

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

3 **Guideline scope**

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

6 ***Topic***

7 This guideline will update the NICE guideline on early and locally advanced
8 breast cancer (CG80) as set out in the [surveillance review decision](#).

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

11 For more information about why this guideline is being developed, and how
12 the guideline will fit into current practice, see the [context](#) section.

13 ***Who the guideline is for***

- 14 • Healthcare professionals involved in the multidisciplinary care of people
15 with early and locally advanced breast cancer.
- 16 • People using breast cancer services, their family members and carers, and
17 the public.
- 18 • Commissioners of breast cancer services (including Clinical
19 Commissioning Groups and NHS England Specialised Commissioning).

20 It may also be relevant for:

- 21 • Healthcare professionals in primary care.

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

25 ***Equality considerations***

26 NICE has carried out [an equality impact assessment](#) [add hyperlink in final
27 version] during scoping. The assessment:

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

30 No equalities issues have been identified.

31 **1 What the guideline is about**

32 ***1.1 Who is the focus?***

33 **Groups that will be covered**

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

39 **Groups that will not be covered**

- 40 • Adults (18 and over) with invasive adenocarcinoma of the breast and
41 distant metastases (clinical or pathological M1)
- 42 • Adults (18 and over) with rare breast tumours (for example, angiosarcoma,
43 lymphoma).
- 44 • Adults (18 and over) with benign breast tumours (for example,
45 fibroadenoma).
- 46 • Adults (18 and over) with phylloides tumour.
- 47 • Adults (18 and over) with locally recurrent breast cancer or DCIS.
- 48 • Adults (18 and over) with lobular carcinoma in situ (LCIS).
- 49 • Adults (18 and over) with an increased risk of breast cancer due to family
50 history.

51 **1.2 Settings**

52 **Settings that will be covered**

- 53 • All settings in which NHS care is provided.
- 54 • Shared care, including social services.

55 **1.3 Activities, services or aspects of care**

56 We will look at evidence on the areas listed below when developing the
57 guideline, but it may not be possible to make recommendations on all the
58 areas.

59 **Key areas that will be covered**

- 60 1 Surgery to the breast.
- 61 2 Management of the positive axilla.
- 62 3 Adjuvant systemic therapy planning.
- 63 4 Endocrine therapy for invasive disease.
- 64 5 Adjuvant chemotherapy.
- 65 6 Adjuvant biological therapy.
- 66 7 Adjuvant bisphosphonates.
- 67 8 Breast radiotherapy.
- 68 9 Post-mastectomy radiotherapy.
- 69 10 Neoadjuvant treatment of early and locally advanced breast cancer.
- 70 11 Lifestyle.

71

72 Note that guideline recommendations will normally fall within licensed
73 indications; exceptionally, and only if clearly supported by evidence, use
74 outside a licensed indication may be recommended. The guideline will
75 assume that prescribers will use a medicine's summary of product
76 characteristics to inform decisions made with individual patients.

77 **Areas that will not be covered**

- 78 1 Identifying people in primary care with suspected early and locally
79 advanced breast cancer and referring them to secondary care.
- 80 2 Bisphosphonates used for the prevention or treatment of osteoporosis.

81 3 The management of breast cancer and related risks in people with a
82 family history of breast cancer.

83 ***Areas in the published guideline that will not be updated***

84 1 Referral, diagnosis, preoperative assessment and psychological support,
85 including the provision of information.

86 2 Breast reconstruction.

87 3 Complications of local treatment and menopausal symptoms.

88 Recommendations in areas that are not being updated may be edited to
89 ensure that they meet current editorial standards, and reflect the current policy
90 and practice context.

91 **1.4 Economic aspects**

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

99 **1.5 Key issues and questions**

100 While writing this scope, we have identified the following key issues, and draft
101 review questions related to them:

102 1 Surgery to the breast.

103 1.1 What is the optimal tumour-free tissue margin in people with invasive
104 breast cancer treated with breast conserving surgery or mastectomy?

105 2 Management of the positive axilla.

106 2.1 What are the indications for axillary node clearance when the axilla
107 has been found by biopsy to contain metastatic disease?

