

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

3           **Guideline scope**

4           **Advanced breast cancer: diagnosis and management**  
5           **(update)**

6           This guideline will update the NICE guideline on advanced breast cancer: diagnosis  
7           and treatment (CG81).

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

10          **1           Why the update is needed**

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

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

20          • biological therapy for advanced breast cancer  
21          • ovarian function suppression for premenopausal and perimenopausal women with  
22          oestrogen receptor-positive advanced breast cancer.

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

25          • Imaging assessment

- 1     – PET-CT scans for diagnosis
- 2     • Monitoring disease status
- 3     – PET-CT scans for monitoring response to treatment

## 4     **2           Who the guideline is for**

- 5     This guideline is for:
  - 6       • All healthcare professionals involved in the care of people with advanced breast
  - 7       cancer
  - 8       • NHS managers and commissioners of breast cancer services
  - 9       • People using breast cancer services, their families and carers and the public.
- 10    NICE guidelines cover health and care in England. Decisions on how they apply in
- 11    other UK countries are made by ministers in the [Welsh Government](#), [Scottish](#)
- 12    [Government](#) and [Northern Ireland Executive](#).

## 13    **Equality considerations**

- 14    NICE has carried out an [equality and health inequalities assessment](#) during scoping.
- 15    The assessment:
  - 16       • lists equality issues identified, and how they have been addressed
  - 17       • explains why any groups are excluded from the scope.
- 18    The guideline will look at inequalities relating to age, disability, gender reassignment,
- 19    pregnancy and maternity, race, religion or belief, sex, socioeconomic deprivation,
- 20    geographical area variation, inclusion health and vulnerable groups if evidence is
- 21    available.

1    **3        What the updated guideline will cover**

2    **3.1       Who is the focus?**

3    **Groups that will be covered**

4    • Adults (18 and over) with suspected or confirmed invasive adenocarcinoma of the  
5      breast with distant metastases (M1).

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

8    **Groups that will not be covered**

9    • Adults (18 and over) with newly diagnosed invasive adenocarcinoma of the breast  
10    of any size (T1 to T4), with or without spread to locoregional lymph nodes (N0 to  
11    N3) and with no distant metastases (M0).

12    • Adults (18 and over) with metastases to the breast from other primary tumours.

13    • Adults (18 and over) with non-epithelial breast tumours (for example,  
14      angiosarcoma, lymphoma).

15    • Adults (18 and over) with benign breast conditions (for example, fibroadenoma,  
16      benign phyllodes tumours).

17    **3.2       Settings**

18    **Settings that will be covered**

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

20    **3.3       Activities, services or aspects of care**

21    **Key areas that will be covered in this update**

22    We will look at evidence in the areas below when developing this update. We will  
23    consider making new recommendations or updating existing recommendations in  
24    these areas only.

25    **1        Chemotherapy.**

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

7 2 Imaging assessment.

8 – PET-CT for diagnosis in people who have suspected advanced breast  
9 cancer.

10 3 Monitoring disease status.

11 – PET-CT for monitoring response to treatment in people with advanced  
12 breast cancer.

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

## 18 **Proposed outline for the guideline**

19 The table below outlines all the areas that will be included in the guideline. It sets out  
20 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.</p>

2 Technology appraisal guidance will be incorporated into the guideline where

3 relevant.

4 Recommendations in areas that are being retained from the existing guideline may

5 be edited to ensure that they meet current editorial standards, and reflect the current

6 policy and practice context.

1 **Areas that will not be covered by the guideline**

2 1 Diagnosis and treatment of early and locally advanced breast cancer.

3 2 Identifying people in primary care with suspected advanced breast cancer and

4 referring them to secondary care.

5 3 The management of breast cancer and related risks in people with family

6 history of breast cancer.

7 4 Imaging assessment used in population-based screening programmes.

