

1 **NATIONAL INSTITUTE FOR HEALTH AND CARE**
2 **EXCELLENCE**

3 **Scope for guideline update (starting 2022)**

4 **Early and locally advanced breast cancer: diagnosis and**
5 **management**

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7 NICE is updating its guideline on [early and locally advanced breast cancer:](#)
8 [diagnosis and management \(NG101\)](#). The guideline was originally published in
9 February 2009 and last updated in July 2018. It was developed as set out in the
10 [original scope for the NICE guideline on early and locally advanced breast cancer:](#)
11 [diagnosis and management](#).

12 New evidence on radiotherapy suggests that the recommendations on dose
13 fractionation may need updating. Full details are set out in the [May 2022 surveillance](#)
14 [review decision](#).

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

17 **1 Who the guideline update covers**

18 The current guideline covers:

- 19 • Adults (18 and over) with newly diagnosed invasive adenocarcinoma of the breast
20 of any size (T1–T4), with or without spread to locoregional lymph nodes (N0–N3)
21 and with no distant metastases (M0).
22 • Adults (18 and over) with newly diagnosed ductal carcinoma in situ (DCIS).
23 • Adults (18 and over) with Paget’s disease of the breast.

24 The groups covered by the guideline will remain unchanged.

1 **Equality considerations**

2 [The equality impact assessment for the original guideline](#) lists equality issues
3 identified during its development and how they have been addressed.

4 This update will look at equality and health inequality issues relating to protected
5 characteristics (age, disability, gender reassignment, pregnancy and maternity, race,
6 religion or belief, sex, and sexual orientation), socioeconomic status and deprivation,
7 geographical area variation, and inclusion health and vulnerable groups. A new
8 equality and health inequalities impact assessment ([EHIA](#)) has been produced which
9 is being used for this update. The EHIA form will replace the equality impact
10 assessment form which was used previously.

11 **2 Activities, services or aspects of care covered by** 12 **the guideline update**

13 We will look at the evidence and consider making new recommendations or updating
14 existing recommendations on:

- 15 • Radiotherapy – dose fractionation: recommendation 1.10.13

16 For all other areas of the guideline:

- 17 • There will be no evidence review.
- 18 • We will retain the existing recommendations, but we may revise them to ensure
19 consistency. In some cases minor changes may be made – for example, to
20 update links or bring the language and style up to date – without changing the
21 intent of the recommendation.

22 **3 Draft review question**

23 We have identified the following draft review question:

24 What is the effectiveness and cost-effectiveness of different hypofractionation
25 radiotherapy regimens in patients with early and locally advanced breast cancer?

1 **Draft PICO table for the review question**

Population	<p>Adults (18 and over) with early and locally advanced breast cancer who have undergone any of the following alone or in combination:</p> <ul style="list-style-type: none"> • breast-conserving surgery • mastectomy (which can include reconstruction) • axillary clearance • sentinel lymph node biopsy • axillary node sampling <p>There are no exclusion criteria</p>
Intervention	<p>Radiotherapy hypofractionation with or without regional node radiotherapy:</p> <p>Using greater than 2Gy per fraction</p> <p>for</p> <p>a) whole breast radiotherapy</p> <p>b) chest wall radiotherapy</p> <p>c) partial breast radiotherapy</p>
Comparator	Any other hypofractionation radiotherapy schedule
Outcomes	<p>Outcomes will be reported at the latest time point reported by the study</p> <ul style="list-style-type: none"> • Quality of life (using validated measures such as EORTC and BREAST-Q) • Breast cancer mortality • All-cause mortality • Local Recurrence • Distant recurrence (also referred as distant relapse) • Normal tissue effects • Treatment-related adverse events

	<ul style="list-style-type: none">• Cosmesis (including breast appearance, breast oedema, appearance of scar, breast size, shape, colour, nipple position, shape of areola in comparison with untreated breast)
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1 **4 Economic aspects**

2 We will take economic aspects into account when making recommendations. We will
3 review the economic evidence and carry out economic analyses, using an NHS and
4 personal social services perspective, as appropriate. We will also consider economic
5 impacts in certain subgroups of patients (for example, those on low income or
6 statutory sick pay who might have a preference for shorter treatment regimes that
7 could have a risk of negative long-term effects).

8 **5 NICE guidance and quality standards that may be** 9 **affected by this guideline update**

- 10 • [Breast cancer \(2011\)](#) NICE quality standard QS12
11 • [Intrabeam radiotherapy system for adjuvant treatment of early breast cancer](#)
12 (2018) NICE technology appraisal TA501

13 **6 Further information**

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

The guideline update is expected to be published in June 2023.

To follow the progress of the update, see the [guideline in development page](#).

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

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