108 2.2 What are the indications for nodal radiotherapy after a positive
109 axillary node biopsy (including indications for radiotherapy to internal
110 mammary nodes)?

- 111 2.3 What are the best strategies for reducing the risk of lymphoedema
112 following axillary surgery?
- 113 3 Adjuvant systemic therapy planning.
- 114 3.1 What is the role of progesterone receptor (PR) testing for adjuvant
115 systemic therapy planning?
- 116 3.2 What prognostic tools should be used for determining adjuvant
117 systemic therapy?
- 118 3.3 What is the role of gene profiling in determining the need for adjuvant
119 systemic therapy? [Subject to discussion with NICE's diagnostics
120 programme.]
- 121 4 Endocrine therapy for invasive disease.
- 122 4.1 What is the optimal adjuvant endocrine therapy for people with
123 oestrogen-positive breast cancer?
- 124 4.2 What is the role of ovarian suppression (in addition to standard
125 endocrine therapy) in pre-menopausal women with oestrogen-positive
126 breast cancer?
- 127 5 Adjuvant chemotherapy.
- 128 5.1 Which people with early and locally advanced breast cancer benefit
129 from adjuvant taxanes?
- 130 6 Adjuvant biological therapy.
- 131 6.1 Which people with T1 N0 human epidermal growth receptor 2
132 (HER2)-positive breast cancers benefit from adjuvant trastuzumab?
- 133 7 Adjuvant bisphosphonates.
- 134 7.1 What are the indications for using adjuvant bisphosphonates in
135 people with early and locally advanced breast cancer?
- 136 8 Breast radiotherapy.
- 137 8.1 What is the optimal radiotherapy technique for people with early or
138 locally advanced breast cancer?
- 139 8.2 Is there a subgroup of people with early breast cancer who do not
140 need breast radiotherapy after breast-conserving surgery?
- 141 9 Post-mastectomy radiotherapy.
- 142 9.1 What are the indications for radiotherapy to the chest wall following
143 mastectomy for people with early and locally advanced breast cancer?

- 144 9.2 Should the decision on breast reconstruction be deferred until the
145 need for radiotherapy is determined?
- 146 10 Neoadjuvant treatment of early and locally advanced breast cancer.
147 10.1 What are the indications for neoadjuvant chemotherapy with or
148 without biological therapy in early and locally advanced breast cancer?
149 10.2 What are the indications for neoadjuvant endocrine therapy for
150 people with early and locally advanced breast cancer?
151 10.3 What is the optimal surgical treatment and/or radiotherapy regimen
152 following neoadjuvant systemic therapy?
- 153 11 Lifestyle.
154 11.1 What lifestyle changes improve cancer-specific outcomes in people
155 treated for early and locally advanced breast cancer?

156 The key questions may be used to develop more detailed review questions,
157 which guide the systematic review of the literature.

158 **1.6 Main outcomes**

159 The main outcomes that will be considered when searching for and assessing
160 the evidence are:

- 161 1 Overall survival.
- 162 2 Disease-free survival.
- 163 3 Disease-related morbidity.
- 164 4 Treatment-related morbidity.
- 165 5 Treatment-related mortality.
- 166 6 Health-related quality of life.
- 167 7 Patient-reported outcome measures.

168 **2 Links with other NICE guidance, NICE quality** 169 **standards and NICE Pathways**

170 **2.1 NICE guidance**

171 **NICE guidance that will be updated by this guideline**

- 172 • [Breast cancer \(early and locally advanced\)](#) (2009) NICE guideline CG80

- 173 • [Trastuzumab for the adjuvant treatment of early-stage HER2-positive](#)
174 [breast cancer](#) (2006) NICE technology appraisal guidance 107 (subject to a
175 NICE technology appraisal review consultation)
- 176 • [Paclitaxel for the adjuvant treatment of early node-positive breast cancer](#)
177 (2006) NICE technology appraisal guidance 108 (subject to a NICE
178 technology appraisal review consultation)
- 179 • [Docetaxel for the adjuvant treatment of early node-positive breast cancer](#)
180 (2006) NICE technology appraisal guidance 109 (subject to a NICE
181 technology appraisal review consultation)
- 182 • [Hormonal therapies for the adjuvant treatment of early oestrogen-receptor-](#)
183 [positive breast cancer](#) (2006) NICE technology appraisal guidance 112