8 **Related NICE guidance**

9 **Published**

- 10 • [Early and locally advanced breast cancer: diagnosis and management \(2025\)](#)  
11 NICE guideline NG101
- 12 • [Spinal metastases and metastatic spinal cord compression \(2023\)](#) NICE guideline  
13 NG234
- 14 • [End of life care for adults: service delivery \(2019\)](#) NICE guideline NG142
- 15 • [Brain tumours \(primary\) and brain metastases in over 16s \(2018\)](#) NICE guideline  
16 NG99
- 17 • [Menopause: diagnosis and management \(2015\)](#) NICE guideline NG234
- 18 • [Suspected cancer: recognition and referral \(2015\)](#) NICE guideline NG12
- 19 • [Familial breast cancer: classification, care and managing breast cancer and  
20 related risks in people with a family history of breast cancer \(2013\)](#) NICE guideline  
21 CG164
- 22 • [Breast cancer \(2011\)](#) NICE Quality Standard QS12
- 23 • [Metastatic malignant disease of unknown primary origin in adults: diagnosis and  
24 management \(2010\)](#) NICE guideline CG104
- 25 • [Improving outcomes in breast cancer \(2002\)](#) NICE guideline CSG1
- 26 • [Radiofrequency ablation as an adjunct to balloon kyphoplasty or percutaneous  
27 vertebroplasty for palliation of painful spinal metastases \(2023\)](#) NICE  
28 interventional procedures guidance IPG759
- 29 • [Radiofrequency ablation for palliation of painful spinal metastases \(2023\)](#) NICE  
30 interventional procedures guidance IPG758

- 1   • [Microwave ablation for primary or metastatic cancer in the lung](#) (2022) NICE  
2    interventional procedures guidance IPG716
- 3   • [Melphalan chemosaturation with percutaneous hepatic artery perfusion and](#)  
4    [hepatic vein isolation for primary or metastatic cancer in the liver](#) (2021) NICE  
5    interventional procedures guidance IPG691
- 6   • [Microwave ablation for treating liver metastases](#) (2016) NICE interventional  
7    procedures guidance IPG553
- 8   • [Electrochemotherapy for metastases in the skin from tumours of non-skin origin](#)  
9    [and melanoma](#) (2013) NICE interventional procedures guidance IPG446
- 10   • [Irreversible electroporation for treating liver metastases](#) (2013) NICE  
11    interventional procedures guidance IPG445
- 12   • [Irreversible electroporation for treating primary lung cancer and metastases in the](#)  
13    [lung](#) (2013) NICE interventional procedures guidance IPG441
- 14   • [Cryotherapy for the treatment of liver metastases](#) (2010) NICE interventional  
15    procedures guidance IPG369
- 16   • [Percutaneous cementoplasty for palliative treatment of bony malignancies](#) (2006)  
17    NICE interventional procedures guidance IPG179

18   **In development**

- 19   • [Suspected cancer: recognition and referral](#). NICE guideline NG12. Publication  
20    date to be confirmed.
- 21   • [Inavolisib with palbociclib and fulvestrant for treating recurrent hormone receptor-](#)  
22    [positive HER2-negative PIK3CA-positive advanced breast cancer after adjuvant](#)  
23    [endocrine treatment](#). NICE technology appraisal. Publication date to be confirmed.
- 24   • [Ribociclib in combination with endocrine therapy and goserelin for previously](#)  
25    [untreated hormone receptor-positive, HER2-negative advanced breast cancer in](#)  
26    [premenopausal women](#). NICE technology appraisal. Publication date to be  
27    confirmed.

