

# NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

## Guideline scope

### Advanced breast cancer: diagnosis and management (update)

This guideline will update the NICE guideline on 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](#).

Discussion during the scoping process indicated that plans to incorporate relevant NICE technology appraisals into the update of the guideline meant that it was no longer necessary to review evidence for some of the areas identified, so the update does not cover all of the areas listed in the surveillance review. The areas not being covered by a separate review are:

- Biological therapy for advanced breast cancer and
- Ovarian function suppression for premenopausal and perimenopausal women with oestrogen receptor-positive advanced breast cancer.

The following area identified by the surveillance review will be included in this update:

- Chemotherapy

Advanced breast cancer: diagnosis and management: NICE guideline DRAFT FOR CONSULTATION (November 2024)

- 1 – Platinum-containing chemotherapy regimens for people with advanced triple  
2 negative breast cancer (a type of breast cancer in which the cells do not over  
3 express receptors for oestrogen and progesterone or human epidermal growth  
4 factor 2) and for people with advanced breast cancer with BRCA germline  
5 mutations

6 As a result of discussions with clinicians during the scoping process, it has been  
7 proposed that some additional areas are included in this update. These are:

- 8 • Imaging  
9 – PET-CT scans for diagnosis  
10 • Monitoring disease status  
11 – PET-CT scans for monitoring response to treatment

## 12 **2 Who the guideline is for**

13 This guideline is for:

- 14 • All healthcare professionals involved in the care of people with advanced breast  
15 cancer  
16 • NHS managers and commissioners of breast cancer services  
17 • People using breast cancer services, their families and carers and the public.

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

## 21 **Equality considerations**

22 NICE has carried out an [Equality and health inequalities assessment](#) during scoping.

23 The assessment:

- 24 • lists equality issues identified, and how they have been addressed  
25 • explains why any groups are excluded from the scope.

1 The guideline will look at inequalities relating to age, disability, gender reassignment,  
2 pregnancy and maternity, race, religion or belief, sex, socioeconomic deprivation,  
3 geographical area variation, inclusion health and vulnerable groups if evidence is  
4 available.

### 5 **3 What the updated guideline will cover**

#### 6 **3.1 Who is the focus?**

##### 7 **Groups that will be covered**

- 8 • Adults (18 and over) with invasive adenocarcinoma of the breast with distant  
9 metastases (M1).

10 Some evidence reviews will focus on specific subgroups of people, as outlined in the  
11 draft questions in [section 3.5](#).

##### 12 **Groups that will not be covered**

- 13 • Adults (18 and over) with newly diagnosed invasive adenocarcinoma of the breast  
14 of any size (T1 to T4), with or without spread to locoregional lymph nodes (N0 to  
15 N3) and with no distant metastases (M0).
- 16 • Adults (18 and over) with metastases to the breast from other primary tumours.
- 17 • Adults (18 and over) with non-epithelial breast tumours (for example,  
18 angiosarcoma, lymphoma).
- 19 • Adults (18 and over) with benign breast conditions (for example, fibroadenoma,  
20 benign phyllodes tumours).

#### 21 **3.2 Settings**

##### 22 **Settings that will be covered**

23 All settings in which NHS-funded care is provided.

### 1 **3.3 Activities, services or aspects of care**

#### 2 **Key areas that will be covered in this update**

3 We will look at evidence in the areas below when developing this update. We will  
4 consider making new recommendations or updating existing recommendations in  
5 these areas only.

6 1 Chemotherapy.

7 – Platinum-containing chemotherapy regimens for people with advanced triple  
8 negative breast cancer and for people with advanced breast cancer with  
9 BRCA germline mutations.

10 2 Imaging.

11 – PET-CT for diagnosis.

12 3 Monitoring disease status.

13 – PET-CT for monitoring response to treatment.

14 Note that guideline recommendations for medicines will normally fall within licensed  
15 indications; exceptionally, and only if clearly supported by evidence, use outside a  
16 licensed indication may be recommended. The guideline will assume that prescribers  
17 will use a medicine's summary of product characteristics to inform decisions made  
18 with individual patients.

#### 19 **Proposed outline for the guideline**

20 The table below outlines all the areas that will be included in the guideline. It sets out  
21 what NICE plans to do for each area in this update.

## 1 Proposed outline for the guideline

Area in the guideline	What NICE plans to do
1.1 Diagnosis and assessment	<p>Review evidence on PET-CT for diagnosis: update existing recommendations and make new recommendations as needed.</p> <p>Review evidence on PET-CT for monitoring response to treatment: update existing recommendations and make new recommendations as needed.</p>
1.2 Providing information and support for decision making	<p>No evidence review: editorially amend/stand down recommendations from existing guideline to align with <a href="#">NG101 Early and locally advanced breast cancer</a> and bring in cross references to <a href="#">NG197 Shared decision making</a>.</p>
1.3 Systemic disease-modifying therapy	<p>Review evidence on platinum-containing chemotherapy regimens in people with advanced triple negative breast cancer: no existing recommendations, make new recommendations as needed.</p> <p>Review evidence on platinum-containing chemotherapy regimens in people who have advanced breast cancer with BRCA germline mutations: no existing recommendations, make new recommendations as needed.</p>
1.4 Supportive care	<p>No evidence review: retain recommendations from existing guideline.</p>
1.5 Managing complications	<p>No evidence review: retain most recommendations from existing guideline but align with <a href="#">NG99 Brain tumours (primary) and brain metastases in over 16s</a> where relevant. Note that NICE is developing a guideline on <a href="#">Lymphoedema: prevention and management in people with early, locally advanced, and advanced breast cancer</a>, expected publication date to be confirmed.</p>

- 2 Technology appraisal guidance will be incorporated into the guideline where
- 3 relevant.