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

185 NICE has produced the following guidance on the experience of people using
186 the NHS. This guideline will not include additional recommendations on these
187 topics unless there are specific issues related to early and locally advanced
188 breast cancer:

- 189 • [Patient experience in adult NHS services](#) (2012) NICE guideline CG138
190 • [Service user experience in adult mental health](#) (2011) NICE guideline
191 CG136
192 • [Medicines adherence](#) (2009) NICE guideline CG76

193 **NICE guidance that is closely related to this guideline**

194 ***Published***

195 NICE has published the following guidance that is closely related to this
196 guideline:

- 197 • [Advanced breast cancer](#) (2009) NICE guideline CG81
198 • [Improving outcomes in breast cancer](#) (2002) NICE guideline CSG1
199 • [Improving supportive and palliative care for adults with cancer](#) (2004) NICE
200 guideline CSG4
201 • [Opioids in palliative care](#) (2012) NICE guideline CG140
202 • [Neutropenic sepsis](#) (2012) NICE guideline CG151

- 203 • [Trastuzumab emtansine for treating HER2-positive, unresectable locally](#)
204 [advanced or metastatic breast cancer after treatment with trastuzumab and](#)
205 [a taxane](#) (2015) NICE technology appraisal guidance 371
- 206 • [Familial breast cancer](#) (2013) NICE guideline CG164
- 207 • [Gene expression profiling and expanded immunohistochemistry tests for](#)
208 [guiding adjuvant chemotherapy decisions in early breast cancer](#)
209 [management: MammaPrint, Oncotype DX, IHC4 and Mammostrat](#) (2013)
210 NICE diagnostics guidance 10
- 211 • [Intraoperative tests \(RD-100i OSNA system and Metasin test\) for detecting](#)
212 [sentinel lymph node metastases in breast cancer](#) (2013) NICE diagnostics
213 guidance 8
- 214 • [Fulvestrant for the treatment of locally advanced or metastatic breast](#)
215 [cancer](#) (2011) NICE technology appraisal guidance 239
- 216 • [Eribulin for the treatment of locally advanced or metastatic breast cancer](#)
217 (2012) NICE technology appraisal guidance 250
- 218 • [Endoscopic mastectomy and endoscopic wide local excision for breast](#)
219 [cancer](#) (2009) NICE interventional procedure guidance 296
- 220 • [Brachytherapy as the sole method of adjuvant radiotherapy for breast](#)
221 [cancer after local excision](#) (2008) NICE interventional procedure guidance
222 268
- 223 • [Interstitial laser therapy for breast cancer](#) (2004) NICE interventional
224 procedure guidance 89
- 225 • [Breast reconstruction using lipomodelling after breast cancer treatment](#)
226 (2012) NICE interventional procedure guidance 417
- 227 • [Endoscopic axillary lymph node retrieval for breast cancer](#) (2005) NICE
228 interventional procedure guidance 147
- 229 • [Laparoscopic mobilisation of the greater omentum for breast reconstruction](#)
230 (2008) NICE interventional procedure guidance 253
- 231 • [Denosumab for the prevention of skeletal-related events in adults with bone](#)
232 [metastases from solid tumours](#) (2012) NICE technology appraisal guidance
233 265

234 ***In development***

235 NICE is currently developing the following guidance that is closely related to
236 this guideline:

- 237 • [Breast cancer \(early\) – intrabeam radiotherapy system](#). NICE technology
238 appraisal. Publication date to be confirmed.
- 239 • [Breast cancer \(locally advanced, metastatic\) – eribulin \(after
240 chemotherapy\)](#). NICE technology appraisal. Publication date to be
241 confirmed.
- 242 • [Breast cancer \(HER2 negative, HR positive\) – everolimus \(with
243 exemestane, after endocrine therapy\)](#). NICE technology appraisal.
244 Publication expected 2017.
- 245 • [Breast cancer \(locally advanced or metastatic\) – ixabepilone](#). NICE
246 technology appraisal (suspended).
- 247 • [Breast cancer – intensity modulated radiotherapy](#). NICE technology
248 appraisal (discontinued).
- 249 • [Breast cancer \(first-line treatment\) – sunitinib \(in combination with a
250 taxane\)](#). NICE technology appraisal (suspended).
- 251 • [Bone loss \(therapy-induced\) in non-metastatic breast cancer – denosumab](#).
252 NICE technology appraisal (discontinued).