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

- 2 • [Capivasertib with fulvestrant for treating hormone receptor-positive HER2-](#)
- 3 [negative advanced breast cancer after endocrine treatment](#) (2025) NICE
- 4 technology appraisal guidance TA1063
- 5 • [Olaparib for treating BRCA mutation-positive HER2-negative advanced breast](#)
- 6 [cancer after chemotherapy](#) (2025) NICE technology appraisal guidance TA1040
- 7 • [Elacestrant for treating oestrogen receptor-positive HER2-negative advanced](#)
- 8 [breast cancer with an ESR1 mutation after endocrine treatment](#) (2025) NICE
- 9 technology appraisal guidance TA1036
- 10 • [Trastuzumab deruxtecan for treating HER2-low metastatic or unresectable breast](#)
- 11 [cancer after chemotherapy](#) (2024) NICE technology appraisal guidance TA992
- 12 • [Talazoparib for treating HER2-negative advanced breast cancer with germline](#)
- 13 [BRCA mutations](#) (2024) NICE technology appraisal guidance TA952
- 14 • [Trastuzumab deruxtecan for treating HER2-positive unresectable or metastatic](#)
- 15 [breast cancer after 1 or more anti-HER2 treatments](#) (2023) NICE technology
- 16 appraisal guidance TA862
- 17 • [Palbociclib with fulvestrant for treating hormone receptor-positive, HER2-negative](#)
- 18 [advanced breast cancer after endocrine therapy](#) (2022) NICE technology
- 19 appraisal guidance TA836
- 20 • [Sacituzumab govitecan for treating unresectable triple-negative advanced breast](#)
- 21 [cancer after 2 or more therapies](#) (2022) NICE technology appraisal guidance
- 22 TA819
- 23 • [Alpelisib with fulvestrant for treating hormone receptor-positive, HER2-negative,](#)
- 24 [PIK3CA-mutated advanced breast cancer](#) (2022) NICE technology appraisal
- 25 guidance TA816
- 26 • [Pembrolizumab plus chemotherapy for untreated, triple-negative, locally recurrent](#)
- 27 [unresectable or metastatic breast cancer](#) (2022) NICE technology appraisal
- 28 guidance TA801
- 29 • [Tucatinib with trastuzumab and capecitabine for treating HER2-positive advanced](#)
- 30 [breast cancer after 2 or more anti-HER2 therapies](#) (2022) NICE technology
- 31 appraisal guidance TA786

- 1   • [Abemaciclib with fulvestrant for treating hormone receptor-positive, HER2-](#)
- 2    [negative advanced breast cancer after endocrine therapy](#) (2021) NICE technology
- 3    appraisal guidance TA725
- 4   • [Trastuzumab deruxtecan for treating HER2-positive unresectable or metastatic](#)
- 5    [breast cancer after 2 or more anti-HER2 therapies](#) (2021) NICE technology
- 6    appraisal guidance TA704
- 7   • [Ribociclib with fulvestrant for treating hormone receptor-positive, HER2-negative](#)
- 8    [advanced breast cancer after endocrine therapy](#) (2021) NICE technology
- 9    appraisal guidance TA687
- 10   • [Atezolizumab with nab-paclitaxel for untreated PD-L1-positive, locally advanced or](#)
- 11   [metastatic, triple-negative breast cancer](#) (2020) NICE technology appraisal
- 12   guidance TA639
- 13   • [Abemaciclib with an aromatase inhibitor for previously untreated, hormone](#)
- 14   [receptor-positive, HER2-negative, locally advanced or metastatic breast cancer](#)
- 15   (2019) NICE technology appraisal guidance TA563
- 16   • [Eribulin for treating locally advanced or metastatic breast cancer after 1](#)
- 17   [chemotherapy regimen](#) (2018) NICE technology appraisal guidance TA515
- 18   • [Pertuzumab with trastuzumab and docetaxel for treating HER2-positive breast](#)
- 19   [cancer](#) (2018) NICE technology appraisal guidance TA509
- 20   • [Fulvestrant for untreated locally advanced or metastatic oestrogen-receptor](#)
- 21   [positive breast cancer](#) (2018) NICE technology appraisal guidance TA503
- 22   • [Ribociclib with an aromatase inhibitor for previously untreated, hormone receptor-](#)
- 23   [positive, HER2-negative, locally advanced or metastatic breast cancer](#) (2017)
- 24   NICE technology appraisal guidance TA496
- 25   • [Palbociclib with an aromatase inhibitor for previously untreated, hormone](#)
- 26   [receptor-positive, HER2 negative, locally advanced or metastatic breast cancer](#)
- 27   (2017) NICE technology appraisal guidance TA495
- 28   • [Trastuzumab emtansine for treating HER2-positive advanced breast cancer after](#)
- 29   [trastuzumab and a taxane](#) (2017) NICE technology appraisal guidance TA458
- 30   • [Eribulin for treating locally advanced or metastatic breast cancer after 2 or more](#)
- 31   [chemotherapy regimens](#) (2016) NICE technology appraisal guidance TA423

