendations in NG101.
Preoperative staging of the axilla	No review of evidence: retain existing recommendations in NG101.

Genetic testing	Review evidence: section to be updated as part of ongoing work to update NG101 and CG81.
Imaging assessment in advanced breast cancer	No review of evidence: retain existing recommendations on imaging assessment in advanced breast cancer (CG81).
Providing information and psychological support	Review evidence: section to be updated as part of ongoing work to update NG101 and CG81.
Surgery	
Surgery to the breast	Section updated in January 2024 as part of ongoing work to update NG101 following new evidence on further surgery after breast-conserving surgery based on tissue margins.
Paget's disease	No review of evidence: retain existing recommendations.
Surgery to the axilla	No review of evidence: retain existing recommendations as they were updated in 2018 and 2023 surveillance review did not identify new evidence to change the recommendations.
Invasive breast cancer	No review of evidence: retain existing recommendations as they were updated in 2018 and 2023 surveillance review did not identify new evidence to change the recommendations.
Ductal carcinoma in situ	No review of evidence: retain existing recommendations as they were updated in 2018 and 2023 surveillance review did not identify new evidence to change the recommendations.
Evaluation and management of a positive axillary lymph node identified by a preoperative ultrasound-guided needle biopsy	No review of evidence: retain existing recommendations as they were updated in 2018 and 2023 surveillance review did not identify new evidence to change the recommendations.
Evaluation and management of a positive axillary lymph node identified by a sentinel lymph node biopsy (in people with a normal preoperative ultrasound-guided needle biopsy)	No review of evidence: retain existing recommendations as they were updated in 2018 and 2023 surveillance review did not identify new evidence to change the recommendations.
Breast reconstruction	No review of evidence: retain existing recommendations as they were updated in 2018 and 2023 surveillance review did not identify new evidence to change the recommendations.

Diagnostic assessment and adjuvant therapy planning	
Predictive factors	No review of evidence: retain existing recommendations as they were updated in 2018 and 2023 surveillance review did not identify new evidence to change the recommendations.
Adjuvant therapy planning	No review of evidence: retain existing recommendations as they were updated in 2018 and 2023 surveillance review did not identify new evidence to change the recommendations.
Tumour profiling tests to guide adjuvant chemotherapy decisions	No review of evidence: retain existing recommendations as they refer to DG34.
Endocrine therapy	
Adjuvant endocrine therapy for invasive breast cancer	No review of evidence: retain existing recommendations as they were updated in 2018 and 2023 surveillance review did not identify new evidence to change the recommendations.
Ovarian function suppression	Review evidence: section to be updated as part of ongoing work to update NG101 and CG81.
Extended endocrine (hormone) therapy	No review of evidence: retain existing recommendations as they were updated in 2018 and 2023 surveillance review did not identify new evidence to change the recommendations.
Endocrine therapy for ductal carcinoma in situ	No review of evidence: retain existing recommendations as they were updated in 2018 and 2023 surveillance review did not identify new evidence to change the recommendations.
Endocrine therapy for advanced breast cancer	No review of evidence: retain existing recommendations to be in line with NICE technology appraisals.
Adjuvant chemotherapy for invasive breast cancer (early and locally advanced)	No review of evidence: retain existing recommendations; evidence will be monitored.
Chemotherapy for advanced breast cancer	Review evidence: section to be updated as part of ongoing work to update NG101 and CG81.
Biological therapy for early and locally advanced breast cancer	No review of evidence: retain existing recommendations; evidence will be monitored.
Biological therapy for advanced breast cancer	Review evidence: section to be updated as part of ongoing work to update NG101 and CG81.

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Bisphosphonate therapy	
Adjuvant bisphosphonate therapy	No review of evidence: retain existing recommendations as no new evidence found.
Bone health	No review of evidence: retain existing recommendations as no new evidence found.
Radiotherapy	
Radiotherapy after breast-conserving surgery	No review of evidence: retain existing recommendations as they were updated in 2018 and 2023 surveillance review did not identify new evidence to change the recommendations.
Radiotherapy after mastectomy	No review of evidence: retain existing recommendations as they were updated in 2018 and 2023 surveillance review did not identify new evidence to change the recommendations.
Dose fractionation for external beam radiotherapy	Section updated in July 2023 as part of ongoing work to update NG101 following new evidence on external beam radiotherapy dose fractionation.
Breast boost following breast-conserving surgery	No review of evidence: retain existing recommendations as they were updated in 2018 and 2023 surveillance review did not identify new evidence to change the recommendations.
Radiotherapy to nodal areas	No review of evidence: retain existing recommendations as they were updated in 2018 and 2023 surveillance review did not identify new evidence to change the recommendations.
Intraoperative radiotherapy	No review of evidence: retain existing recommendations as they were updated in 2018 and 2023 surveillance review did not identify new evidence to change the recommendations.
Primary systemic therapy	
Neoadjuvant chemotherapy	Review evidence: section to be updated as part of ongoing work to update NG101 and CG81.
Neoadjuvant chemotherapy regimens for early and locally advanced breast cancer	Review evidence: section to be updated as part of ongoing work to update NG101 and CG81.
Neoadjuvant endocrine therapy	Review evidence: section to be updated as part of ongoing work to update NG101 and CG81.