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

#### 4 **Areas that will not be covered by the guideline**

- 5 1 Diagnosis and treatment of early and locally advanced breast cancer.
- 6 2 Identifying people in primary care with suspected advanced breast cancer and  
7 referring them to secondary care.
- 8 3 The management of breast cancer and related risks in people with family  
9 history of breast cancer.
- 10 4 Imaging assessment used in population-based screening programmes.

#### 11 **Related NICE guidance**

##### 12 **Published**

- 13 • [Spinal metastases and metastatic spinal cord compression](#) (2023) NICE guideline  
14 NG234
- 15 • [End of life care for adults: service delivery](#) (2019) NICE guideline NG142
- 16 • [Brain tumours \(primary\) and brain metastases in over 16s](#) (2018) NICE guideline  
17 NG99
- 18 • [Early and locally advanced breast cancer: diagnosis and management](#) (2018)  
19 NICE guideline NG101
- 20 • [Menopause: diagnosis and management](#) (2015) NICE guideline NG23
- 21 • [Suspected cancer: recognition and referral](#) (2015) NICE guideline NG12
- 22 • [Familial breast cancer: classification, care and managing breast cancer and  
23 related risks in people with a family history of breast cancer](#) (2013) NICE guideline  
24 CG164
- 25 • [Breast cancer](#) (2011) NICE Quality Standard QS12
- 26 • [Metastatic malignant disease of unknown primary origin in adults: diagnosis and  
27 management](#) (2010) NICE guideline CG104
- 28 • [Improving outcomes in breast cancer](#). (2002) NICE guideline CSG1.

1 **In development**

- 2 • [Early and locally advanced breast cancer: diagnosis and management -](#)  
3 [Neoadjuvant chemotherapy and ovarian function suppression. NICE guideline.](#)  
4 Publication expected March 2025
- 5 • [Lymphoedema: prevention and management in people with early, locally](#)  
6 [advanced, and advanced breast cancer.](#) NICE guideline. Publication date to be  
7 confirmed.

8 **NICE guidance that will be incorporated unchanged in this guideline**

9 Relevant NICE technology appraisals will be incorporated unchanged into this  
10 guideline.

11 **NICE guidance about the experience of people using NHS services**

12 NICE has produced the following guidance on the experience of people using the  
13 NHS. This guideline will not include additional recommendations on these topics  
14 unless there are specific issues related to advanced breast cancer:

- 15 • [Shared decision making](#) (2021) NICE guideline NG197  
16 • [Medicines optimisation](#) (2015) NICE guideline NG5  
17 • [Patient experience in adult NHS services](#) (2012) NICE guideline CG138  
18 • [Medicines adherence](#) (2009) NICE guideline CG76.

19 **3.4 Economic aspects**

20 We will take economic aspects into account when making recommendations. We will  
21 develop an economic plan that states for each review question (or key area in the  
22 scope) whether economic considerations are relevant, and if so whether this is an  
23 area that should be prioritised for economic modelling and analysis. We will review  
24 the economic evidence and carry out economic analyses, using an NHS and  
25 personal social services (PSS) perspective, as appropriate.

### 1 **3.5 Key issues and draft questions**

2 While writing the scope for this updated guideline, we have identified the following  
3 key issues and draft questions related to them:

#### 4 1 Chemotherapy

5 1.1 What is the clinical and cost effectiveness of a platinum-containing  
6 chemotherapy regimen compared to a non-platinum-containing  
7 chemotherapy regimen in people with advanced:

8 ◇ triple negative breast cancer?

9 ◇ breast cancer of any receptor sub-type with BRCA germline mutations?

10

#### 11 2 Imaging

12 What is the clinical and cost effectiveness of FDG PET-CT compared to  
13 CT with or without bone scintigraphy for the detection of distant  
14 metastases in people with suspected advanced breast cancer and does  
15 this use of FDG PET-CT improve outcomes?

#### 16 3 Monitoring disease status

17 3.1 What is the clinical and cost effectiveness of FDG PET-CT compared  
18 to CT with or without bone scintigraphy for monitoring response to  
19 treatment and for detecting disease progression in people with advanced  
20 breast cancer?

21 The key issues and draft questions will be used to develop more detailed review  
22 questions, which guide the systematic review of the literature.

### 23 **3.6 Main outcomes**

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

26 • survival

27 – overall



- 1 – progression free
- 2 – response rate
- 3 • breast cancer mortality
- 4 • adverse events (including treatment related mortality and morbidity)
- 5 • adherence to or completion of treatment
- 6 • quality of life (using validated measures)
- 7 • changes to management or treatment.
- 8 • Measures of test accuracy, for example sensitivity and specificity, likelihood ratios

## 9 **4 NICE quality standards**

### 10 **NICE quality standards that may need to be revised or updated when this** 11 **guideline is published**

- 12 • Breast cancer (2011) NICE quality standard QS12
- 13 • Brain tumours (primary) and brain metastases in over 16s (2021) NICE quality  
14 standard QS203

## 15 **Further information**

This is the draft scope for consultation with registered stakeholders. The consultation dates are 7 November to 21 November 2024.

The guideline is expected to be published in Autumn / Winter 2025.

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

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

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