253 **2.2 NICE quality standards**

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

- 256 • [Breast cancer](#) (2011) NICE quality standard 12

257 **2.3 NICE Pathways**

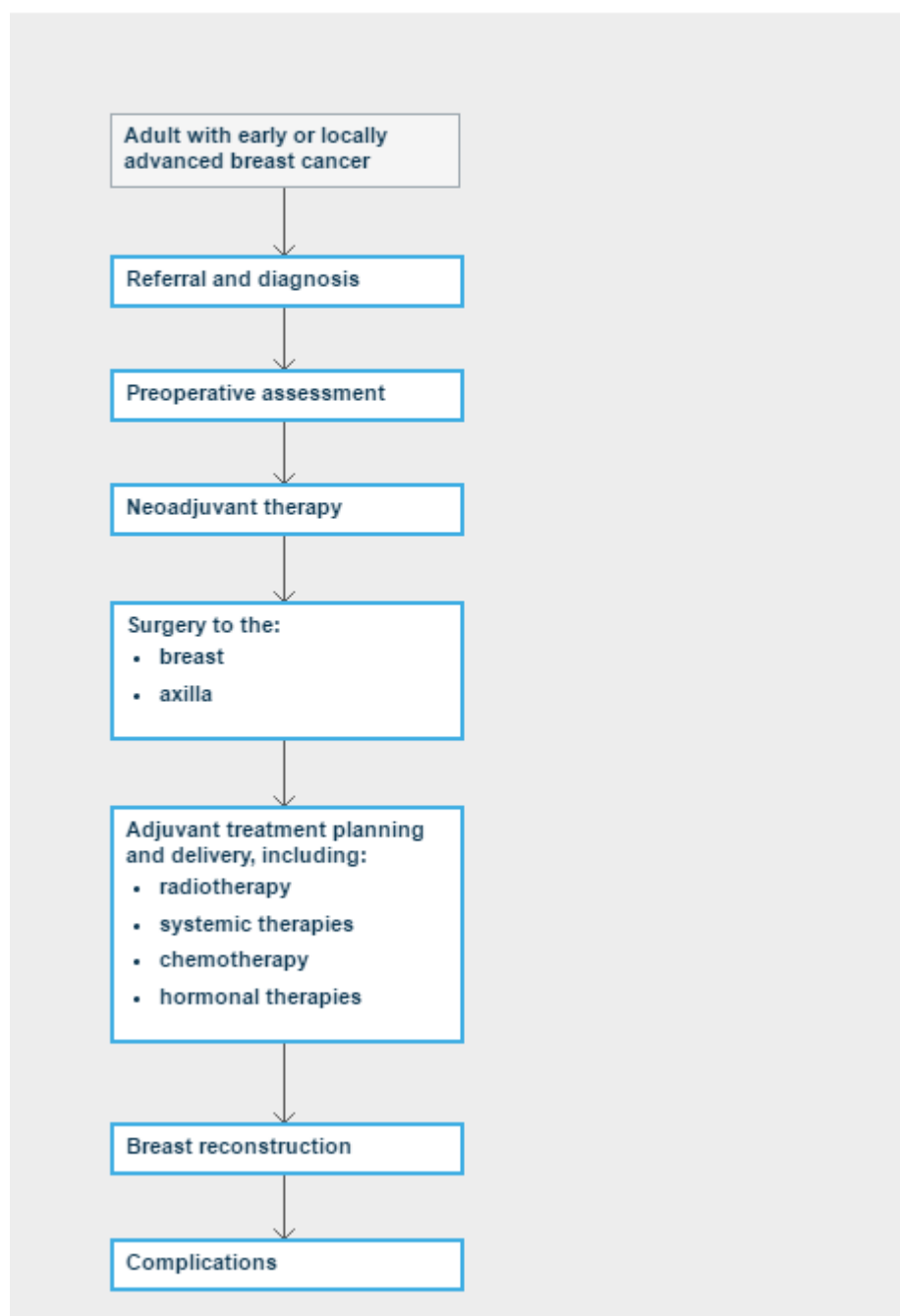
258 NICE Pathways bring together all related NICE guidance and associated
259 products on a topic in an interactive topic-based flow chart.