- [Everolimus with exemestane for treating advanced breast cancer after endocrine therapy](#) (2016) NICE technology appraisal guidance TA421
- [Bevacizumab in combination with capecitabine for the first-line treatment of metastatic breast cancer](#) (2012) NICE technology appraisal guidance TA263
- [Lapatinib or trastuzumab in combination with an aromatase inhibitor for the first-line treatment of metastatic hormone receptor-positive breast cancer that overexpresses HER2](#) (2012) NICE technology appraisal guidance TA257
- [Denosumab for the prevention of skeletal-related events in adults with bone metastases from solid tumours](#) (2012) NICE technology appraisal guidance TA265
- [Fulvestrant for the treatment of locally advanced or metastatic breast cancer](#) (2011) NICE technology appraisal guidance TA239
- [Bevacizumab in combination with a taxane for the first-line treatment of metastatic breast cancer](#) (2011) NICE technology appraisal guidance TA214
- [Gemcitabine for the treatment of metastatic breast cancer](#) (2007) NICE technology appraisal guidance TA116
- [Guidance on the use of trastuzumab for the treatment of advanced breast cancer](#) (2002) NICE technology appraisal guidance TA34

## **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 advanced breast cancer:

- [Shared decision making](#) (2021) NICE guideline NG197
- [Medicines optimisation](#) (2015) NICE guideline NG5
- [Patient experience in adult NHS services](#) (2012) NICE guideline CG138
- [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

1 scope) whether economic considerations are relevant, and if so whether this is an  
2 area that should be prioritised for economic modelling and analysis. We will review  
3 the economic evidence and carry out economic analyses, using an NHS and  
4 personal social services (PSS) perspective, as appropriate.

5 **3.5 Key issues and draft questions**

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

8 1 Chemotherapy

9 1.1 What is the clinical and cost effectiveness of a platinum-containing  
10 chemotherapy regimen compared to a non-platinum-containing  
11 chemotherapy regimen in people with advanced:

12 ◊ triple negative breast cancer?

13 ◊ breast cancer of any receptor sub-type with BRCA germline mutations?

14

15 2 Imaging

16 What is the clinical and cost effectiveness of FDG PET-CT compared to  
17 CT with or without bone scintigraphy for diagnosing distant metastases  
18 and determining subsequent management in people with suspected  
19 advanced breast cancer?

20 3 Monitoring disease status

21 3.1 What is the clinical and cost effectiveness of FDG PET-CT compared  
22 to CT with or without bone scintigraphy for monitoring response to  
23 treatment in people who have been or are being treated for advanced  
24 breast cancer?

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

1 **3.6 Main outcomes**

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

4 • survival  
5 – overall  
6 – progression free  
7 – response rate  
8 – cancer specific  
9 • adverse events (including treatment related mortality and morbidity)  
10 • adherence to or completion of treatment  
11 • quality of life (using validated measures)  
12 • changes to management or treatment  
13 • measures of test accuracy, for example sensitivity and specificity, likelihood ratios

14 **4 NICE quality standards**

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

17 • Breast cancer (2011) NICE quality standard QS12

18 **Further information**

This is the final scope, which takes into account comments from registered stakeholders during consultation.

The guideline is expected to be published in February 2026.

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

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

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