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Radiotherapy after neoadjuvant chemotherapy	No review of evidence: retain existing recommendations; evidence will be monitored.
Complications of local treatment and menopausal symptoms	
Lymphoedema	Review evidence: update existing recommendations in NG101 and CG81 and consolidate content.
Arm and shoulder mobility	Section updated in April 2023 as part of ongoing work to update NG101 following new evidence on arm and shoulder mobility after breast-conserving surgery.
Menopausal symptoms	Review evidence: section may be updated as part of ongoing work to update NG101 and CG81.
Cancer-related fatigue	No review of evidence: retain existing recommendations.
Uncontrolled local disease	No review of evidence: retain existing recommendations.
Brain metastasis	No review of evidence: retain existing recommendations and check for consistency with recommendations in NG99 - management of confirmed brain metastases.
Follow-up	
Follow-up imaging	No review of evidence: retain existing recommendations.
Clinical follow-up	No review of evidence: retain existing recommendations.
Monitoring disease status	No review of evidence: retain existing recommendations.
Lifestyle	No review of evidence: retain existing recommendations as they were updated in 2018 and 2023 surveillance review did not identify new evidence to change the recommendations.

Recommendations in areas that are being retained from the existing guideline may be edited to ensure that they meet current editorial standards and reflect the current policy and practice context.

Related NICE guidance

Published

- [Familial breast cancer: classification, care and managing breast cancer and related risks in people with a family history of breast cancer](#) (2023). NICE guideline CG164
- [Suspected cancer: recognition and referral](#) (2015). NICE guideline NG12

NICE guidance that will be updated by this guideline

- [Early and locally advanced breast cancer: diagnosis and management](#) (2024). NICE guideline NG101
- [Advanced breast cancer: diagnosis and treatment \(2009\)](#). NICE guideline CG81

NICE guidance about the experience of people using NHS services

NICE has produced the following guidance on the experience of people using the NHS. This guideline will not include additional recommendations on these topics unless there are specific issues related to the management lymphoedema:

- [Shared decision making](#) (2021) NICE guideline NG197
- [Medicines optimisation](#) (2015) NICE guideline NG5
- [Patient experience in adult NHS services](#) (2012) NICE guideline CG138
- [Service user experience in adult mental health](#) (2011) NICE guideline CG136
- [Medicines adherence](#) (2009) NICE guideline CG76

3.4 Economic aspects

We will take economic aspects into account when making recommendations. We will develop an economic plan that states for each review question (or key area in the scope) whether economic considerations are relevant, and if so whether this is an area that should be prioritised for economic modelling and analysis. We will review the economic evidence and carry out economic analyses, using an NHS and personal social services perspective, as appropriate. We will also consider the economic impacts in certain subgroups of people, including how a person's

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circumstances might lead to preferences for certain treatment options (for example the treatment of lymphoedema).

3.5 Key issues and draft questions

While writing the scope for this update, we have identified the following draft review questions:

- 1 In people who have, or have had, breast cancer, what non-pharmacological strategies are effective and cost effective for reducing the risk of developing lymphoedema?
- 2 In people who have, or have had, breast cancer and have lymphoedema, what non-pharmacological strategies are effective and cost-effective, for managing it?

3.6 Main outcomes

The main outcomes that may be considered when searching for and assessing the evidence are:

- Incidence of lymphoedema
- Severity of lymphoedema (for example, change from baseline in limb or breast volume/swelling using ultrasound/tissue dielectric constant, arm mobility (including DASH scores), bioimpedance)
- Adverse events (for example, infection, surgical complications)
- Quality of life (including, LYMQOL, FACT B+4, EQ-5D and EORTC-QoL-C30)
- Patient reported outcomes (for example pain, psychological distress and limb function)
- Changes in tissues and skin condition (for example, softening, hardening, tension)
- Reduction in acute inflammatory episodes or cellulitis
- Cosmetic impact and body image

4 NICE quality standards

4.1 NICE quality standards

NICE quality standards that may need to be revised or updated when this guideline is published

No NICE quality standard has been identified that may be affected by this update. NICE quality standard QS12 on [breast cancer \(2011\)](#) does not cover managing lymphoedema.

Further information

This is the final scope.

The guideline is expected to be published in June 2024.

You can follow progress of the [guideline](#).

Our website has information about how [NICE guidelines](#) are developed.

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