260 There is a live pathway for [early and locally advanced breast cancer](#).

261 When the revised guideline is published, the recommendations will be
262 incorporated into a revised pathway. An outline, based on the scope, is

263 included below. It will be adapted and more detail added as the
264 recommendations are written during guideline development.

Early and locally advanced breast cancer overview



265

266 **3 Context**

267 **3.1 Key facts and figures**

268 Breast cancer is the most common cancer in the UK with approximately
269 54,000 new cases of invasive disease and around 7,000 new cases of pre-
270 invasive (in situ) disease diagnosed annually. The vast majority of breast
271 cancers occur in women, but just over 300 men in the UK are also diagnosed
272 with invasive breast cancer every year.

273 Most breast cancers are diagnosed at an early stage and are therefore
274 potentially curable with modern treatments. Survival rates have improved over
275 recent decades with almost 90% of women diagnosed with breast cancer
276 surviving their disease for 5 or more years after diagnosis. Survival is however
277 linked to the stage of the disease at diagnosis; only 15% of women diagnosed
278 with stage IV disease are alive at 5 years. Breast cancer remains the leading
279 cause of death in women aged 35–49 years and is second only to lung cancer
280 as the leading cause of cancer death in all women.

281 The main risk factor for breast cancer is being female; the disease is
282 100 times less common in men. It is also a disease of aging with risk of breast
283 cancer increasing with increasing age. Some breast cancers are linked to
284 lifestyle factors that include obesity, alcohol intake and use of hormone
285 replacement therapy, whereas other lifestyle factors, including physical activity
286 and breastfeeding, protect against breast cancer. About 5% of breast cancers
287 are due to inherited mutations in high-risk genes such as BRCA1/2 and p53.

288 **3.2 Current practice**

289 Breast cancer is diagnosed at specialist breast units across the UK following
290 routine breast screening or GP referral after presentation with suspicious
291 symptoms. At the specialist breast unit, patients are cared for within the
292 context of a specialised multidisciplinary team. Most people are diagnosed
293 with early stage disease and are treated with curative intent. The treatment
294 depends on the type of breast cancer but would generally involve surgery with
295 the addition of drug therapy (including chemotherapy, endocrine therapy and

296 HER2-directed therapy with drugs such as trastuzumab) and radiotherapy, as
297 appropriate.

298 Some patients present with, or are subsequently diagnosed with, secondary
299 breast cancer. The aim of treatment for these patients is to control the cancer,
300 relieve symptoms and maintain quality of life; all for as long as possible.

301 Again, different types of treatment will be used depending on the type of
302 cancer but drug therapy is the mainstay of treatment, with therapies such as
303 radiotherapy and surgery being used to treat localised problems such as pain
304 or fracture risk.

305 **3.3 Policy, legislation, regulation and commissioning**

306 **Policy**

307 This guideline will address at least 1 of the aims in [Achieving world-class](#)
308 [cancer outcomes - a strategy for England 2015 2020](#) (NHS England 2015) by
309 helping to deliver a 'modern high quality service'. It will also look at care after
310 treatment to improve outcomes as set out in [Commissioning cancer services](#)
311 (Department of Health 2011) and [2010 to 2015 government policy: cancer](#)
312 [research and treatment](#) (Department of Health 2013).

313 **Legislation, regulation and guidance**

314 This guideline will contribute to the evidence base for the commissioning of
315 services for people with early and locally advanced breast cancer as set out in
316 [Implementing the Cancer Taskforce recommendations: commissioning](#)
317 [person-centred care for people affected by cancer](#) (NHS England 2016).

318 **4 Further information**

This is the draft scope for consultation with registered stakeholders. The consultation dates are 26 May 2016 to 24 June 2016.

The guideline is expected to be published in September 2018.

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

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

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